HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 1

TUESDAY, APRIL 26, 1966

THURSDAY, MAY 12, 1966

TUESDAY, JUNE 7, 1966

WITNESSES:

The Hon. Allan J. MacEachen, Minister of National Health and Welfare, and Dr. R. A. Chapman, Director of the Food and Drug Directorate of the Department of National Health and Welfare.

ROGER DUHAMEL, F.R.S.C.
QUEEN'S PRINTER AND CONTROLLER OF STATIONERY
OTTAWA, 1966

24083—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

Vice-Chairman: Mr. Patrick T. Asselin (*Richmond-Wolfe*)*

and

Mr. Brand,
Mr. Chatterton,
*Mr. Clancy,
Mr. Côté (*Dorchester*),
Mr. Enns,
Mr. Haidasz,
Mr. Howe (*Hamilton South*),
Mr. Howe (*Wellington-Huron*),
Mr. Hymmen,
Mr. Isabelle,
Mr. Langlois (*Chicoutimi*),
Mr. MacDonald (*Prince*),
Mr. O'Keefe,
Mr. Orlikow,
Mr. Pascoe,
Mr. Patterson,
Mr. Prud'homme,
Mr. Roxburgh,
Mr. Rynard,
Mr. Tardif,
*Mr. Whelan,
Mr. Yanakis—(24).

(Quorum 13)

Gabrielle Savard,
Clerk of the Committee.

NOTE: Replaced Mr. Mitchell on April 25.

Replaced Mr. Macquarrie on May 5.

Replaced Mr. Mackasey on May 16.

ORDERS OF REFERENCE

TUESDAY, February 15, 1966.

Resolved,—That a Special Committee be appointed to continue the inquiry into and to report upon costs of drugs, begun by Special Committees during the Twenty-Sixth Parliament;

That the Committee consist of 24 Members to be designated later by the House; and be empowered to sit while the House is sitting;

That the Committee be empowered to consider and recommend, as it may deem expedient, respecting a comprehensive and effective program to reduce the price of drugs;

That the Committee be empowered to send for persons, papers, and records, and to report from time to time, to print such papers and evidence from day to day as may be deemed advisable, and to engage the services of counsel, accountants, and such other technical and clerical personnel as may be deemed necessary;

That the Minutes of Proceedings of and evidence given before the Special Committees at the 26th Parliament be referred to the said Committee and be made part of the records thereof;

That the provisions of Standing Orders 66 and 67(1) be suspended in relation to such Committee.

THURSDAY, February 24, 1966.

Ordered,—That the Special Committee on Drug Costs and Prices appointed February 15, 1966, be composed of Messrs. Brand, Chatterton, Côté (*Dorchester*), Enns, Haidasz, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), Hymmen, Isabelle, Langlois (*Chicoutimi*), MacDonald (*Prince*), Mackasey, Macquarrie, Mitchell, O'Keefe, Orlikow, Pascoe, Patterson, Prud'homme, Roxburgh, Rynard, Tardif and Yanakis.

MONDAY, April 25, 1966.

Ordered,—That the name of Mr. Asselin (*Richmond-Wolfe*) be substituted for that of Mr. Mitchell on the Special Committee on Drug Costs and Prices.

THURSDAY, May 5, 1966.

Ordered,—That the name of Mr. Clancy be substituted for that of Mr. Macquarrie on the Special Committee on Drug Costs and Prices.

MONDAY, May 16, 1966.

Ordered,—That the name of Mr. Whelan be substituted for that of Mr. Mackasey on the Special Committee on Drug Costs and Prices.

Attest.

LÉON-J. RAYMOND,
The Clerk of the House.

24083—1½

MINUTES OF PROCEEDINGS

TUESDAY, April 26, 1966.

(1)

The Special Committee on Drug Costs and Prices met this day at 2:10 o'clock p.m. for organizational purposes.

Members present: Messrs. Brand, Chatterton, Enns, Haidasz, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), Hymmen, Isabelle, Langlois (*Chicoutimi*), Mackasey, O'Keefe, Pascoe, Patterson, Prud'homme, Rynard, Yanakis (17).

The Clerk of the Committee attending and having called for motions of nomination, Mr. Rynard moved, seconded by Mr. Brand, that Mr. Harley be elected Chairman of the Committee.

There being no other nominations, Mr. Harley was unanimously declared Chairman of the Committee. The Chairman thanked the Committee for the honour conferred on him.

The Clerk read the Orders of Reference at the Chairman's request.

The Chairman opened nominations for Vice-Chairman.

Moved by Mr. O'Keefe, seconded by Mr. Mackasey, that Mr. Asselin (*Richmond-Wolfe*) be elected Vice-Chairman of the Committee.

On motion of Mr. Prud'homme, seconded by Mr. Hymmen,

Agreed,—That nominations be closed.

Mr. Asselin (*Richmond-Wolfe*) was declared Vice-Chairman of the Committee.

Moved by Mr. Mackasey, seconded by Mr. Howe (*Hamilton South*),

Resolved,—That a Subcommittee on Agenda and Procedure composed of the Chairman, the Vice-Chairman, and three (3) Members named by the Chairman upon consultation with the Whips of the Parties, be appointed.

Moved by Mr. Prud'homme, seconded by Mr. Chatterton,

Resolved,—That the Committee print from day to day 1000 copies in English and 500 copies in French of its Minutes of Proceedings and Evidence.

It was suggested by Mr. Haidasz that the question of Quinidine, its price increase and behaviour, be referred to the Subcommittee on Agenda and Procedure as a first item on the agenda of the next meeting.

It was suggested by Mr. Chatterton and agreed that briefs by interested parties be submitted to the Clerk at least one day previous to its presentation to the Committee.

At 2:30 o'clock p.m., on motion of Mr. Patterson, seconded by Mr. Brand, the Committee adjourned to the call of the Chair.

THURSDAY, May 12, 1966.

(2)

The Special Committee on Drug Costs and Prices met *in camera* today at 11.10 a.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Messrs. Asselin (*Richmond-Wolfe*), Brand, Chatterton, Clancy, Enns, Haidasz, Harley, Howe (*Hamilton South*), Isabelle, Langlois (*Chicoutimi*), MacDonald (*Prince*), Mackasey, Orlikow, Patterson, Prud'homme, Tardif, Yanakis (17).

The Chairman announced the names of the Members who will act with him and the Vice-Chairman on the steering subcommittee on agenda and procedure, namely: Messrs. Howe (*Hamilton South*), Patterson and Rynard.

The Chairman presented the First Report of the subcommittee as follows:

"Your Subcommittee recommends:

1. That the Minister of National Health and Welfare, the Honourable Allan J. MacEachen, the Minister of National Revenue, the Honourable E. J. Benson, and the Director of the Food and Drug Directorate, Dr. R. A. Chapman, be invited to appear before the Committee;

2. That the proposed witnesses, whose names appear on the Chairman's list, be called with the addition of the top six drug manufacturers in Canada;

3. That the Committee hold its meetings on Tuesdays and Thursdays, at 11 o'clock a.m., subject to the approval of the Coordinator Committees;

4. That consideration of individual drug products be only taken as examples, and that the Committee should confine its major studies to general inquiry;

5. That Mr. A. M. Laidlaw, of Ottawa, be hired as legal counsel at a daily rate of $250. per working day, and be given an allowance of 10 days at this pay rate for research; and that Mr. W. J. Blakely, of Kingston, Ont., be hired as chartered accountant at the daily rate of $150. per working day, and that he be allowed up to 4 days at such pay rate for research;

6. That both Mr. Laidlaw and Mr. Blakely be given the power to cross-examine the witnesses appearing before the Committee."

The recommendations of the subcommittee were severally discussed.

Paragraph 1 was adopted.

On paragraph 2—Agreed that interested parties wishing to submit a brief should send copies to the Clerk of the Committee one week prior to its presentation.

On paragraph 3—The suggestion of the Coordinator of Committees that the meetings be held on Tuesdays at 11.00 a.m., and on Thursdays at 3.30 p.m. or after the Orders of the Day, *carried unanimously.*

Paragraph 4 was adopted.

On paragraph 5—Agreed that it be amended by adding at the end of the paragraph: "subject to the approval of the Commissioners of Internal Economy."

Paragraph 6 was amended by adding after the word "Committee": "subject to the discretion of the Chair." It carried on the following division: YEAS, 11; NAYS, 2.

The Subcommittee's First Report was adopted as amended.

At 12.10 p.m., the Committee adjourned to the call of the Chair.

TUESDAY, June 7, 1966.

(3)

The Special Committee on Drug Costs and Prices met this day at 11.25 o'clock a.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Messrs. Haidasz, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), Hymmen, Isabelle, Langlois (*Chicoutimi*), MacDonald (*Prince*), Orlikow, Patterson, Roxburgh, Rynard, Yanakis (13).

Also present: Mr. Bryce Mackasey, M.P.

In attendance: The Honourable Allan J. MacEachen, Minister of National Health and Welfare; Dr. R. A. Chapman, Director of the Food and Drug Directorate of the Department of National Health and Welfare.

Also in attendance: Mr. A. M. Laidlaw, of Ottawa, Legal Counsel for the Committee.

The Chairman introduced Mr. Laidlaw and gave the names of the witnesses who have been invited to appear during the month of June.

The Minister made a short statement.

Dr. Chapman made a brief review of the regulations promulgated under the Food and Drugs Act which contribute to the cost of pharmaceutical products, and was questioned thereon.

Mr. MacEachen was also questioned.

At 12.30 p.m., the Committee adjourned to 3.30 p.m. Thursday, June 16, at which time the Minister of National Revenue will make a statement.

Gabrielle Savard,
Clerk of the Committee.

EVIDENCE

(Recorded by Electronic Apparatus)

TUESDAY, 7 June, 1966.

● (11.27 a.m.)

The CHAIRMAN: Gentlemen, I see a quorum. Before we hear a statement from the Minister this morning I would like to give a list of those witnesses who will be coming before the committee up until the end of June. Today we have the Minister of National Health and Welfare; he has with him the Director of the Food and Drug Directorate, Dr. Chapman. On Thursday we will have the Minister of National Revenue, the Hon. Dr. Benson. On June 14 the Canadian Pharmaceutical Association—this is the druggists and pharmacists themselves—will make a presentation. On June 16, 21 and 23 we will have the Pharmaceutical Manufacturers Association of Canada, and on June 28 the Canadian Medical Association. I am quite confident that I have a witness lined up for June 30. There are many other people who have been invited to appear, most of whom have asked for a later appearance and I have said that we definitely want to see them in the fall; this includes the Canadian Labour Congress, the Consumers Association of Canada and seven individual drug firms. Some of these have already written and accepted our invitation; others have not as yet.

I would like to suggest to the committee, if I might be so bold, that the required reading material for the committee over the next week, in keeping with the briefs which are going to be presented in the near future, are the Report of the Restrictive Trade Practices Commission on Drugs—and if any of you do not have it I am sure we can get copies for you; the Hall Commission report, particularly as it relates to drugs and deals with patents and compulsory licences; for those who are interested in the safety of drugs and how to relate costs, the last report of this committee to the house. This afternoon you will all receive from the Clerk of the Committee the brief of the Pharmaceutical Manufacturers Association of Canada. As I have mentioned they will be here for three appearances. When you see the brief you will understand why the three appearances are necessary. It is an excellent, well organized brief but it is quite thick. It will take quite considerable reading and study. I would suggest to the members that although they will be receiving this report this afternoon that it remain confidential until such time as the Association is actually before the Committee.

Mr. HOWE (*Hamilton South*): Before we begin investigating I think that it would be of interest to this committee to determine if any of the members of the committee have financial interests, directly or indirectly, with any of the drug companies in order that this may be investigated in a thorough manner, as we intend to do, so that no member may be prejudiced in any way in this investigation.

The CHAIRMAN: I do not think the Chairman should ask. I think it would be obvious that anyone who has a conflict of interest should declare that. I am not

sure that everyone should go around and say, "I have no conflict of interest". Certainly, as Chairman, I am quite willing to say that I personally have no conflict of interest in any of these areas.

Mr. HOWE (*Hamilton South*): Mr. Chairman, other than asking, I was not asking for an investigation; I do not mean that. But I think anybody who has an interest should declare it so we may approach this from an unbiased point of view. I purposely said directly or indirectly because an indirect interest could be just as great as a direct interest.

The CHAIRMAN: I appreciate your remarks and I am sure all the other committee members also do.

Before we begin I have one other matter to bring up. As you know at our last meeting we appointed both legal and financial counsel to the committee. They both will will be here on Thursday to meet the committee in a more less official capacity. The legal counsel, Mr. Laidlaw is present this morning just to listen to the proceedings and perhaps he would stand so he would be known to you, Mr. Laidlaw?

Mr. A. M. LAIDLAW (*Legal Counsel*): Thank you, Mr. Chairman; it is a pleasure.

The CHAIRMAN: As I have mentioned, Mr. Laidlaw is the legal counsel for the committee and I anticipate that we will be having meetings with Mr. Laidlaw and Mr. Blakely, the accountant, to discuss the various things we should be interested in and what we should be looking for.

Unless anyone has anything further to say at this the first official meeting of this committee, I would like to introduce the Minister of National Health and Welfare, Mr. MacEachen, who has a statement for us this morning.

Hon. A. J. MACEACHEN (*Minister of National Health and Welfare*): Mr. Chairman and members of the committee. I welcome this opportunity to make a very short statement to the special committee, if only for the purpose of clarifying the role of the Department of National Health and Welfare in this very complex field. You are examining some very important matters, important both to the public and the government of Canada. You have been charged by the House of Commons to consider and make recommendations, as it may deem expedient, respecting a comprehensive and effective program to reduce the price of drugs. We are most anxious to co-operate in any way we can in the work of this committee and in this connection I am speaking for the Government and for the Department and the officers of the Department.

I would like to say a word about the responsibility of the Department of National Health and Welfare with respect to drugs. The basic Federal legislation governing the production and distribution of drugs in Canada is the Food and Drugs Act, Chapter 38 of the Statutes of Canada, 1953 and as amended by Chapter 37 of the Statutes, 1960-61. The main purpose of this act is to safeguard the consumer from health hazards, frauds and deceptions in the manufacture, sale and distribution of drugs and medical devices. It is based on the authority of the Federal Government to legislate on criminal matters and as such stipulates that drug manufacturers and distributors must not do certain things. In other words, it is essentially a prohibitive act. It does not instruct or require drug manufacturers and distributors to perform certain duties or functions since

this would imply that authority was provided to commit a criminal offence. I am really reading here a paragraph from a study prepared for the Royal Commission on Health Services entited The Provision, Distribution and Cost of Drugs in Canada. Drug manufacturers and distributors must ensure that the provisions of the Act and regulations are not violated in the sale or distribution of drugs to the general public. The Act does not approve any particular action or product except; it sets out what must not be done. Any drug or medical device not violating the act or regulations may be sold. The Department of National Health and Welfare is also responsible for the administration of the Narcotic Control Act, Chapter 35 of the Statutes of Canada 1961 and the Proprietary or Patent Medicine Act, Chapter 220 of the Statutes of Canada, 1952. In none of these statutes or regulations has Parliament given authority to the department, or to anybody else, to regulate the price of drugs. In a number of studies carried out on the medical and health services of other countries, including those by the Hall Commission on Health Services, it was found that only a limited number of governments regulate the price of drugs. In each case these regulations were tied to the administration of a drug benefit program under a national medical plan.

The committee has requested or suggested that we say something on the relationship between the cost of procedures to control the quality of drugs and the selling price set by the manufacturer. Officials of the Department of National Health and Welfare, of course, will be pleased to give detailed evidence on the requirements of the Food and Drugs Act and regulations as they relate to the control of quality. However, and unfortunately it is not within the competence of these officers to specify what influence, if any, these requirements might have on manufacturing costs. The manufacturer who is proposing to introduce a new drug into the Canadian market must, under the regulations, provide the Food and Drug Directorate with data on the safety and efficacy of that drug for the purpose it is claimed. I should point out that many of the toxological, pharmalogical and clinical studies involved in the introduction of drugs are carried out in other countries. We do not have access to information on any cost-sharing agreement which may exist between Canadian firms and manufacturers located outside Canada. We do know that such arrangements do exist and that, for example, United States companies will charge their Canadian subsidiary for a portion of the cost of developing certain drugs.

The regulations also require a manufacturer procuding a drug for sale in Canada, to carry out certain quality control procedures in accordance with good manufacturing practices. Officers of the Food and Drug Directorate are prepared to give detailed evidence to the committee on these requirements. The committee, no doubt, is also aware the Research and Statistics Division of this Department prepared a study in 1963 for the Royal Commission on Health Services. This study on the provision, distribution and cost of drugs in Canada, may be of assistance to you in your deliberations. Mr. Osborne, the Director of the division is absent from Ottawa at the present time but he or other officers of the Department will be available to the committee to comment or tell the committee anything it wishes to know about this particular study on the provision, distribution and cost of drugs in Canada.

There has been considerable speculation and public debate on the possible differences between those companies which market drugs under their proper chemical or generic name and those that market them under a brand name. Unfortunately, there is often no clear distinction between a brand name producer and a firm which developed generic name drugs. In fact, even within a single firm there may often be considerable overlapping with one company producing both a generic drug and its brand name equivalent. All manufacturers in Canada are subject to regulations C.01.051 and C.01.052 of the regulations, which I presume are in your possession. Food and drug inspectors examine these plants and their products periodically and appropriate action is taken where deficiencies are detected. In the case of drugs imported into Canada, regulation C.01.055 requires action on the part of the importer before the drug is released for sale. Under the regulations all drugs must carry the proper name on the label. This is commonly known as the generic or chemical name. Some companies choose to adopt a brand or trade name for some or all of their products. These names, I understand, are invariably used in the promotion of these items. The use of the brand name does not necessarily reflect the size of the company or the facilities available for manufacturing or quality control. The most important factor in ensuring the quality of the drug are facilities, ability and attitude of the manufacture. The possession and or use of a brand name has no direct bearing.

Mr. Chairman, I want to conclude with a very few brief general observations on some general factors influencing the cost of drugs, as this is a matter the committee will be going into in great depth. These are merely a few comments on the general factors influencing the cost of drugs in Canada.

Very few basic chemicals used in the drug industry are produced in Canada. We import the bulk of our drugs in raw form or finished state from the United States, Britain, France and Switzerland. The purchase of drugs on the world market may increase competition; it may also enable the manufacturer to purchase raw materials at a lower cost. There has recently been evidence that restrictive trade practices have resulted in a markedly increased cost to the Canadian manufacturer of material for the production of quinidine.

In my opinion, one major factor in the cost of drugs is the size of the Canadian market. We understand that manufacturers generally produce smaller batches in Canada than they do in the United States while the cost of quality control is approximately the same. This naturally increases costs. Competition in the drug industry in Canada is keen and there are a large number of products, many of them similar, competing for the available market. While such competition may tend to keep the selling price in line with manufacturing costs, manufacturing costs are increased due to the smaller size of production. The majority of drug manufacturing companies, as will be seen from this report, are located in the province of Ontario and Quebec. It is possible that this concentration and the increased distribution cost involved in supplying all areas of the country may have some bearing on drug prices.

One final factor which may be of some interest to you and which may be adding to the over-all cost of drugs concerns the practice of certain pharmaceutical manufacturing companies of carrying specialty items which have a very restricted demand. These drugs are usually for a specific disease which does not have a high incidence in the Canadian population and the company

carries these items as a service to the medical profession. I understand that it is not possible for these companies to recover the cost of developing these drugs for the Canadian market.

Mr. Chairman, these very brief comments are certainly not intended to be anything but a very preliminary introduction to the subject and are not intended to anticipate the results of the exhaustive studies which this committee will undertake.

I just want to say in conclusion that we are very much aware of the important task which has been assigned to members of this committee. I hope you will find some effective and equitable answers to the problems involved because they are problems which are of great concern to all Canadian consumers. I wish you well as you begin your undertaking and I place myself and the officers and resources of my department at your disposal in any way in which we can be helpful.

The CHAIRMAN: Thank you very much, Mr. MacEachen.

Mr. MACEACHEN: Dr. Chapman, the Director of the Food and Drug Directorate is here and will be ready to answer questions and give evidence on those areas of this field in which this Department has special responsibilities and special competence.

The CHAIRMAN: Did you wish to say anything, Dr. Chapman?

Dr. R. A. CHAPMAN (*Director-General, Food and Drugs, Department of National Health and Welfare*): Mr. Chairman, I could outline some of the requirements under the Food and Drugs Act and regulations which may influence the cost of drugs, if the committee would be interested in such an outline.

First of all, Mr. Chairman and members of the committee, I consider it a privilege to be asked to make a statement to the Special Committee on Drugs Costs and Prices.

As the Minister has already indicated the act which the Food and Drug Directorate administers does not provide authority to regulate the price of drugs. However, there are requirements, as I have suggested, in the regulations promulgated particularly under the Food and Drugs Act which contribute to the cost of pharmaceutical products and I feel that possibly a brief review of these requirements might be of interest to the members of the committee.

The Minister has referred to sections C01051 and C01052. These are on pages 80A1 and 80B of the Food and Drug Regulations, if you wish to consult them. These provide minimum requirements for manufacturing facilities and control which the manufacturing of a pharmaceutical product must meet in producing drugs for the Canadian market. These requirements include, among other things, that the manufacturer shall have a suitable building with suitable construction, fittings and furnishings provided in the area where the drug is processed and packaged. All premises must be maintained in a clean and sanitary condition. In the event parenteral drugs are processed all filling and aseptic processes must be carried out in a separate and enclosed area. Qualified personnel must be employed as supervisors. Each lot or batch of the raw or bulk material shall be tested to ensure identity and purity. Each lot or batch of the finished drug shall also be tested. Adequate control procedures must be employed in the plant. A system of control shall be provided to permit a

complete and rapid recall of the drug from the market if this should become necessary. Adequate records must be maintained. Samples of each lot of the finished drug in dosage form shall be kept for five years or until the expiration date of the drug. These requirements apply to all drugs sold in Canada as well as those sought to be imported into Canada.

In addition there are special regulations pertaining to the laboratory and clinical testing of new drugs. In this case two submissions are required. First, a pre clinical submission which must be submitted to the directorate by the manufacturer prior to the distribution of the drug to qualified investigators who are willing to obtain clinical evidence as to the safety, dosage and effectiveness of the new drug. When that work has been completed a new drug submission must also be cleared by the Directorate prior to the sale of the drug on the open market. It is the purpose of the pre clinical submission to ensure that the manufacturer has complied with certain basic requirements before approaching a clinical investigator to administer the drug to a patient. This pre clinical submission must include, among other matters, the objectives of the proposed clinical testing; the identifying name or mark of the new drug; its chemical structure; its source; the results of investigations made to support the clinical use for the new drug; the contra-indications and precautions that are known in respect of the new drug and the suggested treatment of overdose of the new drug; the method; equipment, plant and controls used in its manufacture; tests applied to control the potency, purity and safety; and name and qualifications of all investigators to whom the drug is to be sent. Before the sale the manufacturer of the new drug ascertains that each of the qualified investigators to whom the new drug is to be sold has the facilities for the investigation and all the other relevant information in regard to this drug.

The Directorate has prepared a Guide for completing reclinical submissions on investigational drugs and, Mr. Chairman, I would be very pleased to make this guide available to members of the committee if they should wish to have it. It will give you an indication of the types of tests which are required.

Following the submission of a satisfactory preclinical submission, then clinical testing is carried out and at its conclusion, a new drug submission must be filed with the Minister. This again, briefly, should contain the following information: a description of the drug; the name under which it is proposed to be used; a quantitative list of all the ingredients; again a description of the plant and equipment used; details of the manufacturing procedures and controls; reports of the tests to establish the safety of the new drug; substantial evidence for the clinical effectiveness of the new drug; the names of all clinical investigators; and copies of all promotional material. When the new drug submission has been found to be—and I quote from the regulations—"in a form having a content satisfactory to the Minister", then a "Notice of Compliance" is issued. At this point the manufacturer may market the new drug in Canada provided it meets all other requirements of the Food and Drugs Act and Regulations.

I am sure the requirements for manufacturing facilities and controls and the regulations pertaining to new drugs have an impact on the cost of drugs in Canada. At the same time I consider these requirements essential in order to reduce the hazards involved in the use of drugs to the lowest practicable level. I am sure that reputable manufacturers of pharmaceuticals would agree that such

requirements are necessary. I do feel, however, that our regulations should be reviewed at regular intervals to ensure that no unnecessary obstacles are being placed in the way of the development of new drugs and at the same time to strengthen any areas where additional hazards have become apparent. I might add that our requirements for preclinical submissions, Mr. Chairman, are undergoing a thorough review at the present time in accordance with the recommendations of this same committee on food and drugs.

As indicated at the outset, I have outlined the principal requirements of the Food and Drug Regulations which will have an effect on the cost of drugs. Just how much they contribute to the total cost I am not in a position to say. I might draw the attention of the committee to one of these reports which the Chairman has already referred to, the Report concerning the manufacture, distribution and sale of Drugs, of the Restrictive Trade Practices Commission which studied this matter in some detail. On page 152 of this document under Expenditures on Quality Control in Relation to Value of Sales, the following statement appears:

> From the evidence which was heard by the Commission—

That is the Restrictive Trade Practices Commission.

> —it would appear that many firms would have difficulty separating some costs of quality control from costs of manufacturing generally, as, in many cases, steps to insure quality enter into each stage of production until the drug is put in package form. On the basis of the information received from 22 of the 27 firms reporting expenditures on quality control it was calculated that such expenditures represented approximately 3.62 per cent of the cost of the goods sold. The survey of drug firms made on behalf of the Canadian Pharmaceutical Manufacturers Association included information on quality control expenses in 1960 of 35 companies. The figures reported included amounts spent in Canada and amounts charged to Canadian companies by parent or affiliated companies outside Canada for the operation of quality control laboratories and to cover the cost of testing in outside laboratories. However, the figures did not include the cost of inspection staff and other techniques designed to control the manufacturing process required to produce a quality product. For the 35 firms the cost of quality control as described—

And this is important because it does not include all these other techniques designed to control the manufacturing process.

> amounted to 4.2 per cent of total production cost in 1960.

I presume these figures would require to be re-examined in the light of present costs.

I should like to conclude by referring again to the point made by the Minister to the effect that the quality of the drug is dependent upon the manufacturing facilities available; the control procedures employed; the training, experience and ability of the personnel employed by the company and finally, the integrity of the firm itself.

Mr. Chairman, the committee may wish to explore the impact of some of these factors on drug costs and prices. If we can be of any assistance, as the Minister has indicated, the officers and facilities of the Directorate are at your complete disposal.

The CHAIRMAN: Thank you, Dr. Chapman. The meeting is open for questions.

Mr. ISABELLE: Dr. Chapman, you mentioned many times in your comments the requirements of new drugs. Could you give us a practical definition of what constitutes a new drug and an old drug, and what are the requirements to manufacture both?

Dr. CHAPMAN: Well, the term "new drug" means a drug that has not been sold as a drug in Canada for a sufficient time and in sufficient quantity to establish the safety and effectiveness of that substance for use as a drug. That is just the bare core of the definition of a new drug.

Mr. ISABELLE: How do you determine when a new drug is no longer a new drug but becomes an old drug?

Dr. CHAPMAN: This is a matter of judgment. At a point when it is considered to have been sold for a sufficient time in Canada and in sufficient quantity to establish the safety and effectiveness of that drug then it is no longer considered to be a new drug. There are a number of factors which may enter into this judgment: Certainly the amount that has been sold, the lack of serious adverse reactions; whether or not it has been tested, for example, in institutions where it has been under very careful control; whether or not a monograph on the drug has been published in one of the recognized compendia of drugs such as the British Pharmacopoeia or the United States Pharmacopoeia. These are the type of factors that are taken into consideration as to when a new drug is no longer a new drug.

Mr. ISABELLE: And after that what happens? Let us suppose a drug is new and two or three years later it is decided a drug is no longer new. Could I obtain a certificate under the Patent Act—or whatever you call it—to manufacture this drug. Suppose I want to buy in Italy some Chlordiazepoxide which is the trade name for Librium, could I obtain a licence to manufacture without having to meet your requirements for new drugs because it is no longer a new drug. What happens if I buy the substance from Italy, bring it here to Canada, have someone manufacture this, and put it on the market under a new name without any surveillance at all.

Dr. CHAPMAN: Well first of all I would not anticipate that a new drug would be taken out of the new drug status within a period of three years. We would feel that at least five years would be necessary and in many instances it would be longer than that. Now if it were no longer a new drug then it would have to meet all the other requirements of the Food and Drug Regulations. I have referred earlier to the manufacturing facilities and controls. So far as the Patent Act is concerned I am certainly not an expert in that field and I do not feel I should attempt to describe how the Patent Act would apply.

Mr. RYNARD: Mr. Chairman, I would like to ask Dr. Chapman a question. Question was made that some firms were manufacturing both the brand name and the generic name. What becomes of the generic drug they manufacture; is it sold on the open market or is it sold to other firms to market?

Dr. CHAPMAN: Well, so far as I am aware—and I should point out that our responsibilities do not extend to this type of statistic—firms might very well be selling both forms. For instance an institution might ask firms to tender on a

particular drug and they would ask for it by its generic name. At the same time this same firm might sell that drug under its generic name but it might also be marketing the same drug under a brand name.

Mr. RYNARD: They could not sell the generic drug over the counter then?

Dr. CHAPMAN: They might.

Mr. RYNARD: They might.

Dr. CHAPMAN: Yes, or they might sell it under a brand name, either one.

Mr. RYNARD: Now there is another question I would like to ask Dr. Chapman. Practically all our drug firms are American and one of the factors in the cost, the minister said, was because of the small runs, which helped put the price up. I am wondering if some pact or agreement could be worked out similar to that in the auto industry that would bring our price down?

Dr. CHAPMAN: I do not believe, Mr. Rynard, that I am really in a position to comment on that.

The CHAIRMAN: Mr. Orlikow is next.

Mr. ORLIKOW: I must say I was disappointed in the statement of the Minister. Here is a subject which has been of concern to the people of Canada for quite a number of years, the high cost or what is believed to be and what I believe to be the excessively high cost of prescription drugs, which are not a luxury; they are a must. If there is any point in going to a doctor when a person is sick then it is essential that person follow the advice of the doctor, including the taking of prescription drugs, if they are prescribed. In 1961 there was a report by the Director of Investigational Research under the Combines Investigation Act, and this led to a report in 1963 of the Restrictive Trade Practices Commission; both of them made a number of specific recommendations about how the high cost of prescription drugs might be reduced. The Hall Commission dealt with this, yet the Minister comes here and says in effect that the Department has not really made a study of the question or even of the specific recommendations involved. There are a whole series of recommendations which I could list for the minister and say: Have you looked at this; have you an opinion on this? But it seems obvious that the Department has looked upon its responsibility in a very narrow and legalistic sense, and we are not going to get any advice or recommendations from the Department. There are a host of recommendations in these reports and it seems to me that this matter having been before the public for at least five or six years that the Department should have investigated the recommendations. We spent a good deal of time on safety. I am not certain we have solved all the problems, but I do not want to ask some questions which I would like to ask because I think we would just postpone again the date when we would get down to the question of drug prices. There are some of us who have wanted to look at them since this committee was formed more than two years ago. I would like to ask the Minister, has not the Department or anybody in the Department been assigned to the job of looking at the studies of these various bodies which have looked at drug prices and the recommendations they made to the Department. After all, the Department plays an important role not only for the general public, but it should play an important role for example for the Veterans Affairs hospitals which the

government operates all across the country. I would like to ask the Minister, has not the Department looked at these recommendations; has it not formed opinions and has it not recommendations for this committee?

Mr. MACEACHEN: Mr. Chairman, may I make some comments about Mr. Orlikow's opening statement. These remarks somewhat fall into the category of the old drug status because this kind of opening comment Mr. Orlikow has used over such a long time and in such sufficient quantities that we have been able to assess their toxic effect.

The first point I want to make is that the committee has been charged by Parliament to bring in a comprehensive program for the lowering of the price of drugs. Parliament has already given that job to the committee and the government is prepared to co-operate with the committee in producing recommendations. We are not coming forward to the committee with a series of proposals to reduce the price of drugs because I am sure if we did that we could be properly accused of usurping the functions of this committee.

We have in the Department various responsibilities in the field of drugs. The Special Committee on Food and Drugs in 1964, presented a report on the safety of drugs and we have considered its recommendations; if the committee wishes to hear what we have done about this particular aspect of the drug problem we would be glad to give as much information as we can. We have had a report from the Hilliard Committee in our own field on the various aspects of compulsory licencing and we are prepared to report on that. In other words, we are prepared to report to the committee on all aspects of the drug problem which have been assigned to this Department by the statutes of Parliament. There are other aspects as my hon. friend will realize, that are really within the purview of other departments, and it is my submission that no effective program could be developed in this field without hearing from a number of sources and without developing a program in co-ordination with other departments. I had not expected the committee would want me to present a series of proposals developed by the Government in this field. I had expected the committee would want to hear evidence and develop recommendations which then could be considered by the Government. I regret, Mr. Orlikow, if once again I have disappointed you.

Mr. ORLIKOW: I think the Minister knows me and other members of the committee well enough to know that if the Department had the kind of recommendations which I suggested that they should have the members of the committee would not accept them without discussion and go on from that. The fact is, Mr. Chairman, you have already mentioned earlier that we are going to have a very comprehensive and I am sure a very carefully prepared and well researched brief, from their point of view, from the Canadian Pharmaceutical Manufacturers Association and later from the individual drug companies. I am certain without seeing their brief that the whole tenor of the brief will be to prove that the cost of prescription drugs is not too high. That is very legitimate from their point of view. We are going to be faced with this tremendous mass of information and it does seem to me that it would be quite proper for the Department of National Health and Welfare, which is involved with the health of the people of Canada in so many ways, to put somebody to work full time in their Department who is much more conversant with these problems than the

members of the committee are, to look at the investigations which have been held, to look at the enquiries which have been held by, for example, the Kefauver committee and, if not today at some point before the committee has to write its final report, to make recommendations on a whole series of things, for example, what the Department thinks would be the effect of amending the patent laws. Generally the patent laws do not come under health and welfare but the patent laws as they affect the manufacture, distribution, sale and price of prescription drugs do affect the people of Canada and, therefore, I think the Department of Health and Welfare should have an opinion.

Mr. MACEACHEN: Mr. Chairman, I agree the committee is embarking upon a very important and complicated subject matter. I understand the committee already, has acquired the services of counsel and a financial adviser, both of whom will be able to assist the committee a great deal. Naturally the Department of Health and Welfare and other departments will be interested in the work of the committee; it may be that as the work of the committee develops it will be possible to assist the committee in making some suggestions. I agree with the point of view that the committee ought to be given all the help it needs and we will give all the help we can in formulating the conclusions from the committee.

Mr. ORLIKOW: Mr. Chairman, I am not going to pursue this but I still do not see why the Department could not do in this question essentially what it does in a normal way when it presents its estimates. When it presents its estimates to the House and to the committee it looks at its estimates and it says, here is what we think we need in the way of money for the programs we are going to carry on; the committee discusses that and makes suggestions which may or may not be accepted by the Government and the Department. I do not see why at some point—I do not say today—the Department could not bring in recommendations and suggestions and say, here is what we think should be done; we think the committee should consider it.

Mr. MACEACHEN: Well I would not quarrel with your line of argument, that the Government might be asked to do this, but we attempted in the Department to remain within our own area of responsibilty which does not permit us to provide the kind of expertise in the field of prices which other departments have. We considered this very carefully before we appeared before the committee, Mr. Orlikow, and we felt this was the only responsible approach we could take. However, we certainly will assit the committee and if it can be done at all we will attempt to assist the committee in reaching conclusions.

Mr. ORLIKOW: Mr. Chairman, I would just like to ask a couple of very specific questions. Has the Department given study to amending the regulations, as the U.S. Food and Drug Administration did, to provide that in the advertising and labelling of prescription drugs it be required that information as to such matters as side effects, contra-indications and effectiveness be included in both the labelling and the advertising of prescription drugs?

Dr. CHAPMAN: This would come under the provision of 9(1) of the Act. I might point out that in Canada authority over advertising of food, drugs, cosmetics and medical devices, is provided under the Food and Drugs Act. In the United States general advertising is not; it comes under the Federal Trade Commission, although they do have certain requirements about new drugs and

the necessity for indicating possible adverse reactions. But we do have this authority now. No person shall advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quality, composition, merit or safety.

Mr. ORLIKOW: Mr. Chairman, there have been a whole series of books and articles written recently in the United States which would indicate there was considerable length of time between some of the biggest drug companies getting reports of adverse effects on new drugs and when they start advising the medical profession and so on, that they have this information. I wonder if we have reports on similar problems. I can bring a book here at a later date and list specific drugs which these books and articles have reported.

As I said earlier, Mr. Chairman, I do not think we should start another investigation into drug safety but I want to know whether the department feels that the law gives them the authority to do what we hope they are doing.

Dr. CHAPMAN: Yes, Mr. Orlikow, I think we have the necessary authority in the Food and Drugs Act?

Mr. ORLIKOW: Do you have the staff to enforce it?

Mr. MACEACHEN: It is likely the answer is no.

Dr. CHAPMAN: At the present time we do not have the staff that I consider necessary to do the job we would like to be doing and that we would like to see done. However, I can say that it is government policy, and it has been cleared with Treasury Board, that our staff will be increased by approximately two and one half times over a period of twelve years. The actual increase was from 718 to 1733 positions. This has been cleared and we have been given assurance that we will be allowed to recruit as the qualified personnel become available. One of our problems at the present time is that in certain areas it is very difficult to recruit the highly qualified type of person that we require.

Mr. HOWE (*Hamilton South*): Mr. Chairman, would you advise members of the committee again what the terms of reference are. I thought the only subject we were to deal with was the toxic effect on the Canadian pocketbook.

Mr. PATTERSON: Mr. Chairman, that is one of the issues I was going to raise at the moment. I was going to suggest that you, Mr. Chairman, indicate very clearly what the terms of reference of this committee are. Although, I was not on the committee prior to this time I understand a very thorough study was given to some of the other aspects of these problems. If we are going to start reviewing and going over again what has already been done it is going to seriously affect the efficiency of the committee in its study of what I understand now from the terms of reference encompassing the cost of drugs.

Mr. Chairman, I find it a little difficult to find my way into the discussion and to know where these questions should properly be put. First of all, I would like to ask if the Guide to which Dr. Chapman referred will be distributed or will it be incorporated into the minutes of the committee for today?

The CHAIRMAN: I am not sure a decision was taken. It is called—a Guide for Completing Pre Clinical Submissions on Investigational Drugs. It only has an indirect relationship to the question of cost. I would think it should be distributed to the members; those who wish to read it can and those who were

on the committee last time and got a careful briefing of this probably will not find it necessary.

Mr. PATTERSON: That will be fine then. In the Minister's presentation he made a statement to which Dr. Rynard referred when he stated that the rather limited domestic market would necessarily affect to some degree the cost of drugs in Canada. I was wondering just how many Canadian drug companies have operated in the past in Canada because at the present time I have been given to understand that there are no Canadian drug companies. Is that right?

The CHAIRMAN: "No large Canadian manufacturing company," I think would be more accurate.

Mr. PATTERSON: Solely Canadian. I was given to understand that Frosst was the largest and the last Canadian company and within the last several months it passed into American control. Would this situation affect either favourably or unfavourably the cost of drugs in Canada? As I say, I do not know just when or to whom I should direct this question, but it came to my mind this morning, and was raised by the Minister in his opening statement.

The CHAIRMAN: I do not know whether the Minister wants to deal with it. I would think this is probably a question which the committee are eventually going to have to answer when they come up with their recommendations. Certainly the Pharmaceutical Manufacturers Association will probably want to comment on this. I do not know if the Minister wishes to comment further on his statement about ownership and how it relates to the cost of drugs.

Mr. MACEACHEN: No, Mr. Chairman. I merely mentioned it as one of the facts the committee might want to consider. I would mention to Mr. Patterson that there is in this publication, which I mentioned earlier, a fairly good description of the structure of the drug industry in Canada, the ownership as between foreign firms, subsidiaries and Canadian companies; it might be helpful to refer to that particular chapter called Present Methods of Production and Distribution of Drugs in Canada, Chapter 2 which has some very good information.

The CHAIRMAN: Which is not completely up to date because of some of the things that have happened since.

Mr. PATTERSON: Could anyone answer the question. Are there any truly Canadian drug companies, large or small, operating at the present time?

The CHAIRMAN: I think, perhaps, Dr. Chapman can tell us the number of drug manufacturers there are in Canada if that would be of any value to you.

Dr. CHAPMAN: There are approximately 480 drug manufacturers that we would define under our definition of a manufacturer. I might say that also there are between 800 and 900 firms that register products under the Proprietary or Patent Medicine Act. Now some of these are included in the 485 and some of those firms who register products under the Proprietary or Patent Medicine Act would probably only be producing one product, a cough medicine or something of that sort. So, I think the figure of 480 would be an approximate figure and probably the most realistic figure.

The CHAIRMAN: Any other question, Mr. Patterson?

Mr. PATTERSON: No.

Mr. MACKASEY: Mr. Chairman, I think it only fair to point out that I am no longer a member of the committee but having sat in on 24 or 27 committee meetings in the last session I thought I would avail myself of the opportunity of the new rules of the House to participate in perhaps one meeting and perhaps make some observations to the Minister. I hope the Minister or the Department will pay a little more attention to the recommendations of the committee when it bring in a report than has been the case in the past. I refer to the Hilliard Report which Dr. Chapman mentioned quite favourably and point out that most of the basic recommendations of the Hilliard Report were the recommendations of this committee many months earlier and had some amendments been put into legislation on these recommendations the Hilliard Report would'nt have been necessary.

Mr. Chairman, there has also been a certain amount of discussion about Charles E. Frosst and I would like to say, at the risk of being ruled out of order, that the sale of Frosst to American interests was precipitated by our outmoded approach to inheritance tax, forcing the owners of that particular all-Canadian firm to sell their plant long before they would have liked to have done so; it was up for sale for many years to Canadian interests who refused to take advantage of it, and perhaps this is another good reason why the Canada Development Corporation should come into existence in order to keep Canadian companies in the hands of Canadians. If it passed into the hands of Americans it was only after Canadians refused to take advantage of it as everybody knew it was up for sale.

The CHAIRMAN: I will not rule you out of order, Mr. Mackasey but—

Mr. MACKASEY: I said all I wanted to say on it.

The CHAIRMAN: —I suggest you come back and make that statement to Mr. Benson on Thursday.

Mr. MACKASEY: The point, Mr. Chairman, that I really want to get to, and I side with Mr. Orlikow in this connection, is that you and the members of the committee will find it very difficult to divorce safety from cost, regardless of what Mr. Patterson says because the industry's defence is that the cost of implementing the safety measures of Dr. Chapman have a direct bearing on the cost of production. Perhaps the mistake our committee made, and I am to blame as much as anybody else, Mr. Chairman, was trying at the beginning to divorce our hearings and to take the subject of safety first and then the cost later on, forgetting that the personnel or the membership of the committee was bound to change. Therefore, many members are not aware of the arguments which were advanced at the time we discussed safety. It is only fair to Mr. Patterson and others that you be very lenient when the question of safety is introduced.

Finally, Mr. Chairman, I think one of the nicest things that anybody could say about the last committee—and I speak for the public and the manufacturers —was the degree of objectivity which prevailed at our hearings, in contrast to the Kefauver hearings in the United States. That is why I would like to point out to you that on four occasions Mr. Orlikow mentioned the high cost of drugs. This is a premise Mr. Chairman; we are out to prove whether the cost is high, fair or normal. This is the mandate of this particular committee. To start out on the premise that automatically the costs of drugs are high is unfair, I submit, to

the reputation for objectivity which this committee had, and I would respectfully point out to the Chairman that we are here to investigate the cost of drugs and the possibility of reducing the cost of drugs, and we should not automatically presume the costs of drugs are high, Mr. Chairman.

I would point out again to the Minister that this committee recommended very strongly in the last session that the 11 per cent sales tax be removed from drugs, and I fail to understand why this recommendation was not implemented sooner by the Government.

The CHAIRMAN: Mr. Mackasey, in relation to your last statement about the terms of reference and whether drug costs are high or not, actually in our terms of reference the high cost of drugs is not mentioned at all. It just says that the committee will produce a comprehensive and effective program to reduce the price regardless of whether they are high or low.

Mr. MACKASEY: You allowed Mr. Orlikow to read into the record on three occasions the phrase "the high cost of drugs"; it is becoming almost a cliché around here. We are out to determine whether the costs of drugs are high.

The CHAIRMAN: There is one point I should mention. I do not think this committee ever recommended the removal of the federal sales tax because it was not considered.

Mr. MACKASEY: Well we certainly discussed it at great length. I know Dr. Rynard and other members of the committee spoke in the House on it as a result of our meetings.

The CHAIRMAN: This is true.

Mr. MACKASEY: I stand corrected. I apologize.

The CHAIRMAN: Are there any other questions of the Minister or of Dr. Chapman?

If not, the meeting is adjourned until 3.30 on Thursday or after the orders of the day if they take longer than that. At that time we will have the Minister of National Revenue here to discuss customs, tariffs and Federal sales tax.

OFFICIAL REPORT OF MINUTES
OF
PROCEEDINGS AND EVIDENCE

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LÉON-J. RAYMOND,
The Clerk of the House.

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 2

THURSDAY, JUNE 9, 1966

WITNESSES:

The Hon. Edgar J. Benson, Minister of National Revenue; Mr. Raymond C. Labarge, Deputy Minister, Customs and Excise; Mr. L. J. Vetter, Assistant Director, Excise Tax Administration; Mr. A. R. Hind, Assistant Deputy Minister, Customs; and Mr. M. D. O'Heare, Acting Head of Division B of the Department of National Revenue.

ROGER DUHAMEL, F.R.S.C.
QUEEN'S PRINTER AND CONTROLLER OF STATIONERY
OTTAWA, 1966

24085—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

Vice-Chairman: Mr. Patrick T. Asselin (*Richmond-Wolfe*)

and

Mr. Brand,
Mr. Chatterton,
Mr. Clancy,
Mr. Côté (*Dorchester*),
Mr. Enns,
Mr. Haidasz,
Mr. Howe (*Hamilton South*),
Mr. Howe (*Wellington-Huron*),
Mr. Hymmen,
Mr. Isabelle,
Mr. Langlois (*Chicoutimi*),
Mr. MacDonald (*Prince*),
Mr. O'Keefe,
Mr. Orlikow,
Mr. Pascoe,
Mr. Patterson,
Mr. Prud'homme,
Mr. Rosburgh,
Mr. Rynard,
Mr. Tardif,
Mr. Whelan,
Mr. Yanamis—24.

(Quorum 13)

Gabrielle Savard,
Clerk of the Committee.

MINUTES OF PROCEEDINGS

THURSDAY, JUNE 9, 1966
(4)

The Special Committee on Drug Costs and Prices met this day at 3.45 p.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Messrs. Asselin *(Richmond-Wolfe)*, Enns, Harley, Howe *(Hamilton South)*, Howe *(Wellington-Huron)*, Hymmen, Isabelle, MacDonald *(Prince)*, O'Keefe, Pascoe, Patteron, Prud'homme, Roxburgh, Rynard, Whelan, Yanakis (16).

In attendance: The Hon. Edgar J. Benson, Minister of National Revenue; Mr Raymond C. Labarge, Deputy Minister, Customs and Excise; Mr. L. J. Vetter, Assistant Director, Excise Tax Administration; Mr. A. R. Hind, Assistant Deputy Minister, Customs; and Mr. M. D. O'Heare, Acting Head of Division B of the Department of National Revenue.

Also in attendance: Mr. A. M. Laidlaw, of Ottawa, Legal Counsel for the Committee, and Mr. W. J. Blakely, of Kingston, Accountant for the Committee.

The Minister made a statement outlining some aspects of the Canadian Customs treatment of drugs and pharmaceuticals in relation to the cost of these products on the Canadian market; he also indicated the application of the Sales Tax in this area.

The Chairman introduced Mr. Blakely to the Committee.

The Minister was questioned; he was assisted by Messrs. Labarge, Vetter, Hind and O'Heare.

Messrs. Laidlaw and Blakely also asked questions of the Minister.

At 4.55 p.m., the Committee adjourned to 11.00 a.m. Tuesday, June 14th at which time The Canadian Pharmaceutical Association will present a brief.

GABRIELLE SAVARD,
Clerk of the Committee.

24085—1½

EVIDENCE

(Recorded by Electronic Apparatus)

THURSDAY, 9 June, 1966.

The CHAIRMAN: Gentlemen, would you please come to order. The Minister of National Revenue, the Hon. Mr. BENSON, is going to make a statement this morning relative to the cost of drugs.

Hon. E. J. BENSON (Minister of National Revenue): Gentlemen, I thought the committee would find it helpful if I outlined some aspects of the Canadian customs treatment of drugs and pharmaceuticals in relation to the cost of these products on the Canadian market.

Following my comments on the customs treatment I intend to indicate the application of the sales tax in this area. The Restrictive Trade Practices Commission dealt with the subject in its report on the manufacture, distribution and sale of drugs in Canada as did the Royal Commission on health services in its report. The recommendations of these commissions related to ethical drugs for human use which may be defined in a general way as those drugs which may not be advertised to the public and which may only be sold through a drugstore under the supervision of properly qualified pharmacists or supplied through a hospital or doctor. This definition excludes propriety or patent medicines. Ethical drugs may be further defined as either pharmaceutical drugs or pharmaceutical preparations. The former are basic drugs consisting of single substances without admixture, often imported in bulk form, while pharmaceutical preparations consist of basic drugs, as the active ingredient plus other substances which are added to facilitate use in dosage form. Thus, pharmaceutical drugs are mainly used in the manufacture of pharmaceutical preparations for ultimate sale to the consumers.

The Restrictive Trade Practices Commission on page 507 of its report, inclined to the view that "with respect to ethical drugs and more especially antibiotics and tranquillizers, the dumping duty rules may sometimes operate to increase the costs of some Canadian importers without giving any substantial protection to Canadian manufacturers". Implicit in this comment was recognition of the fact that while most of the pharmaceutical drugs used in the manufacture of antibiotics and tranquillizers are not produced in Canada, most pharmaceutical preparations containing these drugs are ruled to be of a class or kind made in Canada for purposes of dumping duty. Because of the valuation base used, this liability to dumping duty appeared to the Commission to cause imported finished dosage forms to be higher priced than would otherwise be the case, especially when the importer is a subsidiary of the exporting company.

The Royal Commission on Health Services recommended that the Tariff Board be requested to review the tariffs on drugs (Recommendation No. 71). In Tariff Board Reference No. 120 which commenced before the Royal Commission recommendation was made, the Tariff Board examined many fine chemicals which are used by the pharmaceutical industry although this reference did not extend to pharmaceutical products, drugs

and preparations. The report and recommendations of the Tariff Board have not as yet been released, but it is anticipated that they will be forthcoming shortly.

The Royal Commission on Health Services also recommended (Recommendation No. 72) that, in the administration of anti-dumping regulations in respect to drugs, the Minister of National Revenue be given discretion to establish "market value" at lower levels than that resulting from present practice. A change in the customs valuation legislation would be required if finished pharmaceutical preparations were to be valued in any other than the present manner. As a different approach to the problem some thought has been given to limitation of the liability for anti-dumping duty to drugs of a *kind* made in Canada. Different drugs used for the same general purpose are considered to be of one "class or kind" for purposes of dumping duty, and it has been suggested that the combined effect of the anti-dumping and customs valuation laws usually force prices up in import transactions between related companies. If dumping duties were limited to these drugs of a *kind* made in Canada, it has been suggested that the undesirable effect of inflating prices of drugs not actually manufactured in Canada could be eliminated while at the same time the necessary protection of existing and future Canadian production could be continued.

Concerning the customs valuation, in general, finished pharmaceutical preparations in dosage form are valued at the prices at which like goods are freely sold at the time and place of shipment to purchasers at the same or substantially the same trade level as the importer and in the same or substantially the same quantities, for consumption in the country of export in the ordinary course of trade. This is the standard basis of valuation that is used not only for drugs but used generally to determine whether or not dumping is taking place into Canada. In situations where the goods imported are not sold in the same condition in the country of export, drugs and pharmaceuticals are valued at manufacturing cost plus an advance. The "cost plus" valuation is used only when fair market values do not exist, as in cases where drugs are imported by subsidiaries of the exporter for further processing. Such further processing would normally be done by the exporter in his home market and thus he would not sell the drugs in the country of export in the condition exported to Canada.

Basic drugs imported in these circumstances would usually be valued at manufacturing cost plus 50 percent, when requiring further manufacture with other materials in Canada. Pharmaceutical preparations in bona fide bulk for packaging in bottles, vials, boxes, etc. in Canada would usually be valued at manufacturing cost plus 75 percent. These gross profit advances do not apply when the exporter's gross profit on home market sales of the finished product is less than the percentage advance stipulated. In such cases, a lower mark-up is determined. In no instances would the advance exceed 100 percent.

The advances over manufacturing cost were authorized under the Ministerial authority outlined in section 38 of the Customs Act in 1960. They were established some years earlier on the basis of a survey of the pharmaceutical industry in the United States and are thought to be reasonable in relation to gross profits in the drug industry in exporting countries, it being recalled that the purpose of the advance is to establish the nearest ascertainable equivalent value for the imported goods. This means that there should be a relationship between the advance on the imported goods and the advance on the finished goods as sold for home consumption. Indeed, if anything, these advances are low in terms of the current profit structure of the industry. A study conducted by the Department in this connection indicates that gross profits from 200 per cent to 1200 per cent are common in

the United States drug industry. Selling costs in the industry are high because ethical drugs may not be advertised and numerous free samples are distributed to prospective customers. Such costs plus the cost of research may account for much of the gross profit spread. However, a report published by the United States Government indicates that the American drug industry realizes a *net* profit after taxes of about 11 per cent. Not only are customs mark-ups low as compared with industry profits, but also the factory costs to which they apply are low in relation to the total costs incurred in marketing pharmaceuticals. Thus the values for duty now prescribed under section 38 of the Customs Act are low in terms of normal selling prices in the industry, and for this reason there is some doubt that any lower valuation would greatly reduce the price of drugs in Canada. A lowering of value would have no effect on the transaction unless the exporter were prepared to reduce his price to Canada and there is no assurance that this would be done in all cases. In this connection, it is understood the United States Internal Revenue Service has authority to insist that a certain level of profit be realized by American firms on sales to foreign subsidiaries and that balance of payments problems have resulted in increased exercise of this authority, although it is essentially designed to prevent tax evasion — that is, in the United States.

When pharmaceutical preparations in final dosage form are imported by subsidiaries of the exporter, the exporter may be willing to extend lower prices to his related company than to other purchasers. Such prices are not legal values for duty under the present customs valuation legislation. If a change in the legislation were made to recognize such transactions, it might affect only the distribution of profits rather than prices to consumers. In addition any change in the legislation concerning the basis of valuing finished pharmaceutical preparations would likely have to be extended to all industries, with far-reaching effects.

Pharmaceutical drugs of a *kind* not produced in Canada (i.e., the identical drug is not produced) are generally classified under item 20839-1 at 15 per cent ad valorem (MFN) or free (BP). If a kind produced in Canada, such drugs are generally classified under item 71100-1 at 20 per cent (MFN) or 15 per cent (BP). Pharmaceutical preparations, on the other hand, not being single substances, are generally classified under item 22001-1 or 22002-1 at 20 per cent (MFN) or at the effective BP rate of 15¾ per cent (17½ per cent less 10 per cent), regardless of their "made in Canada" status.

Pharmaceutical drugs of a kind not made in Canada (tariff item 20839-1) are also held by the Department to be of a "class or kind" not made in Canada and hence are exempt from dumping duty. This administrative practice is based on the premise that single chemicals do not generally lend themselves to grouping into a "class", and therefore "kind" becomes the determining factor. By the same token, pharmaceutical drugs classified under tariff item 71100-1 are subject to dumping duty.

Pharmaceutical preparations are, by and large, held to be of a class or kind made in Canada for purposes of dumping duty. For example, if at least one tranquillizer preparation is made in Canada in the necessary quantities, all imported tranquillizer preparations are subject to dumping duty, regardless of whether the active ingredient present in the imported preparation is in fact produced in Canada. Basic to the Department's attitude is the assumption that, of necessity, most imported pharmaceutical drugs must be used in the manufacture of preparations in Canada.

A preparation can only be described in terms of its composition, and if "class or kind" were defined in terms of the Canadian manufacturer's formula (e.g. 20 per cent A, 20

cent B, and 60 per cent C) an exporter could avoid dumping duty by merely altering the proportions or substituting one component material for another while leaving the active ingredient the same. Thus, it has been thought necessary to classify all broadly competitive or substitutable preparations as of one "class or kind", if any protection is to be afforded Canadian producers. However, due to the different approach taken with respect to basic drugs, there is no doubt that this practice has tended to foster manufacturing operations in Canada which are confined to refining and preparing dosage forms, rather than producing basic drugs, the majority of which are imported.

A survey of a number of Canadian pharmaceutical companies was conducted by the Department to ascertain the impact of customs duty on the selling prices of ethical pharmaceutical drugs and preparations in Canada.

From the information furnished, only 1.9 per cent of the finished ethical pharmaceutical drugs and preparations sold in Canada are imported in the finished condition. Of this category, customs duty represents an average of 6¼ per cent of the Canadian selling price to consumers. Approximately 19 per cent of the pharmaceutical drugs and preparations are imported in an unfinished condition for further manufacture in Canada or in bulk for full or partial packaging in Canada. Customs duty is understood to represent an average of 2½ per cent of the consumer selling price of this group of products. The remaining 79.1 per cent of sales are made predominantly from Canadian materials, together with, of course, some imported raw materials and supplies. On this great portion of domestic sales, the Customs duty is approximately 7/10 of one per cent of the selling price to Canadian consumers. All of this is based on a survey carried out by my department.

The amount of Customs duty included in the selling price to consumers of ethical pharmaceutical drugs and preparations is perhaps well illustrated by a statement made by one of the companies which were good enough to furnish us with information, ". . . Customs duty has little or no impact on the selling price of our manufactured products."

Implementation of the suggestion that dumping duty be limited to those drugs of a *kind* produced in Canada would affect only pharmaceutical preparations because such treatment is already given to basic drugs. In the case of preparations, adoption of the recommendation would deny dumping duty protection to most of the Canadian manufacturers who now enjoy such protection. If dumping duty applied only to those formulations actually manufactured in Canada, very few imported preparations would be subject to the anti-dumping regulations. Competitors would merely import substitutes for the Canadian product, and although the imported preparations would be used for the same purpose they would, technically, be of a kind not made in Canada and free of dumping duty. Additionally, it should be mentioned that in the matter of applying the "*kind*" concept to pharmaceutical preparations, when considering "class or kind", in Appeal Number 409, the Tariff Board said, "The application of a "produced in Canada" test to mixtures of chemicals is, we believe, virtually impossible".

A partial implementation of the suggestion might be feasible if pharmaceutical preparations were categorized in terms of active ingredients. For example, all pharmaceutical preparations whose active ingredient is of a kind not made in Canada could be exempted from dumping duty. Such an exemption would, of course, subject a large part of the Canadian drug industry to increased import competition in view of the fact that most

Canadian produced pharmaceutical preparations incorporate at least some imported ingredients. It would, however, preserve some of the protection now given the basic drug industry, although by no means all of it, because active ingredients are also to a great extent substitutable. Action taken along these lines could be taken administratively by merely defining "class or kind" in terms of active ingredients, but due to the change of basic approach involved, it might be better to authorize the exemption under section 6(2) (b) of the Customs Tariff and thus avoid criticism by the Auditor General, I suppose.

This course of action would seem preferable to altering the valuation base. The latter expedient would require a change in the law in so far as finished pharmaceutical preparations are concerned. However, limitation of the application of dumping duty in the manner outlined carries with it no assurance that the savings resulting from dump import prices would be passed on to the consumer. Before implementing such a scheme, Government should ensure that the loss of protection to Canadian industry will be offset by lower drug prices at the consumer level. It would also be useful to consult the Canadian drug industry on the subject.

In addition to remedial action under the Customs Act, there is the possibility of action under section 16(1) of the Customs Tariff. This section allows the Governor in Council to reduce or remove regular and/or dumping duty where producers of goods use any such duty to maintain prices at levels deemed by the Governor in Council to be higher than should prevail, having regard to the general economic conditions in the country. No action has been taken under the authority of this section. I do not feel that a case has been made that pharmaceutical drug and preparation prices are higher than should prevail by reason of the regular customs duty or dumping duty.

In general, and here I am not trying to arrive at a conclusion for the Department but rather based on our examination of the facts with respect to customs duty within the Department we are not convinced that a reduction in the value for duty or a narrowing of the "class or kind" administration would result in a meaningful lowering of consumer prices of pharmaceutical preparations. Duty on unfinished pharmaceutical preparations is computed on manufacturing cost plus an advance. Manufacturing cost is inclusive of material, labour and factory overhead only. Having in mind the high cost of research, development and selling, manufacturing cost is quite low in relation to the total cost. For this reason, the duty on manufacturing cost, even with an advance of 100 per cent, is believed to be a minor element of the selling price of the preparation in its finished form. The saving might well be absorbed by the Canadian importer in increased profits and, even if passed on to the consumer, would probably not result in a significant change in drug prices.

A narrowing of the class of goods on which special duty applies could reduce prices but, at the same time, it would probably remove virtually all of the protection presently afforded Canadian manufacturers by reason of the substitutable nature of many of the products which are involved.

I have here with me my Deputy Minister of Customs and Excise, Mr. Ray Labarge; Mr. Lou Vetter from our Sales Tax Section; Mr. Reg Hind, Assistant Deputy Minister, Customs and Mr. Maurice O'Heare from my Department who can answer any questions you may ask which are beyond my technical competence, and I am sure there are lots of them.

Now to deal with the sales tax, it might be useful for me to outline briefly the sales tax treatment of pharmaceuticals under the Excise Tax Act. That is the Act that imposes the sales tax as such.

At the present time, there are 714 persons, firms or corporations licensed under the Excise Tax Act as manufacturers or producers of pharmaceuticals. Some years ago, it became apparent that Canadian manufacturers of pharmaceuticals were at an extreme disadvantage because these products could be imported in bulk and tax paid on the duty paid value. In 1959, it was decided to amend the Act to take care of the situation and to provide, among other things, that those importers who repackage for sale would be regarded as manufacturers and responsible for payment of the tax at time of sale rather than at time of importation. This necessitated a definition of pharmaceuticals which is now to be found in Section 2(1)(cc) of the Excise Tax Act. And here pharmaceuticals are defined as follows: "pharmaceuticals means any material, substance, mixture, compound or preparation, of whatever composition or in whatever form, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in man or animal, or for restoring, correcting or modifying organic functions in man or animal."

I should point out that this definition is much broader than that of drugs in the Food and Drugs Act because it also covers proprietary, vitamins and medicines as well as pharmaceuticals for animals. In case it may be useful to the committee I will table a copy of a listing of the pharmaceuticals which we deem to be under our Act, and if more copies are necessary I will be happy to supply them. I think this is important because some of the figures I mention later on as being applicable to revenue derived from this source and the tax applied include a much broader range than the drugs which are defined under the Food and Drugs Act and which are considered basically for human consumption.

Other amendments, of course, were required to include as manufacturers or producers not only those persons who repackaged pharmaceuticals prior to sale but also those persons who sell pharmaceuticals under their own trade name. These amendments, however, did not include retail stores. It is to be noted that retailers who repackage in their retail stores are not regarded as manufacturers or producers.

Generally speaking, pharmaceuticals are marketed by manufacturers through all levels of trade so that we have manufacturers who sell to wholesalers only, others sell to wholesalers and to retailers, others to retailers only, and still other manufacturers who sell only directly to the consumer door to door. In saying this, one must understand what I have pointed out before, the much broader definition of pharmaceuticals that we have than is under the Food and Drugs Act.

In order to ensure that sales tax is not a determining factor in competition by reason of the method of distribution those manufacturers who regularly sell their pharmaceuticals to bona fide independent wholesalers in representative wholesale quantities are permitted to account for sales tax on sales to retailers, physicians, veterinarians and users on the same basis as if the sales had been made to wholesalers. The sales tax of course is applied at the manufacturers level.

Where a manufacturer does not sell in representative wholesale quantities to bona fide independent wholesalers, such manufacturers are permitted to account for sales tax on sales to retailers, physicians, veterinarians or users calculated on the determined whole-

sale value which, at the present time, is the suggested sales tax included list selling price to users, less discounts of 40 per cent and 15½ per cent, or a total discount of 49.3 per cent below the retail price. All manufacturers of pharmaceuticals, regardless of which basis is being used, are required to account for sales tax on sales to wholesalers on the sale price.

The discount of 40 per cent and 15½ per cent was determined in 1959 after a survey of the industry and is the weighted average at which manufacturers selling to wholesalers in representative quantities sell their pharmaceuticals to wholesalers. Using the determined discounts, that is, list less 40 per cent and 15½ per cent, the average sales tax paid by manufacturers of pharmaceuticals amounts to 4.96 cents on each dollar of sales to users. So when people are speaking of 11 per cent sales tax, on the basis it is applied and applying it to the selling price — and this is across the broader range, which we have — it comes to 4.96 cents on each dollar of sales to users.

With regard to pharmaceuticals sold on prescription, the class of drugs the committee is most concerned with, the determination of the sales tax content expressed as a percentage of the selling price to the user is rather more difficult to determine. This is so because retail pharmacists use different methods for arriving at the selling price. Some pharmacists simply add to the cost of the pharmaceuticals an amount which represents their professional fee plus mark-up. In those cases where the cost of pharmaceuticals was extremely low, the mark-up could represent 175 per cent. In the case of expensive pharmaceuticals, the mark-up could be as low as 50 per cent. In the light of this information, the tax content of the retail price of pharmaceuticals sold on prescription could vary between 1.8¢ and 3¢ on each dollar of sales.

Based on the latest available Dominion Bureau of Statistics figures plus information received from the Canadian Pharmaceutical Association and the Proprietary Association of Canada, sales of pharmaceuticals amounting to approximately $240,000,000-$250,000,000 at manufacturers' selling price, were made, in the last fiscal year. Included in these figures are sales of imported pharmaceuticals which amounted to approximately 7 per cent of the total sales.

Sales tax paid on pharmaceuticals during the last fiscal year amounted to approximately $19,000,000.00.

But here again, I must point out this is on the wider range of pharmaceuticals as defined under the Excise Tax Act.

I should close my comments on the excise tax application to these goods by bringing to your attention that in addition to the exemptions afforded charitable institutions by way of refund and bona fide public hospitals, exemption is also provided for Adrenocorticotrophin (ACTH), cortisone, insulin, radium, liver extract for use exclusively in the treatment of anaemia, vaccine for use in the prevention of poliomyelitis, and material for use exclusively in its manufacture.

Now the Hon. Mr. Gordon, when he was Minister of Finance, and Mr. Sharp have stated, in the House, the view of the Government with respect to the sales tax on pharmaceuticals. Perhaps I could just read what Mr. Sharp said in *Hansard* on page 6094, Tuesday, June 7, 1966:

> In my budget address I made it clear that the Government is prepared to remove the sales tax from drugs, should this course be recommended by the

committee of this House which is concerned with the question of drugs and drug prices. The reason is that the Government would like to be assured that the benefits of a reduction in the tax would be passed on to the consumers; this is the only reason for our reluctance to move ahead now before the report of the committee has been presented.

I think this has been somewhat substantiated by some of the figures I quoted you where in the case of prescription drugs we have estimated in the survey we carried out that of the retail price only between 1.8 cents and 3 cents per dollar of sales price is accountable to the manufacturers sales tax imposed by the Federal Government.

I would be pleased to answer any questions you may have although I will probably have to confer with my officials to get the answers if the questions are too technical.

The CHAIRMAN: Thank you, very much Mr. Benson. Gentlemen before we begin questioning, the other consultant who has been employed by the committee is here today, the accountant, Mr. Blakely. If you would please stand, Mr. Blakely and make yourself known to the committee? Thank you very much. And for those who were not here before, Mr. Laidlaw from Ottawa is our legal consultant.

The meeting is open for questions.

Could I ask the minister if that table he referred to is very extensive?

Mr. BENSON: Yes, it is. We have only one copy here but we have many copies and we would be pleased to supply them.

The CHAIRMAN: Perhaps I could ask the Minister if he would see that the committee is provided with 25 copies in English and five in French if, possible. There is no necessity for them today.

Mr. BENSON: We will be glad to do that.

Mr. PATTERSON: Mr. Chairman, I think it would have been to our advantage had we had copies of the Minister's speech before it was given here.

Mr. BENSON: I am willing to come back again.

Mr. PATTERSON: I think it requires pretty close study.

The CHAIRMAN: As you are aware, the Committee had agreed that all organizations and individuals who wish to present a brief before this Committee should do so at least one week in advance of their appearance. You all now have in your possession at least, I think, three briefs which will be presented to us in the near future. You have the one for presentation on Tuesday by the Pharmaceutical Association. The only people exempt from that rule were the Minister of National Health and Welfare and the Minister of National Revenue.

Mr. BENSON: Well this was not really a brief. It was just a little off the cuff talk.

Mr. WHELAN: The Minister said he is going to appear before the Committee again. Does this mean he has another off the cuff talk like this?

Mr. BENSON: If you wish to digest this before questioning I would be pleased to come back to answer any further questions you may wish to ask.

Mr. ENNS: I suppose one of the main considerations of the Committee is to ascertain whether or not the reduction of the one item, the sales tax, will really be a reduction in the cost of drugs to the consumer, and from what the Minister said this afternoon I begin to wonder just what proportionate reduction in cost would actually result in this. It seems that we should still explore every means of bringing down the cost; if it is only 3 cents on the retail dollar well, that is fine, instead of the 11 cents the public might think it is. If it is really that then I am satisfied this is so. If there are three cents here there may be three cents at the manufacturing level and another three cents somewhere else. These are all ways of doing it and for this reason I would feel very strongly that we should move towards that recommendation after due consideration.

I was interested in an earlier comment the Minister made about gross profit which is an interesting term. I always thought it was a "net" thing; I am not as accountant and, therefore, I am not familiar with that kind of terminology. You said the American firms reported a $200 gross profit as being quite normal and this would reduce down to something like 11 per cent in terms of net profit. This makes me wonder just what the actual turnover is or where the gross quantity is taken up.

Mr. BENSON: We were, of course, quoting American statistics which have been prepared or which my Department have dug out and it read from 200 per cent to 1200 per cent. Of course, this does not include the cost of research or the very high selling costs which are involved. The gross profit defined in these terms would be merely the cost of material and manufacturing costs in the plant, deducted from the selling price. That, of course can be very high. The pertinent thing which would point it up later was that when they got through the other expenses which would include such things as distribution, advertising, research and these various items the profit after taxes, in the United States, came to about 11 per cent of sales.

Mr. ENNS: Well I am convinced that when we want to effect any sharp decline in the cost of drugs we will not accomplish this by way of reducing or eliminating taxes on drugs. It seems we must find another avenue although, certainly I would endorse the elimination of the tax as well.

Mr. BENSON: We tried to bring out the magnitude of the two items which come under our Department and can affect the cost of the drugs. The first is the customs tariff and I will admit my statement on that was not quite off the cuff. It was fairly complicated. Then, the sales tax, on the other hand, applied at the manufacturers level. We have said it is difficult in the case of prescription drugs to do this because of the method of pricing at the retail level, but the best information we have been able to acquire is that it is between 1.8 and 3 cents on the consumer dollar.

The CHAIRMAN: For clarification, Mr. Benson, on all drugs did you say it averaged out at 4.96 per cent?

Mr. BENSON: That is on everything we have — and you can correct me if I am wrong — under the pharmaceutical classification. This includes a great many things, as you will find, that you would not define as drugs, perhaps.

Mr. HOWE *(Hamilton South)*: The Minister off the cuff pulled this figure of 4.97 or 4.96, and that is fairly accurate for off the cuff. According to my financial calculations as a doctor, which makes them very crude why is this amount reduced when the 11 per cent

is added on at the manufacturers level and then profit is added on to the gross amount, I presume, thereby actually making this percentage higher to the consumer rather than lower.

Mr. BENSON: The price it is applied to is not the retail price, or the consumer's price. The 11 per cent is applied back and this is 100 per cent, in many cases, below the retail price. For example, something may be selling for $2 and the tax is being applied at 11 per cent on $1.

Mr. HOWE: I am just going to apply it my way. If I take the $1 and add the 11 per cent, which would make it $1.11, and then I add 100 per cent profit onto that I would end up with $2.22 which still is 11 per cent of a higher figure. This is a greater amount so far as the consumer is concerned.

Mr. BENSON: Really what you are talking about is the pyramiding of the sales tax which some people maintain takes place in some cases. It depends entirely on your method of pricing, whether you do take an amount and apply a fixed percentage to it. But the 1.8 to 3 per cent which we used in the case of prescription drugs, is taking the amount of tax paid and applying it to the selling value.

Mr. HOWE (*Hamilton South*): In other words you are saying that the manufacturers, the distributors and the retailers are not adding profit onto this 11 per cent, that this 11 per cent remains as a set figure of the original cost with no profit added to it.

Mr. BENSON: Well I really could not say how all people do their pricing but it would appear that in a product such as this where there is a differential, and a necessary differential perhaps but I am not going to judge that, between the cost on which the sales tax is applied and the ultimate selling price that there are other factors which come into the pricing besides merely applying a flat percentage upwards.

Mr. HOWE (*Hamilton South*): Is there no actual rule or law whether they can or cannot apply it on that $1.11 rather than just on the $1?

Mr. BENSON: It is hard to say how people are going to determine how much they will charge for a product. Somebody can manufacture something in a plant and claim it costs $1 to manufacture; I pay 11 per cent sales tax in order to make a profit; I must charge 90 cents more to cover distribution, and this sort of thing. Generally, prices are determined by competition. The manufacturer does not determine his price by adding $1.20 to his cost of $1.20 and selling the product at $2.40 because somebody else down the street may be selling a very similar product and do the same thing for $2.10. I am not saying whether or not this is the case in the drug industry; I just do not know.

MR. HOWE (*Hamilton South*): If you simply left the 11 per cent off and it carried on, as you said, and became 4.96 per cent then it would simply add a larger amount on to the dollar in the first place which is virtually the same thing.

Mr. BENSON: All I am saying is if you cut the sales tax out entirely, according to the best of our calculations, it would make a difference of from 1.8 to 3 cents per dollar of selling price. And, the selling prices per capita are relatively the same as they are now; the only reduction was the sales tax, and it would make a difference of from 1.8 to 3 per cent.

The CHAIRMAN: Mr. Whelan?

Mr. WHELAN: That was the question I wanted to ask.

The CHAIRMAN: Mr. Howe?

Mr. HOWE (*Wellington Huron*): Well, it is rather interesting, after the statement the Minister has made, when I look at the Royal Commission on Health Services' report on cost of drugs in Canada at page 53, and note an example there, which sums it up with the following statement:

> It should be observed from the above example that the addition of 11 cents to the price of $1 established at the manufacturer level has the effect of increasing the retail price of the drug by 23 cents. It is estimated that the proceeds from the federal sales tax of 11 per cent on drugs and medicines sold by retail drug stores amount to $15 million.

In other words you say this is not correct, that it does not increase by 23 cents?

Mr. BENSON: They have to use assumptions. It might increase the price by 23 cents if you apply the assumption that you double everything including the sales tax in arriving at your selling price. But according to the best data we have the amount we collected last year on all pharmaceuticals — and these are figures supplied to me by the Department — was $19 million under our broad definition of pharmaceuticals. From the research we have done, and we have indicated in that brief the difficulty in determining in prescription drugs the amount of tax per dollar of sales, it works out to from 1.8 to 3 per cent and over the whole class to 4.96 per cent, I think the figure was.

Mr. HOWE (*Hamilton South*): But, 23 cents on over $2 is still only 11 per cent. It is not higher, as I said, in the first place.

The CHAIRMAN: Mr. Prud'homme?

Mr. PRUD'HOMME: I will ask my question in English. After visiting many pharmaceutical manufacturers last year, I came to the conclusion that they insisted very much that we take into consideration the costs of research. Are we in a position to ascertain if research costs are as high as indicated? Should we not try to reduce the cost of drugs rather than take for granted that the taxes are the reason for the high price of drugs?

Mr. BENSON: All I can say as Minister of National Revenue is I cannot tell you how much various companies spend on research in Canada. If you want to find this out you will have to go to them because I cannot disclose information with regard to individual concerns that are contained in individual tax returns which are filed.

The CHAIRMAN: As we will have the individual companies before us we hope they will give us this information. Are there any other questions of the Minister?

Mr. ROXBURGH: Would the minister then give us the total that all drug manufacturing concerns spend on research which is not giving anything away with regard to the individual manufacturing concern?

Mr. BENSON: No, I do not think I could.

Mr. ROXBURGH: Why?

Mr. BENSON: This would involve my going into the tax returns which are not in this division of my department at all. These are under another Deputy Minister, and these

would involve personal and corporate tax returns and taking statistics from these returns for a specific group of people and turning them over to Parliament. I do not think — I would like to reserve judgment on this — that this would be a proper action for me to take. I am sure if you go to the drug companies, and they will be coming to you, you will get honest figures with regard to what they spend on it. Some of these companies are public companies and they have to publish financial statements. In their financial statements they have to show what they spend their money on.

The CHAIRMAN: I do not think there are any public companies.

Mr. BENSON: Maybe there are no public companies in Canada in this field.

The CHAIRMAN: I understand there are not. I should point out in the brief from the Canadian Pharmaceutical Manufacturers Association there is a large portion devoted to research and they break down their manufacturing cost per dollar. We will have the individual drug companies before us as well so we hope they will be able to come up with this information. Are there any other questions of the Minister?

Mr. Laidlaw did you wish to ask any questions?

Mr. A. M. LAIDLAW (*Legal Counsel*): Mr. Chairman, I feel very much like one or two members of the committee, that following the excellent and complex statement by the Minister it would take even counsel more than a week or so to analyze it and possibly to ask questions on it. Having said that I wonder if it would be useful to the committee if certain conclusions at least could be drawn by the committee today in the hope, perhaps, that later on, after the Minister's statement has been completely digested, he would be kind enough to come back and be examined again by the members. As I understand it, Mr. Benson, the Hall Commission recommended a review of the tariff structure as it applied to drugs only should be reviewed by the Tariff Board. I believe that it also comes within the competence of this committee to investigate the tax structure. I would like to ask the Minister if he felt it would be advisable to let the Tariff Board examine the tariff structure of drugs rather than this committee, particularly because of the experience the Tariff Board has already gained respecting chemicals generally.

Mr. BENSON: We are expecting, as I mentioned in my statement, a report on the reference on fine chemicals which will cover a good many of the items included in the drug classification. Of course, the committee in its wisdom could ask the government to make a reference to the Tariff Board on drugs only and specifically on pharmaceuticals. However, I would not like to indicate that you would get a quick report. As you know, the Tariff Board takes a good deal of time and they do a very thorough and careful job of looking into these things. The reference to the Tariff Board on fine chemicals was made before the Hall Commission made its report and we still have not got it, although we are expecting it soon. There is a time factor which you have to consider.

Mr. LAIDLAW: Another question I would like to address to the Minister, Mr. Chairman, or to Mr. Labarge, is with respect to the tariff items under which drugs are imported into Canada. One item particularly, are drugs of a kind not produced in Canada and the tariff rate for this particular form of drugs, drugs of a kind not produced in Canada, is more attractive than any other tariff structure. There are two questions I would like to ask. First, is this particular tariff item used to any great extent and second, if the word "kind" is interpreted extremely strictly.

Mr. WHELAN: Mr. Laidlaw, what do you mean by more attractive? If I understood you right you said this tariff item was more attractive than any other tariff item?

MR. LAIDLAW: It is more attractive in the sense that the tariff rate applied to drugs of a kind not produced in Canada are lower than those which are produced in Canada.

Mr. BENSON: I think the best person to answer this question is Mr. Hind, the Assistant Deputy Minister of customs because he is dealing all the time with this particular type of problem.

Mr. A. R. HIND (*Assistant Deputy Minister, Customs, Department of National Revenue*): Mr. Chairman, the tariff item to which Mr. Laidlaw has referred is number 20839-1. The rates are duty free under the British preferential tariff, 15 per cent under the most favoured nation tariff. To qualify for entry under this tariff item the goods must be of a kind not produced in Canada. Now Mr. Laidlaw's question was, is this item used extensively? I would be inclined to say yes, extensive use is indeed made of this item. His second question was, what interpretation is put on the word "kind"; is it a narrow interpretation or is it a broad interpretation? The answer is that we interpret the word "kind" to mean identical. It is a very narrow interpretation.

Mr. LAIDLAW: Thank you, Mr. Hind. Now, Mr. Chairman, if I may continue. Apart from the other tariff items which are applied to drugs on which no duty is charged and on those drugs which are formed of combinations or mixtures, I would like to ask for the benefit of the members if the tariff item most used applicable to imported drugs — that is the bulk of the drugs imported into Canada — fall into this category, that is, item 71100-1.

Mr. HIND: Conversely, any of these drugs that are of a kind produced in Canada would fall into the item Mr. Laidlaw has just mentioned which is 71100-1, the rate of duty from British Commonwealth countries, 15 per cent, and from most favoured nation countries the rate is 20 per cent. Unfortunately I do not know what the breakdown is; that is, what proportion of drugs comes under the first tariff item mentioned and what proportion comes under the second tariff item.

Mr. LAIDLAW: I would gather then that this item is used extensively?

Mr. HIND: This item is used extensively. I think I could go so far as to say that perhaps more drugs coming into Canada fall into the first mentioned item with the lower rates of duty than is true of the second tariff item with the higher rates of duty in the sense that we hold fewer drugs to be of a kind made in Canada than we do of a kind not made in Canada.

MR. LAIDLAW: Mr. Chairman, going one stage further and attempting to follow the Minister's statement, in the ascertainment of fair market value under section 38 of the Tariff Board which allows the discretion of the Minister to operate I assume that this method of determining fair market value has been in operation for quite a few years?

Mr. BENSON: Since 1959 I believe.

Mr. HIND: We have followed this general scheme of arriving at the value of these good for duty purposes for many, many years. The particular percentages that have been mentioned by the Minister have been in formal use since about 1960.

Mr. LAIDLAW: Thank you, sir. When the Minister proceeded further along these same lines I gathered he felt it would be unwise to amend section 38, for example, so that fair market value in so far as drugs and medicines are concerned, to give it a fixed value such as, for example, the cost of production in the home country plus say 5, 10 or 15 per cent for gross profit, and if this were done it might open up a Pandora's box which would bring many pressures on the Department, and this proposal — I do not know just who originated it — would presumably not be entirely satisfactory? In other words, by making one remedy you might create more ills?

Mr. HIND: This is correct sir.

Mr. LAIDLAW: Going one stage further, Mr. Benson, into the anti-dumping duty, section 6 of the customs tariff where it discusses not only goods in kind being imported into Canada but goods of a class or kind imported into Canada, I believe, sir, and I hope I have not misinterpreted your statement, that if the word "class" were removed from that section this might be unfair to the pharmaceutical industry generally, and that eventually predatory dumping might come about.

Mr. HIND: This would require a change in the law. If you removed the word "class" it would narrow the coverage which grants protection to Canadian manufacturers; this would apply not only to drugs and pharmaceuticals but it would apply to all other goods imported into Canada, because we would have to give the same interpretation to the word "kind" as it applies to all imports, not only drugs and pharmaceuticals.

Mr. LAIDLAW: Could not the section be amended, for example, where the word "class" would be omitted with reference only to ethical drugs and medicines?

Mr. BENSON: You would have to have a new section if you wanted to do that rather than changing the general section. It would, of course, establish a precedent within the Customs Tariff Act. It is a decision of course, which would have to be made by Parliament.

The class or kind rulings we make, and I am not just speaking of the pharmaceutical field, are not always very popular with some of the countries that ship to us. A step in this direction would undoubtedly bring pressure with regard to other goods as well, I think, and the Government would have to decide whether in making this kind of a change it would be willing to face up to the matter in other situations.

Mr. LAIDLAW: I can quite understand that. Those are all the questions I have, Mr. Chairman, at least all that I was able to formulate during this period.

The CHAIRMAN: May I ask one question here? In line with Mr. Laidlaw's question, I wonder if the Minister or his officials could tell us how often, in the drug or pharmaceutical industry, dumping duty has been applied in the past.

Mr. HIND: It is almost impossible for us to present any figures in this regard. I would say that dumping duty actually is not collected very often. When it is, it is very often done at the level of the port of entry and headquarters never hear about it. I would feel that we would not be able to establish the amount of dumping duty that is collected on drugs or pharmaceuticals.

The CHAIRMAN: It functions more as a threat than being in use?

Mr. HIND: Yes, this is true.

Mr. BENSON: I might just add for the information of members something about the nature of dumping duty, as such. If you ship something into Canada at $1 which is a dump price and the fair market value on the some market is $2 it means you have to pay the other $1 in duty. It is 100 per cent duty bringing it up to market value. Therefore what the dumping duty does is to ensure that people ship into Canada at fair market value in the home market in almost all cases It is not applied across the board. It is not applied that often.

Mr. LAIDLAW: Mr. Chairman, if I might ask the Minister a supplementary question. Does this mean that exporters of drugs, from the United States for example, approach the Department of National Revenue here in advance to ascertain what the fair market value is and having done that they set an invoice price to their Canadian subsidiary, for example, for precisely that amount?

Mr. BENSON: They do not have to do this really. They can, of course, and we have a good many people from all industries approaching us with respect to fair market value. They can determine it themselves because they simply have to apply the price, in shipping into Canada, that they would ship in representative lots in their own country. If they do this there is no question involved.

Mr. ROXBURGH: Where does the check in our country come in of the fair market value of goods being shipped in from other countries?

Mr. BENSON: Well, we have people in other countries looking into this question. Mostly it arises when someone in Canada raises a question with regard to a product being dumped. Then our investigators look into it. There are other cases where something comes to our attention; we think the value appears out of line and we will have our people look into it. We have people in the United States, in Britain, on the continent, in Brussels, and in Japan.

Mr. ROXBURGH: In other words this is not done unless it is brought to the attention of the Department by manufacturers, buyers or whatever the case may be in our own country.

Mr. BENSON: Or by our examination of entries and it appears to us there is a possibility that dumping is going on.

Mr. WHELAN: A supplementary question, Mr. Chairman, on the examination of entries. Are these done regularly or from time to time. Can you tell exactly whether these are imported and if so, by whom?

Mr. BENSON: Well, of course, every time somebody bring something into the country there is an entry made. I would not like to say anything specific because there are hundreds of thousands, perhaps millions of entries; I do not know how many entries are made in a year. We do not go through all of these all the time. Usually, when we look for dumping, somebody has brought it to our attention.

Mr. WHELAN: Do you keep a record of the imports on file so they could be checked within two or three days if an inquiry was received?

Mr. BENSON: Oh yes, we do. We keep a copy of the entry records. It is quite a job to turn these up. If somebody says John Jones is dumping we have two ways of examining this. We can look at John Jones' records and find out where he is importing from and then

look at the port entries to verify his entries. He will have a copy of the entry with regard to each importation but we have the hight to look at a person's books in Canada.

Mr. HOWE (*Hamilton South*): In a matter of clarification, Mr. Chairman, what is the significanceor the meaning of the word "dumping"? I do not understand the significance of the word.

Mr. HIND: We have in our legislation regular duty and this represents the rates of duty that are set out in the Customs Tariff Act; the rates I have just mentioned such as 15 per cent and 20 per cent are what we refer to as regular duty. In addition to regular duty there is another impost which is sometimes called dumping duty and sometimes called special duty. They are both the same. This is applied in addition to the regular duty but only in certain circumstances. The main circumstance is that the imported goods must be of a class or kind made in Canada. In other words, dumping duty does not apply to goods of a class or kind not made in Canada for the simple reason that if they are not made in Canada there is no one to protect. So, the first thing is that dumping duty applies only on goods that are held by the Department to be of a class or kind made in Canada. Now given such goods, dumping duty is payable only when the exporter sells to Canada at a price below the fair market value. As the Minister has indicated, the fair market value is taken to be the price at which the exporter sells for home consumption on his own domestic market.

Mr. HOWE (*Hamilton South*): In other words, the act of dumping is selling a product at a cheaper rate to get rid of it. This is simply what dumping is.

Mr. HIND: Yes.

Mr. BENSON: This happens some times. For example, a country will have a great production of a particular product. Now, in order to make their normal profit in their own country they sell at a certain price, but they could make a marginal profit — not as much profit — by producing an extra million units and shipping them into Canada at a lower price, and this is what we try to stop. We try to get people to sell at the same price as they would sell on their own market.

Mr. HOWE (*Hamilton South*): There is a bit of a potential loss in their country and they take a small profit on a large volume here.

Mr. BENSON: That is right. I should also indicate that where there is a state controlled economy such as in mainland China, for example, or Hungary or Russia, when we look for prices in home markets we do not accept the prices in the controlled economy; we will take the nearest country to that country which ships similar types of goods to Canada because they could fix prices at any level as the whole price system is within their control.

Mr. HYMMEN: One general question for the Minister. He mentioned $19 million raised by the 11 per cent sales tax. Is there a figure available for the amount collected in customs duty on drugs and pharmaceuticals for last year?

Mr. HIND: I think we could get this information for some of the goods but I am not sure we could get it for all of them. For example, the item covering chemicals of a kind not produced in Canada is a separate item. I think we could get the information from the Dominion Bureau of Statistics. In respect of the drugs of a kind produced in Canada, the tariff item is a general one which covers a great variety of other commodities and I would

not be very optimistic that we could segregate these and pick up the information you are looking for.

Mr. HYMMEN: The report suggests around $3 million?

Mr. HIND: This might be.

Mr. BENSON: They did not get the figures from us.

The CHAIRMAN: Incidentally, I should mention that the book that was passed around to you was for your general information on this topic. It was one of the items I mentioned last week, that might be useful to members of the committee, and we were able to obtain copies. Does the committee have any other questions? Mr. Laidlaw?

Mr. LAIDLAW: No.

The CHAIRMAN: Mr. Blakely?

Mr. BLAKELY: Well, Mr. Chairman, the financial information contained in Mr. Benson's statement can best be analyzed in greater depth when we have the statement to read. At this moment I would like to raise one point for clarification. It is clear how much of the retail dollar is represented by sales tax. I made quick notes at the time the Minister was referring to this same item on customs duties and I cannot quite recall whether this is 1.9 per cent. Was that the figure mentioned?

Mr. BENSON: It was 1.8 per cent.

Mr. BLAKELY: One point eight is the sales tax, I believe. It was in reference to a departmental survey.

Mr. HIND: What the Minister read out was information which breaks down imports into three different groups. The first group covers drugs that are sold in Canada in the same condition as imported. In other words, nothing was done to these drugs in Canada. The impact of customs duty in this case is 6.25 per cent. In other words the duty represents 6.25 per cent of the sales price to the consumer in Canada. The second category of goods relates to drugs and pharmaceuticals that are imported in an unfinished condition for further manufacture in Canada or imported in bulk for full or partial packaging in Canada and the impact of duty in this case, on the sales price to the consumer in Canada, is 2½ per cent. The third category of the survey, which accounts for approximately 80 per cent of all pharmaceuticals sold in Canada, represents a customs duty impact of .7 per cent, less than one per cent of the selling price.

Mr. BLAKELY: Mr. Benson made reference to United States statistics with respect to net profit as a percentage of sales. May I ask if there are similar percentages available with respect to the Canadian situation? If so, are they available?

Mr. BENSON: I am not sure, Mr. Blakely. I would have to look and see if our taxation statistics or D.B.S. statistics break this down. I just do not have it at hand.

The CHAIRMAN: Perhaps your Department could look into that and see if they could provide the figures to the committee, if available.

Mr. BENSON: Yes. If this is broken down the figures would be with the other side of my Department, the Taxation Division, and I am not sure it is broken down.

Mr. BLAKELY: I suggest a much more interesting figure, if it is at all possible to obtain, would be the rate of return on capital employed. I suspect that this is information we will have to try and ferret out from the other bodies that will be appearing before this committee.

Mr. BENSON: I suggest that is where you should get it, Mr. Chairman.

Mr. BLAKELY: Thank you, Mr. Chairman.

The CHAIRMAN: Are there any other questions? If not, the meeting is adjourned until next Tuesday. I would hope by that time you all will have read the brief from the Canadian Pharmaceutical Association which you all now have in your possession.

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 3

TUESDAY, JUNE 14, 1966

WITNESSES:

Mr. J. C. Turnbull, B.S.P. of Toronto, Executive Director of The Canadian Pharmaceutical Association, Inc.; Mr. W. J. Blakely, of Kingston, Accountant for the Committee; and Mr. A. M. Laidlaw, of Ottawa, Legal Counsel for the Committee.

ROGER DUHAMEL, F.R.S.C.
QUEEN'S PRINTER AND CONTROLLER OF STATIONERY
OTTAWA, 1966

24087—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

Vice-Chairman: Mr. Patrick T. Asselin (*Richmond-Wolfe*)

and

Mr. Brand,	Mr. Howe (*Wellington-Huron*),	Mr. Pascoe,
Mr. Chatterton,	Mr. Hymmen,	Mr. Patterson,
Mr. Clancy,	Mr. Isabelle,	Mr. Prud'homme,
Mr. Côté (*Dorchester*),	Mr. MacDonald (*Prince*),	Mrs. Rideout,
Mr. Enns,	Mr. Mackasey,	Mr. Rynard,
Mr. Haidasz,	Mr. O'Keefe,	Mr. Tardif,
Mr. Howe (*Hamilton South*),	Mr. Orlikow,	Mr. Whelan,
		Mr. Yanakis—(24).

(Quorum 13)

Gabrielle Savard,
Clerk of the Committee.

NOTE: Mrs. Rideout and Mr. Mackasey replaced Messrs. Roxburgh and Langlois (*Chicoutimi*) on June 13.

ORDER OF REFERENCE

MONDAY, June 13, 1966.

Ordered,—That the names of Mr. Mackasey and Mrs. Rideout be substituted for those of Messrs. Langlois (*Chicoutimi*) and Roxburgh on the Special Committee on Drug Costs and Prices.

Attest.

LÉON-J. RAYMOND,
The Clerk of the House.

24087—1½

MINUTES OF PROCEEDINGS

TUESDAY, June 14, 1966.
(5)

The Special Committee on Drug Costs and Prices met this day at 11:25 a.m., the Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout and Messrs. Asselin *(Richmond-Wolfe)*, Brand, Clancy, Enns, Harley, Howe *(Hamilton South)*, Isabelle, MacDonald *(Prince)*, Mackasey, O'Keefe, Orlikow, Prud'homme, Rynard, Yanakis (15).

In attendance: Mr. J. C. Turnbull, B.S.P., of Toronto, Executive Director of The Canadian Pharmaceutical Association, Inc.

Also in attendance: Mr. W. J. Blakely, of Kingston, Accountant for the Committee; and Mr. A. M. Laidlaw, of Ottawa, Legal Counsel for the Committee.

The Chairman referred to a list of goods classified as Pharmaceuticals by the Department of National Revenue for sales tax purposes, copy of which was distributed to the Members.

The Chairman also brought to the attention of the Committee a letter received from the American Marketing Association of Toronto, expressing the wish to present a written submission to the Committee.

After discussion, on motion of Mr. MacDonald *(Prince)*, seconded by Mr. Isabelle,

Agreed,—That the Committee accept written submissions in lieu of appearances only where appearances are not possible.

The Chairman introduced Mr. Turnbull.

Agreed,—That the brief of The Canadian Pharmaceutical Association, Inc. be taken as read.

Mr. Turnbull made a short statement.

Mr. Orlikow moved, seconded by Mr. Howe *(Hamilton South)*, that pages 1 to 25 of the brief be printed as part of todays' proceedings.

Agreed on division.

Mr. Turnbull was questioned by the Members and by Mr. Blakely, Accountant for the Committee.

At 1.10 p.m., the Committee adjourned to 3.30 p.m., Thursday, June 16, when The Pharmaceutical Manufacturers Association of Canada will present a brief.

Gabrielle Savard,
Clerk of the Committee.

EVIDENCE

(Recorded by Electronic apparatus)

TUESDAY, June 14, 1966.

The CHAIRMAN: Ladies and gentlemen, I see a quorum.

Before we go on with the presentation there are two small matters I would like to bring up. First, at the meeting last week Mr. Benson discussed a table of pharmaceuticals. It was far too large to be reproduced in the record so you will all get it in the mail this afternoon, in either French or English, as is appropriate.

Second, I have received a letter from the American Marketing Association of Toronto. They wish to present a brief to the committee but point out in their letter that they are a non-profit voluntary organization and they would prefer to submit a brief in writing. Now, this is something the committee has not really considered before, to submit a brief in writing rather than to appear in person. Is it the wish of the Committee that anyone who wishes to do so, in order to save the time of the Committee, may submit a brief in writing rather than appear?

Mr. MACKASEY: Mr. Chairman, how do you check the accuracy of the brief?

The CHAIRMAN: I would say you do not. I would think a presentation that is written to me would not be as meaningful as a visit followed by questioning, and I will point this out to them.

Mr. ORLIKOW: I do not see any reason why they could not send a letter to you, as Chairman, enclosing the brief. The letter and the brief could be printed as an appendix and as you and Mr. Mackasey have pointed out the veracity, and the value of the brief would be reduced by the fact that there is no opportunity to question the people who prepared the brief. For what it is worth there is no reason we should not receive it.

The CHAIRMAN: Would someone make a motion that the committee is prepared to accept written submissions in lieu of appearances only where appearances are not possible.

Mr. MACDONALD (*Prince*): I so move.

Mr. ISABELLE: I second the motion.

Motion agreed to.

The CHAIRMAN: Gentlemen, we have with us this morning, Mr. Turnbull, who is representing the Canadian Pharmaceutical Association. You all received, at least a week ago, a brief to be presented this morning. Therefore, the brief will not be read; it will be taken as read and the meeting will be confined to questioning of the witness on the brief. However, I think before we do that, he has a short statement he wishes to make.

Mr. John C. TURNBULL *(Executive Director, The Canadian Pharmaceutical Association, Inc.):* Thank you, Mr. Chairman. Ladies and gentlemen, it is my pleasure to represent The Canadian Pharmaceutical Association before you this morning. A word of explanation: I would point out that The Canadian Pharmaceutical Association is a professional association, and also non-profit, not only by intent but it works out that way, founded in 1907 to bring together the provincial organizations of pharmacy. As such we represent something over 8,000 registered pharmacists across Canada in various fields of pharmaceutical endeavour, retail, hospital, government, industry, teaching and so on. I would point out that these are members as individuals. Because of their licensing we do not have as members any companies or any organizations which represent corporate bodies, in the association.

It is our pleasure to present ourselves in a somewhat briefer form than we have before various committees and commissions which have studied this problem in depth on previous occasions. Rather than do otherwise we respectfully draw your attention to those submissions and the reports arising from the committees and commissions which have heard them. The brief as transmitted to your Chairman, did contain a few minor points that we asked to be corrected by a follow-up letter. I presume all members received that addenda page. One point was not covered. I would draw your attention to paragraph 13(4), on page 21, in which the association comments on patents and patent legislation. In the fifth line from the last of that paragraph, the line begins "by the particular nature of the drug", and reads at present "providing that". Would you stroke out "providing that" and insert "unless". That is the only change I have noted. I believe I inserted a dollar sign in one place, beyond the correction sheet but it is self-evident and I do not have a note on it at the moment.

We have prepared a summary of this brief which I have left with your Chairman. Other than that, he has indicated you would wish to take the brief, possibly section by section, and while I do not have any back-up personnel with me, I will attempt to supply answers to your questions or discuss the brief with you. This is a very busy month for pharmacy in Canada, with various provincial meetings and as a result our officers are here, there and everywhere across this vast nation. In any event, our premise is one of averages rather than specifics with which our officers would possibly deal more fully in relation to their own personal and isolated experience. Thank you, Mr. Chairman.

The CHAIRMAN: Thank you, Mr. Turnbull. It was my feeling, in order to bring a little system to the questioning this morning, that as the brief covers 15 main points by number, the most effective way to deal with it would be to bring up each point number and ask our questions as we cover each point. If the committee feels this is a reasonable thing to do we could start with all these things that are headed No. 1. That would be 1.1, 1.2 and 1.3.

Before we get into this I was going to bring up the question whether the whole brief should be printed as part of today's proceedings. The problem with this, I would point out to you, is that the next brief to be presented to the Committee is one by the Pharmaceutical Manufacturing Association which is an inch thick. It seems to me it is a little impractical to think of printing it as part of a day's proceedings. If you wish to print today's brief I would suggest that only the white pages actually be printed rather than the yellow or green pages

which are statistical in nature and really serve as a backup. I do not think they add much to the brief itself. If you wish we could print the white pages?

Mr. BRAND: Mr. Chairman, I do not think it is necessary to append it to the proceedings. I would rather see the proceedings come a little faster. If additional copies of this were available to members who wished to have them for purposes of distribution this would suffice.

Mr. ORLIKOW: Mr. Chairman, the only difficulty—I do not think it applies to today's brief, but it might very well be a difficulty for the next brief—is that hopefully, this Committee is going to make some recommendations about drug prices. We certainly have been asked by the government to make recommendations with regard to one specific item, the question of the 11 per cent sales tax. If this Committee make a recommendation on this and members of the government who are directly involved and members of Parliament who will be involved in discussing and voting on any recommendations that we make or that the government may make do not have the opportunity of looking at all the presentations, then it seems to me that their work is going to be very difficult. Certainly, other committees that I have been on—I am thinking of the transport and communications committee which has had a tremendous number of briefs, maybe no single one as long as the one from the Pharmaceutical Manufacturers Association will be but a tremendous number of briefs from dozens of organizations—have insisted that the whole brief either be read into the proceedings or be printed as an appendix. I just do not know how one can later make a logical decision on these matters unless one has the whole record. It is true members of the Committee will have the whole record but the other members of Parliament will not. I think, before we deviate from what has been a common practice, not just here but in other committees, we should give it some very serious thought. I move, for today, anyway, Mr. Chairman:

> That, pages 1 to 25, the white pages, of a brief by the Canadian Pharmaceutical Association be printed as part of today's proceedings.

The CHAIRMAN: I was going to say there is one other alternative which I think might be acceptable for general evidence. Mr. Turnbull has mentioned there is a summary available of which I will see each member receives a copy. When the pharmaceutical list comes around I will see that you get a copy of this summary of today's evidence. I understand there is also a summary available of the brief from the Pharmaceutical Manufacturers Association. Perhaps it would be more acceptable to print the summary as part of the proceedings rather than the whole brief?

Mr. Orlikow has already moved a motion about today's proceedings. What would you think about the summary, or would you like the complete evidence of today, Mr. Orlikow?

Mr. ORLIKOW: I do not think this brief is too long, Mr. Chairman.

The CHAIRMAN: Today's brief is not.

Mr. ORLIKOW: Yes, with regard to the question of the next brief, we have a couple of days to think about it and perhaps you, Mr. Chairman, could speak to the appropriate officials, whoever they are, with regard to the problems arising out of printing. The other brief is a very large one. Perhaps you could give us the information when the Committee next meets?

The CHAIRMAN: Mr. Orlikow has moved that today's presentation, pages 1 to 25, be printed as part of today's proceedings. Is there a seconder for his motion?

Mr. HOWE (*Hamilton South*): I second the motion.

Motion agreed to on division.

(The Brief follows):

A SUBMISSION BY

JOHN C. TURNBULL

on behalf of

THE CANADIAN PHARMACEUTICAL ASSOCIATION, INC.

to the

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES
OF THE HOUSE OF COMMONS

Ottawa, June 14, 1966

* * * *

PRESIDENT:	C. R. McLean, Ph.C., Saint John, New Brunswick
PAST-PRESIDENT:	J. L. Summers, B.S.P., M.Sc., Saskatoon, Saskatchewan
FIRST VICE-PRESIDENT:	D. A. Denholm, B.S.P., Vancouver, British Columbia
SECOND VICE-PRESIDENT:	P. W. Goldman, Phm.B., Toronto, Ontario
EXECUTIVE DIRECTOR:	J. C. Turnbull, B.S.P., Toronto, Ontario

* * *

Canadian Pharmaceutical Association, Inc.,
175 College Street, Toronto 2B, Ontario.

A Brief Presented by

THE CANADIAN PHARMACEUTICAL ASSOCIATION, INC.

to the

HOUSE OF COMMONS' SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

We are pleased to present the Canadian Pharmaceutical Association before the House of Commons' Special Committee on Drug Costs and Prices. In so doing, it is our aim to make known the views of the Association and to factually disseminate its knowledge of matters having to do with drug costs in Canada, particularly with respect to their distribution and the provision of comprehensive pharmaceutical services by practising pharmacists in the widespread communities of Canada.

IDENTIFICATION AND ORIENTATION

1.1 The Canadian Pharmaceutical Association Inc. was founded in 1907 and incorporated by Federal Charter in 1924. It is representative of the Provincial Statutory Pharmacy Organizations in Canada and their over 8,000 registered pharmacists, excepting those of the Collège des Pharmaciens de la Province de Québec, which withdrew from constituent membership in the Association, effective July 1, 1962. Hence, the Association membership comprises pharmacists in all fields of pharmaceutical endeavour in Canada—community retail, hospital, teaching, industry, production control and distribution, government, armed forces, etc. In addition to the representatives of each Provincial Statutory Pharmacy Organization, there are seated on its Council the delegates of the Canadian Conference of Pharmaceutical Faculties, the Canadian Society of Hospital Pharmacists and the Canadian Society of Industrial Pharmacists. For the sake of clarity, we would point out that the latter bears no relation to the Pharmaceutical Manufacturers Association of Canada which is an organization of certain companies involved in the manufacture and distribution of pharmaceutical products in Canada.

> Note: The initials "C.Ph.A." which appear from time to time in this Brief refer to the long-standing abbreviation of the name of the Canadian Pharmaceutical Association, Inc.

1.2 The views of Canadian Pharmacy respecting drug costs and prices and related matters having an effect, direct or indirect, on the health and welfare of Canadians have, from time to time, been made known by the Canadian Pharmaceutical Association in presentations both to legislators and to those charged with the administration of legislation. In particular, we respectfully draw the attention of the Special Committee on Drug Costs and Prices to the Briefs presented by the Association before hearings and meetings of (1) The Royal Commission on Government Organization, July 31, 1961; (2) The Restrictive Trade Practices Commission, October 24-27, 1961; (3) The Royal Commission on Health Services, May 25, 1962; (4) The Special Committee of the Royal College of Physicians and Surgeons reviewing new drugs, September 27, 1962; (5) The Royal Commission on Taxation, May 2, 1963; and (6) the

House of Commons' Special Committee on Food and Drugs relative to Quality Control and Safety, June 5, 1964. In addition, the Association has assisted during hearings of certain provincial Select Committees on Drugs and has published its views on their reports. Too, Pharmacy's organizations in every province have extended the wholehearted co-operation of the profession to provincial legislators and provincially-orientated committees.

1.3 This presentation, then, will, in the main, attempt to recapitulate many of the matters pertinent to a particular subject of interest which has been discussed previously and, where possible, will update the facts and figures believed to be of particular interest.

Pharmaceutical Services

2.1 Although the Terms of Reference of the Special Committee refer particularly to the word "drugs", the Association respectfully suggests that it is not possible to do other than to consider the whole matter of comprehensive pharmaceutical services of which drugs and preparations thereof are but the tangible ingredient. In so doing, services pertaining to prescribed medication as well as those connected with commerce in pharmaceutical preparations purchased for purposes of auto-therapy must be given consideration.

The "Drug Business"

3.1 The preparation, distribution and provision of drugs is possibly regarded by the untrained and uninformed as only another business while, in fact, it is truly an encyclopedic chain of precise undertakings demanding specific expertness relative to the complexities of sciences combined with a grasp of economics in relation to the means by which health services and, more particularly, pharmaceutical services are available in every community.

3.2 Quality and quantity, efficacy and safety, consistency of therapeutic value and availability, are all attributes in modern pharmaceuticals—each quite rightfully demanding the special attention of costly, special, control legislation, professional and scientific education, prestige manufacturing and unfailing attention to progressive researching and the means by which drugs can most advantageously be added to the armament of our constant battle against ill health.

3.3 These special features make pharmaceutical endeavours so markedly different from other business enterprises. All have their intangible, little-understood, dollar effect on the consumer pocketbook: yet, each contributes to the fact that modern pharmaceutical services available today from Canada's retail pharmacies probably constitute the biggest bargain offered to the consumer.

3.4 The cost of drugs, a subject of popular debate, is not something which community pharmacists ask the public to "excuse", but they do ask that their charges be "understood" and placed in perspective with their value and usefulness and with the prices of other goods and services, be latter elective or required, essential items of modern life.

Retail Pharmacy Practice

4.1 Pharmacy is customarily practised as part of a retail business establishment which, viewed in its entirety, may seem a composite of diverse interests,

with the pharmacist being a profit-seeking retailer as well as a professional practitioner. Only in a small minority of businesses has commerce in medicinals been sufficient for the maintaining of a strictly professional pharmacy for the purposes of dispensing prescriptions and overseeing the sale of drug preparations.

4.2 From the retail point of view, pharmacy is not "big business". A community pharmacist has a particular stake in good business policies. He operates under high overhead costs and is subject to legislative restrictions not common to other retailers. Only a few drug preparations have, because of their very nature, been placed under the sole control of the licensed pharmacist by our legislators. His non-drug items frequently subsidize prescriptions and, in so doing, make the availability of complete pharmaceutical services financially possible in most communities. There is no evidence that the merchandising of "other lines", although not all necessarily condoned by official Pharmacy, has reduced the quality of pharmaceutical service. Indeed, it is exceedingly high in Canada and is rendered quickly and efficiently by community pharmacists.

4.3 It is the pharmacist's primary responsibility to render a complete prescription service, including the many activities which fall within the important area of personal, professional judgment related to the drug therapy which has been ordered or which the consumer may deem to request for purposes of self-medication. He does this in keeping with the knowledge gained through expensive academic training and re-training, the standards of which equal or surpass those of most other countries.

Statistics

5.1 The C.Ph.A. is currently conducting the twenty-fourth of its Annual Surveys of Retail Pharmacy Operations. (The 23rd Annual Survey is appended to this presentation.) These annual studies, as well as those of D.B.S. are relied upon strongly by the Association.

5.2 We quite appreciate that statistics can only deal with averages and that any discussion of averages is academic, particularly to those whose experiences may be far in excess of the stated averages. For example, statistics state that Canadians spend an average of only $9.00 annually on prescribed drugs; and that the cost of consuming the daily dose of the average, individual prescription about equals the amount expended for the business man's two cups of coffee.

5.3 The Association does not suggest that the price of prescription services is not high to persons with very limited means or to those suffering from debilitating conditions requiring vast amounts of medication over extended periods of time. These individuals are deserving of particular consideration and it is our belief that the profession of Pharmacy can assist them and the agencies which may accept responsibility on their behalf by making available a professionally-oriented, low-cost prescription services plan to protect against above-average expenditures and catastrophic situations.

Retailing and Drug Prices

6.1 The Association strongly states its belief that pharmacists' charges for complete, first-class pharmaceutical services are completely justifiable and proper. Drug costs to these vast majority of Canadian citizens are neither high nor exorbitant.

6.2 In 1964, on the average there were 3,854 persons per pharmacy. Each of these procured 2.68 prescriptions at an average price of $3.31. This per capita expenditure of $8.87 represents less than 1c. of the consumer dollar.

6.3 Preliminary figures for 1965 coming from the 24th Annual Survey indicate a utilization rate of 3.0 prescriptions per person, averaging $3.32 each for a per capita expenditure of $9.95. The increased utilization rate is significant.

6.4 In 1964, the 'average' pharmacy experienced $131,039 in gross sales, of which 27.4% ($36,375) was due to the dispensing of 10,962 prescriptions (30 in each of 365 days). Gross margin for the overall drugstore operation was 34.2% from which costs of 29.4% left a net profit, *before* taxes, of 4.8%. Only 37.6% of reporting pharmacies reported sales exceeding the average. Median gross sales were $112,995.

THE RESULTS OF THE 23rd C. Ph. A. PHARMACY SURVEY

(*with figures of former surveys for comparison*)

Total Pharmacy Sales for 1964 ..... $623,775,180

Number of Prescriptions

1964	51,635,671	1959	43,916,605
1963	48,946,090	1958	40,445,325
1962	44,630,198	1957	40,036,416
1961	42,540,814	1956	35,102,361
1960	42,840,810	1955	32,908,185

Value of Prescriptions

1964	$170,914,399	1959	130,187,483
1963	156,627,512	1958	112,438,004
1962	141,031,428	1957	103,230,236
1961	133,578,157	1956	87,404,881
1960	131,092,880	1955	74,372,498

Average Cost of a Prescription

1964	$3.31	1959	2.98
1963	3.20	1958	2.78
1962	3.16	1957	2.61
1961	3.14	1956	2.49
1960	3.06	1955	2.26

6.5 Subsidization of prescription service by commercial transactions is well illustrated in the Survey. Within each sales category, total expenses grow with prescription volume—for example, in the $100,000 to $125,000 group, those in which prescriptions represented 12.9% of sales show expenses as 27.2%, while those with 42.9% prescription volume show 33.6% expenses (a substantial 6.4% gross difference).

6.6 From previous Surveys, a gradual increase is noted in the ratio of prescription revenue to gross retail pharmacy sales. Among the circumstances

influencing this change will be: (1) the ratio of population per pharmacy has increased; (2) More prescriptions dispensed (e.g., higher utilization) and the average prescription price has increased (see table below); (3) Traditional, non-prescription sales are now shared more with other outlets such as supermarkets, thus proportionately lowering the gross sales of retail pharmacies; (4) Greater urban population with resultant urban convenience and accessibility to pharmacies and other health care facilities; (5) More health dollars available as a consequence of various health insurance schemes; (6) Generally improved standard of living and health and the desire to maintain same.

PRESCRIPTION COST/UTILIZATION

1961 = 100

Year	*Price*	*Utilization*
1961	100.0	100.0
1962	100.1	104.9
1963	101.9	115.1
1964	105.9	121.4
1965	107.6	142.9

Prescribed Drugs: Prices and Expenses

7.1 A prescription is not an ordinary item of commerce or trade, nor is it a merchandising commodity.

7.2 An Association-sponsored study (appended to this presentation) of 233,000 prescriptions (November 8-21, 1964) showed that 25 per cent were dispensed at a loss below an average break-even cost of $1.93. It showed, too, that 84.3 per cent of all prescriptions were dispensed at less than $5.00, while 1.4 per cent were over $10.00.

7.3 This Study showed the average price (involving a sample of less than 1/2 per cent of yearly volume) during that period as $3.47, with 50 per cent of this being the cost of the tangible commodity as purchased from manufacturers and distributors. During that year, retail pharmacists dispensed prescriptions valued at $171,000,000 with ingredients used solely in those prescriptions being, presumably, $85.5 million and the balance representing the cost of procuring local services to provide needed drugs to the community.

7.4 Time-motion studies, extremely expensive undertakings, have not been conducted and we do not believe that there are sufficient published statistics to provide a factual, national average breakdown related to prescription transactions in isolation from the total operation of a retail pharmacy—nor, possibly, would it be practical to do so either relative to the prescription ingredients or the local dispensing of them.

7.5 It can be realistically assumed, however, that the pharmacy having a 42.9 per cent prescription volume probably gained a substantial portion of the balance of its $129,500 gross revenue from items which, by their nature, are necessarily and/or legislatively restricted to pharmacy-only distribution, prescription accessories and related items. These constitute a comprehensive, total

community pharmacy service. Hence the breakdown of the consumer's dollar for services and goods:

62¢	— paid to the manufacturer/distributor
23½¢	— paid for salaries to locally resident employees
2½¢	— paid to rent to local landlord
2½¢	— for advertising in local media
	— for delivery service by local citizens
	— for repairs by local tradesmen
1½¢	— for heat, power, telephone, taxes to local utilities and government
½¢	— for insurance purchased from local agents
1¼¢	— for depreciation, interest and bad debts
2¢	— for miscellaneous expenses of an internal and local nature
4½¢	— profit *before* deductions for income tax, surplus account, etc.
$1.00	

7.6 As stated in previous representations, it is generally accepted—contrary to the above-stated 62 cents—that, in view of the professional fees applied, ingredients represent 50 cents of the prescription dollar. However, existing statistics do not permit the pharmacist's "direct expenses" (salaries, spoilage, delivery costs, depreciation, interest) and "indirect expenses" (rent, power, telephone, etc.) relative to prescriptions alone to be factually apportioned and/or completely divorced from the operation of the retail pharmacy as a whole. Mere weighting of the breakdown of the 38 cent portion to bring it up to a 50 cent level would not provide an adequate answer and, in any event, would be a misrepresentation of the facts surrounding an all-inclusive pharmaceutical service.

7.7 At the same time, we do not disagree that the 50 cent ingredient cost be referred to by others having a direct responsibility for it. It is not the purpose of this particular Brief by the C.Ph.A. to discuss the disposition by the manufacturer of the amounts paid to him by the community pharmacist. Industry, a vital area of modern pharmaceutical endeavour, provides Canadian practitioners with the tools with which to fight disease, and in so doing, faces problems—scientific and economic—characteristic of its highly specialized nature not shared by any other manufacturing undertaking.

7.8 Two matters directly related to drug ingredient costs and prices must be understood:

(1) The highly improper tax on illness—the 11 per cent Federal Sales Tax—is included in the 62 cents paid by the retail pharmacist and hence, its influence constitutes a 9 cents portion of the consumer dollar. In relation to the 50-50 prescription dollar, its 8.3 cents influence cost the ill and diseased over 14 million consumer dollars in 1964.

(2) The retail pharmacist pays top dollar for his drug preparations. This causes a disproportionate weighting on the prescription purchased by

the private patient and a substantial subsidization of the sometimes unrealistic prices available to other practitioners, hospitals, governments and similar agencies. This situation is not appreciated by the uninformed. It is certainly not condoned by Pharmacy and we repeat our often stated, firm belief that this gap should not exist.

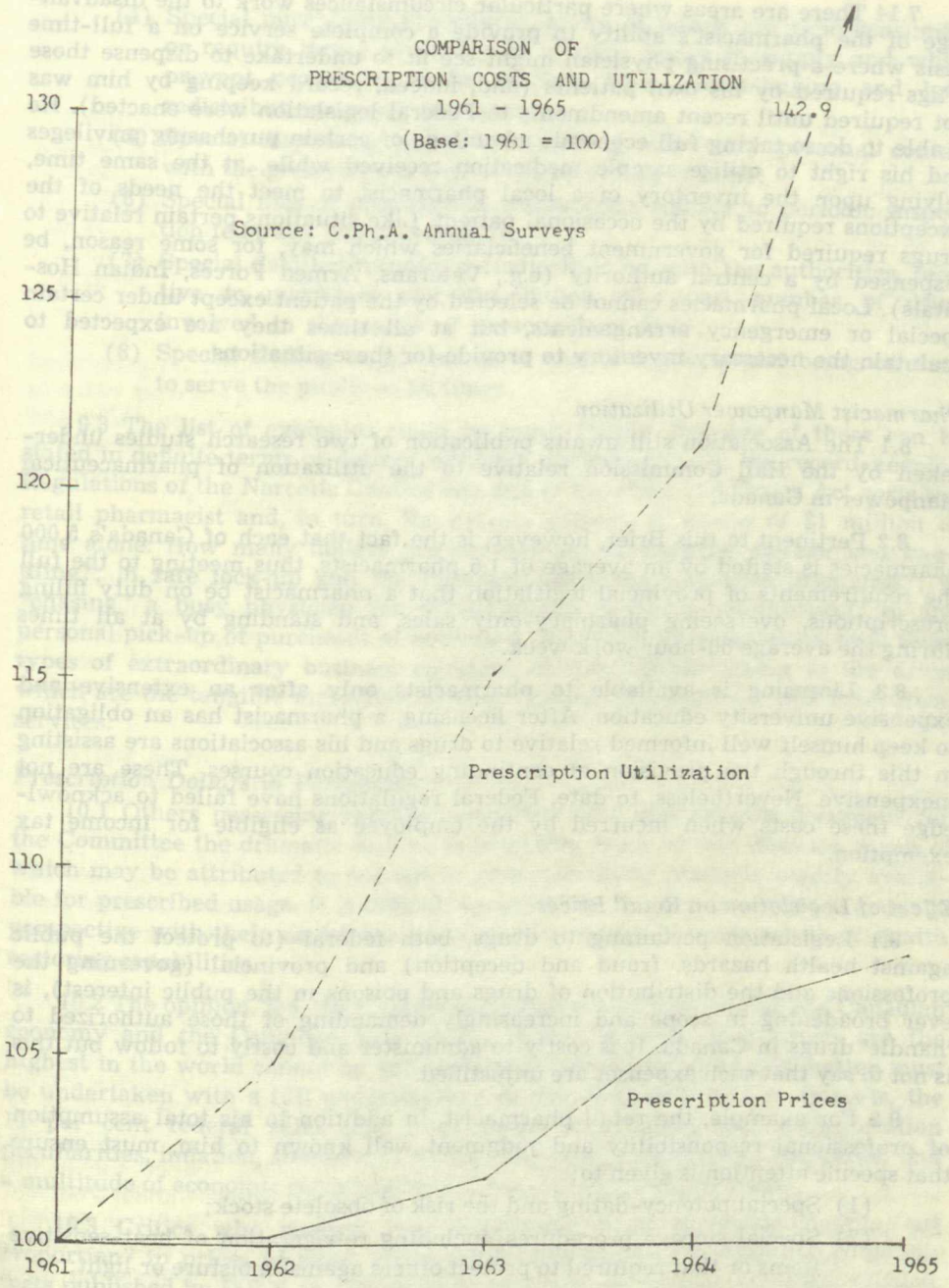
7.9 *Prescription Pricing Methods*: Generally speaking, two pricing methods are followed: (i) that involving a basic percentage mark-up based on retail list price plus a minimal professional fee of up to 75 cents related to the multiplicity of extra responsibilities and legislative requirements which are not part of a commercial transaction; and (ii) a cost-plus-professional fee concept of pricing. The latter is proving popular as it becomes better understood. It permits public assessment of the service being rendered as separate from variations in the cost of ingredients, and is used in various contractual agreements with paying agencies.

7.10 *Price Increases*: The chart presented earlier in this Brief illustrates the increase in the average price of a prescription that has been experienced over the years. These increases are, of course, expressed in terms of the inflated dollar and are very realistically influenced by (1) inflation and consumer price index; (2) inflation and wage rates, both in the general economy and relative to remuneration of personel; (3) the increased quantity of doses per prescription; (4) increased cost of ingredients with specific drug therapy available today as opposed to symptomatic treatment of just two decades ago, and with federal sales tax on drugs having increased from 8 per cent to 11 per cent between 1951 and 1958; (5) greater use of drugs for chronic, ambulatory treatment; (6) greater demand arising from the knowledge that today's drugs can quickly return the patient to full health. (A graph illustrating the increase in the the average prescription price from 1961 to 1965 is shown on page 12.)

7.11 *Retail Subsidization of Prescribed Drugs:* Previously in this Brief, evidence is presented to illustrate the manner in which the sale of non-drug items does, in effect, subsidize the financial ability of the retail pharmacist to provide a comprehensive pharmaceutical service in conveniently located community facilities.

7.12 Elsewhere, too, attention is drawn to the multi-pricing policies of manufacturers which force the retail pharmacist to purchase his drug supplies at prices which far exceed those paid for the same quality, strength and quantity by others who may legally purchase them—more specifically, hospitals and similar institutions, and government agencies. With sales to the latter no longer representing only a minor percentage of the manufacturer's gross, such prices cannot be considered promotional costs and hence, the depressed prices must be subsidized by sales to the normal retail channel.

7.13 In most areas, provincial or municipal agencies finance the health service needs of welfare recipients. Drug services are provided under contractual agreements involving the granting by the retail pharmacist of substantial discounts. Direct losses due to those discounts, and indirect expenses due to the paper work involved as well as the extremely long waiting period for payment must be considered in the gross expenses of the operation of a prescription service.


COMPARISON OF
PRESCRIPTION COSTS AND UTILIZATION
1961 - 1965
(Base: 1961 = 100)
Source: C.Ph.A. Annual Surveys
142.9
Prescription Utilization
Prescription Prices
130
125
120
115
110
105
100
1961
1962
1963
1964
1965

24087—2½

7.14 There are areas where particular circumstances work to the disadvantage of the pharmacist's ability to provide a complete service on a full-time basis where a practising physician might see fit to undertake to dispense those drugs required by his own patients (and, indeed, record keeping by him was not required until recent amendments to Federal legislation were enacted). He is able to do so taking full economic advantage of certain purchasing privileges and his right to utilize sample medication received while, at the same time, relying upon the inventory of a local pharmacist to meet the needs of the exceptions required by the occasional patient. Like situations pertain relative to drugs required for government beneficiaries which may, for some reason, be dispensed by a central authority (e.g., Veterans, Armed Forces, Indian Hospitals). Local pharmacies cannot be selected by the patient except under certain special or emergency arrangements, but at all times they are expected to maintain the necessary inventory to provide for these situations.

Pharmacist Manpower Utilization

8.1 The Association still awaits publication of two research studies undertaken by the Hall Commission relative to the utilization of pharmaceutical manpower in Canada.

8.2 Pertinent to this Brief, however, is the fact that each of Canada's 5,000 pharmacies is staffed by an average of 1.6 pharmacists, thus meeting to the full the requirements of provincial legislation that a pharmacist be on duty filling prescriptions, overseeing pharmacy-only sales, and standing by at all times during the average 60-hour work week.

8.3 Licensing is available to pharmacists only after an extensive and expensive university education. After licensing, a pharmacist has an obligation to keep himself well informed relative to drugs and his associations are assisting in this through the provision of continuing education courses. These are not inexpensive. Nevertheless, to date, Federal regulations have failed to acknowledge these costs when incurred by the employee as eligible for income tax exemption.

Effect of Legislation on Retail Prices

9.1 Legislation pertaining to drugs, both federal (to protect the public against health hazards, fraud and deception) and provincial (governing the professions and the distribution of drugs and poisons in the public interest), is ever broadening in scope and increasingly demanding of those authorized to 'handle' drugs in Canada. It is costly to administer and costly to follow but this is not to say that such expenses are unjustified.

9.2 For example, the retail pharmacist, in addition to his total assumption of professional responsibility and judgment well known to him, must ensure that specific attention is given to:

(1) Special potency-dating and the risk of obsolete stock;

(2) Special storage procedures, including refrigeration of heat-sensitive items or that required to protect others against moisture or light;

(3) Special security facilities for narcotics and similar, socially-abused drugs;

(4) Special purchasing procedures, many of which are time-consuming or require larger inventory to obviate delays in supply and which prevent economies to be realized from group-buying and local redistribution among pharmacists;

(5) Special dispensing procedures making mandatory personal contact with the prescriber as well as the recording of same;

(6) Special files of prescription transactions subject to periodic inspection federally and provincially;

(7) Special detailed records, periodically filed with the authorities, relative to purchases and distribution of a vast number of drugs involved in thousands of prescriptions daily;

(8) Special staffing requirements to ensure a pharmacist being on duty to serve the public at all times.

9.3 The list of examples could be much longer. Not one of these can be stated in definite terms of dollars, although conformity with the record-keeping Regulations of the Narcotic Control Act and of the Food and Drugs Act costs the retail pharmacist and, in turn, the private patient, in excess of $1 million in time alone. How many dollars are represented in essential storage and handling?; in safe lock-up and the resultant risks and insurance premiums?; in "chasing" a busy physician for authorization of repeat medication?; in the personal pick-up of purchases of restricted items? Pharmacists alone bear these types of extraordinary business expenses all directly pertaining to the drugs which are the tangible ingredient of their community-available pharmaceutical services.

Prescription Dollars in Perspective

10.1 Others possessing specific expertness will undoubtedly document for the Committee the dramatic decline in mortality from certain diseases, much of which may be attributed to the newer pharmaceutical products readily available for prescribed usage. It is difficult to undertake to completely place drugs in perspective with their usefulness or to place a monetary value on their health restoring capabilities.

10.2 The opinion, too often expressed without consideration of the Canadian economy and the Canadian way of life, that Canadian drug prices are the highest in the world cannot be substantiated. Consideration of this matter must be undertaken with a full understanding of the effect of tariffs on imports, the 11 per cent federal sales tax, wage rates, distribution and transportation peculiarities, inflation, standard of living, strictness of applicable legislation and a multitude of economic considerations not common to foreign lands.

10.3 Critics who suggest that drug costs have increased "out of all proportion" to prices of other commodities and services are not aware of the facts published by D.B.S. in "Prices and Price Indices", December, 1964. Therein it is shown that while prices in general increased 36.8 per cent between 1949 and 1964, the price of drugs increased only by the amount of 20.7 per cent, this

being considerably less than any other component of total health care. Price increases are as follows:

	%		%
Total index of prices	36.8	Theatre tickets	108.4
Total health care	80.5	Newspapers	94.0
Drugs	20.7	New cars	19.9
Prepaid health care	126.6	Telephone rates	52.2
Dentists' fees	84.0	Footwear	54.0
Doctors' fees	57.5	Rents of dwellings	45.4
Hospital rates	113.5	Cereal products	62.5
Men's haircuts	115.7		

10.4 Other D.B.S. statistics indicate a per capita expenditure on prescribed medicine in 1963 of $6.42. During that same year, Canadians spent over twice as much on newspapers and magazines; over four times as much on radio and television sets; over six and one-half times as much on tobacco; over eight times as much on alcoholic beverages; and over ten times as much on the operation of motor vehicles. A chart of price movements in Canada is on page 18.

Pharmaceutical Services in Hospitals

11.1 *Hospital drugs:* Approximately 38 per cent of the dollar value of manufacturers' drug shipments goes to hospitals and government institutions. In view of the substantially lower prices paid by hospitals (coupled with the 11 per cent sales tax exemption and the advantages of quantity and contract purchasing), it is impossible to ascertain the physical volume of dosage forms represented by this 38 per cent of the total dollar market.

11.2 No fair comparison can be made between hospital prices and retail prices, either relative to the dosage forms in the total inventory or to the cost of private, complete pharmaceutical service to the patient.

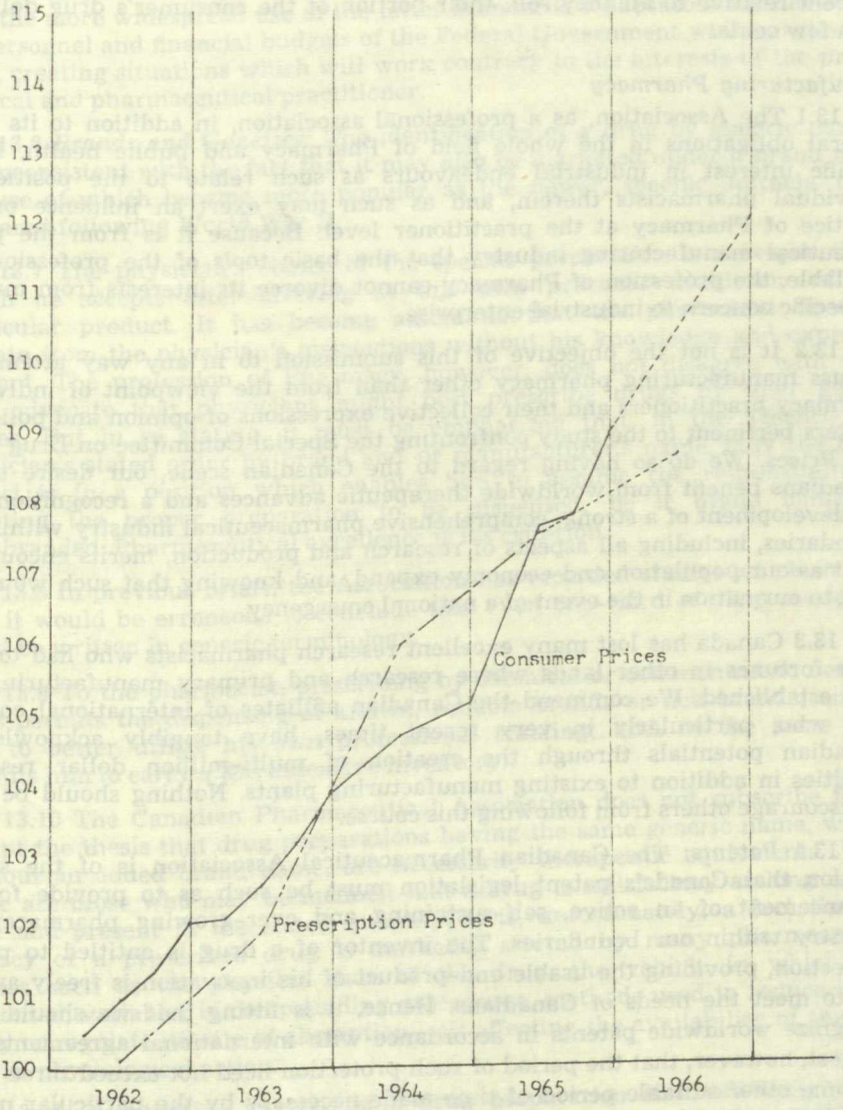
11.3 In addition, all too many institutions, merely as a dollar saver, fail to adequately protect the public by employing pharmacists, and, too, drug distribution by hospitals and government agencies is not faced with the high expense of adherence to a multitude of legislative requirements which are common to retail practice.

11.4 It must be kept in mind that drugs in a hospital are specifically selected with the concurrence of the relatively small number of physicians practising therein to meet the needs of the illness situations of the small proportion of the population which, for one reason or another, requires active, institutional care. Institutional confinement of the patient and ready access to professional care at all times make the selection, storage, dispensing and administration of drug therapy and its consequent cost very different from the use of drugs by the physician in his private practice for ambulatory patients. The Drug Formulary System, embodying features which make it readily adaptable to localized, day-to-day situations in the hospital could not be applied at the community level where it is so necessary that the prescriber have available those drug preparations which he personally selects for use in view of his expectation of therapeutic results in an individual who is other than under his constant scrutiny.

PRICE MOVEMENTS IN CANADA 1962 - 1965

(1961 = 100)

Projected through 1966 at same percentage increase as in 1965



Source: D.B.S.
C.Ph.A. Annual Surveys

Wholesaling

12.1 The combined effects of a multiplicity of valuable, specific drug preparations and the vastness of the Canadian geography and its widespread communities make the role of the service drug wholesaler vital to both the manufacturer and the retail pharmacist. The wholesaler's warehousing and distributive function relative to drugs embodies procedures and costs not common to distributors of trade goods. Operating on a gross revenue of some 12 per cent relative to all they sell, their portion of the consumer's drug dollar is but a few cents.

Manufacturing Pharmacy

13.1 The Association, as a professional association, in addition to its more general obligations in the whole field of Pharmacy and public health, has a specific interest in industrial endeavours as such relate to the position of individual pharmacists therein, and as such may exert an influence on the practice of Pharmacy at the practitioner level. Because it is from the pharmaceutical manufacturing industry that the basic tools of the profession are available, the profession of Pharmacy cannot divorce its interests from matters of specific concern to industrial enterprise.

13.2 It is not the objective of this submission to in any way attempt to discuss manufacturing pharmacy other than from the viewpoint of individual pharmacy practitioners and their collective expressions of opinion and policy on matters pertinent to the study confronting the Special Committee on Drug Costs and Prices. We do so having regard to the Canadian scene, our desire to see Canadians benefit from worldwide therapeutic advances and a recognition that the development of a strong, comprehensive pharmaceutical industry within our boundaries, including all aspects of research and production, merits encouragement as our population and economy expand, and knowing that such would be vital to our nation in the event of a national emergency.

13.3 Canada has lost many excellent research pharmacists who had to seek their fortunes in other lands where research and primary manufacturing are well established. We commend the Canadian affiliates of international companies who, particularly in very recent times, have tangibly acknowledged Canadian potentials through the creation of multi-million dollar research facilities in addition to existing manufacturing plants. Nothing should be done to discourage others from following this course.

13.4 *Patents:* The Canadian Pharmaceutical Association is of the strong opinion that Canada's patent legislation must be such as to provide for the enhancement of an active, self-sustaining and ever-growing pharmaceutical industry within our boundaries. The inventor of a drug is entitled to patent protection, providing the usable end-product of his innovation is freely available to meet the needs of Canadians. Hence, it is fitting that we should fully recognize worldwide patents in accordance with international agreements. We suggest, however, that the period of such protection need not exceed three years or some other suitable period of time made necessary by the particular nature of the drug, unless it be produced in Canadian-based manufacturing facilities. As at present, the patent holder should have the right to license other producers

and compulsory licensing provisions of the Patent Act should continue to be exercised to facilitate legal production in Canada.

13.5 *Quality and Quality Control* is, today, more strictly supervised as stipulated by Federal Regulations. In addition to those of the Food and Drugs Act, there are the requirements of the Canadian Government Specifications Board, 74GP-1a, applicable to government purchases. The Association has expressed its concern that such a double standard exists. We are also of the opinion that the more widespread use of the latter Standards will place a further burden on personnel and financial budgets of the Federal Government while, at the same time, creating situations which will work contrary to the interests of the private medical and pharmaceutical practitioner.

13.6 *Brands and Generics:* The identification of a drug by generic name is not inconsistent with the fact that it may also be marketed under a brand name, the use of which became more popular as the newer, specific 'miracle' drugs appeared following World War II.

13.7 The physician's choice of the specific preparation is a responsibility which he accepts after arriving at this own practical evaluation of that particular product. It has become axiomatic that the pharmacist does not deviate from the physician's instructions without his knowledge and expressed consent. The profession of Pharmacy, however, does not disagree with those who advocate that physicians might best prescribe drugs by their generic names. But in so stating, it must be emphasized that, in the absence of a physician's stated order by brand and or manufacturer's name, only the pharmacist is in a position which enables him to assume the responsibility of selecting the proper preparation to be dispensed, be it brand named or non-branded. Pharmaceutical excellence is his criterion.

13.8 In previous briefs, the Association has recorded studies which indicate that it would be erroneous to conclude that even one-third of all prescriptions could be written in generic terminology.

13.9 To the pharmacist, prescribing by chemical or common name designations permits the dispensing of known, reliable brands or non-brands; enables him to better utilize his own professional training; and, at the same time, permits him to carry a less extensive inventory.

13.10 The Canadian Pharmaceutical Association does not subscribe to nor accept the thesis that drug preparations having the same generic name, with or without an added brand name, are necessarily therapeutic equivalents. While there are those who may be inclined that a drug is satisfactory as long as it is pure and present in the stated quantity, it is, unfortunately, a fact that the efficacy of a prescribed drug is markedly altered by many pharmaceutical factors such as the physical state of the drug, the vehicle in which it is presented, variables in compounding procedures, methods used to reduce irritability or regulate its rate of absorption—all affecting the availability of the drug and its physiological action.

13.11 Quantitative analysis of a drug preparation is a relatively simple procedure using the facilities of a chemical laboratory. Qualitative analysis of the therapeutic efficacy of the preparation is a very different thing, possibly

requiring nothing less than the facilities of universities and university-affiliated hospitals. Nevertheless, it is suggested that this matter merits a searching study by a responsible, representative group having a particular competence in such matters.

13.12 *Information Service*: The dissemination of completely up-to-date information on drug preparations is expensive. Some of this information is available from many sources and in a great variety of forms, ranging from purely scientific to consumer material.

13.13 There is a great desire to create a complete "Drug Information Service" which would bring together every piece of available information on each and every drug preparation. Such a service is being advanced by the Canadian Society of Hospital Pharmacists and we believe its proposal merits the attention of foundations and governments, as well as industry and the health services practitioners so that money is made available for its development.

13.14 Recommendation No. 62 in the Hall Commission Report suggests a National Drug Formulary. Because this "Formulary", as suggested, would contain information about only some drug preparations based on the criteria of their acceptability to only some authorities, and on price, we do not believe that it would be an adequate, comprehensive service.

13.15 At the present time, the Association is rewriting its "Compendium of Pharmaceuticals and Specialties" in a manner which will enhance the factual information which it presents in summary form concerning all drug preparations on the Canadian market. Previously sold to pharmacists and physicians, it is the Association's expectation that, through the co-operation of the pharmaceutical industry, this complete reference text will be placed in the hands of every pharmacist, physician and hospital in Canada so that they may have ready access to basic, essential information.

General Economics and Drug Costs

14.1 There are many matters of general economics peculiar to the availability of drugs in Canada which are of considerable significance in the study confronting the Special Committee. This Brief has summarized but a few of the matters, many of which have been expounded on at greater length in more extensive compilations and presentations.

14.2 The Canadian Pharmaceutical Association firmly believes that the Canadian scene and way of life must be acknowledged and that any discussion related to costs and prices must also keep in mind the safety, quality and efficiency of drugs, their manufacture, distribution and sale.

15.1 The Government of Canada, representative of the individual citizens of our nation, the officials charged with the administration of our laws respecting the professions and respecting commercial activities, and the public, generally, are assured of the desire of the Canadian Pharmaceutical Association, representative of the profession in all of its aspects, to be of continuing assistance in all matters having to do with the enhancement of health and welfare, particularly with regard to the safe and economical availability of drugs required by the ill and diseased.

15.2 We have welcomed this further opportunity of discussing drug matters. We deem it a privilege to work with this Special Committee on Drug Costs and Prices of the House of Commons. Of necessity, the representative problem cannot be discussed in depth in a Brief such as this, but you are assured that the Canadian Pharmaceutical Association would be pleased to assist in the obtaining of further information which may provide desired clarity on any particular point.

* * * * *

The CHAIRMAN: May I ask the members of the Committee if they have any questions on section 1, identification and orientation. No questions on that portion? No. 2, pharmaceutical services?

Mr. TURNBULL: May I comment, Mr. Chairman, that we have inserted this paragraph to emphasize tothe Committee that we do not believe it is possible, particularly at the community distribution level, to divorce drugs per se from the complete field of rendering pharmaceutical services in total. This is the premise of our brief and of our statistical presentation.

Mr. BRAND: Do you mean by this you are including such things as cameras and such?

Mr. TURNBULL: No. I said pharmaceutical services sir. The whole gamut of related items to a prescription service, prescription accessories, those items which are by their nature necessarily restricted to pharmacy only; its distribution, the areas of judgment into which the pharmacist's practice falls generally. It does not pertain to those items which some of us may not condone for sale in the drugstore as we commonly know it.

Mr. MACDONALD *(Prince)*: I would like to ask a question because I am still not too clear. You describe drugs and preparations as only part of the output, if you like. Could you elaborate on that point?

Mr. TURNBULL: We have not gone too extensively into that in this particular brief. When we presented ourselves before the Hall Commission, with a more extensive brief, we went into the full field of all the itemization of what constitutes pharmaceutical services over and above the tangible ingredients of a prescription; that is, the record keeping, the consultation, the storage, the security, and have you, of the drugs, in relation to prescribed therapy. Also, the area of activity in which the practising pharmacist finds himself with regard to self medication being sought by individuals within the community. This falls within that complete area of pharmaceutical services which cannot be rendered by anyone other than the practising pharmacist in the community.

M. MACDONALD *(Prince)*: Surely, what you are saying here is the common experience of many businesses which would have to keep like records in terms of stock control but also keep records in connection with the way in which stock might be sold in a certain order.

Mr. TURNBULL: Oh, yes.

Mr. MACDONALD *(Prince)*: Or, is what you are saying something similar to a talent fee that must be kept in mind in terms of the actual skills which are being exercised here in the distribution.

Mr. TURNBULL: That is a term which could be used sir. However, other than the normal inventory control and stockkeeping which might be part of shoes and dresses, and so, on there are the many legislative requirements over and above that, which pertain to pharmaceuticals and drug distribution only. We have made mention of a few of these under paragraph 9.2 on page 15.

The CHAIRMAN: Are there any other questions in relation to section No. 2? Are there any questions under the heading of drug business which is No. 3?

Mr. ENNS: Mr. Chairman, an item in paragraph 3.3, at the bottom of the page, reads:

> Canada's retail pharmacies probably constitute the biggest bargain offered to the consumer.

This is further elaborated upon in paragraph 3.4, on the next page, where the pharmaceutical industry does not want "to excuse" the cost of drugs but wants the charges to be better understood. Perhaps this is very necessary because I doubt whether the Canadian consumer would generally admit that he is getting the biggest bargain in the payment of prescription drugs. It may quite reasonably be so but the latter part of the brief gives further substantiation of thi statement. However, it is an interesting statement and I wanted to draw attention to it.

Mr. TURNBULL: We feel very strongly about that statement and we truly believe it.

The CHAIRMAN: Are there any other questions on that section? Now we will pass on to No. 4, retail pharmacy practice. Are there any questions in relation to that section?

Mr. MACKASEY: I would like to comment, Mr. Turnbull, on section 4.1. I think what you are saying is that it is increasingly more difficult for a druggist to live off the pharmaceutical end of his business alone.

Mr. TURNBULL: There is much evidence of this as well, not only his ability to gain a living from the practice of pharmacy but also to stay in business as such. The number of pharmacies is dropping in the large urban concentrations, and most certainly we readily recognize, and all the statistics back up our statement, that without the so-called front shop, many communities would be without a comprehensive pharmaceutical service. This is possibly not so in the highly concentrated urban areas, but I was raised in a small community, not too far from Mr. Clancy's constituency, and we have many of them across Canada, which could not support, as a separate entity, a pharmaceutical service.

Mr. CLANCY: I would like to ask Mr. Turnbull if this is not true, I think he knows it is, that the drugstores as they were known in the west are closing down very rapidly for the simple reason that we cannot be professional pharmacists, there is not enough volume, and to keep in business we have to become a chain store. In many of these communities—Mr. Turnbull is talking about a community I know and he knows my community—pharmacists are closing out. They are just locking the door. Would you not say it was also true that most of us, who are licenced, are moving in and working with the doctors in the clinics. This pays us a better salary with less responsibility.

The CHAIRMAN: Do you care to comment on that, Mr. Turnbull.

Mr. TURNBULL: No; there is nothing I can add to that. I believe we present statistics which certainly show that retail pharmacy, as we know it in Canada, is not big business, with something like $130,000 as a gross sale figure, some 27 to 28 per cent of which is due to prescription volume. The fact that pharmacies are closing and others are opening is maintaining a stable number of pharmacies across Canada. But the population per pharmacy has increased tremendously over the past few years. It is now something like 3800 in our last statistic, and the indication for 1965 is that it will be well over 3900 per pharmacy, on the average, across Canada.

Mr. ENNS: This must mean that those lesser number of pharmacies are really doing more and more business, because in your own table on page 6 you indicate that the number of prescriptions has increased substantially as well as the value of these prescriptions. I relate this to page 4 under paragraph 4.2 where you speak of these other lines of merchandise. The front business does not really in any demonstrable way affect the quality of the pharmaceutical service in the community. I imagine in many ways this keeps the man in business..

Mr. TURNBULL: This is correct, yes.

Mr. ORLIKOW: I would like to ask if the Pharmaceutical Association has given any consideration to and wishes to express an opinion on the effects on the ability of the retail pharmacy as it has existed to meet the needs of the community and to fill prescriptions at a reasonable price in the light of the development of the doctor-owned clinic-operated dispensary. I do not know if the same is true in other cities, but in Winnipeg there are three or four large clinics which have their own dispensaries and in which, according to reports, all the pressure is on the patient to have his prescription filled in that dispensary rather than taking it to his neighbourhood drugstore. A larger and larger percentage of the prescriptions in the city of Winnipeg, I know, is being filled in these clinic, doctor-owned dispensaries. I am wondering if the Canadian Pharmaceutical Association has considered this problem and its effects on the local drugstore.

Mr. TURNBULL: We have given much consideration to it. First, I should emphasize that the profession's main concern is that the individual patient receives top care. Therefore, the other matter is a matter of economics. Economics cannot enter into the health and welfare of the sick person, other than if the clinic is involved with private formula which is not available in other pharmacy outlets where the patient cannot take his prescription, if he is an out of town patient, to obtain it in the first case or to obtain an authorized refill of that prescription within the therapy ordered by the physician. Most of these clinics are operating with proper pharmaceutical supervision. Some, regrettably, are using secretaries and nurses aids, and what have you, but this is more in the individual office of the so-called dispensing physician who might dispense to his own patients but not for the patients of other physicians. This does happen and certainly is contrary to the interests of pharmacy and of the patient himself. Other than the private formula and this type of thing, no, we cannot be concerned with it.

Mr. ORLIKOW: To the extent that it may not make any difference to the patient of the doctor or to the customer where he buys the actual prescription

that is written but to the extent that you have the development of these clinic, doctor-owned pharmacies which are filling more and more prescriptions, it means that the local community pharmacy gets less prescriptions. That being the case, naturally he has got to make a bigger mark-up per prescription in order to break even if he does less business, does he not?

Mr. TURNBULL: I do not know. I do not think so. I do not think this actually happens. The economics of it would be that he would have to charge more to stay in business so that he could render a standby service in that community. However, there is every evidence that this is not happening. In most cases these people are not too far from wholesalers and this kind of thing, because they are in large areas and they are working more and more with the service wholesaler to do their warehousing for them. This is not possible in the isolated community, of course. It has had its effect on community pharmacy, yes, and it is obvious. In Toronto, for example, there have been 50 pharmacies close in the past year or so. Most of these pharmacists have gone into partnerships with others in the area.

Mr. ORLIKOW: Has the Canadian Pharmaceutical Association looked at, I think it is, the code of ethics of the American Medical Association which—I have not got it here but I could bring it—says that doctors should not be owners of, amongst other things, dispensaries and that there should not be, for example, direct telephone lines between doctors and any dispensary.

Mr. TURNBULL: Yes, we are very much aware of this and this is written in less definite terms in the code of the Canadian Medical Association. I believe that other speakers before me have indicated that it is a very untoward practice, shall we say that the one who signs the birth certificate, diagnoses the illness, prescribes the therapy and signs the death certificate. It is a rather dangerous principle to be followed in health care.

Mr. ORLIKOW: Has there been any discussion between your organization and the Canadian Medical Association about these matters?

Mr. TURNBULL: Yes.

Mr. ORLIKOW: With any specific results?

Mr. TURNBULL: I cannot recall that there have been, no.

Mrs. RIDEOUT: Mr. Turnbull, I want to compliment you on your brief. I note at the bottom of page 4 it says:

> It is the pharmacist's primary responsibility to render a complete prescription service,—

To render a complete prescription service all of your pharmacists would have to be completely up to date on the latest drugs, and the newest ones on the market must be available to the people on prescription?

Mr. TURNBULL: Right.

Mrs. RIDEOUT: Just as a matter of interest to me, how do you control this? Do you have regulations? Do you have people who make sure that outdated drugs or drugs that are no longer considered advisable to use do not remain on the shelves of your pharmacists? Is there a protection for the consumer, in other words?

Mr. TURNBULL: Well, yes. The protection of the consumer is paramount. By legislation all drugs which fall within such categories require a date and these are checked periodically, of course. In addition, the practising pharmacist has the wholehearted co-operation of the representative of the company concerned. Over the years—and certainly this is a factor in the price of drugs—there has developed a very fine working relationship whereby this representative working with the pharmacist is prepared to ensure that he does not have outdated stocks on his shelves. This pertains of course to what we call unbroken packages. Once the package is broken, naturally, it cannot be returned for the necessary credit or replacement. It would have to be discarded and discarded in a very safe manner.

With regard to those drugs coming under specific strict legislation, such as narcotics and controlled drugs, the procedures are much more difficult and much more intricate in any destruction of drugs. However, the consumer is very well protected. Here, again, is one of the intangible parts of the costs of drugs.

Mrs. RIDEOUT: This is why I was making the point. I am sure pharmacists have a tremendous overhead, actually, protecting the consumer.

Mr. TURNBULL: Very much so.

Mrs. RIDEOUT: I know that it always fascinates me to go into a drugstore and see all the little bottles. I wonder how they can possibly keep track of all the various new drugs that are on the market.

Mr. TURNBULL: Well, this is part of the pharmacist's responsibility and he is expected to assume this responsibility to the best of his ability.

Mr. HOWE (*Hamilton South*): Mr. Chairman, I want to pursue the line which Mr. Orlikow took a few moments ago, as far as the doctor is concerned. I believe the O.M.A. did come out recently with a statement discouraging doctors from indulging in business other than their own; that their time should be devoted fully to the practice of medicine and not dispensing and worrying about drugs. Second, I think there is more responsibility to the patient through a druggist than through a doctor because of the system of inspection, and so on. Doctors are not as rigorously inspected in the same way as a pharmacy. Also, a doctor dispensing drugs does not offer the same choice of drugs that a drug store is doing because he buys a stock of drugs and writes his own prescription for the type he wants to dispense and he is not going to have any left over because he can dispense right down to the last tablet in the bottle.

Mr. TURNBULL: This is true.

Mr. HOWE (*Hamilton South*): Whereas, a drugstore must keep every drug in stock to appeal to the whim of every doctor in that neighbourhood and many times outside the neighbourhood. This I say in defence of the druggist and in opposition to doctors dispensing which I think is wrong. I did want to ask Mr. Turnbull about the calculation of the prices of drugs. You give, in this brief, a gross profit and then an over-all net profit which is, of course, of necessity much smaller. Is the cost other than that of the drug done on a prorated basis on the over-all expense of the store and the per cent of business which is done by the dispensary so that you are not putting all the expenses in on the dispensary when you calculate the net profit made on prescriptions over the period of a year.

Mr. TURNBULL: Do you mean in the statistical compilation, doctor?

Mr. HOWE (*Hamilton South*): Yes.

Mr. TURNBULL: The best way to answer that is yes and no. It is impossible without some very elaborate time motion, rent, direct and indirect expense calculations to completely isolate the dispensary from the rest of the physical structure. We have attempted to do so. Indeed, there was a very expensive time motion study undertaken in the states several years ago. I am not too sure what they accomplished but this is beside the point at the moment. Briefly, to answer your question, we have not been able to take these various figures and completely divorce one section of the pharmacy from the other. This is why in the presentation of this brief we have given a very positive statement that in presenting the figures we have picked on a group of pharmacies which have answered our survey which would seem to have about a total pharmaceutical services facility with a minimum of the other merchandise which we might find in the corner drug store. We have relied on the statistics coming from them to present to you this morning.

Mr. HOWE (*Hamilton South*): One could take the pure prescription dispensing drugstore and maybe find out what this is, but this is not the rule. We are talking about the average drugstore that handles drugs and related and unrelated items within that store.

Mr. TURNBULL: We are not taking the average; we are taking a group that would be as close to what you are describing as possible; that is, with over 45 per cent of their volume coming from prescription practice.

Mr. HOWE (*Hamilton South*): Is it not easy to determine the per cent of the over-all business that is prescription?

Mr. TURNBULL: Oh, yes, very easy.

Mr. HOWE (*Hamilton South*): That is easy to determine but then your costs tend to overlap but an attempt is made to prorate.

Mr. TURNBULL: Yes. This is presented here on page 9.

Mr. HOWE (*Hamilton South*): One other question which is not related but I want to ask you now. On page 15 of your brief is it coincidence or in error that the capital "S"s are dollar signs.

Mr. TURNBULL: No, it is by intent.

The CHAIRMAN: I think the question, with all respect, possibly is not under the section we are discussing and I would prefer to leave the question of cost and so forth until we get into that particular section, if possible, otherwise we are going to take a long time. Did you have a question, Dr. Rynard, on this section?

Mr. RYNARD: Mr. Chairman, I would like to ask Mr. Turnbull a couple of questions. For example, when you say that you are in favour of taking drugs out of doctor's offices, surely you have to qualify that statement because there are many, many towns in which doctors are practicing where there is no drug store.

Mr. TURNBULL: Most certainly.

Mr. RYNARD: Therefore, you would be taking a very essential service away from the people. I may have misunderstood you on that. I think this has to be taken into consideration, also, that doctors now have to list their prescriptions and keep their books the same as anyone else. The other thing I have been told is that it is not the clinics that are making the big cut-in, it is the cut-rate druggists themselves. This applies very aptly to the city of Toronto—the big city near me. I am told the druggists there have cut-rate stores where they operate with a minimum of expense either in upper storeys or in backs of buildings. I do not know if this is right, I want to be quite honest about this, but this is what I have been told by druggists themselves; and that when the prescription goes there, and it is often a firm name drug, at some time or other the druggist who is operating in that place will call up the doctor and say, "well, we could give this a little bit cheaper if we switched the name of this drug; we will give you the generic drug." Many of those drugs as you know have been imported. They would refill the prescription without the consent of the doctor if it had to be filled say three or four times; otherwise they would of course have to call the doctor and say, "we can fill this prescription much cheaper if you would allow us to use so and so." I would like your comment on this matter.

● (12:00 a.m.)

Mr. TURNBULL: First of all, I certainly agree with your comments on doctor's dispensing. I would not want it to be interpreted otherwise. Where there is no pharmacy in the area the patient is entitled to the assurance that he has at least basic service coming from the prescribing or diagnosing doctor. This would be best. We are concerned, however, that this be undertaken actually by the professional involved and not by non-professional personnel such as the physician's wife, receptionist, stenographer, bookkeeper or what have you. Certainly, we are pleased to see that the public of Canada now has the benefit of proper record keeping so the authorities concerned are fully aware of the whereabouts of these various dangers from potent medication.

So far as cut-rate pharmacies are concerned, that is what the name of the outside reads. I am not sure just how accurate the signs are but that is for others to determine. I would respectfully suggest that each individual knows the value of his own service and places a monetary fee on that. Certainly, we do not discourage the individual public from going to the pharmacist of his choice.

You made mention of certain prescription refilling activities and the activities of those who see fit to dispense the so-called generic preparations if the physician is prepared to agree that those preparations be dispensed. I have no comment on that. I believe, from the association's point of view, that where the physician does not designate by brand or by company name, then the pharmacist must use his knowledge and ability to ensure that the patient does receive the medication best suited to him. However, at the same time I would suggest that we have to find a way in Canada of assuring the pharmacist, every pharmacist, not just the so-called cut-rater that you made mention of, that a certain standard is in those preparations so he can make a suitable choice.

Returning for a moment to the backroom operator, we hope we are eliminating these. Possibly, you are referring to some of the so-called mail order people. I would respectfully suggest that I have evidence in my office which would indicate that one mail order individual, at least, is distributing his prescriptions not at the price which he advertises but at three times the price of

locally procured pharmaceutical services. Here again, I insist the patient should have the right of free choice of pharmacist.

Mr. RYNARD: Yes, Mr. Chairman, but I would like to say to Mr. Turnbull that there is a question of ethics in this. There is also a question of ethics where the druggist phones the doctor and suggests another drug.

Mr. TURNBULL: Well, of course, doctor, this would depend on his ability to supply at that particular moment the preparation which the doctor has written on the prescription. If the doctor has written for Brand "X" and Brand "X" happens to be out of stock at the moment, something must be done to ensure that the patient receives service. If, in the opinion of the pharmacist, he can offer the physician a comparable product to which the physician will agree and which the physician recognizes, then the pharmacist is acting in the best interest of the patient and of good medical practice. This is one of the areas of pharmaceutical service which goes beyond the tangible ingredients which happen to end up in a bottle.

Mr. RYNARD: I still question the ethics of this situation. If it was a matter of being out of the drug, then this is a different story but I am referring, as I said, to your mail order business.

Mr. TURNBULL: We do not favour the mail order operator, so we are on your side in that one.

Mr. BRAND: First of all, I do not know whether you should take the time to explain your statement that you thought it was terrible that the same person who signed the birth certificate, gave the care and prescriptions, and then signed the death certificate. Could you tell me what you based that on. I am just curious.

Mr. TURNBULL: Well, let us just think about the statement for a moment. It might take too much of the Committee's time but is this not a principle that is not in keeping with what we truly believe in namely double checking in health services. The statement I made was that where we are faced with the situation of one individual being responsible only to himself for bringing a life into being and signing it out later it is a very dangerous principle, yes.

Mr. BRAND: It is not a principle; it is occurring all over Canada at the present time. If you go into a small community with one doctor, is this not what happens? Are you suggesting he is responsible only to himself?

Mr. TURNBULL: I think we are talking of the exception here and I am not suggesting that I am here to cast reflections on the medical profession, anything but. No one respects them more than I. However, this is a topic which has come up, particularly with reference—and this is brought up later in the brief—to where the physician is dispensing from his own inventory and the pharmacist in that community is still standing by to provide his patients with emergency service. Of course, this, as Mr. Orlikow mentioned earlier, is possibly going to influence the price at which the pharmacist must sell his services, but I do not know whether this other part of it comes into the cost and price of drugs or not.

Mr. BRAND: If I could ask another question, Mr. Chairman. Is it not true, as far as Saskatchewan is concerned, the province I represent, that though the doctor can own a drugstore, a druggist must own at least 51 per cent of the

stock within the store and that doctors are not allowed to prescribe and keep medications unless they are in an area where there is no druggist available. Is that correct?

Mr. TURNBULL: No; this is not quite accurate, sir. The pharmacy must be owned and controlled to the extent of 51 per cent except as it relates to co-operatives. A physician who sees fit to dispense or provide drugs to his own patients may do so under an exemption of the pharmacy act but where he becomes involved with drug services to other than his own patients he must be registered and licensed under the pharmaceutical legislation of the province and this pretty well applies across Canada, with exceptions.

Mr. BRAND: I certainly know in Saskatchewan it is not the practice for physicians, except in areas where there is no druggist.

Mr. TURNBULL: You are very intelligent in Saskatchewan.

Mr. BRAND: This problem does not occur. I do also know, this brings up another point which you brought up yourself, that if he decided to set up a drugstore in his office, say in the city of Saskatoon, which I represent, he would not be able to obtain supplies through the National Drugs which is the one monopolistic dispensing house for prescription drugs in Saskatchewan.

Mr. TURNBULL: That is a business principle which has nothing to do with the pharmacy legislation in the province and National Drugs Limited as set up in—perhaps we are devoting too much time here, too, but I happen to know the area—Saskatchewan is a subsidiary of National Drug and Chemical Co., and it is partly owned by the pharmacists of Manitoba and Saskatchewan. They have set the policy of with whom they will do business. I used to be associated with National Drugs and we had physician accounts but these were physician accounts which were licensed under the pharmacy act and were, indeed, operating what you may call a drugstore, for example, in Meadow Lake.

Mr. BRAND: Where there was no other drugstore.

Mr. TURNBULL: There are, I believe, five physicians licensed under the pharmacy legislation of Saskatchewan.

Mr. BRAND: Since you opened up the subject, is it not also true then that if you open a drugstore you must obtain shares in National Drug?

Mr. TURNBULL: I believe to buy from National Drug you must be a shareholder of National Drug.

Mr. BRAND: This gives the pharmacist an additional source of income.

Mr. TURNBULL: Only as it relates to his purchases from National Drug; those purchases which happen to be in certain categories.

Mr. BRAND: In other words, the figures you give for percentage profit later on in the brief do not take into account the percentage profit they may obtain through their dealings with National Drug.

Mr. TURNBULL: Oh, yes, certainly they do. That is part and parcel of their purchase cost. If at the end of the year National Drug's books, and there are other co-operative wholesalers in Canada, indicate that a surplus can be distributed to the buying members of the organization, then this is distributed

and it automatically comes off the cost of the ingredients. Actually, it is not distributed by cheque; it is distributed by taking it off future invoices.

Mr. BRAND: This is reflected in the figures you present?

Mr. TURNBULL: Yes.

Mr. MACKASEY: Mr. Chairman, I find it very difficult to stick to a particular page and if I am out of order you can let me know. There was some mention before of the gross profit of 34.2 per cent—

The CHAIRMAN: Yes, I would like to leave that until later. I should say we are proceeding very slowly and this is the only appearance of this group before us. Unless we move more quickly we are going to have sit this afternoon.

Mr. HOWE (*Hamilton South*): Mr. Chairman I have just one brief question in view of what Dr. Rynard said about an individual doctor or clinic in a town providing a service because there is no drug store. It is not often so that individual doctors and clinics in such a town act as a deterrent to a man opening a drug store in that town.

Mr. TURNBULL: Oh, well, yes: but on the other hand, we have found many instances where a pharmacist has gone into a town where there might be a couple of dispensing physicians and has convinced them that he can better serve them through a comprehensive inventory, and the arrangement has been most satisfactory. The physicians have been able to go fishing and so has the pharmacist.

Mr. MACKASEY: Mr. Chairman, it takes less than half an hour to determine there are some dishonest doctors and some honest doctors. I think the same thing is true of the druggist. I do think if we stopped worrying about that we might get a little further on in the brief.

Mr. HOWE (*Hamilton South*): I agree, let us press on.

The CHAIRMAN: Are there any other questions on section 4? Section 5? On statistics I do not think—

Mr. MACKASEY: Well, going back to section 5.3, I am interested in this proposal that there could be a specially oriented low-cost prescription service made available by the pharmacists to those persons who have excessively high medication costs. I wonder what Mr. Turnbull would say in explanation of that.

Mr. TURNBULL: My reference here, sir, is to a program, one of which exists in Canada, in the Windsor area, of prepaid prescriptions and another which has been worked on for some time by the association toward coming up with a highly co-ordinated Canada-wire prescription service insurance program if you will, which is specifically written to provide a means by which welfare groups and the medical indigents as well as the general public can get together in a program to share, through the insurance principle, the cost of pharmaceutical services. We have seen fit to incorporate a company under the name of Pharmacare Limited to encourage these plans to be brought into existence in the various provinces of Canada.

Mr. ENNS: Does the pharmacist get the full normal price for the drug under that kind of plan or does he have to accept a reduced price?

Mr. TURNBULL: Under the Windsor program which has been in existence for some eight years the pharmacist, I believe, is getting something less than

100 cents on the dollar. The pharmacist, in other words, is subsidizing it. Under the program outlined by Pharmacare—it is still in the planning stage; it is not in existence in any province as yet—naturally all calculations are based on providing the pharmacist with 100 cents on the dollar under existing situations. He at the same time enters into a contract to guarantee the service regardless of the ability of the client to pay him 100 cents in any particular period. In this regard we have been working with the pharmaceutical industry to see if there is not some way in which they will share this financial guarantee. We believe it a quite proper thing.

The CHAIRMAN: Mr. Mackasey?

Mr. MACKASEY: No, I am still ahead of myself, Mr. Chairman. What section are you on?

The CHAIRMAN: No. 5.

Mr. W. J. BLAKELY (*Accountant*): Mr. Chairman, in connection with the last part concerning the professionally oriented low-cost prescription services, surely this is not reducing the cost of drugs. It simply results in an amortization of a spreading of the same cost over a broader base.

Mr. TURNBULL: This is correct. It is based on the average experience of the average individual in Canada; to provide a means by which he can insure himself against the above average or the catastrophic situation. It is a sharing; it is not a reduction, as you might wish to term it, of drug prices.

The CHAIRMAN: Are there any other questions on this section?

Mr. BRAND: Are you aware of the drug cost plan in Saskatchewan under Medical Services Incorporated?

Mr. TURNBULL: Very much aware.

Mr. BRAND: I know you mentioned there was one in Windsor and I just wanted to mention this one.

Mr. TURNBULL: Well, there are other programs. I am very much aware of it and I had a half day in Saskatoon last Monday discussing just that plan.

The CHAIRMAN: Section 6, retailing and drug prices.

Mr. ORLIKOW: Mr. Chairman, I am one of those who do not believe the vast majority of druggists are getting rich, so I would agree with the first sentence of 6.1. At the same time, Mr. Chairman, I wonder how much information the Canadian Pharmaceutical Association has on which it bases the second sentence of 6.1: They say, "Drug costs to the vast majority of Canadians are neither high nor exorbitant". I say that, Mr. Chairman, because there have been a large number of studies done by the Restrictive Trade Practices Commission, by the Hall Commission, by the Kefauver Committee in the United States, and all of them indicate that the cost of prescription drugs to the consumer, in Canada and in the United States, is much higher than in other countries. I am not blaming your organization for that, but I just wonder on what you base this statement. We have lots of information, some from the reports I have mentioned, some has been collected privately, that some of the largest companies, I will just mention a few of them, Lilly, Parke Davis, and so on, charge anywhere from 200 to 500 per cent more in Canada for a particular prescription drug than

they do for the same product in Great Britain or in France. This is true even when the actual research was done in those countries. I can give you a very personal illustration. My wife some ten years ago, had to take largactil which was one of the first of the tranquilizers. Largactil was developed completely in Switzerland and France. When my wife started to take it it was retailing for three cents a tablet in France. It had been developed in France. It was selling in Canada at the retail rate of that time, somewhere between 17 and 20 cents a tablet. This is an actual case and I am wondering on what your organization bases this statement that the price of pharmaceuticals is neither high nor exorbitant.

Mr. TURNBULL: I will try to be brief. The statement here, of course, makes direct reference to the survey which is attached as an appendix. It shows that something under 85 per cent of all prescriptions dispensed in Canda were dispensed at $5 or less which certainly cannot be considered high or exorbitant in the Canadian economy; and that something like 1½ per cent were over the $10 figure, contrary to our own particular feelings when we have to dig into our pockets for an unexpected expense.

Now, in relation to your other comments about 200 and 500 per cent higher costs, I regret that my office has not experienced any figures along this line; indeed, they have been to the contrary. We have noted that in some cases, one of the companies you mentioned, is actually selling its drugs at a lower price in Canada than it is across the line in the United States. I think, also, that this is a question more suitably directed to the pharmaceutical manufacturers who undoubtedly will have figures related to the comparative economies of these various countries rather than just a straight dollar and cents comparison in relation to the value of the inflated dollar as we know it in Canada. But, my statement, of course, makes direct reference to community service in pharmacy.

Mr. ORLIKOW: Of course the proper place to go for the information is to the pharmaceutical manufacturers but I raised the question now because it seemed to me that the Canadian Pharmaceutical Association really can give evidence only as it relates to the operations of their own members. I do not expect an answer but for example, there is ample evidence that the price of very important prescription drugs to government institutions and to hospitals is a fraction of the price charged to the pharmacist.

Mr. TURNBULL: Most definitely. We bring this out in this brief, that the retail prescription is subsidizing every purchase by every hospital and government agency in Canada.

Mr. ORLIKOW: Yes, but Mr. Chairman, I would like to know from Mr. Turnbull, what is the evidence that your organization has that the pharmaceutical manufacturers are selling to government agencies or to hospitals at a loss because when you say that you are subsidizing you are saying in effect that they are selling at a loss. The Kefauver investigations indicated very clearly that they were not selling at a loss.

Mr. TURNBULL: I think this should be clear, Mr. Chairman. We do not believe the manufacturer is selling to these other sources at a loss. There was a time when these prices were an advertising and or promotion expense. This does not apply any longer. This is 38 to 40 per cent of the total dollar volume of

drugs sold by industry in Canada. But if this dollar volume happens to represent 25 per cent of the price at which retail pharmacy buys its products, the quantity volume or the dosage is much higher in proportion than that 38 or 40 per cent. We do not believe they sell at a loss. They are selling very close to the margin and possibly on a margin which would not enable them to stay in business if governments and hospitals were their only customers.

Mr. ORLIKOW: It also may mean that they are charging the retail pharmacist an exorbitant price and making an exorbitant profit, you do not know.

Mr. TURNBULL: We have not stated that, no. We have merely stated that the pharmacist pays top dollar for his drug supply.

Mr. ORLIKOW: I do not question that, Mr. Chairman, but I do not think the Canadian Pharmaceutical Association has any right to say that they are subsidizing other sales. I think that is a matter of statistics which should be discussed with the people who make these decisions who are the Canadian pharmaceutical manufacturers.

Mr. MACKASEY: Mr. Chairman, I have a question on section 11 now. Are we finished with all the others?

The CHAIRMAN: We were accepting it as a basis for the question on section 6.1. We are still on six.

Mr. MACKASEY: Mr. Orlikow a few minutes ago made a statement concerning certain firms, Lilly, a few others, and the mark-up on drugs of 200, 300 or 500 per cent. He made this as a matter of statement. Is this to be the procedure, because the people involved are not here to refute that statement? It is very unfair to Mr. Turnbull to ask him to comment on something which has nothing to do with him, and Mr. Orlikow, after making the statement, then points out that it perhaps would have been best addressed tomorrow or later on to the Canadian Pharmaceutical Manufacturers' Association. But the significant thing is that it has now been said and headlines tomorrow across Canada could very well say that the drug companies take 500 or 1,000 per cent mark-up on a drug, and, nobody here today is in a position to refute a statement which may or may not be true.

Mr. ORLIKOW: Mr. Chairman, I do not want to interrupt Mr. MacKasey, but on a question of privilege, I did not say that the manufacturers are making the 500 per cent. He made this as a matter of statement. Is this to be the procedure, pharmaceutical manufacturers are here, that the prices they charge in Canada are anywhere from 200 to 500 per cent more than they charge for the same product in countries like Britain and France. I did not say anything about their mark-up nor, Mr. Chairman, did I ask Mr. Turnbull to make any comment about the manufacturers. Instead, I tried to find out from Mr. Turnbull how much information his organization had to back up that one sentence on page 6 in which his organization says that drug costs to the vast majority of Canadian Citizens are neither high nor exorbitant. I will fulfil my obligation to question pharmaceutical manufacturers when they are here. It is not only my duty; it will be a great pleasure.

• (12:30 p.m.)

Mr. TURNBULL: I must point out, Mr. Chairman, that we do have in our private files in our office, a considerable amount of documented information that

would be in line with the references Mr. Orlikow has made, with respect to prices, not only here in Canada but in many countries and this is why I mentioned the fact that we have no evidence of any 200 or 500 per cent increase of prices in relation to the Canadian economy and the inflated dollar in Canada.

Mr. MACKASEY: Mr. Turnbull, in paragraph 6.4 you talk about the gross margin for the over-all drug store operation of 34.2 per cent. Does this include the areas of the store which are not considered pharmaceutical.

Mr. TURNBULL: This is the total drug store, sir.

Mr. MACKASEY: Mr. Chairman, with your permission, because I think the brief would have been even more effective if page 9 was considered right after 6.4, because there you do have a more direct breakdown of the pharmaceutical dollar, if I may use that expression. Am I right, Mr. Turnbull?

Mr. TURNBULL: That is correct, yes, the consumer's pharmaceutical dollar.

Mr. MACKASEY: The point I am trying to make, Mr. Chairman, is that I take execption to the remarks or rather the conclusions of the Minister of Revenue the other day at which time he said the sales tax effect was 2 to 3 per cent on the consumer dollar. I was not here and I am only going by hearsay. I worked it out from Mr. Turnbull's statistics on page 9—I have not had a chance to get any further into the brief—as a minimum effect of at least 9 per cent. I do not know what your opinion is, Mr. Turnbull.

Mr. TURNBULL: Most definitely; this is the figure—some 9 per cent—that we calculate the minimum effect of the federal 11 per cent tax to be in relation to pharmaceutical services.

Mr. MACKASEY: May I ask a series of direct questions for information, Mr. Chairman, so that I can understand this brief a little better. Mr. Turnbull, from whom does the average druggist procure his drugs?

Mr. TURNBULL: Direct from the manufacturer and from the service wholesale nearest to him.

Mr. MACKASEY: And or both, but normally? Is it from a wholesaler, a distributor?

Mr. TURNBULL: I would suggest the majority from the wholesaler.

Mr. MACKASEY: In other words, he does not vary from most businesses which do buy from wholesalers; some because of volume buy directly from manufacturers?

Mr. TURNBULL: Right.

Mr. MACKASEY: You mentioned 34 per cent. I read in one of your tables that your average gross profit median is around 33 per cent, in some cases 34 per cent?

Mr. TURNBULL: Yes.

Mr. MACKASEY: I have been in manufacturing business and I know sales tax. This suggests that the mark-up practice of the druggist is to take the cost of the invoice plus 50 per cent?

Mr. TURNBULL: Are you relating this to prescription?

Mr. MACKASEY: Well, yes, because this is the area where you show a gross profit of 33 per cent.

Mr. TURNBULL: No; this is not quite correct. Those who are basing their prescription pricing on a mark-up principle are taking the normal merchandising mark-up of some 33⅓ to 35 or 40 per cent, depending on its reference to sharing and adding a small fee which might be 75 cents.

Mr. MACKASEY: Let us forget the fee.

Mr. TURNBULL: The fee is necessary.

Mr. MACKASEY: I am trying to get to the sales tax; I will talk about the fee later. If you buy a product from a wholesaler at a dollar, what would you normally expect to charge the consumer?

Mr. TURNBULL: My calculations are not too good, but depending on the nature of the drug and the record requirements, and what not, it would probably come out at around $2.

Mr. MACKASEY: Yes, well, now forget that; it includes the professional fees which is logical—

Mr. TURNBULL: Yes.

Mr. MACKASEY: But apart from the professional fees.

Mr. TURNBULL: The normal mark-up would come to $1.60, would it not?

Mr. MACKASEY: Yes, 60 per cent. In other words 20 per cent off.

Mr. TURNBULL: Would make it $1.80.

Mr. MACKASEY: The point I am getting at, Mr. Chairman, is that in that dollar is included 11 per cent sales tax. The 11 per cent sales tax of that dollar becomes pyramided by the 60 per cent mark-up.

Mr. TURNBULL: Correct.

Mr. MACKASEY: So the 11 per cent is affected by the 60 per cent mark-up. In effect, the 11 cents which is passed on from the manufacturer, through devious steps, to the consumer is no longer 11 per cent but is now 17.6 per cent which is a far cry from the information we received last week. I would suggest, Mr. Chairman, that since we have hired an accountant we put the problem to the accountant. In other words, put him to work between now and the next meeting and find out whether the Minister is right with his 4 per cent or whether Mr. Turnbull is right with his 9 per cent or whether I am right with what I think is much closer to 17 per cent.

Mr. TURNBULL: Your 17 cents is on $1.80, is it not sir?

Mr. MACKASEY: My 17 cents, Mr. Turnbull, comes in the over-all picture from the manufacturer to the consumer, not necessarily through your intermediate step that you suggested involved 9 per cent. I suggested the other 8 per cent comes in at the pricing of the wholesaler.

Now, one last point: the Canadian Manufacturers Pharmaceutical Association say that 37 cents of the consumer's dollar—

The CHAIRMAN: You are making reference to a brief which has not been presented to the committee.

Mr. MACKASEY: No, this was last year on safety. I have not seen this year's brief. Mr. Chairman, 37 cents is supposed to be the cost of the consumer dollar as far as manufacturing is concerned; Mr. Turnbull's is 50 cents on the dollar, or rather 33 cents; that is why we need the blackboard. I think the wholesaler, Mr. Turnbull, is getting an abnormal mark-up, almost 30 per cent.

Mr. TURNBULL: No, as I indicate in this brief—these figures were taken from D.B.S. figures—the wholesaler on the average is working on a gross of about 12 per cent. This is his complete field. He is working on about 16⅔ with regard to pharmaceuticals. The Dominion Bureau of Statistics is our best source of information although I will not comment on their particular value or otherwise; but they show the wholesaler is riding at about 2.1 per cent.

Mr. MACKASEY: Mark-up?

Mr. TURNBULL: Net.

Mr. MACKASEY: But I am not interested in that.

Mr. TURNBULL: But this is why the mark-up is indicated as 12 per cent. It is taken from D.B.S.

Mr. MACKASEY: I think, Mr. Chairman, I will bring a table of what I am trying to discuss.

The CHAIRMAN: I think the best thing to do would be to have the distributors and wholesalers before us and ask them the particular question.

Mr. MACKASEY: Mr. Chairman, do I need to put it in the form of a motion, that the accountant be instructed to verify the actual effect of the sales tax?

The CHAIRMAN: I am sure the accountant has listened to what you said and will be quite willing to discuss the sales tax with the Committee.

Mr. ORLIKOW: I would just like to say, Mr. Chairman, that I agree with Mr. Mackasey, probably for the first time since these hearings were set up.

Mr. MACKASEY: Even the most dense brain can be penetrated.

Mr. ORLIKOW: Possibly.

Mrs. RIDEOUT: Whose brain are you referring to?

The CHAIRMAN: Are there any other questions?

Mr. BLAKELY: Mr. Chairman, I am a little confused because I am not quite sure which section we are dealing with.

The CHAIRMAN: We are really on 6.2 but we have spread into 7.1 because the two are related to one another.

Mr. BLAKELY: Well, I have a question which relates to 6.5 but before I get into it, with reference to the previous speaker, I think there was a time limit put on his request which was between now and the next meeting which is Thursday.

Mr. MACKASEY: Well, I think that is a 15 minute exercise in elementary arithmetic. If you take 100 per cent and add 60 per cent to it you end up with 17. something. It has to be charged somewhere because it is in something and it has not got lost on the street anywhere. It may be buried in many steps from

the manufacturer to the consumer but in the final analysis it is there because it is charged at the source.

Mr. ORLIKOW: I do not think we should spend much time at it, neither do I not think we should insist that our accountant have the answer in two days. This is one of the few, if not the only specific question, we have been asked to consider, the effect of sales tax on the price to the consumer, and I think the accountant should do a first class job on that. If he cannot do it by Thursday, then he should do it later. Certainly, when the government asks us to look at a specific matter we should look at it and report on it before we finish.

The CHAIRMAN: I will discuss this with the accountant and we will come to a suitable agreement.

Mr. TURNBULL: We have calculated in here, as you know, that the delay in the abolition of the federal sales tax, has according to our calculations, cost the Canadian public over $14 million prescription dollars in 1964.

The CHAIRMAN: I think Mr. Benson used the figure $19 million for this year, but your figures are for 1964 are they not?

Mr. TURNBULL: Right.

The CHAIRMAN: Mr. Benson's were for 1965.

Mr. BLAKELY: Mr. Chairman, on item 6.5 at page 7, the comments I have to make here also apply to page 11, item 7.11. I think we could refer to paragraph 6.5. It is stated here:

> "Subsidization of prescription service by commercial transactions is well illustrated in the Survey".

I have to confess that this conclusion is not apparent to me from review of the information submitted to us, and particularly taking into account the statement upon which the conclusion appears to have been reached. Again, I quote :

"Within each sales category, total expenses grow with prescription volume". From the results of the 1964 survey which I believe would be Tables 21 to 26 in the green pages, I suggest a strong case can be made for this last statement, although if you look at it in depth you will also notice that there are sales categories where expenses remain relatively unchanged, even though there is a significant increase in volume of prescriptions. However, my point is that even accepting that total expenses do grow with prescription volume, I suggest, Mr. Chairman, it does not automatically follow that prescription services are subsidized by commercial transactions. You cannot look at the change in expenses without also looking at the change in the rate of gross margin. If you are to do this, in the tables I mentioned, you will find that within each sales category that while total expenses do grow with prescription volume, so does gross margin and at a higher rate.

Mr. TURNBULL: No, I am sorry, but the tables do not illustrate that. The tables, in many instances, are the reverse of that. However, even where the gross margin may increase, the expense part, the cost of providing the local service, the cost of renting from a local landlord and hiring a local individual to do this work, is much higher in relation to those that have a higher volume of prescription revenue, even though their gross may increase.

Mr. BLAKELY: Mr. Chairman, in support of the point I was making, I can illustrate this in every one of the categories, but just taking one, dealing with the same one you dealt with, Mr. Turnbull, in paragraph 6.5 which, incidentally, I think has an incorrect reference. The sales category of $125,000 to $150,000 comes from table 24 not table 23. The percentages you quote there, come from table 24 and the sales category you indicate comes from table 23. If you refer to table 24, you will find that in the lowest category, that is, the lowest volume, where prescriptions are 12.9 per cent of total volume expenses are 27.2 of total sales. If we go over to the highest, where the prescription volume is 42.9 per cent of total, we will find that there, Mr. Turnbull, the expenses are now 33.6 per cent of sales.

Mr. TURNBULL: Correct.

Mr. BLAKELY: First of all, that is a difference of 6.4 per cent, as you stated. However, if you go to the gross margin, for the same two groups of figures you find that the change is from 30.8 to 38.2 which is 7.4. It is at a higher rate, sir.

Mr. TURNBULL: Correct.

Mr. BLAKELY: So it does not—

Mr. TURNBULL: Here we have a situation, of course, where the first category to which you referred is writing 10 to 20 prescriptions a day; in other words, probably an individual operator in a fairly small community with a wholesaler doing the majority of his warehousing for him. As a consequence he is paying slightly more for that particular service. In the other category, there are over 40 prescriptions a day, I would suggest well over 40, where he is buying direct and getting a better gross mark-up, doing his own warehousing and paying for it. He has had to hire professional staff over and above his own capabilities to maintain the legislative requirements pertaining to pharmacy practice. You will notice that the greatest difference is in the 8.6 and 15.0 as opposed to 6.6 and 11.63 in the salary categories; in other words, the salaries required by professionally trained individuals.

Mr. BLAKELY: I do not agree with the conclusion, Mr. Chairman.

Mr. TURNBULL: In your study, sir, I would direct your attention to the more elaborate discussion of this as we presented it in our brief to the Hall Commission. We indicated the position of the individual who might have to get along in a small community on prescription revenue only, and 27 per cent of $130,000 is around a $34,000 to $35,000 gross. I do not think he would live too long as he would not eat too well.

Mr. ISABELLE: Just one question, Mr. Chairman: it is too bad Mr. Orlikow has left but Mr. Clancy is here. The drugstore business is regressing in the west, maybe you should move east. I have a question here. Maybe you can comment on this. How is it that in the Ottawa area, if you give a prescription of 50, for Librium, 10 milligrams, if you go to a normal pharmacy the price will range from $6 to $7.85, and if you go to a shopping centre where they employ a pharmacist the Librium, 10 milligrams by the 100 will cost $7? You could go this afternoon and see the prices.

Mr. TURNBULL: I have no comment on this, other than what I said earlier. Each individual, be it you or I, knows the value of their own particular services

and the monetary value they wish to place on their services. I do not know how the shopping centres operate. I do not know whether they provide a standby emergency service on a 24 hour basis. I do not know how these other people might price. As a matter of fact, looking at that price—maybe I should not say this—I would seriously question that you are getting Librium at $7 a hundred. and I said Librium.

Mr. ISABELLE: When you are talking about services from a drugstore are you including professional fees and things like that?

Mr. TURNBULL: Most certainly. The individual pharmacist has a tremendous obligation to his community. I would suggest with respect that some of the larger installations, many of which do not have a telephone, do not provide a prescription copy, do not provide any emergency care service hours. The pharmacist is acting as a technician and a technician only for the purpose of counting out tablets or pouring out a liquid. There is no pharmaceutical service, as we deem it necessary, in these particular shops. The laws of our land say they shall stay in business and it is probably a good thing; competition is a good thing.

Mr. ISABELLE: Mr. Chairman, may I point out that if we discuss the price of drugs here we are wasting our time. I think the problem which is more important than the price itself is the whole organization of the pharmaceutical industry which should be looked into. The Hilliard Report which was tabled in the House of Commons on May 12 is one of the best reports that has ever been presented. If the Food and Drug Directorate does not have the power to implement the recommendations of the Hilliard Report, then we are working for nothing here. This Committee will go nowhere because these recommendations are the only ones which will bring about, in the long run, the lowering of the cost of drugs. This is my feeling.

The CHAIRMAN: This Committee will be going into all aspects of this. Our list of witnesses is very extensive and we hope we cover every aspect of this field.

Mr. BLAKELY: Mr. Chairman, I have a few questions. I do not think they will take very long as they are really for clarification.

Mr. Turnbull, the statistics you have on item 7.5 at page 9 to which reference was made earlier, appear to have come also from table 24, is that correct?

Mr. TURNBULL: Correct.

Mr. BLAKELY: These statistics represent something like 42 pharmacies. I am not quite clear as to the reason these figures were chosen. Is it because you feel this is more typical of the industry?

Mr. TURNBULL: No. As I stated, it can be realistically assumed that a pharmacy having 43 per cent prescription volume probably gained a substantial portion of the balance of its $129,500 gross revenue from items which by their nature are necessarily and/or legislatively restricted to pharmacy only distribution such as prescription accessories and related items. These constitute a comprehensive total community pharmacy service and hence the breakdown of the consumer's dollar for services and goods. Here we are talking of the

pharmaceutical dollar. We do not believe that statistics exist at any level related specifically to the prescription dollar and its breakdown. We agree that a fifty-fifty apportionment occurred at the retail community level. Fifty per cent represents ingredient costs, and in that ingredient cost are many factors such as this $14 million federal sales tax. Fifty per cent represents the cost of providing a local service. We cannot break down that 50 per cent in relation to this 38 per cent, because there are so many items, such as the pharmacist's direct expenses related to a prescription; the salaries; the spoilage; the delivery cost; depreciation and interest and the indirect expense such as rent, power and telephone.

The place needs a telephone if it is a drugstore per se or if it is just a pharmacy. So how much do you apportion to them. This is why we say there are no existing statistics at any level of distribution which can be directly related to the prescription dollar.

Mr. MACKASEY: Mr. Chairman, surely this problem is no different from any other store that has departments; for instance, Simpsons, Morgans, they have a way of knowing the value per foot of floor space, everything is costed this way. Every department has a different mark-up. How many outlets are there in Canada which are devoted purely to the dispensing of drugs?

Mr. TURNBULL: How many devoted purely to the rendering of pharmaceutical service? There are some 5,000 retail pharmacies in Canada, and I would suggest there are no more than 12 to 15 pharmacies in Canada devoted exclusively to dispensing.

Mr. MACKASEY: Have you the statistics pertaining to these 12 or 15?

Mr. TURNBULL: No; we have them from two but we do not believe that two are sufficient.

Mr. MACKASEY: Well, why have you not got them from 15? Is it voluntary—

Mr. TURNBULL: Oh, yes. We do not have an arm on these people—

Mr. MACKASEY: You say there are 5,000 and you are asking us to presume that a very small sampling is indicative, or descriptive of the 5,000 outlets?

Mr. TURNBULL: Yes, because this is information that we have been gathering now for some 24 consecutive years. It is not something we went out last month and picked up. All the surveys have shown the gradual progression in each of these tables. None of this has just suddenly happened. We have got this information over a period of years.

Mr. MACKASEY: What Mr. Turnbull is saying is that the drugstore, because it is selling drugs in one corner and silk stockings in the other, has no particular way of knowing precisely the income from each section. This is hardly believable.

Mr. TURNBULL: No, I am not saying that Mr. Mackasey. I am saying that the available statistics we have here, and which are published, are possibly the most accurate that can be obtained in relation to the rendering of a pharmaceutical service with a minimum of these other activities.

Mr. MACKASEY: You say they are the most accurate available. What you are really saying is they are the only ones available? The thing is you cannot vouch for their accuracy because you have nothing to compare them with?

Mr. TURNBULL: Oh, I do not know. There is a group called the American College of Apothecaries which is composed basically of pharmacies throughout the states, shall we call them professional pharmacies, with a very small amount of the other activity going on. Our statistics presented here compare very favourably with their statistics. As a matter of fact we have, if anything, erred on the professional side, as opposed to this information.

Mr. MACKASEY: Has any effort been made here to break down the proportion of fixed cost, fixed overhead, indirect cost, direct overhead to volume coming out of one department as opposed to another?

Mr. TURNBULL: Yes; although they are not used in this brief because they are not a published statistic and at the moment they are still confidential. However, a very extensive study was done in one of the provinces for some of its negotiations with a provincial government. We made reference to that in our study which led up to the use of these figures. When that study is published I think you will find these figures do pertain and that study does go into depth on these direct and indirect expenses and apportions them. For example, it shows that the Canada pension plan is going to influence the prescription dollar by one-fifth of a cent.

Mr. MACKASEY: Mr. Turnbull, you mentioned the median gross sales, as opposed to the average gross sales, as being $112,000. What percentage of that $112,000, what volume of that $112,000, could be directly attributed to the sale within the drug store of products other than what are considered pharmaceuticals?

Mr. TURNBULL: I believe, without digging it out, 24.6 per cent was due to prescription receipts. I would have to search through this to come up with that figure.

Mr. MACKASEY: Well, about 75 per cent of the drugstores' business today is directed to other than the filling of prescriptions.

Mr. TURNBULL: But not to other than the items which come within this field of pharmaceutical services. The items, which by their very nature, must be sold only in a pharmacy. Here let us refer to your codeine preparations and certain of the cough preparations and so on. These not only have to be sold in a pharmacy but an individual would be very foolish to pull these off the supermarket shelves.

• (1:00 p.m.)

The CHAIRMAN: Gentlemen, it is now after one o'clock and it is obvious that we are not going to get through this brief at this sitting. However, the Committee does have authority to sit while the House is sitting but I understand that the business of the House this afternoon is a topic which will engage many of the people here. It just is not the same problem.

Mr. MACKASEY: What is the business?

The CHAIRMAN: I understand the House will be debating today the health resources fund, and there are many people in the room who have already told me they would be unable to attend this afternoon because they want to take part in the debate in the House of Commons. Therefore, I take it that if it is agreeable to the Committee and to Mr. Turnbull, we will arrange another

sitting at a later date in order to finish the brief. A sitting this evening would be unreasonable for the same reason it is unreasonable this afternoon.

Mr. MACKASEY: Mr. Chairman the best part of the brief is still to come; there is reference here to generic and to hospital—

The CHAIRMAN: As I pointed out, unless we are prepared to cover these briefs with a great deal more speed than we have to date we are not going to make very much progress.

Mr. MACDONALD (*Prince*): Mr. Chairman, I think in view of the fact the Chair should, perhaps, be a little more ruthless in keeping us to the areas being discussed in order that we do get through this in good time.

The CHAIRMAN: When the problems are related in one way or another it is difficult to pin down the questions.

Mr. MACKASEY: Such an elaborate brief deserves more than two hours of our time, Mr. Chairman.

The CHAIRMAN: I would suggest that Mr. Turnbull and I make suitable arrangements and that we call the meeting again at a later date. On Thursday, at 3.30 in the afternoon we will meet to hear the beginning of the presentation from the Pharmaceutical Manufacturers Association of Canada. I hope by then everybody will have read the brief.

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 4

THURSDAY, JUNE 16, 1966

WITNESSES:

From The Pharmaceutical Manufacturers Association of Canada: Dr. Wm. W. Wigle, M.D., of Ottawa, President; Mr. Robert F. Daily, Chairman of the Board of Directors and Vice-President and General Manager, Smith Kline & French Inter-American Corporation; Mr. E. Glyde Gregory, Vice-Chairman of the Board and President, Ayerst Laboratories; Mr. Harry D. Cook, Immediate past Chairman of the Board and President, Abbott Laboratories Ltd.; Dr. Peter C. Briant, Vice Dean and Director, School of Commerce, McGill University; Dr. Arthur Grieve, Director of Quality Control, Ayerst Laboratories, all of Montreal; Mr. Gregory J. Gorman, Barrister; Mr. Gordon F. Henderson, Q.C., Patent Attorney, both of Ottawa; Mr. Peter Howsam, Vice-President and Gen. Mgr., Warner-Chilcott Laboratories; Mr. Fred R. Hume, Q.C., Barrister, both of Toronto; Mr. Roger Larose, Vice-President, CIBA Company Limited, Dorval, Quebec; Dr. Brian Stewart, Director, Pharma-Research Canada Limited, Pointe-Claire, Quebec, and Mr. Guy Beauchemin, of Ottawa, Executive Secretary.

ROGER DUHAMEL, F.R.S.C.
QUEEN'S PRINTER AND CONTROLLER OF STATIONERY
OTTAWA, 1966

24628—1

DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

Vice-Chairman: Mr. Patrick T. Asselin (*Richmond-Wolfe*)

and

Mr. Brand,
Mr. Chatterton,
Mr. Clancy,
Mr. Côté (*Dorchester*),
Mr. Enns,
Mr. Haidasz,
Mr. Howe (*Hamilton South*),
Mr. Howe (*Wellington-Huron*),
Mr. Hymmen,
Mr. Isabelle,
Mr. MacDonald (*Prince*),
Mr. Mackasey,
Mr. O'Keefe,
Mr. Orlikow,
Mr. Pascoe,
Mr. Patterson,
Mr. Prud'homme,
Mrs. Rideout,
Mr. Rynard,
Mr. Tardif,
Mr. Whelan,
Mr. Yanakis—24.

(Quorum 13)

Gabrielle Savard,
Clerk of the Committee.

MINUTES OF PROCEEDINGS

THURSDAY, June 16, 1966.
(6)

The Special Committee on Drug Costs and Prices met this day at 3.45 p.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout and Messrs. Asselin (Richmond-Wolfe), Brand, Chatterton, Enns, Harley, Howe (Hamilton South), Howe (Wellington-Huron), Hymmen, Isabelle, MacDonald (Prince), Mackasey, O'Keefe, Orlikow, Patterson, Prud'homme, Rynard, Tardif, Yanakis (19).

Also present: Mr. Matte, M.P.

In attendance: *From The Pharmaceutical Manufacturers Association of Canada*: Dr. Wm. W. Wigle, M.D. of Ottawa, President; Mr. Robert F. Daily, Chairman of the Board of Directors and Vice President and General Manager, Smith Kline and French Inter-American Corporation; Mr. E. Glyde Gregory, Vice-Chairman of the Board and President, Ayerst Laboratories; Mr. Harry D. Cook, Immediate past Chairman of the Board and President, Abbott Laboratories Ltd.; Dr. Peter C. Briant, Vice Dean and Director, School of Commerce, McGill University; Dr. Arthur Grieve, Director of Quality Control, Ayerst Laboratories, all of Montreal; Mr. Gregory J. Gorman, Barrister; Mr. Gordon F. Henderson, Q.C., Patent Attorney, both of Ottawa; Mr. Peter Howsam, Vice-President and Gen. Mgr., Warner-Chilcott Laboratories; Mr. Fred R. Hume, Q.C., Barrister, both of Toronto; Mr. Roger Larose, Vice-President, CIBA Company Limited, Dorval, Quebec; Dr. Brian Stewart, Director, Pharma-Research Canada Limited, Pointe Claire, Quebec, and Mr. Guy Beauchemin, of Ottawa, Executive Secretary.

Also in attendance: Mr. W. J. Blakely of Kingston, Accountant for the Committee; and Mr. A. M. Laidlaw, of Ottawa, Legal Counsel for the Committee.

The Chairman introduced Dr. Wigle who, in turn, introduced the members of the delegation.

Dr. Wigle read a prefatory statement, a summary of the brief, and the recommendations of the Association relating to the cost of drugs.

On motion of Mr. Enns, seconded by Mr. Asselin (Richmond-Wolfe),

Agreed,—That an abstract of the submission prepared by PMAC be printed as part of today's proceedings and that Appendix K to the submission be printed as an appendix to the proceedings. (*See Appendix "A"*).

On motion of Mr. MacDonald (Prince), seconded by Mr. Isabelle,

Resolved (unanimously),—That the Committee seek permission to reduce its quorum from 13 to 10 members.

24628—1½

Agreed that each member be limited to 10 minutes when questioning a witness.

Dr. Wigle was examined on different sections of the brief; Messrs. Hume, Larose, Briant and Beauchemin also supplied information.

At 5.45 p.m. the Committee adjourned to 11 a.m. Tuesday, June 21, to resume study of the submission of PMAC.

Gabrielle Savard,
Clerk of the Committee.

EVIDENCE

(Recorded by Electronic Apparatus)

THURSDAY, 16 June, 1966.

● (3.45 p.m.)

The CHAIRMAN: Gentlemen I think we could start our hearing this afternoon. There is no correspondence at the present time. I may interrupt the testimony later on to ask for a motion but at the moment we will listen to the brief presented by the Pharmaceutical Manufacturers Association of Canada. As most of you probably will remember, representatives of this association will be before the committee for the next three sittings of this committee, on Thursday afternoon at 3.30 and Tuesday morning at 11 a.m. They are rather unusual hours but this is the wish of the committee. I would therefore, introduce Dr. Wigle, the President of the Pharmaceutical Manufacturers Association. There are certain portions of the brief that Dr. Wigle wishes to read. I think we might have questioning after each section of the brief; the portions to be read are actually a very small part of the brief. Then it is our hope in keeping with what we have done with other briefs that we will study them one section at a time.

Dr. WM. W. WIGLE (*President, Pharmaceutical Manufacturers Association of Canada*): Thank you very much, Mr. Chairman. It is my understanding that I have your permission to remain seated?

The CHAIRMAN: Most certainly. Of course, that goes for everyone in the room. This is completely informal.

Mr. WIGLE: First of all, Mr. Chairman and members of the committee, I would like to say this climaxes a couple of years of preparation and hard work in anticipation of presenting the story of the pharmaceutical manufacturers in Canada to your committee. Indeed, it is a pleasure and an honour for us to be here today.

Before I begin I would like to introduce the members of our delegation who are here to support me with special knowledge in those areas, which are very numerous, with which I am not familiar myself. I might quickly point them out, starting at the far end, Dr. Brian Stewart, who is in full time research; Mr. Harry Cook who is the president of Abbott Laboratories; Mr. Glyde Gregory of Ayerst Laboratories; Mr. Guy Beauchemin who is a pharmacist and executive secretary of our association; Dr. Arthur Grieve who is in quality control; Mr. Peter Howsam who is vice president and general manager of Warner-Chilcott; Professor Peter Briant from McGill University, our consultant economist; Mr. Gordon Henderson, patent consultant; Professor Larose of CIBA; Mr. Gregory Gorman our legal consultant and patent consultant also; Mr. Fred Hume, our official legal consultant, and the Chairman of our Board of Directors, Mr. Robert Daily of Smith Kline and French.

Mr. Chairman, with your permission I would hope that you might indulge us while I read the section of the brief which is marked as preamble and briefly run through the summary indicating the sections into which we have broken the brief, look at the introduction and then summarize our recommendations. Following that we would hope to be able to answer questions.

My colleagues and I in PMAC have addressed ourselves to the question of the present level of drug prices in this country. We gave long and careful consideration to the peculiarities of ethical drug manufacturing that make this industry unique of its kind. Our deliberations, on the evidence adduced in the main body of this brief and documented in the appendices, impelled us to the fundamental conclusion that the cost of drugs to Canadians is fair and reasonable. The plain fact is that if we consider the *real* cost of any product or service—the hours of labour necessary to earn the money for the purchase—we find that Canadians come off well in terms of the pharmaceuticals necessary to our national health and well being. A Canadian citizen is obliged to work fewer hours than the peoples of most other countries for the ethical drugs needed for the maintenance of his and his family's health.

Our recognition of this fact, however, has not deterred us from exploring every conceivable means of reducing the prices of pharmaceuticals to Canadians. As good corporate citizens, our member companies have expressed their willingness to work with responsible government authorities in seeking sensible means of lowering drug costs and prices to the people of Canada, along the lines suggested in the principles advanced by the Association and outlined in the body of this brief. And as sound business people, the chief executives of our member firms are well aware of the advantages that can accrue to any company able to pare its costs and its prices in a highly competitive industry. But there are stern realities that must be faced by any company doing business in Canada, as well as certain characteristics of drug manufacturing that must be carefully considered. I should like to review these briefly for the Committee.

First of all, the costs involved in the producing of pharmaceuticals tend to be higher than they ordinarily would be because of the need for building quality into the product through every stage in the manufacturing process. The reasons for this should be obvious. It is not simply a matter of building a better mousetrap; it is in fact a matter of safety. Within the past three decades the use of pharmaceuticals has loomed ever larger in the practice of medicine, and the drugs themselves have become more and more potent and complex. The high costs of quality control necessary to ensure the availability of drugs that are of the required safety, strength, and therapeutic effectiveness influence every facet of the manufacturing process. Because we are, after all, concerned with supplying the means to relieve human suffering and to treat and to cure those conditions that have plagued mankind over the centuries, we must continually pay a premium to make sure that our products perform these functions. Any company that cuts corners on the matter of quality control does so at its peril.

I am reminded at this point, Mr. Chairman, of an observation which we have not made in the brief, in my opinion, as often as we might; that our previous submission to this committee on safety, we believe, is fundamentally linked with this problem of costs because the two cannot be divorced.

Our distribution costs are far higher than we like them to be. This is, of course, partly owing to the geographic facts of Canadian life. High quality pharmaceuticals must be readily available to all physicians no matter where they may be practising in Canada, to all hospital dispensaries, and to the vast network of pharmacies that serve a great and thinly-populated country. The costs associated with controlling the distribution of fragile and, in many instances, perishable, pharmaceuticals are real enough for any manufacturer, but to those must be added the record-keeping costs of the increasing number of drugs that the physician now has at his disposal.

Our costs of marketing are high. This is a matter of concern to the members of our industry and to me personally. But this is one aspect of the industry's economics that is most difficult to control. Our member companies do not advertise to the general public; they inform the medical profession of the availability of new pharmaceuticals. And while introductory and reminder advertising in professional publications make up a sizeable item in the marketing budget of every drug manufacturing company, by far the heaviest marketing expense that must be borne is the cost associated with sending highly-trained professional representatives into the field to make our medical people aware of the existence of new drugs, of their indications and contra-indications, of their side effects and therapeutic potential. We would like to reduce these costs and we will propose a recommendation to this effect presently, among the other recommendations we are prepared to make to this Committee.

But the greatest concern, without question, is the matter of pharmaceutical research and the patent position of the pharmaceutical manufacturer in Canada. This is a research-based industry that spends internationally something in the order of half a billion dollars a year to provide us with the new life-saving drugs that have in the past two decades all but revolutionized the practice of medicine. Better than ninety per cent of the drugs prescribed today were unavailable twenty short years ago. And yet the irony is that some of the life-saving and curative pharmaceuticals that I have the privilege of prescribing today will never earn a dime for the companies that developed them. There are a couple of searching reasons for this state of affairs. In the first place, some of these discoveries have been products of other intensive research programs, results, as it were, of a total research activity. In this instance the man in the street gains because our companies give these drugs that cure rare diseases to our doctors and hospitals either at factory cost or free of charge. And again, the company that spent perhaps $5 million developing a new drug may not fully recover its investment if, after developing the new product and creating a Canadian market for it, an imitating company infringes its patents or secures a manufacturing licence for a token royalty. And this, it seems to me, is the nub of the problem that faces Canada at the present time. In recent years the Hall Commission and the Restrictive Trade Practices Commission have suggested that the abolition or sharp reduction of patent protection is a necessary move to reduce the cost of prescribed drugs. I can think of no more misguided step for the government of this country to take. Canada can not have a free ride. If we stand to one side and wait for the United States or Europe to develop new drugs with the notion that we will then import them, we may wind up paying

more than we should for questionable products and we will wait longer to receive them. We must pay our way. The cost of pharmaceutical research is a fact of twentieth century life.

We have, perhaps, devoted what might be considered a disproportionate amount of time to consideration of the patent position of this industry. In my judgment it is called for. Our patent laws should encourage swift and full disclosure of new pharmaceutical developments. And it should reward those companies or individuals that are willing to invest time and huge sums of money in Canada's medical future. At the present time one large international pharmaceutical company, Ayerst, McKenna and Harrison, under the name of Ayerst Laboratories, is doing all of its continental research in Montreal. Other companies, for example, Pharma-Research Canada Limited, Bristol Laboratories, Smith, Kline & French and Warner-Lambert have built new laboratories in Canada to continue this trend. Still others of our member companies have begun to expand their research facilities. But if this trend is to continue, we must foster the incentive that gave rise to it in the first place. Above all, we must not set up conditions that would destroy that incentive. The cost of drugs, whether we like it or not, is very closely linked to the maintenance of laboratories that will provide new drugs. If Canada is to do its share in helping to establish new beachheads in the eternal conquest of disease, it must foster the conditions that will enable the drug industry to grow and flourish in this country and throughout the world.

We have some recommendations to make. They are not startling, but they will, if adopted, reduce the cost of drugs to Canadians without damaging an essential industry. Our principal recommendations are these: abolition of the federal sales tax on prescription drugs; a wider availability of drug insurance to prevent catastrophic drug expenses during medical emergencies; and the establishment of an independent source that would provide doctors and pharmacists with accurate and up-to-date information about pharmaceutical products and their prices. And because of the vital importance of safety and reliability of the drugs Canadians receive, we make the further recommendation that a properly qualified tribunal be established to decide the merits of compulsory licence applications from would-be secondary manufacturers. If we are to reduce the cost of drugs, we must not do so at the expense of the very health of the industry itself or to the hazard of the consumer.

I should like to close my remarks with two thoughts that I believe are worthy of this Committee's consideration. The first is that during my years with the Ontario Medical Association and the Canadian Medical Association my greatest preoccupation was with the quality of the medical care being received by Canadians. I am more convinced than ever now of the vital link between high quality pharmaceuticals and effective medical care. And I wish that during those years I had been aware of the problems that beset this industry and the dangers that threaten therapeutic advances. Mr. Chairman, I, as a physician, feel that the one thing that has compelled me to work with the pharmaceutical industry and I must emphasize this, is not for its economic survival per se but because I am firmly convinced that therapeutic advance, the best chance of new cures for arterial sclerosis, cancer, multiple sclerosis and all those things with which people now suffer, is to have a continuing, productive, thriving phar-

maceutical industry. The fundamental products in the past 30 years have come from that industry, much more than I and many other physicians ever realized. I had no idea that 57 out of 66 of the most commonly prescribed drugs today came from the industry while I was practising and prescribing them.

And finally, my investigation of this industry has convinced me that the use of the products of responsible, research-oriented drug makers is a positive contribution to new cures, remedies, and disease prevention. In almost every study we look at in relation to the safety, effectiveness and purity of drugs, we reach the common conclusion that the greatest guarantee of quality rests in the integrity of the manufacturer.

With these thoughts, Mr. Chairman, our brief is respectfully submitted.

Now, as I had indicated I would like to run through the summary, the introduction and the recommendations, with your permission.

The CHAIRMAN: May I interrupt you for a very simple technical reason of which all the committee members are aware. First of all, the question of what portions of the brief should be reproduced in the printed evidence of this meeting was discussed at the last meeting. I would suggest we print an abstract of the submission of this association as part of today's proceedings.

It is much shorter than the brief itself, consisting of 37 printed pages.

Agreed.

The abstract is as follows:

INTRODUCTION

The Pharmaceutical Manufacturers Association of Canada, a non-profit organization whose 57 member companies account for more than 85 per cent of the pharmaceuticals made and sold in Canada, is presenting this brief as an evaluation of the factors underlying the present level of drug prices in Canada. It is PMAC's contention that in a country that has attained the general standard of living of Canada, no citizen should go without needed medication because he cannot afford it. Our brief, therefore, concludes with certain recommendations which, we believe, will help ensure that every Canadian is able to obtain the drugs prescribed by his physician, and that these drugs meet the highest standards of safety, reliability and therapeutic effectiveness. We would caution against any consideration of drug costs which divorces them from these three essential qualities.

The prescription drug industry has its own significant characteristics: its customers do not themselves decide what products they are to buy or how much the purchase will cost them; demand for prescription drugs is influenced primarily by the incidence of illness and demand is relatively unresponsive to changes in pricing; the industry is composed of strongly competitive companies whose products call for a high degree of responsibility in the conduct of competition; these companies must meet a high level of fixed costs (e.g. research and informational services) which must be borne even in the face of a decline in sales revenue; companies must ensure that all products are available on a national basis, even though only limited revenues can be expected from

many that are used for rare illnesses; and the industry is subject to a growing body of government controls that add to the operating costs of the drug companies.

The Canadian drug industry cannot be considered in isolation, for it is an international one. Moreover, it is a young evolving industry created by the research discoveries of the past 30 years.

The tremendous expansion of the drug industry in Canada as elsewhere in the world stems from the beneficial flow of new drugs, which in turn has at its source an intense, sustained effort in basic and applied research, based on international cooperation between universities, hospitals, government and industry. It is the function of industry to turn the discoveries of research into drug products of therapeutic value.

"The dynamics of progress in the drug field," in the words of the Hall Commission Report, "are illustrated by estimates which indicate that 90 per cent of the drugs prescribed in 1960 were introduced in the previous two decades." But this lesson will be of only academic significance unless it influences the policies which shape the future. Very great challenges remain; they will be overcome only with the massive dedication of all resources. The major drug companies, for instance, are continually increasing their investment in research and development, even though this is yielding fewer new products. Although the cost of research is only one element in the total cost of prescription drugs, it is an important one. Further, only companies operating at a risk-related profit can afford the commitment to an uncertain future which maintenance of a large pharmaceutical research establishment demands.

This research activity has paid large economic and social dividends through the control of formerly fatal diseases and through the savings to the community which arise from the use of drugs to combat mental illness.

The contribution prescription drugs have made to the national economy is well evidenced in the savings in productive time for millions of Canadians who otherwise would not be able to work or take care of their families, and the savings in hospital facilities and professional care. The present health care structure is, in fact, built on the ready availability of reliable pharmaceuticals.

Responsible citizenship on the part of our member companies demands wholehearted cooperation with those administering the laws of the country. In this spirit our scientists and technical people have collaborated with the Food and Drug Directorate in the elaboration of many regulations bearing on standards for both manufacturers and particular products. We have consistently supported the strengthening of the Directorate, and put forward the concept of registration to assist the Directorate in enforcing its standards. Representatives of our Association serve on the Drug Advisory Committee, appointed by the Minister of National Health and Welfare.

Nevertheless, as a competitive industry in a free enterprise economy, we are concerned to defend what we believe to be the freedoms essential to our efficient operation. To serve the people of Canada properly, we must be able to conduct our business realistically and to make a fair profit.

A sense of practicality should determine the allocation of responsibilities to agencies of government. They have important regulatory functions. They can also

assist greatly in obtaining and disseminating scientific and technical information. However, it is most undesirable that government become the final arbiter of therapeutic efficiency, or infringe upon the physician's professional rights and responsibilities.

Breakdown of The Prescription Dollar

Out of every prescription dollar, on the average, 37½ cents go to the manufacturer. The remaining 62½ cents are required for distribution through the retailer and wholesaler and to pay the federal sales tax.

Economic Structure of The Drug Industry

For the 41 reporting companies in 1964, sales of packaged human pharmaceuticals amounted to $110,465,396, not including proprietary or patent medicines. It is estimated that total sales of packaged human pharmaceuticals of all PMAC members amounted to $136,000,000. Of this amount, approximately 70 per cent was distributed through retail pharmacies.

Market surveys show that no single company holds as much as six per cent of the Canadian pharmaceutical market. It is significant that in the three largest classes—antibiotics, hormones, vitamins and nutrients—no single company has as much as 21 per cent of the market, and that only in five of the 24 therapeutic classes into which the market is divided does the share of the top company exceed 40 per cent.

Our brief to the Hall Commission, submitted in May 1962, reported that approximately 83 per cent of the prescription products sold in Canada were manufactured here, the remaining 17 per cent being imported. It has not proved economically feasible to develop a pharmaceutical chemical industry itself, primarily because of the limited size of the Canadian market.

Pharmaceutical companies in Canada have developed principally to serve the domestic market, and at present few of them are exportive. Certainly it would encourage exporting activity if conditions in Canada fostered a more comprehensive manufacturing operation, including the manufacture of active ingredients.

The pharmaceutical industry, which has expanded steadily in recent years, makes an appreciable and growing contribution to the national economy. Our 38 reporting companies had 6,098 employees in 1964, and the total employment is estimated at something over 10,000. It is interesting to note that of the total employees of those companies reporting, approximately 25 per cent are university graduates.

Companies are substantial purchasers of goods and services in Canada. In 1964, out of a reported final sales volume of $107,790,000, materials purchased abroad and other payments accounted for about $22,215,000, the remaining $85,575,000 being represented by payments and investments made in Canada.

Profits in the pharmaceutical industry are consistent with the risks involved. This is a research-based industry in which progress results from vigorous and sustained competition. According to a review of profit ratios for 1962, published by Canadian Manufacturers Association, profit as a percentage

of sales for all manufacturing before taxes came to 7.6 per cent; this included severally chronically or temporarily depressed industries. Pharmaceutical preparations were listed as 11.4 per cent. Manufacturing industries earning higher profits were: soft drinks, alcoholic beverages, pulp and paper mills, engraving, stereotyping and allied industries. Total operating earnings before taxes reported by the 41 companies replying to our 1964 survey was 10.8 per cent on sales. Profit after taxes was 5.2 per cent. Relating earnings to the resources employed by our 41 reporting companies, the rate of return for the industry amounts to 15.6 per cent before taxes and 7.6 per cent after taxes which would seem to be in line with results for other industries.

Research has been one area where pharmaceutical manufacturers located in Canada have been singled out by the Hall Commission. Its report questioned the value of the reported earnings of the Canadian drug industry because subsidiaries are being charged for research done by parent companies. We would like to state that although 37 of our members which answered a question on this subject reported that they spent in 1964, $5.5 million in research in Canada and were charged $1.5 million by their parent companies for research done in their behalf, our members have at their disposal the results of over $400,000,000 spent in research by the total world pharmaceutical industry.

The average annual rate of investment over the five-year period 1960-64 was 9.3 per cent. In every year plant investment exceeded the depreciation charged during the year.

The members of our Association responding to annual surveys report that over a five-year period 1960-64 they paid excise and sales taxes of $43,783,000 and income taxes of $41,712,000. Their net income over the period totalled $43,781,000, of which $21,053,000 were paid in dividends. Thus for every dollar earned, the companies paid two dollars in taxes; and for every dollar paid in dividends, the companies paid four dollars in taxes.

The Cost of Drugs to Canadians

It has been widely maintained that the cost of drugs to the Canadian consumer is unduly high in comparison with what is paid in other countries, this allegation being based on evidence produced before the Kefauver Committee. These comparisons were made in terms of actual prices, translating the foreign currencies into Canadian dollars. To present a fair picture, we believe it is essential that standards of living and earning powers in the countries concerned be taken into account.

To present a fair picture, we selected 17 major drugs selling in good volume under their brand names in Canada, according to these criteria: they represent the most important therapeutic classes; they are the products of a number of major drug companies; the same products are sold in similar strengths and dosage forms in other countries. Seven countries were selected for comparison with Canada, and wage rates of manufacturing employees were obtained from reliable sources. We then related these wage rates to the selected drugs and obtained comparisons in terms of labour hours, the comparisons being worked out both for actual hours of labour and as an index of labour hours, using Canada as 100. The impact of the federal sales tax was reflected and a

simple average was developed for the hours of labour indices. The significant finding is that most products cost less in terms of labour as the standard of living rises, and Canadians therefore can buy drugs with less labour than people in most other countries. Despite the existence of National Health Service in the U.K., the real cost of drugs there is higher than in Canada. In Sweden, where the standard of living approximates that of Canada, the price to the retailer is in line with the Canadian price.

Distribution and Pricing

There are various methods of distribution, direct and indirect. Pharmaceutical manufacturers will normally sell to hospitals and governments direct, though hospitals on occasion buy through regular trade channels. Products for retail sales may be sold to pharmacists direct or through a wholesaler. This also holds true for dispensing doctors.

Larger manufacturing companies frequently maintain warehouses or depots strategically located in cities such as Moncton, Halifax, Montreal, Toronto, Winnipeg, Calgary, Edmonton and Vancouver, either operating their own warehouses or using the facilities of a warehousing company. To ensure that drugs are available everywhere immediately or with a minimum delay in a large and sparsely populated country constitutes a tremendous distribution problem.

Pricing considerations are many, and they are based on a forecast sales pattern that takes into account the size and nature of the market, the competitive strength of existing products, and the product's therapeutic advantages. Prices will also be influenced by the following factors: the type of therapy for which the drug will be used; whether the length of therapy calls for price on a daily cost basis or a price based on the anticipated size of the average prescription; certain operating costs which sales of all products must cover (e.g. products sold at a loss or provided at no cost for use in the treatment of rare diseases); a proper allocation to the companies' research program; production costs; and the cost of an effective program of information and promotion.

Finally, there is the cost involved in the manufacturer's policy of returned goods, which we believe is unique in the manufacturing industry in Canada.

The Pricing Structure

It has been a policy of the Association to refrain from any activity in the matter of price and the pricing practices of its members.

Our member companies must unilaterally determine their own policy in this area. Until the enactment of Section 34 of the Combines Act, most companies established the resale price. Since the enactment of this section, it has been a common practice in many manufacturing industries to suggest a retail price. Most pharmaceutical manufacturers have continued the practice of selling to retail pharmacists at a discount of 40 per cent off this price.

However, some manufacturers have given up this system for "prescription only products" and have adopted a policy of "net" prices to pharmacists.

In contrast to the retail market, there is no clear pricing pattern known to us for drug purchases by hospitals, institutions and government. Prices here are

influenced by a number of special considerations and also depend upon the individual manufacturer's policy.

There are various reasons for the differences between the price to the retail pharmacist and the price to hospital or government. Firstly, hospitals do not pay the 11 per cent sales tax. Secondly, these customers buy in large quantities and the discounting of bulk purchases is normal business practice, Moreover, it may be advantageous to the manufacturer to have his product used substantially in hospitals, so that physicians become acquainted with it, and are therefore more likely to prescribe it in their own practice.

Finally, the competitive situation will have a strong influence. There is normal and continual competition within all therapeutic categories, but when the competition comes from a so-called generic equivalent the original manufacturer must decide whether to abandon the hospital or government market or reduce the price to the level of a competitor who is free of the costs of research and product introduction and who carries little or no scientific overhead.

The Cost of Manufacturing and Quality Control

The 1964 statistical survey shows that the manufacturing costs of goods for human pharmaceuticals is estimated at 32 per cent of net sales. About 10 per cent of manufacturing costs are expended in quality control activities.

The Cost and Value of Research

Pharmaceutical research is an essential activity of mounting cost that carries no guarantee of success or profitable return. International expenditures exceed $400 million a year, and some companies spend millions on a given project with no result at all apart from the knowledge of what cannot be accomplished. It is estimated that only one in every 3,000 new compounds tested will yield a drug of sufficient value to justify its introduction.

Pharmaceutical research is both a cooperative and competitive endeavor. Fostering the health of any nation requires that the fruits of world-wide research be exchanged among universities, hospitals, government laboratories and pharmaceutical companies. On the other hand, it is our strong contention that a research-based industry develops its maximum potential only under the spur of sustained competition. In this connection patent laws are valuable since to obtain a patent an inventor must reveal the facts of his invention. This information suggests new goals to other researchers and steers them away from duplication. But lack of patent protection leads to disruptive secrecy and discourages investment.

The sequence of research proceeds from the discovery and synthesis of new chemical compounds through pharmacological testing on animals, identifying undesirable side effects and toxicity, establishing therapeutically effective dosage forms, cautious evaluation in humans, followed by intensive human testing, and culminating in a New Drug Submission to the Food and Drug Directorate which agency prohibits marketing of the product until it has issued a Notice of Compliance.

The expenditure required to bring a new drug to the market has been increasing sharply. This is owing to, among other things, the general increase in

research expense, the growing complexity of the research, a shift in emphasis from the treatment of symptoms to the treatment of chronic diseases, as well as to the more extensive testing requirements of regulatory authorities. The accumulated data needed to satisfy FDD requirements before limited human testing may begin often forms a stack of documents several feet high.

The rate of discovery in any research-based industry fluctuates, and the past few years have seen a marked reduction in pharmaceutical research productivity. In the United States from 1954 to 1961, the annual rate ranged from 31 to 63 new products. It dropped to 27 in 1962, 16 in 1963 and 17 in 1964. in 1965, it rose to 24, due in part to more rapid processing by the regulatory authorities. A similar pattern can be discerned in Canada.

Expenditures on research and development in terms of net sales in the pharmaceutical industry runs at about three times the average for the manufacturing industry generally.

The Hall Commission is critical of the expenditure on research by Canadian companies on two counts: the amount spent in this country and the amount charged for the work done elsewhere. Actually, expenditures in Canada have gone from $2,500,000 in 1959 to $6,500,000 in 1965, and should conditions remain favourable there is every indication that the present rate of growth will be maintained in the years ahead. It would be unrealistic to claim that we can ever be the authors of the major proportion of the prescription drugs used in this country, but we can be worthy collaborators in an international venture. This must remain an international industry, with the main foci on endeavor in those countries where the major companies have been long established.

Nine of our members now operate research and development laboratories in Canada. Further growth can certainly be expected so long as the treatment of our industry does not preclude the necessary investment.

Scientific personnel employed by the industry on research and development work have increased substantially in recent years. For instance, the number of physicians employed full-time in research by members of the Association rose from 12 in 1958 to 45 in 1964. At last count—in 1964—there were 73 Ph. D's or S. Sc's working in company research laboratories, 31 M. Sc's and 108 B. Sc's or B. Phm's.

This expansion of research activity in Canada reflects the growing scientific maturity of the country. However, it takes time for a laboratory to become productive—as much as five to ten years from its establishment to the marketing of its first compound. And even the best staffed and equipped laboratories are of themselves no guarantee of success. Indeed the risks of any research undertaking must be directly related to the potential benefits to mankind sought by the researchers.

Public Service Products

The research laboratories of the international pharmaceutical companies have developed many products—some of them life-saving—that are specifics for rare illnesses. These products are often made available to physicians either free of charge or at factory cost. A recent survey of our members showed 18 companies listing 84 products of this type. The cost of these products cannot be easily determined but their value to Canadians is inestimable.

MEDICAL INFORMATION AND THE COST OF MARKETING

Our annual statistical survey for 1964, which includes the marketing expenses for 41 PMAC companies, showed that physicians' information accounts for 23.3 per cent of the manufacturer's sales dollar. Other marketing expenses, primarily direct selling to the pharmacist, account for 6.6 per cent. The net result is that the manufacturer's marketing expenses amount to approximately 11 per cent of the prescription dollar.

To secure and maintain medical acceptance must be a major part of the operating costs in this industry. Companies have to ensure that every physician and pharmacist across Canada is properly informed about their products, and the fixed cost of the necessary marketing machinery must be borne whether or not a particular product is commercially successful. Nor do companies benefit from a mass market. They handle a large number of separate products, many with quite limited sales volume. In fact, at present in Canada only nine prescription drug products have an annual manufacturer's sales revenue exceeding $2 million.

The geographical and other facts of doing business in Canada must be faced. We operate across a vast country with a scattered population. Qualified representatives must be paid salaries on a North American scale. But except for those who serve in major cities, where there may be a concentration of physicians in a small area, they cannot hope to maintain a call average comparable with other western countries. In cases where territories are so sparsely populated that companies cannot afford to send in representatives, they must rely on journal advertising and literature to carry essential information to physicians.

The cost of providing full information and promotion services in two languages is also substantial. This calls for highly qualified translators and the duplication of relatively short printing runs.

Pharmaceutical marketing is concerned with two related requirements—the provision of scientific information and the promotion of its products. Ideally, companies would like to do business successfully by a single, introductory provision of objective data. But success in this industry means developing useful new drugs and making them widely available, and this in turn is founded on competition and enterprise, including effective promotion.

Two characteristics largely fashion our marketing practices. On the one hand, drug products are numerous, varied, and, increasingly, potent and complex. On the other, the use of those products is determined by the 20,000 members of the Canadian medical profession. This group determines a pharmaceutical company's principal asset: its reputation, both for the reliability of its products and for the information it provides about them. Both of these are subject to control by the FDD, which not only passes judgment on safety and efficacy, but also approves the basic circular about a product on which all promotion is based, and which has lately established requirements and standards for advertising material.

The first purpose of pharmaceutical promotion is to arouse interest in a new product, because it cannot become widely used unless physicians are properly informed about it. This requirement is not merely commercial—it is an

industrial responsibility since delay in informing doctors about new drugs, once they have received a notice of compliance from the FDD, can well cause unnecessary loss of life and suffering.

Nor can marketing activity—information, promotion and advertising—be limited to new products. New information may develop including new indications or new contra-indications. And companies have found that the market for even well-established products depends on the maintenance of promotional flow, a fact of competitive life.

Today there are approximately 8,000 prescription preparations immediately (or very rapidly) available in this country through any of the 5,000 pharmacies across Canada. All required drugs are equally available in all hospitals. Physicians, dentists and pharmacists must be fully informed about them, and as a result marketing becomes a rather rigid cost for the pharmaceutical company. Extensive reviews of the purposes and costs of detailing and pharmaceutical mail, together with journal advertising, are contained in the appendices.

The need has been recognized in Canada by doctors, pharmacists and manufacturers alike for objective, independent reporting on new products. At the initiative of PMAC, a committee has been set up to investigate the development of a coordinated drug information system in this country. Represented on it are FDD, the Canadian Medical Association, the Canadian Pharmaceutical Association and the Canadian Association of Hospital Pharmacists. It is our strong opinion, coinciding, we believe, with that of the medical profession, that this is a task for an independent professional body composed of representatives of medicine and pharmacy operating with the support of government, not a responsibility of government itself. There is, we believe, a marked danger of the views of an official body being treated as a seal of official approval or disapproval, and so becoming an undesirable limitation on the professional freedom of the physician.

Pharmaceutical companies carry out a number of activities included in marketing expense but not related directly to product information or promotion, although they do have a general marketing purpose—the establishment of the company in the minds of doctors as a responsible, scientifically-oriented organization. These include the organization of symposia relating to particular diseases; distribution of the record of proceedings; and the support of professional meetings in various ways, including closed circuit coloured television facilities and the setting up of international links.

The Cost of Safety

The cost of safety is a growing one that stems from the awareness of government, industry and the medical profession of the toxic potential of modern pharmaceuticals. It adds to the cost of research through delays encountered in getting new products approved, whether for clinical testing or market introduction. It adds to the cost of manufacturing through the maintenance of high standards of quality control. And it has had an impact on the cost of marketing through the need to ensure that full information about side effects and contra-indications is widely disseminated among physicians and pharmacists. Moreover, distribution costs are influenced by stringent controls on the

distribution of Schedule G pharmaceuticals, such as barbiturate and amphetamine products, which call for very detailed supervision and extensive record keeping.

Pharmaceutical Patents

The purposes of a patent system are to stimulate invention, to bring new devices or processes into public use, and to encourage the full disclosure of new ideas. The value of a patent system in respect to pharmaceuticals can be further assessed in terms of the industry's contribution to economic development and the therapeutic value of goods and services that result from the granting of a patent.

Two recent reports, those of the Restrictive Trade Practices Commission and the Hall Commission, criticized even the present scale of patent protection for pharmaceuticals and maintained that either the abolition or emasculation of this protection was a necessary move to reduce the cost of prescribed drugs. They apparently based this position on the belief that the consequent wide-open competition in pharmaceuticals would best serve the national interest.

An effective patent admittedly confers a temporary monopoly and so rewards the industrialist who makes the invention public. However, there are virtually no drugs that possess a therapeutic monopoly. For almost every means of treatment, patented or not, there is one or several alternatives. And these have a major influence on price levels.

Further, the public interest is not limited to the provision of drugs at the lowest possible price. Quality and safety are extremely important. The availability of a full range of drug preparations for both frequent and rare diseases is extremely important. The continuing flow of new discoveries is extremely important. And, finally the growth of a research-based industry that makes large-scale investments and provides good employment opportunities is extremely important.

There is ample evidence of Canada's recognition that it can enhance its industrial status only if it encourages innovation through research and development. In both its annual reviews published so far, the Economic Council of Canada has underlined the need for increased R and D expenditures. And of course, a patent system provides industry with the very primary incentive to innovation. But the present administering of Section 41(3) of the Patent Act creates a problem for the pharmaceutical industry. To quote from a memorandum submitted by the Association of the British Pharmaceutical Industry to the British government on the subject:

> "...If one is to diminish the monopoly granted to a particular group of inventors the group selected should be one that confers upon society a smaller than average benefit. We believe that the pharmaceutical inventor deserves as well of public esteem and reward as does the inventor of any other kind of invention. Yet the inventor of a new drug that for the first time would effectively treat coronary thrombosis is subject to the particular severities of Section 41, whereas the inventor of a new hair curler, machine-gun, whistling top or mouse-trap is not subject to the special provisions of that section..."

Two counter arguments have been advanced by those who would abolish Canadian patents for pharmaceuticals: (1) It is claimed that abolition of patents would have little effect on the expansion of research and development activity within Canada. (2) It has been suggested, notably by the Hall Commission, that pharmaceutical research can and should be directed and financed by government.

In recent years expenditures for prescription drug research have risen steadily, from $2.5 million in 1959 to $6.5 million in 1964, with nine companies, nine companies now operating research laboratories in this country. This expansion has been due in part to tax incentives offered by the federal government, and a few companies have been given direct grants for specific projects. An inhibiting influence, however, has been the increase in the past year or two of applications for compulsory licences under Section 41(3) and the apparent ease with which such licences have been granted. If the development of pharmaceutical research is held to be a national interest for Canada, the denial to the industry of reasonable patent protection calls for the closest scrutiny. Canada can ill afford decisions that could endanger its long-term interests as a rising industrial power.

The second argument—that pharmaceutical research should be financed by government—ignores the realities of industrial, and notably pharmaceutical research. This is an increasingly complex and costly activity; several international companies each spend more than $20 million yearly on research and development. Their activities are carried on in close cooperation with universities and hospitals; they form part of an interwoven pattern of scientific exchange, and they are devoted to a specific and essential purpose—the application of scientific and medical knowledge to the development of pharmaceutical products of direct benefit to mankind. But, the fundamental objection is that government-sponsored research is usually isolated from the practicalities of therapeutic necessity and this research therefore connot be directed economically or effectively.

There are significant services performed for Canadians by a research-based international pharmaceutical industry which would be seriously endangered if the treatment of pharmaceutical patents discouraged an orderly pattern of drug development and control. Genuine patent protection encourages a company to devote considerable resources to the introduction and marketing of its products. It does this through a carefully planned program of scientifically-based information. An imitating company merely takes advantage of the medical information provided by the originating company, and is probably incapable of either maintaining or advancing it.

The activity of a research-based company is a total operation, and many life-saving drugs of limited market potential are made available only because they are part of the total operation. Without reasonable patent protection for its main products, a company might well decide that it could not afford to introduce new products if they were to be used only for rare diseases or conditions. Significantly enough, a study of applications made for compulsory licences under Section 41(3) will reveal that the applicants, naturally enough, are interested in products which have already obtained substantial sales.

Drug safety calls for extensive and continuing work in pharmacology and toxicity beginning with assembly of the material necessary to meet the rigorous demands of a New Drug submission. We do not believe that an imitating company possesses the scientific resources to meet this requirement or to provide the FDD with the information on which to base manufacturing standards, essay procedures and the like. If the research-based company does not carry out this work and incur the related expense, nobody else will. Here again, patent protection is the key. A company which has merely acquired the right to manufacture or distribute a product will not have the resources in personnel, clinical experience or accumulated international information to place at the disposal of the medical profession and government. There has been at least one important case where a licencee was completely unable to meet the scientific requirements of government in this connection. Uncontrolled compulsory licensing of potent drugs will distort or destroy the validity of much clinical experience because the active ingredient alone does not determine the therapeutic behaviour; reactions can be caused by the formulation as well as the drug. The general danger to drug safety is intensified by the encouragement that Section 41(3) offers to patent infringement. It is a fact, however undesirable, that patent-holding companies hesitate to take action against infringers because the immediate counter-measure may well be an application for a compulsory licence.

The price of drugs is and should be a matter of public concern. But price cannot be properly considered apart from drug safety, reliability and availability. Significantly, the Special Committee of the Commons on Food and Drugs put drug safety before cost when establishing its order of priorities. The public interest is best served when the relationship between price and product is in proper balance.

Section 41(3) should be studied against the background of this industry's industrial contribution to the Canadian economy, and the determining influence the state of patent protection has on the industry. Section 41(3) clearly discriminates against food and drugs. The question is whether such discrimination serves the public interest. If, as we believe, it subordinates the real interests of Canadian users of pharmaceuticals to those of a small number of imitative manufacturers making very large profits out of their licences, then effective remedies for this situation should be implemented.

The origin of Section 41(3), which was introduced in 1923 having been modelled on a similar section of the English Patent Act of 1919, was the danger of a shortage of drugs in England, a situation which in no way applies in Canada today. The products to which it is now applied are immeasurably more potent and complex, the requirements for medical information more demanding, the research that yields new products far costlier.

The actual wording of Section 41(3) intensified the problem. In effect both the first and final decisions as to the granting of a compulsory licence are made by the Commissioner of patents. Well qualified though he is in patent technicalities, he does not have experience either of the economics of this industry or of its medical and scientific aspects. And under the present regulations he is not required to obtain expert advice in these areas. The section provides that the Commissioner shall grant a licence unless he sees good reason to the contrary.

And the courts have refused to interfere with his decision on the ground that the section provides that the decision is one for the Commissioner to make. The section is defective in that it contains no objective standard for judgment by the Commissioner. No guidance is given by the section, and no guidance has been given by the courts as to what matters the Commissioner should examine or investigate to determine if good reason does in fact exist for refusal of a licence.

To sum up: Section 41(3) of the Patent Act subordinates the real interest of Canadians in the availability, quality and safety of pharmaceuticals and in the stimulation of research to limited and temporary price advantages. This misconception of the real interest would be even more dangerous were the practice of compulsory licensing under Section 41(3) to be extended to drug imports, as recommended by the Hall Commission.

The establishment of royalties has been based on a widespread misunderstanding about the nature and cost of the essential functions performed by a responsible company. These include the cost of research and development, the cost of manufacturing, including sustained quality control, and the maintenance of scientific information services that go far beyond the promotional activities usual in other industries. Unless the holder of a compulsory licence is required to pay a royalty that covers the cost of necessary functions being performed by the patentee, the licencee is being given something for nothing. An examination of the licences which have been granted under Section 41(3) will show that the applications were made in the expectation of a "free ride" in relation to certain of these functions. If, indeed, the royalties granted had borne a reasonable relationship to the cost of the functions, it is doubtful whether the applications would have been perused.

There appears here a fundamental misunderstanding of the nature of the pharmaceutical industry. The cost of production, the cost of operating the plant, is only one of its continuing and essential costs. The basic purpose of the industry is to provide the means for medical treatment; it is as much a service industry as a manufacturer of goods for retail distribution. In these circumstances, to maintain research and a proper flow of scientific information are two crucial functions.

Essentially, what the applicant for a licence under Section 41(3) seeks is the right to copy the patentee's dosage form so as to claim that this copy has a therapeutic effect identical with the original. In so doing he is, at minimal cost and with no lasting commitment, taking advantage of a substantial market created by the patentee. Further, he relies on the patentee continuing the necessary efforts and expenditure to support the market. And he will enjoy automatically any benefits that result from any new therapeutic use the patentee may discover, having played no part whatsoever in such discovery. There is no true competition between patentee and licensee since the patentee is in effect continuously subsidizing his competitor. Further, the patentee carries expense burdens immeasurably greater than the licensee's, yet is quite unable to discard them.

Concern about the dangers resulting from the inadequacies of second manufacturers under compulsory licensing led the government to set up a

special committee of investigation last summer under Dr. Irwin Hilliard of the University of Toronto. The report of the Hilliard Committee, tabled May 12, 1966 in the Commons, dealt with the hazards which could arise under compulsory and voluntary licensing and made a number of recommendations, all of which the Association heartily endorses. There are, in addition, other vital aspects of the situation that must be dealt with as well. For this reason our own recommendations regarding pharmaceutical patents would range beyond those of the Hilliard Committee and are covered at the end of this section.

Section 67 of the Canadian Patent Act contains effective provisions for action through compulsory licensing to prevent the abuse of a patent. Because of the existence of Section 41(3), no recourse has been had to Section 67 with regard to patents on drugs, yet this would appear to be the true defender of the public interest. Moreover, implementation of Section 67 would provide strong encouragement for the extension of pharmaceutical manufacturing and pharmaceutical chemical manufacturing in Canada. At present Section 41(3) actually discourages manufacturers from working their patents in this country because whether they work them or not has no bearing on the granting of compulsory licences. Hence Section 41(3) as presently administered directly contradicts the normal purposes of patent legislation. Moreover, Section 19 gives the Government of Canada the right to use any patented invention on payment of reasonable compensation, providing additional protection for the public interest.

In international terms, Section 41(3) discriminates against pharmaceutical patents in an all-embracing way quite rare in other industrial countries, concerned as they are to make drugs of high quality widely available and to foster research and industrial expansion. There is nothing similar in the patent law of the United States. Some West European countries have compulsory licensing provisions, but these are generally dependent on abuse of the patent.

New legislation in Italy has been approved by the Council of Ministers, providing for process patents of ten years' duration, compulsory licensing provisions, fair compensation to the patentee, and royalty agreements providing full appeal to the courts. The draft European Patent Law prepared by the European Economic Community would grant a patent life of 20 years and permit compulsory licences only in case of proved abuse. Moreover, in Britain, where Section 41(3) originated, the treatment of the patentee is notably more realistic than in Canada with regard to both the granting of licences and the establishment of royalties. The licence is granted on the basis of the public interest and the royalty is based on the costs of research and medical information as well as a return on the capital invested in both of these functions.

The Association's reasons for its position on the Patent Act as it now relates to prescription drugs are as follows:

1. The public interest requires the continuing availability of the products of international pharmaceutical research at reasonable prices.
2. The public interest also requires that a reward be given for an invention so that further research is encouraged and the industrialist has an interest in making public the results of the invention. This is the basic purpose of the Patent Act.

3. The public interest is opposed to discrimination against pharmaceutical patents since such discrimination inhibits the fulfilment of both these purposes.

4. Section 41(3) of the Patent Act, as it is now interpreted and applied, discriminates severely against patents on pharmaceuticals, and so works against the public interest in the following respects:

   (*a*) it permits compulsory licensing of pharmaceutical patents without setting out any objective standards against which to determine whether the public interest is already being served;

   (*b*) a single individual, the Patent Commissioner, holds absolute power to decide whether a licence should be granted, and to determine the royalty to be paid;

   (c) it does not provide that the patentee should be adequately compensated for what he loses when a licence is granted;

   (*d*) there is a clear threat to the public health in the proliferation of imitative products introduced without adequate attention to the scientific capabilities of the secondary manufacturer or distributor.

5. Section 67 of the Patent Act contains full provision for compulsory licensing where a patent is not being worked or is otherwise abused. In addition, Section 19 allows for the over-riding interest of the Canadian Government.

6. Effective application of Section 67 would serve as a strong incentive to the expansion of pharmaceutical and pharmaceutical chemical manufacturing in Canada, since it treats the non-working of a patent as grounds for compulsory licensing.

In the light of these facts, we make the following recommendations:

1. The protection of the public interest requires the establishment of a properly qualified tribunal to decide on compulsory licence applications in the first instance. This tribunal should be composed of men able to pass judgment on legal matters, economic arguments, and medical and scientific implications.

2. It should be clearly stated what matters this tribunal will take into account during its review of a licence application, including the elements to be considered in arriving at an equitable royalty.

3. A compulsory licence should be granted on economic grounds only if the tribunal finds that the patent is being abused or not used for the public interest.

4. There should be full right of appeal from the decisions of the tribunal, with a definite determination of the bases on which an appeal can be made regarding both the licence itself and the royalty granted.

5. There should be an early revision of the Patent Act, leading to the establishment of a tribunal with the composition and powers outlined above.

The Question of "Generic Equivalency"

There are two ways of designating a pharmaceutical chemical: by its lengthy chemical name; and by what has come to be known as the proper, non-proprietary, common or generic name. This is derived from the chemical name. A brand name, however, fulfills a different function. It establishes the manufacturer's responsibility for a particular drug product.

An editorial in the Journal of the American Medical Association of November 9, 1964 concluded its comments on "Drug Names" with the following advice:

> "... The physician who prescribes meprobamate as such has no way of knowing that his patient will receive the drug in a form of highest quality and expected potency. Careful prescription writers provide the necessary assurance in one of three ways: by writing the non-proprietary name plus the name of a manufacturer known to be reliable; by writing the desired brand name; or by writing the non-proprietary name plus the desired brand name. The third method has the modest advantage of reducing the likelihood that the pharmacist will make a mistake in filling the prescription.
>
> "When a physician uses a brand name or a manufacturer's name to designate the source of supply, he is fulfilling a part of his professional obligation to his patient. Having decided that medication is required, he should assume the responsibility for selecting a manufacturer who will supply the drug in a therapeutically effective form at the lowest possible cost to the patient..."

The members of our Association and most other Canadian companies market most of their products under brand names. But there are also a smaller number of companies which market products according to the generic name of the active ingredient.

Both the Restrictive Trade Practices Commission and the Hall Commission called for wider generic prescribing by Canadian doctors in order to reduce the cost of drugs. Certain questions are raised here.

Since about half of the prescription products available are mixtures and only about a quarter of them have generic equivalents, how is the physician to prescribe these generically? And can the physician be confident of the quality of drugs prescribed generically?

Dr. Showalter of the Department of Industry testified before the Special Committee of the Commons that the government has had its troubles with products bought by price alone. Said he: "The practice of competitive bidding on price seems to have resulted in obtaining supplies mainly from the least competent or possibly the least scrupulous suppliers." This was the origin of the decision to develop CGSB standards for companies wishing to tender for government business, as well as for the Committee's recommendation that all manufacturers and distributors be registered so that they can be inspected by the FDD.

In April 1962 the Alberta government passed a bill that enabled pharmacists to substitute generic-name equivalents for brand-name products unless

specifically ordered not to by the physician. This legislation has had little or no impact. According to "*Drug News Weekly*" of February 15, 1964, Donald Cameron, Registrar of the Alberta Pharmaceutical Association, has stated that about 88 per cent of the doctors in the province prescribe by brand name. Said he: "Doctors are wary of prescribing generics because there have been too many reports of cases where cheaper drugs were used without success or with disappointing results, thus eventually increasing the overall cost."

The problem of generic drugs is a problem of quality, and it should be recognized that government inspection can never guarantee the quality of all drugs sold in Canada. According to Dr. C. A. Morrell, then head of the FDD, in his appearance before the Special Committee of the Commons:

> "...I am loath to have people say that a drug is guaranteed by the Food and Drug Directorate. I do not see we can guarantee it. There are many subtleties, and we have not the facilities to detect differences. ...You cannot put 'government approved' on a drug."

A major weakness in the Hall Commission approach to prescription drug services is its failure to appreciate the inevitable limitations on government action. This is most evident in the section of the Hall Commission report entitled "Quality of Drugs" (pp. 366-370)

It is our belief that open competition between qualified suppliers is the best way to serve the interests of the Canadian people where drugs or any other products are concerned. But such competition is not encouraged by the destruction of long-accepted methods of protecting the legitimate rights of the manufacturing companies—as represented by the companies' brand names.

The requirements for sound drug purchasing were described by Dr. Morrell, when he headed the FDD, in a press statement to the "Globe and Mail," August 18, 1960:

> "When it comes to buying top-quality drugs, the things to check are the ability, facilities, personnel and conscience of the drug manufacturer. Neither a brand name nor a drug's generic name is the sole reliable guide to quality. The real point is who makes the drug and how it's made—the control system that ensures careful and scientific testing for potency and reliability."

There is finally the broad question of whether any two prescription drug products, even though containing the same active ingredient, can be considered truly equivalent. Long experience, backed by considerable scientific evidence, leads our companies to conclude that this is rarely the case. Said Dean F. N. Hughes of the School of the Pharmacy of the University of Toronto before the Hall Commission:

> "We believe the principle of requiring practitioners to prescribe medicine only by chemical or generic name to be entirely wrong. This presupposes that any given dosage form containing the same quantities of a drug will have the same clinical effect. It has been clearly shown that this does not necessarily follow."

The many factors of drug formulation (24 of them) which can affect therapeutic efficiency were reviewed succinctly in an article by Dr. Max S.

Sadove and others which appeared in the February issue of "American Professional Pharmacist."

The practising physician should certainly be informed about the cost of therapy as he is about its effectivenesss, and we support the Hall Commission recommendation for more extensive efforts in this area. However, maintenance of the physician's freedom to prescribe the drug of his choice is of overriding importance.

The Provision of Prescribed Drugs Under Medicare and Welfare Programs

There is growing interest throughout Canada in the provision of prescribed drugs as part of medical service plans. The Hall Commission recommended a Prescription Drug Benefit plan, which would require contributory payments and based on a National Drug Formulary. Certain provinces are going ahead with welfare programs, while others are working on broad plans for prescription prepayment or insurance.

We believe strongly that under any assistance program proposed by government the range and quality of preparations doctors may prescribe should depend solely on therapeutic considerations. It would scarcely be logical for government to develop plans designed to assure all citizens of the physician's services they need, and then limit the means of treatment the physicians may prescribe.

Our Association has formulated and made public the following set of nine principles that should govern, we believe, the provision of prescription drugs under health service programs:

1. It is the responsibility of the pharmaceutical manufacturer in cooperation with the professions of medicine and pharmacy to search, develop and provide safe and effective drugs of the highest quality.
2. It is a cooperative responsibility of the manufacturer and the pharmacist to make safe and effective medications of high quality immediately available in all parts of Canada.
3. It is the right of the physician to prescribe the drug preparation of his choice.
4. Nothing must be allowed to interfere with the duty of the pharmacist to respect the integrity of the physician's prescription.
5. It is the citizen's right to consult the physician of his choice.
6. It is the citizen's right to have his prescription dispensed by the pharmacist of his choice.
7. It is the responsibility of any agency paying for drugs to recognize the rights and duties of the physician, the pharmacist and the citizen.
8. The respect of industrial property rights as represented by patents and trade marks is the essential foundation for progress in research and therapeutics.
9. A pharmaceutical benefits program which assists the needy and encourages the self-supporting to provide for themselves will best meet the requirements of the people of Canada.

So far as the general provision of prescribed drugs is concerned, we have worked with the Canadian Pharmaceutical Association in developing its proposals for Pharmacare, and we consider this an effective plan for meeting the real needs of the large majority of Canadians.

Recommendations Relating to the Cost of Drugs

In general we consider the prices charged for the prescription drugs made and sold by our member companies to be fair and reasonable as evidenced by information in Section 4. These are products of high quality and of intense and continuing international research. Their proper availability depends on sustained programs of medical information and on a nation-wide distribution network. Those who manufacture and distribute the drugs must meet the costs of doing business in Canada with regard to salaries, wages and the purchase of materials, goods and services.

We have, however, a number of recommendations bearing on the cost of drugs. Some of these would reduce the price of drugs generally, or the prices of certain products, or the prices to certain groups of citizens. Others would convey to the professions concerned and the general public more extensive and precise information about the cost of particular products. We recommend the following:

1. The abolition of the Federal sales tax on prescription drugs. This would reduce the manufacturer's prices by approximately 10 per cent.
2. The wider availability of programs for drug insurance or prepayment. A joint study has been made by PMAC and CPhA of the feasibility of prescription drug insurance, and a model insurance plan has been developed.
3. The establishment of an independent source which would provide doctors and pharmacists with accurate and up-to-date information about pharmaceutical products.
4. The development of more comprehensive and up-to-date statistics relating to the cost of drugs and expenditures on drugs. We would be happy to work with the Dominion Bureau of Statistics or other authorities in the elaboration of such a program.
5. A cooperative program by the universities, medical and pharmacy associations, and pharmaceutical manufacturers to provide physicians with more extensive information about the cost to their patients of particular drug therapies.
6. The abolition of suggested catalogue prices for drug products available only on prescription, leaving the retail pharmacist to assess the sum necessary for the proper compensation of his services.
7. Sponsorship by the Government of Canada, assisted by the Drug Advisory Committee, of a feasibility study for a voluntary drug price restrain program, for implementation on a trial basis for a period of five years, as recommended by the Hall Commission. The

members of our Association stand willing to enter into any discussions about the prices of their products which the governments concerned may consider desirable.

• (4.00 p.m.)

Mr. MACKASEY: Mr. Chairman, there is also an appendix of interest, at the back of the brief, the Hilliard report. The committee will have to make reference to this at some time in our proceedings. Would it be possible to have this printed as an appendix at the same time?

The CHAIRMAN: If it is the wish of the committee.

Mr. MACKASEY: I think it is fundamental to the whole question of costs.

The CHAIRMAN: Mr. Mackasey has asked that the portion of the brief, which is really the Hilliard report, be printed as an appendix to today's proceedings.

Mr. MACKASEY: It is appendix "K" to the submission, I believe.

Mr. ENNS: I so move.

The CHAIRMAN: That is correct. That is a relatively short appendix. I think that would be reasonable because it is very pertinent to what we are discussing today.

The CHAIRMAN: Is there a seconder?

Mr. ASSELIN (*Richmond-Wolfe*): I second the motion.

The CHAIRMAN: It has been moved by Mr. Enns, seconded by Mr. Asselin (*Richmond-Wolfe*) that an abstract of the brief of the Pharmaceutical Manufacturers Association of Canada be printed as part of today's proceedings and that appendix "K" of that brief be printed as an appendix to the proceedings.

Motion agreed to.

The CHAIRMAN: Gentlemen, we have a very good attendance today but because many other committees are meeting I was wondering if it was the wish of the committee to have its quorum reduced at this time, or shall we carry on?

Mr. MACDONALD (*Prince*): I move that our quorum be reduced from 13 to 10.

Mr. ISABELLE: I second the motion.

Motion agreed to.

Mr. WIGLE: Mr. Chairman, thank you. As I said, I will try to be as considerate of the committee's time as possible but I would like to indicate quickly those contents of the summary, which is the next section in the brief. Just to summarize the brief generally, it includes first the introduction which I propose to go through quickly with you; then the breakdown of the prescription dollar; the economic structure of the drug industry according to surveys carried out by PMAC among its member companies, indicating the size of the prescription drug market and how the market is shared; the extent to which the manufacturing activity is primarily Canadian; market growth and other statistics relevant to the economics of the industry.

You may note that in those sections which deal with our statistical surveys, in part there are 35 companies reporting and in another part 41 companies, and in another one perhaps 28. The reason for this, of course, is that we are a

voluntary non-profit association of companies and when we make a plea to them to participate in a survey they do those portions of it which they feel capable of doing, and all portions do not apply to every company so that the numbers in different sections can be understandably different.

The section on the cost of drugs to Canadians is, as we mentioned in the preamble, a comparison with foreign countries on the basis of the hours of labour that are required to pay for the average prescription. Section 5 is distribution and pricing, the peculiarities of distribution which are characteristic of Canada along with pricing considerations which are influenced by the industry's sales patterns to government customers and to wholesale and retail outlets. The cost of manufacturing and quality control again gives survey figures of the cost of manufacturing and the added cost for quality control. The cost and value of research covers the mounting expenses involved in the discovery and synthesis of new compounds and the steps that must be taken to bring a new drug to the market, along with the co-operative and competitive aspects of research. In this regard, Mr. Chairman, we had intended to bring today exhibit A, which is referred to in section 7 under research but the weather being what it was we were a little lazy and did not cart it across from the office. Exhibit A is a submission on a new drug made by one of our companies, an average sized submission which consists of 28 volumes, eight of which cover the investigation of the new drug and the information which has to be given before obtaining permission from Food and Drug to go ahead with the clinical investigation, and then another 17 volumes which deal with the new drug application. We felt that exhibit A might be of interest to the committee. If the committee feels it would like to see it, well, on some occasion during the next two hearings we will pack it over for you. But it is a very impressive array of documents, I assure you, and not assembled without considerable time and money.

Section eight deals with the public service products which, as mentioned previously, are those rarely used but when needed may be needed in any remote community of Canada, for nobody knows whose child or relative may need it, yet it must be available even though infrequently used. These products too are practically impossible of assessment so far as cost is concerned because they are not used often enough to produce a market for them.

The cost of marketing is broken into physician's information as well as scientific information—promotion and scientific information being difficult to separate. These items are dealt with in that area as are journal advertising and other methods of promotion, marketing and information to the professions of medicine and pharmacy.

The cost of safety is section 10, in which there is a review of the cost of safety and its over-all influence on the cost of research, manufacturing, marketing and distribution.

Section 11 deals with pharmaceutical patents and this, of course, is an area in which we have great concern because of section 41(3) of the Patent Act, which grants compulsory licences in Canada to those secondary manufacturers who wish to apply once the product has been established on the market by the original manufacturer and a good market established for it. It becomes obvious that somebody who would like to capitalize on it can make application for a

compulsory licence in that area. I might just mention with regard to exhibit A we have a lot of concern about whether the granting of the compulsory licence does or does not include having to produce an exhibit A. It might be much more just in the granting of a license if they did. Likewise, the Hilliard Committee report which was mentioned, and which one of your members asked to be added to your proceedings, is relative to this granting of patents, and we are most anxious that the Hilliard Committee report be applied by the Food and Drug Directorate.

Section 12 deals with the question of generic equivalency. This section discusses the differences between non-proprietary or generic names and brand names. It presents the arguments in favour of brand names and establishes the manufacturers' responsibility for their own particular drug products. It considers the broad question of whether any two drug products can be considered truly equivalent and it points up the factors which can affect therapeutic efficacy.

Section 13 is the provision of prescribed drugs under medicare and welfare programs, which is a speculative area into which we have done studies with the pharmacists of Canada and with the medical association. We have established a set of principles which we think should be preserved in the provision of drugs under such programs if we are to continue the therapeutic advance—the development of new cures which I mentioned previously.

Section 14 is our recommendations relating to the cost of drugs.

That is a summarization of the segments of the brief, Mr. Chairman. The other portions I mentioned to you are the introduction and our recommendations. May I proceed?

This presentation is made on behalf of the Pharmaceutical Manufacturers Association of Canada, which at present represents 57 companies who produce about 85 per cent of the prescription drugs sold in this country. Under the by-laws of this Association there are two types of membership, and Appendix A is a PMAC application that outlines the classifications and membership requirements.

Currently, there are 52 full members and five associate members. It will be seen that all companies are required to meet proper conditions for control of quality and standards; ability to qualify under the Canadian Government Specifications Board regulations is a further requirement for membership.

I might say Mr. Chairman, that it is a matter of pride to our Association that we had the privilege of working with the Canadian Government Specifications Board in the setting up of those qualifications listed as 74 GPI under which a manufacturer qualifies in Canada to sell to the Government.

In addition, each member must subscribe to a Code of Ethics and a Code of Marketing Practices. These are attached as Appendix B and Appendix C.

Provision, Distribution and Cost of Drugs in Canada, a study made for the Royal Commission on Health Services by the Research and Statistics Division of the Department of National Health and Welfare, reports that in 1960 there were 198 establishments "engaged chiefly in the manufacturing of pharmaceuticals and medicines".

The following breakdown is given: "It seems that many of these 198 plants are small regional concerns, while others manufacture proprietary medicines exclusively. Probably more than two-thirds of the plants are what might be considered multi-line pharmaceutical manufacturers. Approximately three-quarters are multi-line proprietary manufacturers. The remainder comprise agents, wholesalers and retailers who also manufacture some medicinals plus packaging concerns and other suppliers." Many manufacturers have not sought to join our Association. So far as it is possible to judge from available information, many would not meet the rigorous standards that are a qualification of membership.

I might say, Mr. Chairman, in this regard that we are pleased to say that we had previously recommended to the Food and Directorate some method of notification of product that would identify all of the people who market and produce pharmaceuticals in Canada. The Food and Drug Directorate is proceeding now with such a requirement for the notification of product and in due course we will have a tabulation, we believe, of all manufacturers and producers of pharmaceuticals.

This presentation relates solely to prescription products: those available only on prescription, or designed primarily for sale on prescription, and so not advertised to the general public. These are the products referred to as human pharmaceuticals. However, some of these products can be bought from retail pharmacies by the public without prescription, and some companies have subsidiaries, affiliates or divisions which manufacture and sell proprietary medicines advertised to the public for self-medication. Most of the statistical information in this presentation has been developed for the prescription drug portion of the business alone, but where company earnings are concerned, any separation must be arbitrary.

Our presentation is not intended to give a total picture of the operations of either the drug industry in Canada or our own Association. Rather it takes the question: "What are the reasons for the present level of drug prices in Canada?" and presents the answers as they appear to us, answers based on sustained experience of conducting a highly specialized business in this country.

Further, we believe it axiomatic that in a country which has attained the general standard of living of Canada no citizen should go without needed medication because he cannot afford it. Our brief therefore concludes with certain recommendations which, we believe, will help ensure that every Canadian is able to obtain the drugs prescribed by his physician, and that these drugs meet the highest standards of safety, reliability and therapeutic effectiveness. We would caution against any consideration of drug costs which divorces them from these three essential qualities.

Characteristics of the Drug Industry

The prescription drug industry has its particular and significant characteristics:

(1) When people buy drugs on prescription, they do not, themselves, decide what products they are to buy or, therefore, how much the

purchase will cost them. In addition, the need to make the purchase is in itself usually unwelcome;

(2) The demand for prescription products as a whole is influenced primarily by the incidence of illness. This incidence combines with the medical assessment of comparative value to determine the sale of individual products; demand is relatively unresponsive to changes and differences in pricing;

(3) The industry is composed of a large number of strongly competitive companies, yet the nature of their products requires a notable degree of responsibility in the conduct of competition;

(4) Companies must meet a high level of relatively fixed costs. For instance, an effective research operation must be maintained even though it does not yield immediate products. Similarly, as explained in Appendix D, the costs associated with an effective physicians' information service must be borne even in the face of a decline in sales revenue;

(5) Companies must ensure that all the products they market are available on a national basis, even though only limited revenues can be expected from many that are specifics for relatively rare illnesses and conditions. Similarly, full medical information must be provided about all products. This includes maintaining an advisory service for physicians, based on the latest world-wide scientific knowledge;

(6) Although this is not a regulated industry in the technical sense, it is subject to a considerable, and growing, body of government controls. Necessary in the interest of public safety, such controls, add to the operating costs of the drug companies.

The Canadian drug industry cannot be considered in isolation, for this is among the most international of industries. Firstly, most of the major companis involved in providing Canadians with drugs of quality, like the research through which these drugs have been discovered, are international in scope. Research conducted in Canada both benefits from and contributes to world knowledge. Secondly, the conduct of business in Canada is very similar to that practised in other countries, subject to the specific requirements of government.

Another major factor bearing on our situation is that, as we know it today, this is a young, evolving industry. Essentially, the present pharmaceutical market has been created by the research discoveries of the past 30 years. In many fields, drugs which provide definite cures instead of alleviation of symptoms alone have become widely available. In addition, pain and suffering can be effectively treated in illnesses where no means of alleviation previously existed.

This has led to tremendous expansion of the industry in Canada as elsewhere in the world. Very many new products have been introduced, and there have been frequent changes in company leadership in the various therapeutic categories.

The Benefits Resulting from Research

The beneficial flow of drugs has at its source an intense, sustained effort in basic and applied research, based on international cooperation between universities, hospitals, government and industry. However, it is the function of industry to turn the discoveries of research into drug products of therapeutic value. The Royal Commission on Health Services described the results in the following words:

> The outstanding progress made in medicine in the present generation would not have been possible had it not been accompanied by major advances, and in some cases by a breakthrough in the discovery of new drugs and the development of improved pharmaceuticals to help physicians to combat and in many instances prevent disease and illness.
>
> Effective and judicious use of drugs have made it possible not only to improve the health of the nation but also to raise the economic benefits resulting from the provision of health services . . .
>
> Advances in drug therapy in the last two decades have been particularly spectacular. Most of the progress made has taken place in such industrially advanced countries as the United States and the United Kingdom. Canadians have shared in this progress. The dynamics of progress in the drug field are illustrated by estimates which indicate that 90 per cent of the drugs prescribed in 1960 were introduced in the previous two decades; 40 per cent could not have been prescribed in 1954.

This lesson will be of only academic significance unless it influences the policies which shape the future. Very great challenges to medical and pharmaceutical research remain; they will not be overcome without the massive dedication of all resources. The major drug companies, for instance, are continually increasing their investment in research and development, even though this is yielding fewer new products. Although the cost of research is only one element in the total cost of prescription drugs, it is an important one. Further, only companies operating at a risk-related profit can afford the commitment to an uncertain future which maintenance of a large pharmaceutical research establishment demands.

The economic and social benefits of pharmaceuticals have been widely attested, for instance, through the control of formerly often fatal diseases such as diphtheria, pneumonia, tuberculosis and syphilis.

Most significant, too, are the savings to the community which arise from the use of drugs to combat mental illness. For instance, the rise in the admission rate to mental hospitals in recent years has been far exceeded by the rise in the rate of discharge, due in large measure to the availability of new medication. As a result, mental hospital residency per 100,000 population has declined steadily. According to the Dominion Bureau of Statistics, it dropped from 406.4 in 1955 to 352 in 1962. This has allowed major savings in the provision and maintenance of hospital beds.

On pages 426-9 of the Hall Commission report are printed tables giving the national expenditure on personal health services. From 1945 to 1961, prescription drugs varied from 6.2 to 7.9 per cent of the total expenditure, less than a

third of the cost of physicians' services or a sixth of the cost of hospital services. The figures for prescription drugs do not include drugs dispensed in hospital, but these come to less than a tenth of total hospital expenditures. When all prescription drug costs are added together, they appear to amount to about 10 per cent of all health service expenditures.

In assessing the contribution prescription drugs have made to the national economy, a number of factors must be taken into account, for instance, the saving in productive time for millions of Canadians, who otherwise would not be able to work or take care of their families, and the saving in the occupation of hospital beds and in the attention required from professional staffs. The present health care structure is, in fact, built on the ready availability of reliable pharmaceuticals.

The cost and value of prescription drugs cannot be properly assessed out of the total health care context. The national interest requires clear thinking about the impact of any price-oriented projects affecting drug availability on the adequacy of other health services, as well as about the ultimate cost to the country.

Relations with Government

It seems appropriate at this point to set out what we believe to be a workable philosophy of government-industry relations. Responsible citizenship demands wholehearted cooperation with those administering the laws of the country. In this spirit, our scientists and technical people have collaborated with the Food and Drug Directorate in the elaboration of many regulations bearing on standards for both manufacturers and particular products. We have consistently supported the strengthening of the Directorate, and put forward the concept of registration to assist the Directorate in enforcing its standards. That is really the notification of products which I mentioned previously, Mr. Chairman.

Representatives of our Association serve on the Drug Advisory Committee, appointed by the Minister of National Health and Welfare.

Nevertheless, as a competitive industry in a free enterprise economy and in an advanced industrial nation we are concerned to protect what we believe to be the freedoms essential to our efficient operation. To serve the people of Canada properly, we must be able to conduct our business realistically, and to make a fair profit.

A sense of practicality should determine the allocation of responsibilities to agencies of government. They have important regulatory functions. They can also assist greatly in obtaining and disseminating scientific and technical information. However, it is most undesirable that government become the final arbiter of therapeutic efficiency, or infringe upon the physician's professional rights and responsibilities.

Mr. Chairman, I said I was trying to be as considerate as possible of the time of your committee and I am indeed apologizing for taking the time to read these sections to the committee. I embellish the apology with the explanation that it has taken us two years to put this brief together and I would appreciate your indulgence while we look at the recommendations.

In general, we consider that the prices charged for the prescription drugs made and sold by our member companies are fair and reasonable as evidenced by information in Section 4. These are products of the highest quality, the fruits of intense and continuing international research. Their proper availability across Canada depends on sustained programs of medical information and promotion, and on a nation-wide distribution network. Those who manufacture and distribute the drugs must meet the costs of doing business in Canada with regard to salaries, wages and the purchase of materials, goods and services.

In this connection, we would draw attention to the following statement by the Hall Commission:

> "We conclude on the basis of the evidence presented to us that it is the unequal and generally unpredictable incidence of heavy drug costs that have given rise to the greatest concern on the part of the public, rather than what has been described as the 'high costs' of drugs as such."

I think that paragraph is understood, Mr. Chairman, and this has been explained many times. I am sure that other committees I have worked with have studied this and realized the greatest concern is those areas where there is a catastrophic cost for a particular individual or family. It is not the day to day average cost for us all.

We have, however, a number of recommendations bearing on the cost of drugs. Some of these would reduce the price of drugs generally, or the prices of certain products, or the prices to certain groups of citizens. Others would convey to the professions concerned and the general public more extensive and precise information about the cost of particular products.

1. We strongly support the recommendation made by many groups and individuals that the Federal sales tax on prescription drugs be abolished. This would reduce the manufacturer's prices by approximately 10 per cent.

2. There is a clear requirement for much wider availability of programs for drug insurance or prepayment. These would greatly assist the relatively small number of Canadians who find buying prescription drugs a real burden, whether due to personal circumstances or to the impact of either catastrophic or chronic illness. As reported in Section 13, a joint study has been made by PMAC and CPhA of the feasibility of prescription drug insurance, and a model insurance plan has been developed. Such a program would satisfy the requirements of most Canadians, and would provide an effective vehicle through which government can help those who need assistance.

As mentioned in Section 9 of our brief, we support the establishment of an independent source which would provide doctors and pharmacists with accurate and up-to-date information about pharmaceutical products. The size of companies' expenditures on medical information and promotion relates directly to the effectiveness of these activities. Should such an independent source for the provision of information to doctors and pharmacists prove to have a significant influence on the prescribing habits of physicians then the industry naturally would adjust its activities and might well modify the extent of promotional activity. But this would, of course, be an area of experimentation which we would have to indulge in with the professions concerned, in establishing such an independent source.

4. Recommendation 82 of the Hall Commission calls for the development of more comprehensive and up-to-date statistics relating to the cost of drugs and expenditures on drugs. We believe that the provision of more detailed and more broadly-based statistics would be helpful to all who are concerned with the development of drug benefit programs, and would generate valuable information for the general public. We would be happy to work with the Dominion Bureau of Statistics or other authorities in the elaboration of such a program of more comprehensive and up-to-date statistics.

We favour a cooperative program by the universities, medical and pharmacy associations, and pharmaceutical manufacturers to provide physicians with more extensive information about the cost to their patients of particular drug therapies. In fact, some companies now include information about the approximate cost of therapy in their medical literature.

The Association approves the action taken by some member companies to abolish suggested catalogue prices for drug products available only on prescription, leaving the retail pharmacist to assess the sum necessary for the proper compensation of his services. In this connection, we acknowledge the support given increasingly by representatives of retail pharmacy to a cost-price-plus-professional-fee system for pricing prescriptions. This system generally has the effect of increasing somewhat the price of the cheaper prescriptions but markedly reducing the price of those prescriptions most often criticized as being unduly expensive.

The Hall Commission has recommended that the Government of Canada, assisted by the Drug Advisory Committee, sponsor jointly with the drug industry and such provincial governments as wish to participate, a study of the feasibility of a voluntary drug price restraint program for Canada, for implementation on a trial basis for a period of five years. The members of our Association stand willing to enter into any discussions about the prices of their products which the governments concerned should consider desirable.

I might embellish that a little, Mr. Chairman, because as you know there is a voluntary price restraint program in England which I believe has borne some fruit, and although it is based on a method of calculation which would not be easily applicable to Canada we are prepared to sit down and try to develop some such program with our government if they wish to do so. However, we would reiterate that this position must take cognizance of the nine principles which we set down in section 13 where the freedom of the pharmacists, physicians, citizens and so on and the protection of patent rights are laid out.

Mr. Chairman, this concludes my summation. I have not referred specifically to any of the statistical areas but we are fundamentally here to talk about costs and I might in closing emphasize that in the breakdown of the costs of drugs, we have taken that portion of the prescription dollar for which we feel the manufacturer is responsible. You will see that in the tables which are presented to you this is about 37½ cents of the prescription dollar of which we speak. So we are hoping that as we assess the effect of impositions that might be placed upon the industry to effect changes in price we should continually keep in mind that we are talking about 37½ cents of each prescription dollar or $3.70 out of a $10 prescription. Thank you very much.

The CHAIRMAN: Thank you very much, Dr. Wigle. Gentlemen, I know there will be many questions. The group will be here for the next two meetings. I had hoped we would be able to restrict our questioning to any one section but I realize that this is going to be extremely difficult because one section is going to give rise to another section. However, I would ask you to be a little patient with me if I seem to think you are straying from the point we have under consideration at that moment. I would ask particularly those members who are sitting on the inside of the tables to pick up the microphone and speak into it because otherwise we have trouble with the communication when you speak. This does not apply to those on the outside because they are facing in this direction and the microphone will pick up your spoken word without any trouble.

The meeting is now open for questions.

Mr. ORLIKOW: Mr. Chairman just before you start the questioning I have two questions about groundwork. First of all, are we going to meet tonight? It seems to me that we have a lot of people from out of Ottawa here at considerable expense and if we could have a quorum tonight it would be well worthwhile. That is my first question. The second question is really a suggestion based on my experience in the transport committee. It made a good deal of sense to set a period of time for which any one member could ask questions and then he would go to the bottom of the list. On the transport committee we used 20 minutes for any one member at a time.

The CHAIRMAN: That sounds like a reasonable suggestion. My only reaction would be that 20 minutes, to me, sounds too long. I would say we start off with 10 minutes and see how we go along. The problem with having no limitation at all means that one member may spend the whole session monopolizing the questioning and sometimes the Chair finds it difficult. I think the Chair is in an easier position if there is a time limit. No one will ever be prevented from asking a question if he waits his turn long enough. So far as sitting this evening, I have not discussed this with the witnesses who are before us. We are hoping that they will be here next Tuesday and Thursday. It is a very extensive brief. I certainly feel that we are going to be strapped for time really and if it is the wish of the committee to sit tonight I would certainly agree. I would bring up one small technical problem. At the moment, until it is approved in the House, which cannot be before next Tuesday. The quorum is still 13 members, although when we are hearing witnesses for information only the Chairman sometimes finds it rather difficult to count correctly.

Mr. ORLIKOW: May I suggest that we take a straw vote now and see how many members could be here tonight.

The CHAIRMAN: I would be quite willing to do that, provided the witnesses are available and this is the first consideration.

Mr. Fred R. HUME Q.C. (*Barrister, Hume, Martin and Allen, Toronto, Ont.*): Mr. Chairman, perhaps mistakenly, but most of us here understood that you would sit till six o'clock. Most of them are from out of town and some may have plans. If we could have a minute just to canvass and find out.

The CHAIRMAN: I would say that I think next week, once we are into the depths of this brief, it is going to become obvious that we need more time and I

would like to ask now that both the witnesses and the members be prepared next week to be here both Tuesday and Thursday nights. I think this is going to be a necessity.

Mr. RYNARD: Did you realize that Friday is a holiday?

The CHAIRMAN: Well the House is also sitting until 10 o'clock the night before the holiday.

Mr. RYNARD: Then there is the next Friday after that.

The CHAIRMAN: This is right; St. Jean Baptiste Day is a Parliamentary holiday.

Mr. MACKASEY: I think, Mr. Chairman, you will have a hard time to get a quorum on the Thursday night before St. Jean Baptiste Day. Most of us will be home preparing our floats.

The CHAIRMAN: I would assume then that all members are willing to come to the meetings promptly and perhaps we can stretch them out a little longer. I would ask, particularly for Tuesday night then, that the witnesses be available. As the committee members know, this committee has power to sit without seeking the authority of the House to sit at any hour whether the House is sitting or not. It was my hope that we might be able to conclude today's sitting by sometime between 5.30 and 5.45. I think, Mr. Orlikow, there is an understanding, from what has been said, that the committee does not wish to sit this evening nor are the witnesses necessarily available.

Mr. MACKASEY: Could we take a vote because I think Mr. Orlikow and I are agreeing more and more these days.

The CHAIRMAN: Time will tell.

Mr. MACKASEY: I said that, Mr. Chairman, in order to give Mr. Orlikow an opportunity to even the score.

The CHAIRMAN: If you wish, but I would point out that unless the Chairman sees 13 hands raised as being here tonight there is no point to it.

Mr. MACKASEY: I think it would take three months to do this brief properly. I counted about 10 statements by Dr. Wigle which were very interesting but I think they need substantiation. This is a very deep brief on a very important topic and I do not know how this committee can do without the benefit of these witnesses for many, many sittings let alone three.

The CHAIRMAN: We will have to play this by ear as we go along. There is one date that I just mentioned to Dr. Wigle today which is also free, June 30, if we run over the three sittings.

Mr. MACKASEY: I will be here tonight, Mr. Chairman.

The CHAIRMAN: Will those people who would come to a meeting, say, at eight o'clock this evening please indicate. The Chairman will have to rule, therefore, that there will be no meeting this evening because of the number of members who are unable to attend. May we start the questioning then with Mr. Mackasey and we will have ten minute question periods. We will try to proceed section by section.

Mr. MACKASEY: My questions, Mr. Chairman, arise out of the section Dr. Wigle covered. Is that in order?

The CHAIRMAN: Yes, preferably on the sections on which Dr. Wigle spoke.

Mr. MACKASEY: I will restrain my remarks to that and I certainly will not be 20 minutes.

At the bottom of 14.1 you say as we expected you to say—I think this is a subject that should be exhausted before we get into the alleged combines:

> We strongly support the recommendation made by many groups and individuals that the Federal sales tax on prescription drugs be abolished. This would reduce the manufacturer's price by approximately 10 per cent.

Now I keep coming back to this: "This would reduce the manufacturer's price by 10 per cent." How much would it reduce the consumer's price, which is a fundamentally different problem?

Mr. WIGLE: Mr. Chairman, there has been a good deal of speculation by various types of economists on exactly how this pyramids or does not pyramid, I think is the word they use. From my simple arithmetic it would appear it would be 10 per cent of the 37½ cents that the manufacturer represents in the prescription dollar. However, I would be happy to have Mr. Beauchemin give a further explanation if that is not a satisfactory explanation.

Mr. MACKASEY: Well, it is only the first of a series of questions.

The CHAIRMAN: Two things I would like to mention. First of all, I do not think we could expect the manufacturers association to comment on that part of the consumer's price because they are only concerned with the manufacturers price.

Mr. MACKASEY: Mr. Chairman, I must disagree at this point because reading section 5.3, the manufacturers, the group here today, have a very direct control on the retailers' price so let us not live in a fool's paradise. There is just not different independent areas arriving to the consumer. I think it starts here and I think we must follow it logically right through.

The CHAIRMAN: Fine. The other thing I would like to report to the committee while we are on the subject is that the Minister of National Revenue is producing a paper which will show us where he obtained the figures he quoted to this committee and with which the committee had some disagreement. That should be before the committee prior to our next meeting.

Mr. MACKASEY: I think we have agreed the effect of the federal sales tax on the manufacturing price is approxiamtely 10 per cent. You say, and it is one of the things we are here to find out, that only 37 per cent of the dollar, the consumer's dollar, can be directly attributed to the manufacturing cost, leaving an area of 63 cents, which we should investigate just as thoroughly as the 37 cents. It seems to me to be a wider field to reduce cost. At the bottom of 5.3 sir, you go on to say, contrary to your recommendation—but we have to talk about what exists, not what you recommend—that, "Until the enactment of section 34 of the Combines Act, most companies established the resale price. Since the enactment of this section, it has been common practice in many manufacturing industries to suggest a retail price." This is only a play on words. Now, you go on to say, "Most pharmaceutical manufacturers have continued the practice of selling to retail pharmacists at a discount of 40 per cent off list price." What I

want to know bluntly is the relationship between this recommended price and the manufacturing price. You recommend it sir, or they are, in general, recommending a reduction of 40 per cent from the suggested retail price. Now what is the relationship between the suggested list price and the manufacturing price which includes, incidentally, the sales tax, because it is important.

Mr. WIGLE: Well the economic details we will probably get from our professor of economics but, to me, it would be the list price less 40 per cent, as the manufacturers' price.

Mr. MACKASEY: No, no. What is the relationship between the cost, the 37½ cents, and the list price that you recommend? This here is a breakdown of the consumer's dollar. What I want to know is when you send out a list price to druggists, recommending the price of a particular product you must have a formula; you must have a direct relationship between what you hope the druggist will sell the product at and what you consider your fair price to the druggist or to the wholesaler.

Mr. ROGER LAROSE (*Vice-President, CIBA Company Limited, Dorval, Quebec*): I believe it is very simple.

The CHAIRMAN: I wonder if perhaps it might be convenient also for the witnesses to identify themselves. These meetings are not recorded by a stenographer but are now recorded on tape.

Mr. LAROSE: The suggested retail price when it is the price that the retail pharmacist charges to the consumer yields to the manufacturer, if he actually sells directly to the pharmacist, that price less 40 per cent.

Mr. MACKASEY: Yes, but you have not answered my question.

Mr. LAROSE: I am coming to that. If the manufacturer sells to the pharmacist through a wholesaler then there is a further discount. Then the manufacturer, before he actually keeps a portion of that cost, must remit to the government the 11 per cent sales tax. That brings us from that $1 listed as our suggested retail price to the 37½ cents which Dr. Wigle spoke about.

Mr. MACKASEY: That is not the answer, of course. Let me phrase the question another way. Let us take that area of drugs that you sell directly to a druggist rather than to a wholesaler, for the moment. You have a drug which we will call drug because I cannot pronounce all these words, which you suggest to the druggist should be sold at $5 or, say, $2 because it is more in line. What does that drug cost you? You suggested that the druggist sell it at $2; what do you charge the druggist for it?

Mr. LAROSE: Usually it is $1 less 40 per cent.

Mr. MACKASEY: You charge him 60 cents and he charges—

Some hon. MEMBERS: No, no.

The CHAIRMAN: That is on a dollar.

Mr. WIGLE: We might get Professor Briant to answer Mr. Mackasey.

Dr. PETER C. BRIANT (*Vice Dean and Director, School of Commerce, McGill University*): If the retailer was selling for $2—I just made a quick calculation based on what Mr. Larose said—the manufacturers price would be about 39

cents, I think—sorry, 78 cents; I have to double my 39 cents. So that a product that the manufacturer would sell ex sales tax at 78 cents would retail approximately at $2.

Mr. MACKASEY: If I can put a question to Mr. Briant, when you invoice is the tax included or is the tax extra to the druggist.

Mr. BRIANT: Apparently tax included.

Mr. MACKASEY: Well, Mr. Beauchemin, the 78 cents is tax included and you invoice the druggist at 78 cents.

Mr. GUY BEAUCHEMIN (*Executive Secretary of PMAC*): May I interject something? We are talking about two different things. We are talking about a suggested retail price. Your question was on the suggested retail price and I believe the answer given was on the prescription dollar. This is not quite the same thing because, of course, when the pharmacist performs an extra service other than selling the drug directly to the consumer, such as interpreting the prescription, filling in the different forms and ensuring it is the proper drug and so on he properly charges for his services. The CPhA in their brief last Tuesday, I believe, suggested that the material cost to them for a prescription of $1. was 50 cents—that is the cost to the pharmacists.

Mr. MACKASEY: This is what they suggested and I have that figure in my mind but I want to know what you think it is, because what I am trying to get at, Mr. Chairman, if you will allow me to explain, although I think the witnesses know what I am trying to get at, is this. The 3 cents, say, on the 37 cents, or on the 78 cents approximately 70 cents plus the 11 per cent sales tax are one concern. The relationship between the $2 retail price and the 78 cents is a factor; it is part of a formula. You do not calculate every drug separately. I want to know the precise formula you use to mark up because I contend that at the same time you are marking up the 78 cents you are also marking up the sales tax. This is the point I want to get at.

Mr. BEAUCHEMIN: That is correct.

Mr. MACKASEY: All right, it is correct. I know it is correct that is why I am asking. What I want to know is what does this 7 per cent that we start with cost the consumer. I am not interested in what Mr. Benson's opinion of 3 or 4 per cent is; I want to know what that 7.8 per cent becomes. That is what I want to know.

Mr. BEAUCHEMIN: It becomes approximately 10 per cent. It stays about the same, percentage-wise. Now it all depends, of course, on the method of pricing which the pharmacist may use. There are three different methods. Let us take a product with a suggested retail price of $1. It will cost the pharmacist 60 cents. The Minister of National Revenue has decided that the formula for calculating the sales tax will be the suggested retail price less 40 per cent less 15½ per cent. The 15½ per cent supposedly covers distribution costs. So the tax is applied to the suggested retail price minus 40 per cent, minus 15½ per cent. So the tax is applied on approximately 50 cents. We have 11 per cent of that 50 cents which is approximately 6 cents, and that leaves 44 cents. That is the cost to the manufacturer at a suggested retail price of $1 but, this is on a straight over the counter transaction. Now, if it is a prescription, the pharmacist usually will add

some 50 or 75 cents. Of course this 6 cents, which was applied to the manufacturers level on $1, becomes 11 per cent but on $1.50, of course, this 6 cents may be only 6 per cent.

Mr. MACKASEY: Four per cent.

Mr. BEAUCHEMIN: Four per cent. Now, the pharmacists use an alternative method of pricing prescriptions which is the cost plus professional fee. The strict base cost plus approximately $2 or $2.25. Well that six cents, then, on a prescription which cost them 60 cents will retail at $2.50 or $3.00. This six cents now is only 2 per cent.

Mr. MACKASEY: You are losing me there because you are bringing in the alternative method of pricing which is only coming into vogue, and that is cost plus.

Mr. BEAUCHEMIN: I agree but there are three methods in use.

Mr. MACKASEY: The prevalent one is to take your list price and either sell at full list price or sell above list price which I am sure some must do or sell below. You have no control over that I presume?

Mr. BEAUCHEMIN: No.

Mr. MACKASEY: But you do have a control between your manufacturing cost and the price you suggest that it should be sold at. I am saying the price you suggest it should be sold at has a relationship to your cost including the cost of the manufacturing tax of 11 per cent. I am simply saying that this is pyramided along the way to the consumer. I would suggest that we could easily prove—our accountant will eventually prove—that the federal sales tax has an effect of over 16 per cent on the consumer.

Mr. BEAUCHEMIN: This is quite possible.

Mr. MACKASEY: This is not your fault; it is our fault. It is one of the mandates, Mr. Chairman, that has been given to us. That is why I come back and I would still like to know the formula that you use in arriving at your suggested retail price and its connection or direct relation to the cost of manufacturing. The sole reason for that is to get the effect of the Federal sales tax.

Mr. BEAUCHEMIN: I am not, of course, in manufacturing pharmacy per se, but I would imagine that if it was my product I would establish what price I want to sell it and then I would add the tax which the government forces me to collect, and then add the distribution cost which is the wholesaling cost, the cost of distribution, and then the pharmacist sells it, of course, at the price he wants.

Mr. MACKASEY: Mr. Beauchemin when the druggist has been invoiced including the cost of the federal sales tax, the cost of shipping and so on, he doubles that end price, does he not?

Mr. BEAUCHEMIN: Well if it is over the counter it is usually 60 per cent original or mark up 40 per cent, yes.

Mr. MACKASEY: Forty off the list and 60 per cent markup. Therefore, if you charge him—we will use 10 instead of 11 for easy calculation—that tax is also doubled to 20 cents.

Mr. BEAUCHEMIN: Right.

Mr. MACKASEY: And 40 per cent comes off the 20 cents, 12 cents. In other words the tax at the manufacturing level now has cost the druggist 12 cents. In addition, after he has got that drug, and he paid the government 12 cents, he then includes it in the cost of his drug and marks the 12 per cent up to, say, 60 per cent, which is another 7.2 cents. So, now the consumer, with an ethical druggist—who is not over-charging, is now up to 19 per cent, the 12 cents plus the mark up, say a normal 60 per cent which certainly he is entitled to; 60 per cent of 12 is 7.2 and you are now up to 19.2 cents on the dollar. I think Mr. Chairman, they should straighten out once and for all the effect sales tax has on the cost of drugs because it is in our terms of reference.

The CHAIRMAN: I am sure we will do that Mr. Mackasey. I would point out though that this has nothing to do really with these people. If the pharmacist wants to add it up that way he can but if he wants to do it some other way this is his right and the manufacturers have no control over that.

Mr. MACKASEY: I am not chastising them for it. As a matter of fact, they have no choice; they must charge it. But surely they are the best qualified, Mr. Chairman, to tell me what effect it has on their invoices.

Mr. HOWE *(Hamilton South):* Mr. Chairman, I would like to base my questions on the first paragraph of the preamble which says a Canadian citizen is obliged to work fewer hours than the peoples of most other countries for ethical drugs needed for the maintenance of his and his family's health. I have here in front of me a rather lengthy document which I would like to put in the record, although I am not going to read it into the record today, showing comparative drug prices in England and in Canada of name products manufactured by the same manufacturers, and the same things here cost three to 20 times as much as they do in England. Now these prices were obtained from the chemists and druggists quarterly price list, which is an English publication, dated March 1966 and the Canadian prices were obtained from the price book dated December, 1965 of the Canadian Pharmaceutical Journal, a price book of drugstore merchandise. These prices show definitely that name products of arbitrary choice are, as I say, from three to 20 times as much.

Mr. WIGLE: Mr. Chairman, may I ask if these comparative prices are at retail level?

Mr. HOWE *(Hamilton South):* Yes, they are retail prices.

Mr. WIGLE: Thank you.

Mr. HOWE *(Hamilton South)*: I was reading in section 4, simply because section 4 is applicable to this first paragraph. The comparisons were done by this association on 17 products. This is section 4, page 1 in which it names some 17 products. Last evening I went to the trouble of looking up these prices and transposing them into Canadian money at the present rate of exchange. I do not know if it was today or last night, it does not much matter. An then, I multiplied it by a number given on page 43 taking the country, United Kingdom, at 129.40 as an index which you claim is the differential in labour costs and so on in England and Canada. When I multiplied these out, in every single instance, the drugs cost up to as high as three times as much in Canada as they do in England, even making this allowance that you made. I accepted this

figure of yours without having any way of being able to prove, in my own mind, whether it was correct or incorrect. Going to your price list of 37½ cents you only show labour as being 1½ cents of the 37½ cents. At page 22, it shows manufacturing labour cost at 1½ cents which is roughly 3½ per cent of the 37½ cents. Now it would seem to me that this figure of yours of 129.40 as the index would be a little high when the labour cost is such a small feature of the drug price, and that there drug prices are way out of range in the two countries. I can give actual prices if you are interested in them. In the case of Peritrate it shows 100 10-milligram Peritrate tablets in England costing $1.16 and here costing $3.75; multiplying that $1.16 by the index you give the comparable figure in Canada should be $1.50 and yet they sell for $3.75 here.

Mr. RYNARD: Mr. Chairman, I wonder if the doctor made a mistake or did I mishear him. Did he say 110 milligram Peritrate?

Mr. ORLIKOW: No.

Mr. HOWE (*Hamilton South*): One hundred at 10 milligrams.

Mr. ORLIKOW: One hundred tablets at 10 milligram strength.

Mr. MACKASEY: It would not be the first mistake the doctors have made. I mean that as a joke.

Mr. WIGLE: Well, Mr. Chairman, I hope I have your sympathy as a physician in this accumulation of—

The CHAIRMAN: Is this related to appendix F which shows international drug prices?

Mr. HOWE (*Hamilton South*): It is section 4 and page 1 gives you the names of the 17 drugs I selected which the association uses and page 4.3 gives you the index of price to the retailer of 129.40. That is taking Canada at 100 and, therefore, I multiplied the English price by that index figure to arrive at what an equitable Canadian price should be by your own comparison. Is this not correct Dr. Wigle?

Dr. WIGLE: Mr. Chairman, I will not comment on the particular method by which they are calculated because we do have Professor Briant. I would just like to point out, however, that the list of drugs were chosen by therapeutic category and the first three or four of largest selling products in most therapeutic categories. We have no doubt there are other products on the market and may vary in a different proportion but we did choose the therapeutic categories and the top selling products in each group.

Mr. HOWE (*Hamilton South*): Well, Dr. Wigle, I did those first three Achromycin in England at $3.51 and in Canada as $5.40 and multiplying by the index it is still $4.54 which is almost $1. less or should be almost $1. less. Chloromycetin at $2.11 in England and $4.95 here and, using the index, it brings the Canadian price supposedly to $2.73. Terramycin at $4.21 in England and $6.95 cents here and again using the index it should be $5.45 cents here, which is still $1.50 more in Canada than that index would show.

Dr. WIGLE: Mr. Chairman, could I ask Professor Briant to comment in reply to Mr. Howe?

Mr. BRIANT: There are a number of points. I am as close to being as confused as Mr. Howe is about this. May I just elaborate. The drugs in this list

represent about 8.5 per cent of the total market in dollar terms so that they are, we think, a fairly substantial sample of the market. My second point, Mr. Howe, the breakdown of the sales dollar, showing the proportion of the sales dollar represented by labour costs, has no relationship at all to this particular section. The only other thing that I could say on this is that I would need to see your figures and look at the sources because the prices which you read out, the retail prices, are different from the ones that we obtained.

The CHAIRMAN: The microphone has been pulled out, Mr. Briant; perhaps you would repeat the answer.

Mr. BRIANT: Are we set now? Is it recording now? If so, I will try and remember what I said.

The first point was, so far as the sample is concerned, the drugs that we have down, the 17 products, represent about 8.5 per cent of the dollar value of the total market and this, we believe, is a fairly broad sample of the market. The second point that I made was that the breakdown of the sales dollar with the proportion of the sales dollar represented by labour costs has no relationship to the material in section 4.1 showing the real cost of drugs to Canadians. The fact that the proportion of the sales dollar spent on labour is small does not relate in any sense to the real cost of drugs at retail prices. For those calculations on page 4.2 we used hourly rates in manufacturing so that we are relating the average hourly earnings of the worker to the dollar price of the drugs that he buys to determine how many hours or minutes someone works in Canada to buy a drug product. The third point was that I could not comment on the figures you have there without seeing them. I made a quick check as you went along with the prices of drugs in the U.K. and in Canada and not only are your U.K. prices different from ours but your Canadian prices are too, so we shall just have to get together afterwards, perhaps, and look at these prices and see where our sources differ.

Mr. HOWE (*Hamilton South*): Mr. Chairman I can do better than that. I am willing to table any of these documents to show the prices. I have given the names of them, which will be on the record; I have these here and I am willing to do anything that you wish with them. I also have this other list of drug prices in a documentary form showing the prices of many others that have nothing to do with this. They are admittedly selected drugs showing, as I say, from three to 20 times as much here in Canada as in England. Whatever you would like to do with these documents I would be very willing to table them so they can be seen or to give them to the gentlemen, whichever way would be best.

Mr. HUME: Mr. Chairman, may I point out that Mr. Howe's prices, as I understand them, are prices paid by the consumer and the appendix F referred to in our material is the price to the retailer, so it would be impossible to compare them unless Mr. Howe's prices also indicate the price to the retailer.

Mr. HOWE (*Hamilton South*): This is, of course, a retail price and I would presume it would be less whatever percentage was allowed in these countries. Our interest is the eventual cost to the consumer, in any case, not the cost to the drug store although your prices may have been based on that. Certainly these can be brought down to comparable prices. There is no reason why it cannot be

done. But this is as up-to-date a price list as I could get, dated March 1966 in England, and this other one is December 1965.

Mr. HUME: I would like to point out that the apparent discrepancy is due to the fact that we are talking about different things and while they could be related, here and now that discrepancy is obvious. We are using two different levels of pricing.

Mr. HOWE (*Hamilton South*): Yes, but if you take two levels and one is double the other and you cut the same amount off they are still going to be double.

The CHAIRMAN: I was going to to suggest that perhaps the best thing to do would be to have the professor and yourself get together with your figures and then at the next sitting of the committee, perhaps, if you have not been able to resolve the figures then you put them back on again. As has already been mentioned, we will be coming to an appendix where actual figures have been quoted by the association of prices they have of drugs in various countries and compare them to prices in Canada.

Mr. HUME: There is one other point. I believe Mr. Howe is using 129.4 as a sort of conversion factor. You cannot apply this to any one product and, secondly, it is technically wrong to make this kind of conversion. However, I think we can handle this.

The CHAIRMAN: Perhaps the two of you could get together and if you do not get the answer to your question, Mr. Howe, we can bring it up again.

Mr. HOWE (*Hamilton South*): Well, I would like it left on the record as it is for the time being.

Mr. ORLIKOW: Mr. Chairman, I would like to ask some questions and to begin right at page 1 of the first section, where the brief says Canadians come off well in terms of pharmaceuticals necessary for our national health and well being and the Canadian citizen is obliged to work fewer hours than people of most other countries for the ethical drugs needed and so on. Mr. Chairman, there has been a great deal, as I am sure our delegation knows, of study given to this question and the question of prices has been given a great deal of consideration by the restrictive Trade Practices Commission in Canada, by the Hall Commission, by the Kefauver Committee in the United States and there are some very astounding examples used. I will quote so that our witenesses can check my references later. I will very quickly quote from a book which I am sure they know, called The Therapeutic Nightmare by Morton Mintz and published by Houghton Mufflin, and at page 352 there is an example of the kind of thing which upsets the public and which I think the drug manufacturers have to explain to the public. Here is a prescription drug. These are American examples but I am sure if it varies, it varies by the price to the consumer being higher. Now, here is prednisone which is used very extensively in which the price charged to the druggist by Upjohn, by Merck by Parke Davis was $170 a thousand. I imagine this would be say, two years ago. McKesson and Robbins, which is one of the biggest distributing companies in the United States was offering this to the druggists at $20.95. This is the kind of price discrepancy which the public in increasing number knows about and which I think requires a good dea lof explanation. Let me take another example. Here is a drug widely

used in the treatment of diabetes, orinase, which is distributed in the United States and I am sure, in Canada, by Upjohn, which was developed in Germany. Let me quote from the book:

> Upjohn's price to the wholesalers and to retailers buying $100 or more worth of goods a year, was $83.40.
> Consumers buying in 50-tablet lots paid $139 for the 1000 tablets, while the production cost was only $13.11 and this included the royalty paid to the German company of $6.25.

I could go on, Mr. Chairman, but these are the kind of figures which have to be explained. I can give a personal illustration, Mr. Chairman, because my wife had to use Largactil, a product developed completely, as I understand, researched and developed—and I hope we will have a good deal of discussion about this question of research—in France. The company in France which developed it was selling it retail at 3 cents a tablet when it was selling in Canada and the United States for anywhere from five to ten times that amount. These are the questions, Mr. Chairman, and I do not think we have time today to go further into them. I want other members to have a fair opportunity to ask questions but these are the kind of facts which have come out in recent years on which I think, if not today, we are goin to have to get detailed answers from the pharmaceutical manufacturers.

Mr. WIGLE: Mr. Chairman, I will not attempt to answer the detailed questions because we are not acquainted with the detailed pricing policies of our various members as it is improper for our association to be so acquainted. The document to which Mr. Orlikow has referred, of course, is a book by Morton Mintz and we are quite acquainted with it. We have had quite an exposure to it. He is the ex-reporter of the Washington *Post* who became an expert, I believe, during the Kefauver hearings and published his assessment of the virtues of the pharmaceutical industry in North America. Mr. Mintz has raised these questions which Mr. Orlikow has mentioned but I do not think it is proper for our association to get into comparing the prices of Merck Sharp & Dohme with the prices of somebody else within the same country because it is not association business. I believe that you are having individual companies appear before this committee and I would think that appropriate examples might properly be used at that time. If any members of my delegation feel something more should be added I would ask them to proceed.

Mr. BEAUCHEMIN: Yes. Mr. Orlikow quoted the difference in price between the prednisone of one company with the prednisone of another company. As is well known, there are different methods of fabrication which can entail a different therapeutic effect. On that particular drug I would like to read to you the short testimony which was given by Dr. Gemmell who is Associate Professor of Medicine, University of Manitoba at the Restrictive Trade Practices Commission during its hearings on the drug industry some years ago. He said: "I have a patient who is entirely dependent on the fact that she receives cortisone and this is relatively important, the amount of the cortisone. My prescription read cortisone which is a generic name, 25 milligrams, half a tablet four times a day. Her husband called me and said she was not well at all so I put her in hospital and she was running a high fever and feeling terrible. I asked if she was taking her medicine and she said that she was. Obviously she

needed more cortisone so I gave her intravenous cortisone and the minute I did she became a new woman. The next morning I asked her, where did you get your cortisone. She said from the druggist. I said have you got it with you. And she handed me the thing and it looked like no cortisone medication I had ever seen in my life so I phoned the pharmacist and said what kind of cortisone is this patient getting? He said in the past I have given her such and such a company which is very reputable and so and so which is also reputable but lately as this is very expensive I have given a cheaper form of the drug." This can illustrate one difference which may occur in tablets containing or supposedly containing the same therapeutic element but which were processed differently.

Mr. ORLIKOW: Mr. Chairman, I might just say that instead of taking Largactil at the moment my wife is taking Meprobamate. Now I understand that all the Meprobamate sold on the American continent is made by one company, Carter products, which has the American patent. Now I can buy Equanil and pay the price for Equanil. I can go to the dispensary at the Winnipeg General Hospital and buy Meprobamate at one-third the cost of Equanil. The Professor of Pharmacology at the Medical College of University of Manitoba tells me that it is made by the same company. Now this is a problem which the consumer has to face. It is all very well for the pharmaceutical manufacturers to say it is only a few cents a tablet or a few cents a day but when the patient has to pay $8 and $10 and more for prescriptions, as he frequently does, it makes a tremendous difference.

Mr. MACKASEY: May I ask a question for my information. Can anybody go to the hospital and get this less expensive substitute?

Mr. ORLIKOW: Maybe they should.

Mr. MACKASEY: I did not ask that. At the present moment can anybody go there and get it?

Mr. ORLIKOW: Of course they can. All I am saying is I am sure the hospital is ensuring that it is dispensing reputable and satisfactory drugs, and they are buying drugs much cheaper.

Mr. MACKASEY: Well I want to be fair to Mr. Orlikow and to the committee and point out that the significant point is that in one case it was bought from a hospital where obviously there are different pricing methods and different purchasing methods, and in the other case it was bought from a reputable pharmacist. This is one of the things we should have got into, Mr. Chairman, but our witness, Mr. Turnbull had to leave us. I just wanted to know could anybody go to the hospital?

Mr. ORLIKOW: Mr. Chairman I used that illustration because it is one I know. All I am saying it that the people of Canada who have to buy prescription drugs, and particularly the people who have long-standing and more or les chronic illnesses are finding the price of prescriptions extremely onerous and they are concerned.

I would like to ask some questions arising out of section 2, page 2 where the brief outlines the cost of the manufacturers proportion of prescription dollars. As I read this, and I would like to make sure that I am reading it correctly because I often get lost in figures, in the 37½ cents which the

manufacturers calculate as their share of the prescription dollar, am I correct that the cost of labour is just 1½ cents?

Dr. WIGLE: I believe the breakdown is on the following page, Mr. Chairman.

Mr. ORLIKOW: Or, on the following page it is still what I say, four per cent of the cost is the cost of labour? So the cost of labour is not a very significant factor in the cost of prescriptions?

Dr. WIGLE: I would hesitate, Mr. Chairman, to say that all the labour involved, including the salaries of other people in the pharmaceutical manufacturing establishment, and so on, are all included in that item of labour. There are many other salaries and payments to individuals which are not included under that particular item. That is only what might be classified as a person working in the plant running a machine or sweeping the floor and that sort of thing.

Mr. ORLIKOW: Again, on page 2, section 2, am I right that the cost of research and development is 2½ cents out of the 37½ cents?

Dr. WIGLE: Yes, research and development, 7 per cent.

Mr. ORLIKOW: I compare this, Mr. Chairman, with the item listed as professional service representation, marketing and medical information of 30 per cent. It seems to me, Mr. Chairman, that if there is a cost figure which is significant in the cost to the consumer at the end, it is that figure. It is this figure which both the Restrictive Trade Practices Commission and the Hall Commission dealt with very extensively, the very high cost of each drug company having representatives, detail men, whatever you want to call them, whose major function, if not their only function, is to call on the individual doctor and to convince him that their product is better than another product, and very often better than the same product made by another company.

Dr. WIGLE: Mr. Chairman, I believe I have indicated in the portions of the brief that I read, the preamble, introduction and other areas including a recommendation, that one of the areas of greatest concern to the pharmaceutical manufacturing industry of the world is the cost of providing information on their new products and getting back the information on the old products. There are drugs showing up every day after having been in use for four and five years. Some new factor is discovered and often this is discovered by the fact that a medical service representative visited doctors and got this information back. It is a two-way street. We are concerned about the cost of it. We know that this is high. But this is a process of providing information which has evolved during this drug explosion of the last 30 years and certainly you cannot deny that the health of the world has benefitted very greatly by this explosion, and if there is a better way to provide the physicians and the pharmacists of this country from coast to coast with the information about new products and to get the information back, and a way which will be as successful as this has been, then the pharmaceutical manufacturers stand responsibly ready to help with setting up such a system. Whether you call it a drug information source or whether you have sessions, seminars scattered across the country at three month intervals and everybody makes his doctor go from that community, 30 miles or 100 or 250 miles, as I was, from my nearest city to the nearest city so

that he will get the information, then I think you would be doing something just as safe probably, as long as the doctors went and got the information. But it has been a process of evolution and we do not know the correct answer to this yet.

Mr. ORLIKOW: It is very unlikely and, in fact, I would say it was impossible to get a reduction in the tremendous amount of very expensive promotional and education material which the various drug companies send out on a voluntary basis. Is that not so?

Dr. WIGLE: I would not say that, Mr. Chairman. I think Mr. Orlikow made the presumption that it is very difficult to get a reduction in this. I am very proud to say that our association has as a general principle and policy that any physician who will indicate to a member company or to us generally that he does not want direct mail and/or medical service representatives his wishes will be respected. This has been a policy of the association of British pharmaceutical industry for some years and approximately 2 per cent of the physicians have indicated that they did not want this information.

Mr. ORLIKOW: What would you think of legislation which would restrict for tax purposes the amount of money that could be spent on this form of promotion. I am just speaking from memory but I think that is recommended in one of the Howard books.

Dr. WIGLE: Mr. Chairman, Mr. Orlikow asked me what I would think of it. I would think that if a government could responsibly introduce such a measure and know for sure that these restrictions were not going to endanger your child or my child or somebody else or keep some doctor from having the information, if they were sure of that, then let the government in its wisdom make such recommendations, but I would hesitate to get into that area when it affects the total cost of the final prescription to such a relatively slight extent.

Mr. ORLIKOW: How can you say that when the cost according to your own figures is 30 per cent of the—

Dr. WIGLE: Of 37½ cents on each prescription dollar.

Mr. ORLIKOW: But we could go through with you precisely the same steps which Mr. Mackasey did with regard to the sales tax. Just as the sales tax pyramids as it goes from the manufacturer to the wholesalers to the retailers to the consumers, so your 30 per cent pyramids in the cost to the consumer at the end. I am asking seriously. I realize the difficulties. After all you have a large number of companies and 90 per cent of them could agree that it would be a good idea, from every point of view, to reduce this cost factor but if the other 10 per cent did not and went to the other view they would force the 90 per cent to compete because if they found more doctors and sent out more literature they would get an increasing part of the market. All I am saying to you is, would it not make sense if the government made the same rule for everybody.

Dr. WIGLE: Mr. Chairman, Mr. Orlikow has impressed me with the seriousness of his approach. No one could be more serious than I am about methods to reduce the cost of drugs but I am very reluctant to do things which would endanger anybody's livelihood. My main reason for this is that in the 15 years I was in practice I never had a patient once or a representative of a family who said to me, you just forget it; do not do it if it is going to cost too much or do

not look for that new cure for my baby if it is going to cost too much. They were not that interested. Now, so far as this method of getting the information across to the professions is concerned, there have been some very interesting experiences in Russia and I will ask Mr. Howsam if he would like to comment about the experience there?

Mr. Peter HOWSAM (*Vice-President and General Manager, Warner-Chilcott Laboratories, Toronto*): There are a few comments I would like to make, Mr. Chairman, with regard to Mr. Orlikow's concern about this cost of promotion. As a commercial enterprise we have two responsibilities, as pointed out in section 9 of the brief. The one is the scientific information that Dr. Wigle has referred to and the second is the promotion of our products. If there were such a limitation proposed as you suggest, and no matter how we would like it, I think it would be very difficult for a company. I think the commercial end of life would probably come to the fore first and the manufacturer would try and promote his products, and there would be a real danger when a company would be required to notify a physician of new side-effects or new areas that have come up. I would also point out that when the information is offered from a non-commercial and purely scientific source it does not necessarily induce awareness. This awareness—no matter what its source—does not necessarily induce a trial of the product. The vital function of the marketing man is to create an awareness of this product and the disposition to try it. In Russia they have had a system similar to the one you describe where they have had an official pharmacopoeia and announcements in the medical press and simple one page fliers and so on. This system has not worked out well and we understand there have been repeated official complaints lately that the doctors are not getting adequate information about their products, so perhaps the functionality of our promotion system is not so bad after all.

Mr. ORLIKOW: Well, Mr. Chairman, I would just like to say one more thing and then somebody else can ask questions. I spent a number of years, maybe more than I like to think about, as a pharmacist and I have seen many times a patient come from a doctor with a prescription, where there is obviously a serious illness, for chloromycetin, Aureomycin or something like that and want 15 or 20 capsules or tablets, when I have said to the person, well it is $8 or $10 or whatever the price was at that time and they have said oh, well, I will not bother or I will just take half. I cannot think of anything more useless than to go to the doctor when you are sick, get a prescription and then not be able to get the prescription filled and use it because you cannot afford the price.

Dr. WIGLE: Mr. Chairman, we have expressed considerable concern about those people who are unable to pay for their drugs and we have made recommendations in this regard too. I would just like to mention one thing in closing about the restrictions which might be placed upon methods of getting out information to the profession. It is our opinion that this would practically make it impossible for a new drug company to start in Canada if there were restrictions because I am sure that if I started a company with you and one of our confreres tomorrow, our first year we would have to put about 100 per cent of our budget into promotion or we would not be on the market the following year.

The CHAIRMAN: I think Mr. Brand has some questions. Perhaps we could close today's meeting with Mr. Brand?

Mr. BRAND: I have only a couple of questions. First of all Mr. Chairman, I would ask Mr. Wigle if he has access, in view of recent discussions, to the paper prepared and presented in the Harvard Business Review, comparing the methods of promotion of drugs in the Soviet Union and in the United States. I think this came out very shortly after the Kefauver Commission. If there are any copies of these they might be useful for some members who have not seen it. I think it lays out very effectively the points which Mr. Howsam was trying to make. However, there are a couple of things here that puzzle me a little bit. If we look at 14.3, Mr. Wigle, just for the moment and section 6, where you approve the action taken by some member companies and so on and so forth and you acknowledge the support given increasingly by representatives of retail pharmacy to cost price plus professional fee system for pricing prescriptions. It is stated this system generally has the effect of increasing somewhat the price of the cheaper prescriptions but markedly reducing the price of those prescriptions most often criticized as being unduly expensive. Now, do you believe that the institution of this type of thing, cost plus the professional component would tend to lower the cost of drugs generally? I presume this is your intent since it is one of your recommendations?

Dr. WIGLE: I think, from a statistical point of view, it is difficult, Mr. Chairman, to show over a total sample that this has a great deal of effect, but perhaps Mr. Beauchemin could reply.

Mr. BEAUCHEMIN: In total, the average cost of a prescription, when you take the total sales of prescriptions in Canada, would be approximately the same depending upon, of course, the level of the professional fee involved. But certainly it would have the effect of lowering considerably the price of, say, a $10 prescription which would probably sell under a professional fee system at around $8. It would reduce the price of a $10 prescription by about $2. On the other hand, it would increase the price of a $1 prescription to a level of $2.50 or $2.75 so it would tend to level off the cost.

Mr. BRAND: You think it would be a good thing? That is what I mean.

Dr. WIGLE: Mr. Chairman, I believe the graph which has been drawn in this regard shows that in the middle range, which you would have to average down to, there is a little reduction.

Mr. BRAND: I just did some figuring. Everybody else seems to be figuring so I thought I would get into the act.

The CHAIRMAN: I should say that next week we will have a blackboard.

Mr. BRAND: I think we need one but I have been using these wonderful bits of paper we have been given. Using a professional component fee of $2—I am using Saskatchewan, perhaps coincidentally, but I happen to represent that excellent province—if you add the cost plus the $2 professional fees there will be an increase in the price of 77 per cent of prescriptions, and I refer you to the graphs on this presented by the Canadian Pharmaceutical Association, which are already in evidence. I find that this makes me wonder whether this method that you seem to be supporting will in effect do very much toward reducing the cost of prescriptions to the general public.

Dr. WIGLE: I do not think it was our presumption, Mr. Chairman, that the total cost would necessarily, but in the areas where there have been hardship. I do not believe it is the average $1.50, $2 or $3 prescription which causes the Canadian consumer as much trouble as it is when it is the $10, $12 or $15 prescription and this is the area which would be affected by the cost plus professional fee system.

Mr. BRAND: So by increasing the cost of prescriptions 77 per cent you are going to help the other 23 per cent. Do you think this is a logical assumption?

Dr. WIGLE: I am not aware that it really comes out that way.

Mr. BRAND: I realize I am backing you into a corner but I think if you look at the figures you will find this is substantiated by the figures quite accurately.

The CHAIRMAN: Is the table referring to retail costs or consumer costs?

Mr. BRAND: Cost plus the $2 professional fee.

The CHAIRMAN: What were the costs you started with.

Mr. BRAND: This is in the graph. It starts from the price range of 1 cent, 50 cents and goes up to $25.01 and on up to $50 in this particular chart. It is on page 16.

Mr. HUME: Is this the retail cost with the mark up plus the $2 fee?

Mr. BRAND: The average cost to the pharmacist from the manufacturer plus the $2 component fee which has been suggested in 14.3. I therefore find this somewhat untenable. I get the impression from section 4.3 that,—maybe I am wrong about this—"the simple average developed for the hours of labour indices and this shows in general terms the relationship of Canadian drug prices to those of other countries" that we are on the basis of labour costs, considerably below other countries, except the United States. Is this a fair assumption?

Dr. WIGLE: That is right.

Mr. BRAND: On the basis of that and on the basis of the hourly cost in Canadian dollars of $2.02 compared to the United Kingdom of $1.04 let us go back to appendix F. Let us take equanil since it was brought into the discussion. The price to the retailer in Canada, as listed in your chart here on appendix F.3, is $3.40 and the United Kingdom price to the retailer is .94 cents. In view of the fact that the labour costs seem to be double there seems to be considerably more of a difference there between the United Kingdom and Canada and I would like to know why.

Dr. WIGLE: May I ask Professor Briant to explain it.

Mr. BRIANT: You picked just one particular product.

Mr. BRAND: Well, it is a popular one today, as you know.

Mr. BRIANT: But the others are also popular. You may find that this index does not seem to hold true but the fact is that this index is an average of the 17 products on the list. So, if you look down at some of the other products you do not see such a tremendous discrepancy between them.

Mr. BRAND: Take Peritrate, which was also mentioned today, at $2.50 and 77 cents; that seems like quite a difference.

Mr. BRIANT: I suggest we look at Achromycin, Chloromycetin, Terramycin and Penbritin.

Mr. BRAND: Let us get away from the antibiotics.

Mr. BRIANT: The Canadian dollar prices of these are much closer. So, when you apply the substantial difference in wages, Canada $2.02 and U.K. $1.04, which is about half the wage rate per hour, it is only those products whose Canadian price would be more than doubled that will result in the kind of relationship you bring out with Equanil. Clearly, market factors in the two countries must have a bearing as well on the price at which drugs are made available to the public.

Mr. BRAND: Thank you very much for your explanation. How do you explain Diuril at $4.79 in Britain and $4.38 in Canada? The situation seems to be reversed and I am a little curious. Do you have to go to the bathroom more often because of the effects of the drug, which adds to the labour cost.

Mr. BRIANT: It could be the production costs of this particular drug. I cannot explain the differences in the market prices in the different countries.

Mr. BRAND: I would like to end on this note because it is now time to shut up for the night. I think this is one thing the committee would like to have clarified if at all possible. There are some rather startling differences in some areas. I think if you look at Sodium Seconal at $2.85 to 90 cents or Pyribenzamin at $1.53 to 84 cents, there again is this startling difference. I would hesitate to think the reason it is so much lower is not only that it is much easier to make these or they are using more of it there than in other countries. I wonder if these figures are not just a little misleading in the way they are presented.

Dr. WIGLE: Mr. Chairman, some of them have certainly been studied by the industry and it is obvious that in some countries it is less expensive to produce a product than it is in another country, and yet it is produced in each country. I think that these peculiarities of the industry would be fine to solve. If we could have the same price for every drug in every country of the world I suppose that would be the utopia. It would be nice if watches were that way and shotguns and things; you would not have to do any smuggling.

Mr. BRAND: This brings up one last point sir. If it is much cheaper to produce a certain drug in the U..K would it then, in view of the wide differential in some of these, not to be cheaper to import this particular drug rather than manufacture it here, in order to bring down the cost?

Dr. WIGLE: It would have to be a decision as to what was the best thing to do. Do you want to have those people working in Canada that are presently producing it, and if you do put them out of work where do they go from there?

Mr. BRAND: It would seem obvious that they could go to work producing the drugs which are more expensive to produce in the United Kingdom.

The CHAIRMAN: Are there any other questions, Mr. Brand?

Dr. WIGLE: There might be collusion, Mr. Brand?

Mr. MACKASEY: Mr. Wigle, are you saying that if we take advantage of the lower cost of drugs in foreign countries we would be doing so at the risk of abolishing a manufacturing industry in Canada?

Dr. WIGLE: I think this is a risk which would be involved, Mr. Chairman, if I understand anything about the economics of the industry.

Mr. MACKASEY: Is it a large risk or a small risk?

Mr. BRIANT: I think it is true, Mr. Mackasey, if you go through this list and the price in another country is lower than the Canadian price, this is where we have to balance. The fact is we can buy many products in other countries more cheaply than we can in Canada. Presumably we want an economy that offers diversified employment opportunities for our citizens.

Mr. ISABELLE: Mr. Chairman, now that Mr. Orlikow has made his press communique of 45 minutes could I—

The CHAIRMAN: I was going to ask if anyone noticed that I gave Mr. Orlikow more time. This is so for the simple reason that he had told me he was going to be out ot town and would not be here at the other presentations of this group.

Mr. ISABELLE: I just want to say one thing. I do not think we should take into consideration the prices of drugs today because, you could get a brand new car 15 years ago for $780 and today you are paying for the same brand of car $2,000. What we should look into, as I said previously, is not the price of the drugs but the racketeers in the drug industry, those companies that should disappear. I think there are 50 per cent of the companies who do nothing, not research, not even medical information. They should get out of the drug industry because they give a bad name to the good pharmaceutical industry. That is what I wanted to say and I think I am right.

The CHAIRMAN: Gentlemen, the meeting is adjourned and we will meet again on Tuesday morning.

APPENDIX "A"

(Appendix K to the Submission)

REPORT OF THE SPECIAL AD HOC COMMITTEE STUDYING MATTERS INVOLVING THE PATENT LICENSING OF DRUG MANUFACTURERS

JOHN N. CRAWFORD M.D.,
Deputy Minister of National Health.

Tabled by Mr. MacEachen,
May 12, 1966.

July 12th, 1965.

Miss Judy LaMarsh,
Minister,
National Health and Welfare,
Ottawa, Ontario.

Dear Miss LaMarsh,

I am enclosing a report of the Ad Hoc Committee set up to consider problems involved in the compulsory licensing for the manufacture of new drugs. The Committee met on June 24th and again on July 8th, and although the Committee worked under some sense of urgency, a very comprehensive study was made of matters relating to this subject.

You will see that the Committee went beyond the terms of reference for it became obvious to us that the number of new drugs which were produced under compulsory licence was very small compared to the number produced by smaller companies through arrangement with the original developers of the drugs, to some extent under threat of the application for compulsory licence. In the last fifteen years only ten compulsory licences have been granted. Mr. Michel, the Commissioner of Patents was most helpful and spent several hours with us discussing the problems which he encounters in carrying out the regulations. It was obvious that he was most anxious to cooperate with the Food and Drug Directorate and welcomed their help in ensuring the safety of drugs made under a compulsory licence. It is hoped that whatever changes take place in this department, close collaboration can be developed between the Commissioners of Patents and the Food and Drug Directorate. It was a shock to the members of the Committee to find the heavy responsibility put on the Commissioner of Patents. Many of the newer drugs are so complicated in their formulae that part of the products, the isomers, might not be active therapeutically though chemically pure, and some dangerous impurities may not be sufficient in amount, in small samples, to be detected.

The even greater worry to the Committee was this much larger area of drugs produced under agreement. The Food and Drug Directorate are not informed ahead of time and no inspection is required, although it might occur in the course of time. Samples of the new product prepared by the new company are not now being analysed. The Committee felt that there should be notifica-

tion of intention to make these agreements. We also felt that annual notification of all drug companies of all drugs that they are producing with specifications would be most helpful.

With regard to the specific conditions listed by Dr. Eloise Jones, you will see that (*a*) and (*c*) are covered, that (*d*) is taken care of in a more logical way. Some companies cannot afford to have a physician, or if they could, would not have a job interesting enough to attract the kind of physician who could fulfill the requirements. The Committee felt it was much better to have available within a matter of a few hours all the information which the physician using the drug might wish to have. With regard to (*b*), the Committee did not feel that it was practical to demand repetition of clinical trials. At present in Canada we do not have the facilities or personnel to carry out all the trials which are desirable. It is assumed that the first clinical trials were satisfactory and if the Food and Drug Directorate are assured that it is the same chemical and that the potency is equal and no impurities are present and that the prescription form is identical; adequate protection would seem to be provided for the public.

The Committee is greatly indebted to members of the Food and Drug Committee and Mr. Curran for their help. They are tremendously knowledgeable in this field and were most cooperative in giving their time and providing background information for us. The report is respectfully submitted and we all hope that the recommendations may be of some assistance to your department.

Sincerely yours,

Irwin M. Hilliard, M.D., F.R.C.P.(C)

REPORT TO THE MINISTER OF NATIONAL HEALTH AND WELFARE.

The Special Committee appointed by the Minister of National Health and Welfare has the honour to present its report.

On the 14th day of June, your Committee consisting of

Dr. Irwin Hilliard, Chairman,
Physician-in-Chief,
Toronto Western Hospital.

Dr. Charles Gowdey,
Head, Department of Pharmacology,
Western University, London, Ont.

and

Dr. Roger Gaudry,
Rector,
University of Montreal,

was constituted to examine and report on certain matters, involving patent licensing arrangements with respect to drugs.

The Committee met on June 24 and July 8 to consider the above and, in the course of their enquiry, have had the benefit of the views of the Commissioner of Patents and of officers of the Food and Drug Directorate which they found most helpful.

The problem of adequately protecting the public who are using increasing quantities of potent drugs is a constantly changing one. Many of the drugs currently available and much in demand were not even known when the laws re patents and compulsory licensing were formulated. Moreover, modern drugs are usualy potent and have important side effects, some predictable from animal tests and clinical trials, but some not predictable, and some not even recognized until many thousands of patients have taken the drug.

Very special legislation is necessary, not only because recent scientific and medical advances have made drugs so much more powerful and dangerous but also because the public at large is completely unable to realize some of the dangers inherent in the misuse of some of these products. Drugs, therefore, differ greatly from most other commercial products in this very important aspect of safety.

More and more drugs are being produced by synthetic processes of increasing complexity. Because of the number of steps involved and the need for proper care at each intermediate step, it has become essential that adequate quality control procedures be established and carried out at all levels of the manufacture or synthesis of the chemical involved. It is not sufficient any more to perform a simple test on a finished product. In many cases, such tests would not disclose the presence of potentially dangerous by-products or impurities or even chemical isomers which should be removed from the desired material if at all possible. Minor changes in process may perhaps lead to quite different contaminants in finished products and these contaminants may be toxic and may even be missed by routine chemical analysis.

Chemical producers with insufficient staff and technical facilities may either be unaware of or tend to ignore these problems, or may be unable to institute the necessary control procedures which will ensure a standardized product which is safe when used according to direction.

These safeguards have become necessary because over the past few years newer drugs have been discovered which are so active that they affect some of the very fundamental processes of life itself. This means that they must be administered under the most carefully controlled conditions by specialists who are aware that potentially serious side-effects are inseparable from and in many cases may be part of the desired therapeutic effect. It is therefore essential that the prescriber of such drugs be aware that side-effects are likely to occur and that dosages often need to be individually determined. He must also know what is to be done when these side-effects occur, or when an overdose has been taken.

Therefore any company manufacturing such a drug should always be able to provide complete informational material about the product to the medical and paramedical profession; maintain a complete up-to-date file on the properties of and clinical experience obtained with this drug; and be able to supply the necessary information very rapidly to any physician who needs it. This should be available in a matter of hours.

The three main responsibilities associated with the production and the marketing of a potent drug are:

(*a*) The responsibility of the chemical manufacturer to guarantee the utmost quality of the finished bulk chemical.

(*b*) the responsibility of the marketing company to be completely familiar with all the uses, effects and side-effects of such a drug and to make this information immediately available at all times to the prescribing physician who may require it.

(*c*) The responsibility of the Food and Drug Directorate to ensure that drugs be distributed only when they meet the specifications and standards for such products.

The Committee proposes the following recommendations to deal firstly with a drug in respect of which a compulsory licence under the Patent Act is involved and, secondly, where the holder of a drug patent or a person to whom a notice of compliance has been granted in respect of a drug, proposes to enter into a voluntary arrangement for the manufacture of that drug:

Compulsory Licence

Compulsory licensing for the production of a drug and its implications relevant to the protection of the public were discussed at some length. This subject of licensing was considered important as the Committee feels that patents are valuable in stimulating research and development in the field of drug therapy.

1. A compulsory licence for the preparation or production by chemical or fermentation processes of substances intended for subsequent use in medicines should not be granted unless there is first furnished to the Commissioner of

Patents a favourable report or certification by the Director of the Food and Drug Directorate on the competency of the applicant for such licence to manufacture or produce such substance, including adequacy of manufacturing facilities and controls as required by the Food and Drug Regulations.

2. The necessity for close collaboration between the Commissioner of Patents and the Food and Drug Directorate who are responsible for the safety of the finished product is obvious and the Committee were impressed with the willingness of the Commissioner of Patents to work closely with the Food and Drug Directorate.

Before a licensee to whom a compulsory licence has been issued or any manufacturer under that licence releases the drug in dosage form for sale or distribution

(*a*) he shall furnish to the Director of the Food and Drug Directorate a sample of such drug in dosage form and submit evidence that it has been manufactured in conformity with and meets the requirements of the Food and Drugs Act and Regulations.

(*b*) he shall also furnish to the Director copies of any labels and promotional literature proposed to be used in connection with the sale or distribution of the drug, and

(*c*) there shall have been an inspection of his premises and a report received by the Director indicating satisfactory compliance with the requirements of Section C.01.051 of the Food and Drug Regulations.

Voluntary Licence

In reviewing the number of compulsory licenses granted in the last 15 years (approximately 10) it became apparent to the Committee that another large area of concern should be the problem of voluntary arrangements made by the company holding the patent for the drug with other companies, sometimes possibly under threat of an application for a compulsory licence. Up to the present time the Food and Drug Directorate have not always had prior notification of such arrangements.

Whenever a person who is the holder of a drug patent or who is a person to whom a notice of compliance respecting a drug has been issued pursuant to the New Drug Regulations, enters into a voluntary arrangement with another person to manufacture or produce that drug in Canada, he shall first notify the Director of the Food and Drug Directorate giving the name of the proposed manufacturer, the name of the drug, and the address of the premises where such drug will be manufactured or produced.

A manufactureer of a drug pursuant to an arrangement as referred to in paragraph 3, shall, before releasing the drug in dosage form for sale or distribution, meet the requirements of paragraph 2, namely:

(*a*) furnish to the Food and Drug Directorate a sample of such drug in dosage form and submit evidence that it has been manufactured in conformity with and meets the requirements of the Food and Drug Act and Regulations, and

(b) submit copies of labels and promotional literature proposed to be used in connection with the sale or distribution of that drug, and

(c) submit evidence that an inspection has been made of his premises and a report received by the Director indicating satisfactory compliance with the requirements of Section C.01.051 of the Food and Drug Regulations.

New Drugs

The Committee felt that there was adequate protection of the public through the present regulations, with regard to new drugs. The following recommendations, however, were made to broaden the scope of the term:

That the definition of a new drug be amended to include a drug not currently in new drug status if it is to be manufactured or produced by a method or process that is substantially different from the method or process currently being used in Canada; or if with prolonged use, new or more serious or more frequent side effects, develop.

That if any drug, made subject to a compulsory licence or voluntary arrangement in the opinion of the Food and Drug Directorate or the Canadian Drug Advisory Committee or any sub-committee thereof, requires special manufacturing facilities or controls or further testing, which may include clinical testing, provision be made in the New Drug Regulations that it be dealt with as a new drug.

Availability of Information

7. While it would be desirable for a physician to have ready access to a responsible medical officer on the staff of a drug manufacturer, this may not be feasible or even necessary under all circumstances. The Committee feels that responsible manufacturers will use their best judgment in this regard but whether or not there is a duly qualified medical practitioner available, it recommends that no manufacturer shall market any drug unless he has available a product brochure containing complete information on the indications, contra-indications, precautions, dosage and side-effects, as well as a resume of the pharmacological and clinical studies carried out on that drug and that such prochure be furnished, on request, to any physician, dentist, veterinary surgeon or pharmacist registered and entitled to practise his profession in a province of Canada.

In studying the problem of compulsory licensing of drugs and voluntary agreements, the Committee noted certain other areas of general concern and would make three further recommendations.

Notification

8. That all drug manufacturers in Canada be required regularly to notify the Food and Drug Directorate of their name, address, names (trade and official) of their products, and any other pertinent information. (The Committee understood that this is already under consideration).

Identification

9. That companies marketing drugs use an identification mark on the finished product as well as recording the lot number on the container.

Imported Drugs

10. Distributors receiving bulk, semi-finished or finished drug products from outside Canada must provide satisfactory evidence of testing of the imported drug with regard to identity, purity, and potency before marketing such drugs in Canada.

Dated at Ottawa,
this 8th day of
July, 1965.

Respectfully submitted.

Roger Gaudry
Charles Gowdey
Irwin Hilliard
(*Chairman*)

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 5

TUESDAY, JUNE 21, 1966

THURSDAY, JUNE 23, 1966

WITNESSES:

From The Pharmaceutical Manufacturers Association of Canada: Dr. Wm. W. Wigle of Ottawa, President; Mr. Robert F. Daily, Chairman of the Board of Directors and Vice-President and General Manager, Smith Kline & French Inter-American Corporation; Mr. E. Glyde Gregory, Vice-Chairman of the Board and President, Ayerst Laboratories; Mr. Harry D. Cook, Immediate Past Chairman of the Board and President, Abbott Laboratories Ltd.; Dr. Peter C. Briant, Vice-Dean and Director, School of Commerce, McGill University; Dr. Arthur Grieve, Director of Quality Control, Ayerst Laboratories, all of Montreal; Mr. Gregory J. Gorman, Barrister; Mr. Gordon F. Henderson, Q.C., Patent Attorney, both of Ottawa; Mr. Peter Howsam, Vice-President and General Manager, Warner-Chilcott Laboratories; Mr. Fred R. Hume, Q.C., both of Toronto; Mr. Roger Larose, Vice-President, CIBA Company Limited, Dorval, Quebec; Dr. Brian Stewart, Director, Pharma-Research Canada Limited, Pointe-Claire, Quebec, and Mr. Guy Beauchemin, of Ottawa, Executive Secretary.

ROGER DUHAMEL, F.R.S.C.
QUEEN'S PRINTER AND CONTROLLER OF STATIONERY
OTTAWA, 1966

24630—1

DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

Vice-Chairman: Mr. Patrick T. Asselin (*Richmond-Wolfe*)

and

Mr. Brand,
Mr. Chatterton,
Mr. Clancy,
Mr. Côté (*Dorchester*),
Mr. Enns,
Mr. Howe (*Hamilton South*),
Mr. Howe (*Wellington-Huron*),
Mr. Hymmen,
Mr. Isabelle,
Mr. MacDonald (*Prince*),
Mr. Mackasey,
Mr. O'Keefe,
Mr. Olson,
Mr. Pascoe,
Mr. Prud'homme,
Mrs. Rideout,
Mr. Roxburgh,
Mr. Rynard,
Mr. Scott (*Danforth*),
Mr. Tardif,
Mr. Whelan,
Mr. Yanakis—24.

(Quorum 10)

Gabrielle Savard,
Clerk of the Committee.

NOTE: Mr. Scott (*Danforth*) replaced Mr. Orlikow on June 17; Mr. Roxburgh replaced Mr. Haidasz on June 20; Mr. Olson replaced Mr. Patterson on June 21.

ORDERS OF REFERENCE

FRIDAY, June 17, 1966.

Ordered,—That the name of Mr. Scott (*Danforth*) be substituted for that of Mr. Orlikow on the Special Committee on Drug Costs and Prices.

MONDAY, June 20, 1966.

Ordered,—That the quorum of the Standing Committee on Drug Costs and Prices be reduced from 13 to 10 Members.

Ordered,—That the name of Mr. Roxburgh be substituted for that of Mr. Haidasz on the Special Committee on Drug Costs and Prices.

TUESDAY, June 21, 1966.

Ordered,—That the name of Mr. Olson be substituted for that of Mr. Patterson on the Special Committee on Drug Costs and Prices.

Attest.

LÉON-J. RAYMOND,
The Clerk of the House.

24630—1½

REPORT TO THE HOUSE

FRIDAY, June 17, 1966.

The Special Committee on Drug Costs and Prices has the honour to present its

FIRST REPORT

Your Committee recommends that its quorum be reduced from 13 to 10 members.

Respectfully submitted,

HARRY C. HARLEY,
Chairman.

Concurred in Monday, June 20, 1966.

MINUTES OF PROCEEDINGS

TUESDAY, June 21, 1966.
(7)

The Special Committee on Drug Costs and Prices met this day at 11.15 a.m. the Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout, and Messrs. Brand, Clancy, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), Hymmen, Isabelle, Mackasey, O'Keefe, Prud'homme, Scott (*Danforth*), Whelan, Yanakis (14).

Also present: Mr. Lind, M.P.

In attendance: From The Pharmaceutical Manufacturers Association of Canada: Dr. Wm. W. Wigle of Ottawa, President; Mr. Robert F. Daily, Chairman of the Board of Directors and Vice President and General Manager, Smith Kline & French Inter-American Corporation; Mr. E. Glyde Gregory, Vice-Chairman of the Board and President, Ayerst Laboratories; Mr. Harry D. Cook, Immediate Past Chairman of the Board and President, Abbott Laboratories Ltd.; Dr. Peter C. Briant, Vice Dean and Director, School of Commerce, McGill University; Dr. Arthur Grieve, Director of Quality Control, Ayerst Laboratories, all of Montreal; Mr. Gregory J. Gorman, Barrister; Mr. Gordon F. Henderson Q.C., Patent Attorney, both of Ottawa; Mr. Peter Howsam, Vice-President and General Manager, Warner-Chilcott Laboratories; Mr. Fred R. Hume, Q.C., Barrister, both of Toronto; Mr. Roger Larose, Vice-President, CIBA Company Limited, Dorval, Quebec; Dr. Brian Stewart, Director, Pharma-Research Canada Limited, Pointe Claire, Quebec, and Mr. Guy Beauchemin, of Ottawa, Executive Secretary.

Also in attendance: Mr. W. J. Blakely, of Kingston, Accountant for the Committee; and Mr. A. M. Laidlaw, of Ottawa, Legal Counsel for the Committee.

The Committee resumed consideration of the submission presented by the Pharmaceutical Manufacturers Association of Canada.

The Chairman referred to a suggestion made to have the entire submission printed in the proceedings. After discussion, on motion of Mr. Howe (*Hamilton South*), seconded by Mr. Mackasey,

Agreed,—That the parts of the said submission which are not already appended to the proceedings of June 16, (Issue No. 4) be printed as part of the proceedings. (*See Appendix "A"*).

Dr. Briant tabled two documents with reference to questions asked by Dr. Howe (*Hamilton South*) at the previous meeting, dealing with comparative prices of drugs in Canada and U. K. Copies of these documents were distributed

to the Members and were ordered appended to today's Minutes of Proceedings together with the tables referred to by Dr. Howe. (*See Appendices 1, 2 and 3 to Minutes*).

With the use of a blackboard, Dr. Briant explained fully the figures appearing on the above documents. He was questioned as he went along. Other members of the delegation supplied additional information.

Mr. Laidlaw and Mr. Blakely also questioned the witnesses.

At 12.50 p.m. the Committee adjourned to 3.30 p.m.

AFTERNOON SITTING
(8)

The Special Committee on Drug Costs and Prices met at 3.45 p.m. this day. The Chairman, Mr. Harry C. Harley presided.

Members present: Messrs. Asselin (*Richmond-Wolfe*), Clancy, Harley, Isabelle, Mackasey, O'Keefe, Prud'homme, Scott (*Danforth*), Whelan, Yanakis (10).

In attendance: Same as at the morning sitting, also Mr. Gordon Allmark, Assistant Director Drugs, Food and Drug Directorate, Department of National Health and Welfare.

The Committee resumed consideration, section by section, of the submission of the Pharmaceutical Manufacturers Association of Canada. The delagates of the Association were questioned in relation thereto.

Mr. Laidlaw and Mr. Blakely also examined the witnesses.

Mr. Allmark supplied additional information concerning the Food and Drug Directorate.

At 5.45 p.m. the Committee adjourned to meet again at 8.00 p.m. this day.

EVENING SITTING
(9)

The Special Committee on Drug Costs and Prices met at 8.10 p.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Messrs. Asselin (*Richmond-Wolfe*), Clancy, Harley, Howe (*Hamilton South*), Isabelle, Mackasey, O'Keefe, Scott (*Danforth*), Whelan, Yanakis (10).

In attendance: Same as at morning and afternoon sittings.

The Committee resumed consideration of the submission of the Pharmaceutical Manufacturers Association of Canada, more particularly Section 2.

The delegates of the Association were further examined by the Members and by the Legal Counsel of the Committee.

At 9.45 p.m. the Committee adjourned to 3.30 p.m. Thursday, June 23, to consider Section 3 of the brief dealing with economics.

THURSDAY, June 23, 1966.
(10)

The Special Committee on Drug Costs and Prices met this day at 4.00 p.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout and Messrs. Asselin (*Richmond Wolfe*), Brand, Clancy, Harley, Howe (*Wellington-Huron*, Hymmen, MacDonald (*Prince*), Mackasey, O'Keefe, Rynard, (11).

In attendance: Mr. Robert F. Daily, Chairman of the PMAC Board of Directors and Vice-President and General Manager, Smith Kline and French Inter-American Corporation, Montreal; Mr. E. Glyde Gregory, Vice-Chairman, of the PMAC Board and President, Ayerst Laboratories, Montreal; Dr. William W. Wigle, of Ottawa, President of PMAC; Dr. Peter C. Briant, Vice Dean and Director, School of Commerce, McGill University, Montreal; Mr. Gregory J. Gorman, Barrister; Mr. Gordon F. Henderson, Q.C., Patent Attorney, both of Ottawa, Ontario; Mr. Peter Howsam, Vice-President and General Manager, Warner-Chilcott Laboratories, Toronto; Mr. Fred R. Hume, Q.C., Barrister, of Toronto; Mr. Roger Larose, Vice-President, CIBA Company Limited, Dorval, Quebec; Dr. Brian Stewart, Director, Pharma-Reasearch Canada Limited, Pointe-Claire, Quebec; Mr. Guy Beauchemin, of Ottawa, Executive Secretary of PMAC.

Also in attendance: Mr. W. J. Blakely, of Kingston, Accountant for the Committee; and Mr. A. M. Laidlaw, of Ottawa, Legal Counsel for the Committee.

The Committee resumed consideration of the submission presented by the Pharmaceutical Manufacturers Association of Canada.

Agreed that the questioning of the delegates of the Association by the Members of the Committee be restricted to a five minute period on a particular subject covered by the brief.

During the course of discussion, Mr. Beauchemin tabled, for the information of the Members, several publications containing scientific information which are essential to the intelligent prescribing of pharmaceutical products.

The delegates of the Association were examined.

At the conclusion of the questioning, Dr. Wigle expressed his appreciation to the Committee and made a short statement.

On behalf of the Committee, the chairman thanked Dr. Wigle and all the delegates of the Association for presenting a brief and giving further information to the Committee.

At 5.40 p.m. the Committee adjourned to 11.00 a.m. Tuesday, June 28, at which time the Canadian Medical Association will present its brief.

Gabrielle Savard,
Clerk of the Committee.

APPENDIX "1"

COMPARATIVE PRICES OF DRUGS IN CANADA AND UK

Price Sources:

"The Chemist and Druggist Quarterly Price List", March 1966, Morgan Bros. (Publishers), London.

"Price Book of Drug Store Merchandise", Dec. 1965, The Canadian Pharmaceutical Journal, Toronto.

Generic Name Sources:

"American Drug Index—1965", J. B. Lippincott, Philadelphia, Montreal.

"Pharmacological and Chemical Synonyms", Excerpta Medica Foundation, Amsterdam, London, New York.

"Vademecum International—1966", Cdn. edition, J. Morgan Jones, Montreal.

Exchange Rate Used:

£=$3.02 (Cdn.)

Currency Conversion Table Used:

S.	$ (CDN.)
1	.151
2	.302
3	.453
4	.604
5	.755
6	.906
7	1.057
8	1.208
9	1.359
10	1.51
11	1.661
12	1.812
13	1.963
14	2.114
15	2.265
16	2.416
17	2.567
18	2.718
19	2.869
20	3.02

P.	$ (CDN.)
1	.0126
2	.0252
3	.0377
4	.0503
5	.0629
6	.0755
7	.0881
8	.1006
9	.1132
10	.1258
11	.1384
12	.151

			19.58
Folvite Tabs.	Led.	C	10.38
Folvite Tabs.	"	E	.53

(Folic Acid Tabs. 5 mg #100)

			19.52
Folic Acid Tabs.	Lilly	C	10.35
Folic Acid Tabs.	"	E	.53

(Folic Acid Tabs. 5 mg #100)

			19.39
Rogitine Amps.	Ciba	C	35.10*
Rogitine Amps.	"	E	1.81

(Phentolamine Ciba 1 mil 5 mg #6)
*Cdn. price calc. from price /#3

			10.72
Dienoestrol Tabs.	BDH	C	8.90
Dienoestrol Tabs.	"	E	.83

(Dienoestrol Tabs. 5 mg #100)

			8.82
Soneryl Tabs.	Poul.	C	6.00
Soneryl Tabs.	PSMB	C	.68

(Butobarbitone Tabs. #100)

			8.33
Diethylstilboestrol Tabs.	Lilly	C	13.25
Stilboestrol Tabs.	BDH	E	1.59

(Diethylstilboestrol Tabs. 5 mg #500)

			7.85
Gardenal Tabs.	Poul.	C	3.85
Gardenal Tabs.	PSMB	E	.49

(Phenobarbital Tabs. .1 gm #100)

			6.92
Stilboestrol Tabs.	BDH	C	1.80
Stilboestrol Tabs.	"	E	.26
(Diethysltilboestrol Tabs. 1 mg #100)			
			6.81
Cerevon Tabs.	Calmic	C	3.00
Cerevon Tabs.	"	E	.44
(Ferrous Succinate 150 mg & Folic Acid 1.7 mg Tabs. #100)			
			6.67
Meticortelone Tabs.	Scher.	C	22.70
Prednisolone Tabs.	PD	E	3.40
(Prednisolone Tabs. 5 mg #100)			
			6.67
Meticorten Tabs.	Scher.	C	22.70
Prednisone Tabs.	PD	E	3.40
(Prednisone Tabs. 5 mg #100)			
			6.48
Radiostoleum Caps.	BDH	C	12.25
Radiostoleum Caps.	"	E	1.89
(Vitamin A with Vitamin D Caps. #500)			
			6.32
Sparine Tabs.	Wyeth	C	5.25
Sparine Tabs.	"	E	.83
(Promazine HCl Tabs. 25 mg #50)			
			5.61
Largactil Tabs.	Poul.	C	6.80
Largactil Tabs.	PSMB	E	1.21*

(Chlorpromazine Tabs. 10 mg. #100)
*Eng. price calc. from price/#50

			5.56
Delta Cortril Tabs.	Pfizer	C	22.70
Delta Cortril Tabs.	"	E	4.08

(Prednisolone Tabs. 5 mg #100)

			5.53
Dulcolax Tabs.	Geigy	C	2.60
Dulcolax Tabs.	"	E	.47

(Pyridylmethane Tabs. 5 mg # 30)

			5.29
Mellaril Tabs.	Sandoz	C	8.00
Melleril Tabs.	"	E	1.51*

(Thioridazine Tabs. 10 mg #100)
*Eng. price calc. from price/#50.

			5.20
Fersamal Tabs.	Glaxo	C	2.60
Fersamal Tabs.	"	E	.50

(Ferrous Fumarate Tabs. 200 mg #100)

			5.12
Haldrone Tabs.	Lilly	C	29.60
Haldrate Tabs.	"	E	5.78

(Paramethasone acetate Tabs. 2 mg #100)

			5.00
Fersolate Tabs.	Glaxo	C	1.35
Fersolate Tabs.	"	E	.27

(Compound Ferrous Sulphate Tabs. #100)

			4.88
Norflex Tabs.	Riker	C	24.00*
Norflex Tabs.	"	E	4.91

(Orphenadrine Citrate Tabs. 100 mg #100)
*Cdn. price calc. from price/#50)

			4.69
Medinal Tabs.	Scher.	C	4.60
Medinal Tabs.	"	E	.98

(Diethylmalonylurea Mono Sodium 5 gr. #100)

			4.68
Edrisal Tabs.	SKF	C	29.50*
Edrisal Tabs.	"	E	6.29

(Amphetamine Sulphate 2.5 mg, Phenacetin 2½ gr. & Acetylsalicylic Acid Tabs. #500)
*Cdn. price calc. from price/#250

			4.48
Disipal Tabs.	Riker	C	12.50
Disipal Tabs.	Camden	E	2.79

(Orphenedrine HCl Tabs. 50 mg #100)

			4.45
Amytal Tabs.	Lilly	C	2.85
Amytal Tabs.	"	E	.64

(Amobarbitol Sodium Tabs. 1½ gr. #100)

			4.41
Belladenal Tabs.	Sandoz	C	6.84
Belladenal Tabs.	"	E	1.55

(Bellafoline Tabs. #100)

			4.21
Pacatal Tabs.	Warner	C	10.50
Pacatal Tabs.	"	E	2.49

(Methyl Phenothiazine Chloride Tabs. 25 mg #100)

			4.16
Lanoxin Tabs.	BW	C	3.00
Lanoxin Tabs.	"	E	.72

(Digitalis Lunata Tabs. .25 mg #100)

			4.02
Digitaline Nativelle Tabs.	Welcker	C	3.50
Crystodigin Tabs.	Lilly	E	.87

(Digitoxin Tabs. .1 mg #100)

			3.97
Monodral Bromide Tabs.	WS	C	8.70
Monodral Bromide Tabs.	Bayer	E	2.19

(Penthianate Bromide Tabs. 5 mg #100)

			3.92
Progestoral Tabs	Org.	C	18.35
Progestoral Tabs.	Org.	E	4.67

(Ethisterone Tabs. 10 mg #100)

			3.87
Beplete Tabs.	Wyeth	C	4.50
Beplete Tabs.	"	E	1.16*

(Phenobarbital, Thiamine, Riboflavin, Pyridoxine etc. Tabs. #100)
*Eng. price calc. from price/#50.

			3.84
Parafon Tabs.	McNeil	C	12.20*
Parafon Tabs.	Ortho	E	3.17

(Chlorzoxazone 250 mg & acetaminophen 300 mg #100)
*Cdn. price calc. from price/#50

			3.78
Prostigmin Tabs.	Roche	C	34.30
Prostigmin Tabs.	"	E	9.06*

(Neostigmine Bromide Tabs. 15 mg #500)
*Eng. price calc. from price/#250.

			3.78
Phenergan Tabs.	Poul.	C	20.00
Phenergan Tabs.	PSMB	E	5.29

(Phenothiazine Tabs. 10 mg #500)

			3.77
Amoxal Gel.	SN	C	2.00
Amoxal Gel.	"	E	.53

(Amyloxybenzamide, Amyloxyacetophenone & Salicylic Acid Gel. 25 gm #1)

			3.75
Daraprim Tabs.	BW	C	2.25
Daraprim Tabs.	"	E	.60

(Pyrimethamine Tabs. 25 mg #30)

			3.71
Tuinal Pulv.	Lilly	C	4.50
Tuinal Pulv.	"	E	1.21

(Amobarbital Sodium & Secobarbital Sodium Pulv. 1½ gr #100)

			3.66
Eltroxin Tabs.	Glaxo	C	1.65
Eltroxin Tabs.	"	E	.45

(Laevo Thyroxine Sodium Tabs. .1 mg #100)

			3.64
Gelusil Tabs.	Warner	C	11.00
Gelusil Tabs.	"	E	3.02

(Aluminum Hydroxide Gel & Magnesium Trisilicate Tabs. #500)

			3.64
Paraflex Tabs.	McNeil	C	13.00*
Paraflex Tabs.	Ortho	E	3.57

(Chlorzoxazone Tabs. 250 mg #100)
*Cdn. price calc. from price/#50

			3.61
Ansolysen Tabs.	Poul.	C	6.00
Ansolysen Tabs.	PSMB	E	1.66*

(Pentolinium Tartrate Tabs. 40 mg #100)
*Eng. price calc. from price/#50.

			3.59
Rauwiloid Tabs.	Riker	C	6.25
Rauwiloid Tabs.	"	E	1.74

(Rauwolfia Serpentina Tabs. #60)

			3.47
Rarical Tabs.	Ortho	C	4.00
Rarical Tabs.	"	E	1.15

(Ferrous Calcium Citrate & Tricalcium Citrate Tabs. #100)

			3.46
Ergotrate Tabs.	Lilly	C	8.25
Ergotrate Tabs.	"	E	2.38

(Ergonovine Maleate Tabs. .2 mg #100)

			3.37
Equanil Wyseals	Wyeth	C	5.00
Equanil Wyseals	"	E	1.48*

(Meprobamate Wyseals 400 mg #50)
*Eng. Price calc. from price/#20.

			3.37
Mesantoin Tabs.	Sandoz	C	5.60
Mesontoin Tabs.	"	E	1.66

(Phenyl Hydantoin Tabs. #100)

			3.36
Furoxone Tabs.	Austin	C	6.50
Furoxone Tabs.	SKF	E	1.93

(Furazolidone Tabs. 100 mg #20)

			3.31
Pentoxylon Tabs.	Riker	C	6.50
Pentoxylon Tabs.	"	E	1.96

(Pentaerythritol Tetranitrate 10 mg & Rauwiloid .5 mg #100)

			3.28
Paludrin Tabs.	Ayerst	C	2.50
Paludrin Tabs.	ICI	E	.76

(Proguanil HCl. Tabs. .1 gm #100)

			3.28
Seconal Enseals	Lilly	C	5.45
Seconal Enseals	"	E	1.66

(Secobarbital Sodium Enseals 1½ gr #100)

			3.27
Betnesol Tabs.	Glaxo	C	15.50
Betnesol Tabs.	"	E	4.73

(Betamethasone 0.5 mg #100)

			3.20
Desbutal Caps.	Abbott	C	6.05
Desbutal Caps.	"	E	1.89

(Desoxyn 5 mg & Pentobarbital Sodium 30 mg #100)

			3.18
Panectyl Tabs.	Poul	C	4.20
Vallergan Tabs.	PSMB	E	1.32

(Trimeprazine Tabs. 10 mg #50)

			3.13
Butazolidin Tabs.	Geigy	C	25.00
Butazolidin Tabs.	"	E	7.97

(Phenylbutazone Tabs. 100 mg #250)

			3.10
Moditen Tabs.	Squibb	C	19.00
Moditen Tabs.	"	E	6.12

(Fluphenazine Dihydrocholoride Tabs. 1 mg #100)

			3.10
Miltown Tabs.	Horner	C	5.00
Miltown Tabs.	Wallace	E	1.66

(Meprobamate Tabs. 400 mg #50)

			3.01
Norgesic Tabs.	Riker	C	10.00
Norgesic Tabs.	"	E	3.32

(Orphenadrine Citrate 25 mg, Acetylsalicylic Acid 225 mg, Phenacetin 160 mg, Caffeine 30 mg. #100)

APPENDIX "2"

COMPARISON OF REAL COST OF CANADIAN AND U.K. DRUG PRICES

Product	Strength	Package Size	Canada ($ Cdn.) Price to Retailer	Canada ($ Cdn.) Price to Public	U.K. Price to Retailer £ =	U.K. Price to Retailer $ Cdn.	U.K. Price to Public £	U.K. Price to Public $ Cdn.	Comments
Achromycin	250 mg Caps	16	324	540+	15/16	234	23/3	351	
Chloromycetin	250 mg Caps	16	396	660+	12/5	188	18/8	282	Based on 9/4d and 14/- for P.S. of 12
Terramycin	250 mg Caps	16	417	695+	18/7	281	27/10½d	421	
Penbritin	250 mg Caps	16	537	895+	20/9	314	31/2d	471	Based on 26/- and 39/- for P.S. of 20
Gantrisin	500 mg Tabs	100	414	690	16/-	242	24/-	362	
Decadron	0.5 mg Tabs	100	1,194	1,990+	62/6	944	93/9	1,416	
Librium	10 mg Caps	100	720	1,200	20/-	302	30/-	453	
Equanil	400 mg Tabs	50	340	500+	7/2	108	9/9½	148	Based on 34/9 per doz. packages of 20 to retailer and on 8/11 per package of 20 to public
Stelazine	2 mg Tabs	50	375	625	16/4	247	24/6	370	U.K. price is 1mg tablets of P.S. 100
Ismelin	10 mg Tabs	100	433	650+	27/8	418	41/6	627	
Hydrodiuril	25 mg Tabs	100	312	520+	*29/7	447	42/10d	647	
Diuril	500 mg Tabs	100	438	730+	*32/-	483	48/-	725	
Peritrate	10 mg Tabs	100	250	375+	5/2	78	7/8	116	U.K. wholesale price for a doz. packages of 50 is 31/-d; 100=62/-; and one package of 100=5/2d; retail is 2×3/10d
Doriden	0.5 gm Tabs	100	397	595+	8/4	126	12/6	189	U.K. wholesale is 100/- a dozen; U.K. strength is 250mgm
Seconal	0.1 gm Tabs	100	285	475	5/-	76	7/6	113	
Pyribenzamin	0.5 gm Tabs	50	153	230+					
Banthine	0.05 gm Tabs	100	576	960+					
Cost of Basket of Drugs		(a)	$6,832	$11,140	297/- ($44.75)	4,488	443/- ($66.49)	6,691	
Labour Hours"		(b)	33.82	55.15	42.67	42.74	63.64	63.72	
Canada=100			100.00	100.00		126.37		115.53	

+Prices checked in 31st Edn (Dec 1965) Price Book = U.K. prices from the Chemist and Druggist Quarterly Price List

"b=line (a)÷$2.02 Cdn; & ÷ 1.05 U.K.; also÷6.96s U.K.

*U.K. prices obtained from PMAC source

Hourly Rates in Manufacturing

	£'s	Canadian $'s
Canada	—	2.02
U.K.	6/11½d (=6.96s)	1.05

APPENDIX "3"

COST OF INDIVIDUAL DRUGS IN LABOUR HOURS

CANADA AND U.K.

Product	Cost to Retailer		U.K. Index (Canada = 100)	Cost to Public		U.K. Index (Canada = 100)
	Canada	U.K.		Canada	U.K.	
Achromycin	1.60	2.23	139.4	2.67	3.34	125.1
Chloromycetin	1.96	1.79	91.3	3.27	2.69	82.3
Terramycin	2.06	2.68	130.1	3.44	4.00	116.3
Penbritin	2.66	2.99	112.4	4.43	4.49	101.4
Gantrisin	2.05	2.30	112.1	3.42	3.45	100.9
Decadron	5.91	8.99	152.1	9.85	13.49	137.0
Librium	3.56	2.88	80.9	5.94	4.31	72.6
Equanil	1.68	1.03	61.3	2.48	1.41	56.9
Stelazine	1.86	2.35	126.3	3.09	3.52	113.9
Ismelin	2.14	3.98	186.0	3.22	5.97	185.4
Hydrodiuril	1.54	4.26	276.6	2.57	6.16	239.7
Diuril	2.17	4.60	212.0	3.61	6.90	191.1
Peritrate	1.24	0.74	59.7	1.86	1.10	59.1
Doriden	1.97	1.20	60.9	2.95	1.80	61.0
Seconal	1.41	0.72	51.1	2.35	1.08	46.0
Pyribenzamin	0.76			1.14		
Banthine	2.85			4.75		
Average Index	100.0		123.48	100.0		112.58

24630—2½

EVIDENCE

(Recorded by Electronic Apparatus)

TUESDAY, 21 June 1966.

• (11.00 a.m.)

The CHAIRMAN: Ladies and gentlemen I see a quorum present.

The Pharmaceutical Manufacturers Association, the people who are presenting the brief today, have requested that we consider printing their whole brief as part of the record, with the appendices. They feel that to print only part of it, is not really representative of their whole submission. This is open to the committee. As you remember, we authorized the printing last week of the summary of their presentation plus the appendix dealing with the Hilliard Report and, I think, four sections automatically became part of the minutes because Dr. Wigle read them into the record.

Mr. MACKASEY: Mr. Chairman, I think the argument against the whole report at the time was that it would hold up the printing. Possibly we could do it some other way. It does not have to be appended to the very first minutes of proceedings.

The CHAIRMAN: It was because of the length of time for printing all the reports these days. We are going to wait so long anyway I do not think we should consider the time because the reports of all the committees are very slow in being printed.

Mr. FRED R. HUME, Q.C. (*Barrister, Hume, Martin & Allen, Toronto*): May I just point out to the committee sir, on behalf of the association that at the time of our previous submission on safety the committee did decide to print all the brief. It was quite a considerable one and the importance felt at that time was that there are people in other places who are following with interest the proceedings of this committee and they would have the benefit of that. It is our understanding that this was appreciated by those who buy the proceedings and we therefore felt after your decision last Tuesday, in rediscussing the matter that there are other people who might be interested in having the entire submission. That was our reason.

Mr. HOWE (*Hamilton South*): What about establishing a precedence, Mr. Chairman, for all the other briefs that are going to be submitted by other groups. Will this not get out of hand?

The CHAIRMAN: I would think that probably most of the other briefs, certainly any of the ones that I have seen, are not as voluminous or as complete as this one. It is just a question of volume, I think.

• (11.15 a.m.)

Mr. SCOTT: Well, I was concerned about Mr. Howe's point. On so many of the committees the briefs coming in are almost like Gone With The Wind in size and if you start printing all of them the printing bureau is going to break down.

Mr. MACKASEY: On the other hand, Mr. Chairman, we must be fair to the Pharmaceutical Manufacturers Association; if we only take extracts it may only give part of a picture, distorted perhaps, in their opinion.

Mr. WIGLE: Well, our concern, Mr. Chairman, is that this is the total presentation and any portion just picked out of it at random or serveral sections of it might not give the presentation that we think, as a book of reference, these hearings might eventually become.

Mr. HOWE (*Hamilton South*): I will so move, Mr. Chairman, so we can get a vote on it.

The CHAIRMAN: Is there a seconder for the motion that the entire presentation presented be printed as part of a proceedings—that is, the part that has not already been printed.

Mr. MACKASEY: I will second that, Mr. Chairman.

The CHAIRMAN: Any further discussion on this?

It has been moved by Mr. Howe (*Hamilton South*), seconded by Mr. Mackasey,

> That the parts of the submission by the Pharmaceutical Manufacturers Association of Canada, which are not already appended to the proceedings of June 16, be printed as part of the proceedings.

Motion agreed to.

The CHAIRMAN: Gentlemen, we are going on with the first four sections which have already been presented. As you are well aware there is some difficulty here in trying to separate one section from the other but we are trying to keep to this as much as possible. I wonder if it would meet with the approval of the committee to allow our counsel to ask several questions this morning first, and then the committee members will take on from there. Is there any objection to the counsel asking several questions?

Before we proceed with that, there were several questions put to the manufacturers association last week. Would you like to hear the answers to these questions first before we proceed with today's evidence.

Mr. HOWE (*Hamilton South*): Could we follow up on those prior to our counsel proceeding.

The CHAIRMAN: Fine, that sounds reasonable. There were two different matters, I think both related. First of all, I think, there was Mr. Howe's question about the conversion from English to Canadian labour hours, as I remember it.

Mr. WIGLE: That is right, Mr. Chairman and the other one was the differential in different countries. Professor Briant has prepared an explanation of this if the committee would care to hear him.

Dr. PETER C. BRIANT (*Vice Dean and Director, School of Commerce, McGill University*): I think I will stand up Mr. Chairman as this will take me a little while. Mr. Howe gave me his list of prices of 58 drugs and he gave me his two price books, one for British prices and one for Canadian prices. He also gave me a busy weekend I might say.

The CHAIRMAN: All of which is gratefully acknowledged.

Dr. BRIANT: I checked through some of the prices. I think that is understandable and I confirmed the correctness of the prices he has in his list of 58 drugs. Then I took prices from Mr. Howe's price list and applied them to the 17 selected products comprising appendix F in the association's brief. I have some

hand-outs arising from that; could I have the hand-outs, Mr. Howsam? I would like to table one of these, Mr. Chairman, with the committee and pass the rest around. There are two separate sheets. Would you please see that everybody gets one of each. If I may, I will come up to the front because I should like to make use of the board. Will you be able to pick up what I say? I will be speaking in a fairly loud voice. There are two minor corrections. The typist did not have the sign for British pounds so on the legal size paper in the column marked U.K. there is a dash and an equal sign in the first column, and that should have a pound sign above it. Then the second column has dollars Canadian and the next column should then have a pound sign above it because the prices in the first and third columns under the U.K. are British pounds. Does everybody have a copy of this now? We had fifty run off. We felt that would be enough.

The 17 drugs listed on the legal size sheet are the 17 drugs in the appendix of the association's submission, the same strength and the same package sizes. Looking at where it says, "price to the public" with $5.40, $6.60 and so on they have little plus signs against them. Those items I checked in one of Mr. Howe's price books, the 31st edition, December, 1965 price book, and the prices we used checked out. The ones that are not marked did not appear in the price list, hence, I was not able to check those, but I think we can safely assume that since the bulk are exactly the same as we used the others are probably correct as well. Then under the U.K., I went through the U.K. price list, picked out the U.K. price for equivalent when the equivalent was available. There are some problems in the U.K. price book, as Dr. Howe probably knows: at times, they have a price for a dozen of 100s, package of 100, and so on. The comments in the righthand column I do not need to review, but they indicate where I made some adjustments to the price given for differences in package sizes in the U.K. Now, on working through these, I assumed that a consumer bought a basket of 15 of these drugs, fifteen because pyribenzamin and banthine had no price in the U.K. price book. I presume that the British public are deprived of access to those drugs because they are not in their price book anywhere. So, taking 15, the Canadian would pay $68.32 for his basket of drugs—that is the cost to the retailer. The cost to the public, which Mr. Howe told me he was particularly interested in, and this is understandable, would be $111.40. The U.K. price to the retailer is a total of 297 shillings, which converted at Mr. Howe's exchange rate of one pound equals $3.024475—

Mr. HOWE (*Hamilton South*): That is not my exchange.

Dr. BRIANT: Well the one in your list there, because I has used $3 previously. But, on that basis, the price to the retailer in Canadian dollars is $44.88, and the difference of 13 cents is purely because of rounding in the individual items. Then, similarly, the price to the U.K. public, 443 shillings or $66.49, and taking the converted Canadian dollar total, $66.91. Then the next row shows labour hours. Converting on a labour hour basis the price to the retailer works out to 33.82 labour hours and the price to the public for drugs in Canada 55.15 and the U.K. price to the retailer, reading the second column, 44.724 hours, which is more than the Canadian labour hours figure, and the price to the public in the U.K., 63.72 hours. So converting the Canadian figures to an index of 100 we find that for the 17 products in the association's list, the 15 out of 17 that we can compare, we get U.K. relative indices of 126.37 and

115.53. So, for those 17 products our original position was substantially correct on the basis of the figures; in fact, very correct because we had 129.40 using the $3 to the pound exchange rate, and using the $3.02 and 15 drugs we get 126.37. I had actually worked out before the price to the consumer in the U.K. and had a figure of 117.75. We get 115.53 with those price lists. So, the first point is that our original calculations for those 17 drugs stand up under the application of prices in the price lists which were made available at the last meeting of this committee. The second hand-out is not of such importance but it takes the individual drugs through the cost to the retailer and the cost to the public, showing Canada and the U.K. in terms of labour hours, working out a U.K. index in both cases. We find we had a mixture there, some of the drugs, in fact, six of our drugs have a lower labour hour cost in the U.K. on the price to the retailer, and nine of them had a higher cost. Similarly, for the price to the public, six of our drugs had a lower cost in the U.K. in terms of labour hours and nine of them had a higher cost. So it represented, as we had said last time we thought it was, a fairly balanced selection of drugs.

Now, so far as market data are concerned, I mentioned last time that the 17 drugs on the association's list had a manufacturers' sales value in 1965 of $14,527,000. I will just put that down on the board. I will just put 17D—$14,-527,000. That represent 8½ per cent of the total sales in the Canadian market. Mr. Howe's 58 drugs had aggregate sales in Canada in 1956 at manufacturers' selling prices of $7,135,273. There might be 50 cents on the end but I left that out. That is 4.16 per cent of the total Canadian market. So, the 58 drugs in the aggregate represent a substantially smaller dollar volume than the 17 drugs we had picked. I had said last time we had picked drugs which were the largest selling drugs in their therapeutic categories. On further analyzing Mr. Howe's list I found that only 16 of them had annual sales in 1965 of over $100,000. If we subtract 16 of the largest selling drugs in the list from the $7,135,273 (the actual sales in 1965 were $6,263,000 for sixteen of the 58 drugs) that meant that 42 of the drugs on the list had sales in total in 1965 of $872,000. That is approximately $20,000 total sales for each drug. We had 17 drugs, and their average sales were $850,000 a year. Sixteen of the drugs on the list tabled by Mr. Howe have sales of $6,263,000. That is about $400,000 a year. But, 42 of them are very small selling items, $20,000 a year each, so small I would doubt that it would be profitable for any one to import them and certainly it would not be profitable for an importer to import those 42 drugs and try market them with the high cost of marketing conditions in Canada.

• (11.30 a.m.)

Now, I did some other things as well. With the same index I took the 58 drugs and said, "All right, what happens if a Canadian buys the whole basket of the 58 drugs and what would the price be in comparison to the U.K. price?" Now, the total of the 58 drugs would be, with the prices given, $599.72 in Canada and $130.05 in the U.K. If we apply our regular wage rates of $2.02 in Canada,—I admit I am applying the 1964 wage rate for 1965 prices but it indicates the general picture well enough—and $1.05 in the U.K. we get in terms of labour hours 296.9 for Canada and 123.9 hours for the United Kingdom. Going back to index, we have the Canadian index of 100 and the U.K. index of 41.7. So from that point of view there is no doubt that these drugs can be acquired in the U.K. at cost in terms of labour hours lower than the acquisition

would be for the same drugs in Canada, but subject, of course, to the previous qualification that 42 of them are very small volume items.

Now I decided, and this is statistically reasonable, that I could obtain a comparable index of the 75 drugs, combining the 58 in one list with the 17 in another list and weighting the index relatives by the relative market shares. So these are the calculations that we get: for Canada, market share or 8.5 per cent of the total market for the 17 drugs used by the Association. The 58 drugs represent 4.2 per cent of the market. We have to give a relative weight, knowing that one group of drugs has a greater market importance than the other. The calculations give us automatically Canada, 100. For the U.K., we get 8.5 over 12.7 times 115.53 which is the index given on the large hand-out sheet for the U.K. price to the public, the very last column, and 4.2 over 12.7 times 41.7 which is the index that I found here for the 58 drugs. That gives 77.24 for the large hand-out and 13.80 for Mr. Howe's list, for a total of 91.04. So blending the two lists does show a U.K. labour cost index of 91.04 which is somewhat lower than the Canadian cost, but a difference which is very much less than the 58 drugs on Mr. Howe's list, and this is the U.K. price to the public. We are concerned here, in the Association, particularly with how the manufacturers prices compare in the two countries. It works out if you look at these lists and hand-out one again, that U.K. prices to the retailers have an index of 126.37. Prices to the public have an index of 115.55 because the percentage mark up by the pharmacist in the U.K. is quite a bit less than in Canada, so U.K. manufacturing prices do not compare as favourably to Canada's or the comparison is more unfavourable—let us put it that way—for U.K. manufacturers' prices than for prices to the public. Therefore, we should add 10 per cent to this figure to adjust to the relative manufacturers' price. So, if we add 10 per cent, 9.1, we get for the entire 75 drugs on the list an index in the U.K. of 100.14.

Mr. MACKASEY: What does that 10 per cent represent?

Dr. BRIANT: This represents an adjustment we have to make to the index of the U.K. price to the retailer and labour hours because their price to the retailer compares more favourably than their manufacturers price because the profit margin by the drug stores in the U.K. is lower than it is in Canada.

Mr. MACKASEY: How much?

Dr. BRIANT: It is a 33⅓ per cent mark up as against 40 per cent. There is therefore a 10 per cent difference whenever you do this between the index of manufacturers' labour hour cost and the index of retail labour cost. The U.K. manufacturers prices have to be increased by about 10 per cent to bring them to a comparative basis with Canada. If we adjust this index by 10 per cent this gives us an index for the price to the retailer, not the price to the public; that is, the manuacturers selling price in the U.K. relative to Canada, and it is an index of 100.14. So that for the 75 drugs combining the two lists, including the 42 low volume items, again, I would suggest nobody would really want to import as they are such low volume items, the Canadian prices and the U.K. prices are just about the same at the manufacturers level. Did you have a question Mr. Mackasey?

Mr. MACKASEY: Well I am interested in the manufacturing. In your investigation of the English system did you note whether they have any equivalent, in your calculation, of our 11 per cent sales tax?

Dr. BRIANT: No. Some British drugs have purchase taxes on them but it varies; some do and some do not.

Mr. MACKASEY: I mean at the manufacturing level.

Dr. BRIANT: Not to my knowledge.

Mr. MACKASEY: Now in your calculations have you taken the price before or after sales tax?

Dr. BRIANT: We have the price including sales tax in Canada.

Mr. MACKASEY: I know you have it in Canada but in your calculations do you have it before or after?

Dr. BRIANT: For the U.K.?

Mr. MACKASEY: No, for Canada.

Dr. BRIANT: Sales tax included.

Mr. MACKASEY: Why?

Dr. BRIANT: Because it would take all week to go through and do it without the sales tax; all the prices were included with it. But Mr. Mackasey you make a point that if the sales tax were excluded then U.K. prices would compare even more unfavourably with our prices.

Mr. MACKASEY: You said it. We will evaluate the figures after to ascertain whether they are gospel truth or not but I would imagine if I was representing the manufacturer and trying to make the picture as favourable as possible I would not be sheltering the federal sales tax which I happen to have a bias against. This is obviously what you are doing.

Dr. WIGLE: Mr. Chairman, in defence of our consulting economist I think he has tried to give a factual picture of what drugs cost in Canada at the present time. We have a recommendation that the federal sales tax be removed but we did not think that was pertinent to the presentation of what we see as a factual picture of the drug costs.

The CHAIRMAN: Before we continue I think it would be useful to have the two papers on which Dr. Briant's testimony is based printed as part of today's record. Is everyone in agreement?

Some hon. MEMBERS: Agreed.

Mr. HOWE (*Hamilton South*): Mr. Chairman, I would like to commend the gentleman for the homework he did on the weekend. I am sorry I subjected him to so much mathematics which is more or less over my head, shall we say, for the moment. Maybe I ought to do some homework. You said that you included the low volume drugs but you also made allowances in that last line, as I understand it, for the fact that this is a low volume drug sale in your 4.2 over 12.7?

Dr. BRIANT: Oh yes.

Mr. HOWE (*Hamilton South*): You made full allowance for that. You mentioned it afterwards as if this was an extra but you made this allowance figure?

Dr. BRIANT: Yes. I will explain why I think the prices on those particular drugs in Britain compare so favourably with the price in Canada. I am about half way through if you will bear with me. It might be that the questions you have will be answered as I go along.

Mr. HOWE (*Hamilton South*): May I just ask one thing that has direct relation. Are these hourly rates of manufacture just a figure we must accept?

Dr. BRIANT: Well you could check it.

Mr. HOWE (*Hamilton South*): I do not mean it in that sense but this is something you have actual facts on to confirm the actual manufacturing. This is a manufacturing rate; it is not a labour differential. There is not this much of a labour differential of $2.02 on $1.05 between here and Britain, or is there?

Dr. BRIANT: Yes, I would suggest there is.

Mr. HOWE (*Hamilton South*): Straight labour, the average hourly labour rate?

Dr. BRIANT: I will take that up again after I go back to my desk, as I shall at the end, if I could leave it to then. I got into some correspondence with the U.K. just about the correct rate used for the U.K.—

Mr. HOWE (*Hamilton South*): I have just this one question and I will let you go on. This being the case, if this is allowing for labour—in your own breakdown on manufacturers cost labour is only 1½ cents of that 37½ cents—why does it play such a big factor here?

Dr. BRIANT: Oh, well the $2.02 that we use for Canada has no relationship whatsoever to the 1½ cents labour costs in the manufacturers sales dollar. The $2.02 is the average hourly earning in manufacturing in Canada and we are saying that we take an average Canadian who earns $2.02 an hour for this analysis. Then we have a basket of drugs that cost so many dollars; thus we are taking so many hours of their labour to buy the drugs.

Mr. HOWE (*Hamilton South*): I am sorry, I understand.

Mr. MACKASEY: Why do you not work it out into percentage of his take home pay. This would have saved a lot of confusion, would it not? What you are saying is that the average Canadian working a 40 hour week has an $80 a week income. The average person in England has a $40 income. Therefore a smaller portion of the $80 goes to drugs than the man who has $40.

Dr. BRIANT: That is another way of looking at it.

Mr. HYMMEN: Mr. Chairman, one point for clarification. I understand where the 17 drugs come from. They are representative drugs in your brief. But, where did Dr. Howe's 58 drugs come from, and are there any duplication in these two lists?

Dr. BRIANT: No, there is no duplication in the two lists. Dr. Howe has a black book there, perhaps he can assist you.

Mr. HOWE (*Hamilton South*): Mine were specifically selected drugs to show this differential.

The CHAIRMAN: Selected by Mr. Howe?

Mr. HOWE (*Hamilton South*): Selected by myself.

Mr. HYMMEN: I have another question. Should this list of Dr. Howe's drugs not be tabled as well?

Dr. BRIANT: I believe Dr. Howe offered to table them.

Mr. HOWE (*Hamilton South*): That was where it stood, I offered to table them.

The CHAIRMAN: I think perhaps as we are discussing the 58 drugs, Mr. Hymmen's point is well taken. As they were not tabled perhaps you could provide the list.

Mr. HOWE (*Hamilton South*): I will table them. I was quite willing to do so.

The CHAIRMAN: We will print them as an appendix with these other two pieces of paper.

Dr. BRIANT: Then to carry on with the figure work for just for one brief spell. I took the 16 drugs which I said were in Dr. Howe's list and selling at $100,000 a year or more in Canada. These are the significant drugs in the list—the other 42, I think it is agreed, were not really significant drugs; now, I worked out the very same thing. Sixteen drugs—

Mr. PRUD'HOMME: You are sure that everything would be registered?

The CHAIRMAN: He is taking it up to date.

Dr. BRIANT: I took the 16 drugs, the significant sellers on the list and worked out the composite index for our 17 plus the 16, omitting the other 42 unimportant items. A consumer who bought these 16 drugs in Canada would spend $153.75 and in the U.K. $38.72. In dollar terms again it seems a substantial difference. Using the wage rate of $2.02 once again and $1.05 we get comparative labour hours of—

Mr. MACKASEY: Is this before the Seaway strike?

Dr. BRIANT: That is right. The number of hours provided for the change would undoubtedly be lower today than if they were based on wage rates of a year ago. Those figures are 76.1 and 36.9 again this is dividing the total cost by $2.02. If you earn $2.02 an hour as an average Canadian wage earner and you wanted to buy all 16 drugs in the quantities given that would be $153.75 so you have worked 76.1 hours. In the U.K. the figure is 36.9 hours, the index is 48.4 points which is higher than the index of 41.7 for the 58 drugs. So the larger selling drugs in the U.K. have quite a higher price relative to Canadian prices for same drugs.

Mr. MACKASEY: Could you turn back to the last line?

Dr. BRIANT: The 16 drugs in the U.K. have a higher price relative to the same drugs in Canada than the 42 small selling drugs have, so they tended to weight the sample, not in terms of actual dollar volume but in just looking at the relative prices they weighted the sample.

Mr. MACKASEY: Before you go any further, if I may. The $153.75 in Canadian money and $38.72 in Canadian is then divided by the income per hour of each person?

Dr. BRIANT: Right.

Mr. MACKASEY: We find the average Canadian would have to work 76 hours to buy the 16 drugs. The average person in Britain would have to work approximately 37 hours. Now where does the index come in?

Dr. BRIANT: If we call Canadian 100. Call 76.1 equal to 100, we have 36.9 equals 48.4 which we obtain when we divided 36.9 by 76.1.

Mr. MACKASEY: I know how you get it but what is the significance of it?

Dr. BRIANT: What is the significance?

Mr. MACKASEY: Yes.

Dr. BRIANT: Well, when I flip over the page you will see how we can use that as we did before.

An hon. MEMBER: And the 41.7?

Dr. BRIANT: That is for the 58 drugs. I wanted to demonstrate here that the 42 low volume drugs tended to pull the relative index down. I do not say deliberately, but the fact is that they do. I am working this out with statistical objectivity.

Now I had mentioned that the 16 drugs represent about 3.72 per cent of the total Canadian market for 1965. I had previously mentioned that the Association's 17 drugs represented 8.5 per cent. So, together the 33 drugs account for 12.22 per cent of the market. We can apply the two indices in the U.K. for the 17 and 16 and weight by the relative market shares and come up with another composite index. So U.K. index—Canada's will be 100—8.5 over 12.22 times 115.53, which is on the legal sized sheet. 80.1 is its contribution to the composite index and 3.72 over 12.22 times 48.4, which was the index here (indicating)—we said that relative to Canada they have an index figure of 14.8, so that for the 33 drugs, taking Canada as 100, the U.K. index and labour hour cost is 94.9. But once again we should add 10 per cent to bring up to a comparative manufacturers selling price in the U.K. because we know, as I mentioned, that the U.K. retail prices tend to compare less unfavourably with Canadian prices than do the manufacturers prices. So we add 10 per cent, 9.5, and we get 104.4 as the U.K. manufacturers composite index. So we find for the 33 large selling drugs on both lists that the U.K. manufacturers price in labour hours is 4.4 per cent higher than the labour cost in Canada. I can leave this up. It merits careful thought and study.

Mr. HOWE (*Hamilton South*): You are not working on a basis that if you cannot convince then confuse?

Dr. BRIANT: No, sir, this is statistical logic. Now may I just enlarge on the basis of these figures. The argument is, as I understand it, that we should import, so far as possible, trade marked drugs from other countries when prices in other countries are lower than prices in Canada. I think recommendation No. 70 of the Hall Commission report relates to this, that the Trade Marks Act

should be amended to make sure there is no infringement if trade mark drugs are imported.

I previously brought up the question. I frankly do not know the answer but I suspect I know the answer. Would anybody want to import drugs with a sales volume in Canada of only $20,000 a year, perhaps only $10,000 in the unlikely event that the Canadian manufacturer continued to carry that particular product in his line? The more so because these small selling items are not profitable drugs for them to carry but they have to carry them to provide a full range of products to the Canadian consumer.

The second point is that the importation argument overlooks the importance of field testing of drugs and the importance of quality control. I would like to read something from a memorandum I once wrote on this: "such a procedure would have a highly detrimental effect on the present system for providing Canadians with prescription drugs in which doctors and patients alike can have full confidence. It would serve as an umbrella for the less scrupulous importers. It is doubtful whether any importers would follow the careful control of expiry dates and the related return policy maintained by a reputable company established in this country. Further, they would not have available the extensive background of scientific knowledge which is always at the disposal of the medical profession, pharmacy and government. Whether they would disseminate full prescribing information about the product with the energy practiced by the trade mark holder is also open to doubt. In all this recommendation would introduce several sources of insecurity into the complex machinery required to provide Canadians with prescription drugs".

The third problem would be the shipping problem. The longshoremen's strike and the Air Canada threatened strike and so on should remind us of how dangerous it would be if we were to be completely dependent on the importation of drugs from other countries. This would be particularly so in the case of a large scale epidemic, for example, when we had no Canadian producer carrying the line of drugs because importers had taken over the market from him.

Fourth, importation overlooks the need for a manufacturer to carry a balanced line of products. I would suggest if the domestic manufacturer were to drop these products, which would probably happen if the market were thrown open to imports, then the prices of the remaining products in his line, which compare as we have shown in our brief and as you have seen the large selling items compare very favourably on a real cost basis with prices in the U.K., then the prices of these products would undoubtedly increase because the manufacturer would have extra capacity in his manufacturing and in his distribution.

Fifth, my guess is that the importers of the small scale items and of some of the larger scale, would eventually be the only company in the field in Canada; we would not have a Canadian producer of many of the drugs now on the market. We would be exposing ourselves to the danger of monopoly by foreigners. One case I heard of from a man in the textile field illustrates what can happen. This is the case of Japanese fishing nets. When, apparently, the market was thrown open to Japanese importers of fishing nets there was one Candian producer, many Japanese exporters and they drove the domestic price down until the Canadian producer left the market because he could not afford to stay in the market. Having driven out the Canadian producer the Japanese, in effect, either deliberately or just the way things happened, ganged up on us

and left the field to one Japanese exporter who then promptly raised the price of fishing nets way above their preceding level because he was the only person in Canada making fishing nets available to the people who buy fishing nets. The very same thing could happen I think if we opened the market to the importation of branded products from other countries and allowed them to be sold at lower prices. Now the effect of this, of course, would be to kill the investment in the industry in Canada, in the pharmaceutical industry in Canada, and it would eliminate most of the jobs held now by about 10,000 Canadians in this industry. And the benefits, as we can see, would be extremely slight because the low price drugs are not the major consumption drugs on the market. So we come to the question, which is more important, importing or finding ways to increase investment in Canada and the growth of the pharmaceutical manufacturing industry in Canada?

• (12.00 noon)

The argument that we should import drugs from France, the U.K. and anywhere else from which they can be obtained at lower prices is derived from the doctrine of comparative advantage in economics. Economically, in theory, the doctrine is absolutely inviolable but in practice when we try to relate such a doctrine to the world in which we live we find we have to modify the economics by non-economic sociological factors such as maintaining diversified occupational opportunities for our citizens. This, I know, is a favourite doctrine of many of my university colleagues. There was one on TV the night before the last hearing of this committee. On the program, he distinguished between the quantity and quality of Canadian life and said we are much too concerned with the quantity of Canadian life, too concerned with having as many industries as possible and as diversified domestically produced products as possible. We should be concerned, so he argued, with the quality of our life, and by that he meant that we should concentrate on those products and the production of those products and those goods in which we have a comparative advantage. Now the end consequence of what he was telling the Canadian people on television that night would be that we would return to being hewers of wood and drawers of water because where we have a comparative advantage in this country is in the production of wheat farming, in the development of our natural resources and in acting as guides for the tourist industry. But, I am sure there are many of us here who would say, if those are the only job opportunities that are going to be available to us, "I do not want you to organize the economy on the basis of the doctrine of comparative advantage; I like to work in the production and distribution of pharmaceuticals, or I like to produce automobiles or refrigerators or all kinds of things that people do that they would rather do than just being hewers of wood and drawers of water." This is a very fundamental policy question that has to be resolved in Canada. There is a price for building up secondary industries. There is an economic price. We probably do not have, strangely enough, as high a national income per capita as we would have if we were just to restrict ourselves to the things that we do best. But my guess would be, if we could ask all the workers in this country, that they would say they would rather pay this economic price, because it is not a very high price, in order to have a wide range of jobs available of this type, because this is an area of human freedom as well, and we cannot be solely concerned with maximizing our income per capita if in the process it means a loss of some of our freedom of job selection. Now, if I may, I should like to return to Dr. Howe's list to make a point about the 42 products that—

Mr. WHELAN: May we ask a question as the doctor goes along? Am I understanding right that you are suggesting the drug industry should be protected by import quotas and so on?

Dr. BRIANT: I am suggesting here that recommendation 70 of the Hall Commission report, which really lies at the basis of the argument that we should bring in products from the U.K. and sell them under their Canadian trade mark because they are bought from manufacturers who are related to the Canadian manufacturers, if enacted would lead to a decline in investment in the pharmaceutical industry in Canada and that the benefits of importing these drugs would be minimal because so many of the drugs that are very low in price relative to Canada are not major items in drug expenditures in Canada. When we compare the 33 drugs, the 17 we supplied and the 16 Dr. Howe supplied, and when we take these 33 that are fairly significant items in the market we find that our real cost in labour hours compares favourably to the U.K. cost even though in the U.K. they have a national health scheme and very tight control over prices.

Mr. WHELAN: I just want to ask one further question. You made a comparison to agriculture. I only wish that the agriculture producers of this nation and the importers of agricultural products were under some control. They have no permit at all. They have ruined many agricultural industries here by their very actions and there does not seem to be any great urge by the consumers of Canada to stop this because they get cheaper foodstuffs from other countries that produce their foodstuffs by slave labour.

Mr. HOWE (*Hamilton South*): Mr. Chairman, when costs are actual how can you make allowance for labour differential?

Dr. BRIANT: I am sorry, Dr. Howe, I do not quite understand your question.

Mr. HOWE (*Hamilton South*): When something costs $1 it costs $1 whether it is in Canada or England. How can you adjust these rates to allow for labour in figuring out these comparative prices on a basis of the number of hours you must work. Prices in England on these drugs are less in actual amounts regardless of any labour rate. One would then suggest the prices should not be adjusted by the labour rate in order to figure the prices of drugs because this is an acutual price, or an actual cost.

Dr. BRIANT: Well the argument becomes, do we want to produce these drugs in this country ourselves or do we want to bring them in from overseas? Now, many of the prices that look reasonable in other countries are, in fact not reasonable but, conversely, for many Canadian prices that do not look reasonable, when we adjust and say how long does a Canadian have to work, because we have higher wages than these people to buy our own products, we find that they compare very favourably with all other countries in the world. There is one country that has lower real costs of drugs and that is the United States, because the United States has a higher productivity than Canada. So the general point I am making is that the real cost of products we buy is very closely related to the productivity of the nation, our ability to produce goods, and we produce drugs efficiently and effectively in Canada.

Mr. HOWE (*Hamilton South*): Well this leads to another question. In the case of wholly or partially manufactured drugs or in the case of raw key

chemicals purchased from the parent company, what mark up does the parent company make on these drugs, presuming that this in most instances is the American parent company?

Dr. BRIANT: Well I do not have, quite clearly, the figures for individual companies but in the one statistical appendix to the brief we show there one of the tables. If you look page 4 of appendix "E" you will see item 1b, imported from related companies $10,983,239. That is the total for 41 of the 58 companies in the Association. If we added another 50 per cent we are only talking of $15 to $16 million worth of imports so that if there were a profit factor included, 10 per cent would be high, we are still only talking of $1½ mililon. We are not talking in large sums of money. The other point I wish to make is that when raw materials are imported the U.S. government is interested in seeing they are not shipped to the Canadian company at too low a price so that taxable income is built up in Canada. Conversely the Canadian government is interested in seeing they are not brought in at too high a price to avoid the accumulation of taxable income in Canada. So, the two governments are interested in seeing that proper market prices are established.

Mr. HOWE (*Hamilton South*): I am interested in the mark up of the U.S. parent company. Their interests are possibly to mark this up which might take this profit back to the parent company and yet show up only as a cost here compared with the selling price. Maybe there is a profit there in the mark up of the parent company and this is what I am looking for, a ballooning of the price in the parent company.

Dr. BRIANT: Yes, I realize that. This is one of the contentions made by the Hall Commission. But the point I am making is we are only talking of about $16 million worth of imports from related companies and even that figure may be high.

Mr. HOWE (*Hamilton South*): Does this include the importation of wholly manufactured as well as partially manufactured as well as raw key chemicals? I mean we have three importation items before they are distributed to Canadian drug stores.

Dr. BRIANT: That is total imports from related companies so that the amount cannot be much in relation to the $200 million spent on drugs a year. Far less important, I thought Mr. Mackasey was going to say, than the sales tax.

Mr. MACKASEY: I am reserving my comments.

Dr. BRIANT: If I may, coming back to Mr. Howe's list, 42 of the products that tend to weight the index for comparison are all old products inthe U.K.; these were priced during the early period of the national health service and the establishment of the British voluntary price regulation scheme formula. They did not derive the benefit in price that is accorded in Britain to new products nor were the companies exporting enough of their products under the British formula to get the benefit of a non-negotiated price. So those 42 drugs represent a negotiated price with the U.K. government under the most unfavourable terms for old products and no exports to justify a price concession by the government. I understand the rule is that as long as 25 per cent of an individual item is exported or 20 per cent of all the items in the line, there is no negotiation of price in the U.K. So, clearly with the 42 small selling items 25 per

cent of these items are not exported and 20 per cent of the line is not exported so the government forces the manufacturers to keep their prices down because they are not contributing to other national objectives. I do not know if the British government ever intended it, but their voluntary price regulation scheme encourages the introduction of new products because companies are penalized in terms of the prices they can charge if they have old products in their line and/or do not export.

Another point is that 25 of the 58 drugs on Mr. Howe's list are the products of British companies. British companies are known in the pharmaceutical industry not to have been very aggressive or successful in exports. Again, this emphasizes the point that British companies who were not trying to export suffered in terms of the price the government allowed them to charge. Hence the extraordinarily favourable price comparison with Canada. I know it was not deliberate, Mr. Howe, but it amounts to the dice being loaded in that particular list.

Mr. HOWE (*Hamilton South*): That was intentional.

Dr. BRIANT: You are a gentleman to say it. Our lists happened to have the products of only one British company. The other 16 were Swiss and American. Now, on these 42 products there has been no price change since the inception of the national health scheme despite the increase in wages over the past ten to 15 years. So we are looking really not at true 1965 prices of British drugs but prices that were established many years ago and have not been allowed to change because British manufacturers have not conformed to the industry performance standards established by the British government.

Mr. MACKASEY: How do British firms survive on prices that were established 15 years ago?

Dr. BRIANT: They have new products they have added to their line. This is the incentive that is built in to introduce new products and I would think that their particular scheme might encourage the introduction of new products even when there is no real justification, just to free oneself from the constraint on price which is an unreasonable constraint in the case of these products.

In fact. Mr. Mackasey, you anticipated my next point, that I would suspect that many of the older preparations, that is, the 42 drugs, are being subsidized by newer products which are new and exported and those products, as you have seen, in Britain are priced very close to the Canadian level. To put the matter the other way, in real terms the prices of what are important drugs in Britain are in Canada reasonable; in fact more than competitive in relation to British drug prices.

I basically agree that the figures Mr. Howe had were correct. I should like to emphasize again that while he was comparing the price to the consumer, and this, I understand, is his interest of course, the manufacturers in Canada are only responsible for approximately 37½ cents on the prescription dollar. There are 62½ cents on the dollar over which they have no control whatsoever. Now the distribution costs are different in the two countries. If I may, I should like to illustrate this point with just one drug. I would have liked to have picked more but time ran out. The drug is Butazolidone. I think it is the last or next to the last page. It was really picked at random but it was a large selling drug. This is the point I want to make.

Mr. MACKASEY: Is it a cure for boils or something? I mean for the layman on the committee, what is it?

Dr. BRIANT: I do not know.

The CHAIRMAN: The commonest use is for the treatment of arthritis of various kinds.

Dr. BRIANT: This is a large selling drug. I could give you—in fact Mr. Howsam could look it up—a sheet with market shares and tell you exactly what the Canadian sales of this particular drug were in 1965.

Now, the U.K. retail price is $7.97; that is converting the price in British pounds to Canadian dollars. The Canadian price is $25. This is the price to the consumer. When I say retail, that is the price the consumer pays. Now here is a factor of 3.13. We look and say, my goodness gracious, that is a shocking discrepancy. Now, we take out one-third for the retailer's mark-up in the United Kingdom, $2.65, which gives $5.32 as the price to the retailer. Take out 12½ per cent of that—I hope the people at the back can see the figure but I have to write this small—66 cents, so we get a manufacturers selling price of $4.66. I will put manufacturers s.p. in the U.K. in Canadian dollars. We take here only 37½ per cent of the retail to get down to the Canadian manufacturers selling price. This comes back to our submission on pages 2.2 and 2.3, the breakdown of the prescription dollar, and that gives a manufacturers selling price for the Canadian product of $9.37, the factor is 2. So if we divide by the average wage rates in manufacturing in both countries—we cannot stop at this point—lo and behold what do we get? We get 4.44 hours, 4.6 hours. So, Canadian manufacturers are pricing to the market and to their costs on this particular drug—and this is a new drug, certainly, in Britain, it is not subject to the voluntary price regulation scheme.

Mr. MACKASEY: What does the 12½ per cent represent?

Dr. BRIANT: That is the wholesale market in the U.K., average, as in Canada.

Mr. MACKASEY: You mean the ⅛ mark up is between manufacturing and the wholesaler?

Dr. BRIANT: Yes, it is ⅛ of this figure.

Mr. MACKASEY: You did not tell us what it is in Canada.

Dr. BRIANT: Well I took a short cut to get to 37½.

Mr. MACKASEY: It was a long cut; could you give us the relationship now between the manufacturer and the price to the wholesaler?

Mr. HOWE (*Hamilton South*): What you really want is the difference between the 37½ cents and the 60 cents?

Dr. BRIANT: The 62 , the make up of it?

Mr. HOWE (*Hamilton South*): No, the 60 cents the retail store buys it for and the 37½ cents the manufacturer sells it for. You see, you have 22½ per cent in there that we do not know where the discrepancy is there.

Mr. MACKASEY: Well the point I wanted to make, as Dr. Howe has pointed out, is that your relationship between your manufacturer and your wholesaler

in the United Kingdom is 12 per cent. In Canada it is over 20 per cent. I am interested in the 62 per cent as well as the 72.

Dr. BRIANT: So am I.

Mr. MACKASEY: Well we are agreed but—

Mr. Peter HOWSAM (*Vice-President and General Manager, Warner-Chilcott Laboratories*): May I make a correction please? You are counting 12½ per cent as an average figure, as I understand it. In Canada the figure on an average is closer to 16 per cent, and I might remind you that in Britain, a tight little island of 50 million people, the distances covered by the wholesaler are less but it is about roughly 12½ to 16.

Mr. MACKASEY: You can give me the arguments later as to how you justify it because of different problems. I am not interested in how.

Mr. HOWSAM: You said 20, sir.

Mr. MACKASEY: Professor, while you are getting your booklets out, apart from a source of information, I do not get your final index of 4.444 hours as opposed to 4.6 may be of interest.

Dr. BRIANT: 4.44 to 4.6.

Mr. MACKASEY: Yes, but nobody is buying at that level. What is the hours at the price the consumer is buying. Never mind what the manufacturing is because I cannot walk in and buy it at a manufacturing price.

Dr. BRIANT: We could work it out if you will bear with me. We divide 7.97 by 1.05.

Mr. HOWSAM: It is still the same relative difference.

Mr. MACKASEY: No, it is a hell of a difference.

Dr. BRIANT: I think you will find—

Mr. MACKASEY: I think one is almost 12 and the other case is about 8.

Dr. BRIANT: 7.5 hours. All right what is 25 divided by 2.02?

Mr. MACKASEY: Twelve, over twelve.

Mr. HOWSAM: 12.5.

Dr. BRIANT: 12.5. The Canadian price to the consumer in ours is a great deal higher than—

Mr. MACKASEY: That is not the point you were bringing up. You were bringing up the point that at the manufacturing level it was identical but we do not buy at the manufacturing level. I think this is unintentionally deceptive. I am interested in the consumer's level.

The CHAIRMAN: The only problem, Mr. Mackasey, is that you cannot expect the manufacturers to comment. They can only comment on the manufacturers level. They cannot comment on what happens to it after it leaves their hands.

Mr. MACKASEY: I am sorry. You are right.

Mr. WHELAN: But, Mr. Chairman, they are using the consumer's wages as a—

Mr. HOWSAM: Yes.

Mr. HOWE (*Hamilton South*): My original question what is the justification for that 22½ per cent? The druggist buys a drug at list less 40 per cent; in other words he buys it for 60 cents of the prescription dollar and the manufacturer gets 37½ cents of it so there is still 22½ cents in between the manufacturers selling price and the druggist buying price of 60 cents.

Dr. BRIANT: Well here is a table I have. We take the price to the public of $1. This is an average. Druggists price in different ways. I could not begin to work out what happens in all prices but less what shall we call it, the druggist margin, less the druggist distribution, and dispensing costs—I want to be fair to the druggist in what I say here and I do not really feel equipped to speak on this. The druggist's margin before dispensing and distribution cost. I think it is significant that many pharmacists say they lose money on their dispensing counter. I do not want to be misunderstood on that. That leaves 50 cents on the dollar. Then the distribution to the pharmacist is either direct or wholesale. Distribution to pharmacist 8 cents, or it works out to 8. Forty-two less federal sales tax, 4½ cents, brings us to the manufacturers selling price.

Mr. HOWE (*Hamilton South*): That 50 per cent is average is it? In most instances it is 40 so some must go higher.

Dr. BRIANT: Well they say in the statistical survey, that I can get from my files, that the average market was 50.1 per cent in 1964 for all of Canada.

Mr. MACKASEY: With the Chairman's permission, would you switch back to your seat again.

Mr. HOWE (*Hamilton South*): On prescriptions only.

Dr. BRIANT: Yes, on prescription drugs.

Mr. MACKASEY: I think the Chairman properly pointed out to me the fallacy that I was falling into. I presumed you represent the whole industry instead of the manufacturers. The point I would like to get back to is this. At the manufacturing level your figures, presuming they are accurate, indicate the manufacturing cost after certain adjustments for normal take home pay is relatively fair and that it is 4.44 here, as opposed to 4.64 in the United Kingdom? Then, of course, there is a discrepancy at the consumer level which would indicate to me the problem lies more with the distribution from the manufacturer than to the consumer.

• (12.28 p.m.)

Dr. BRIANT: Well, you said it.

Mr. MACKASEY: No, I am asking you. Now, would you mind saying it, yes or no.

Mr. HOWSAM: Mr. Chairman, there is only one word that was used and that is the problem. I am not just sure that the problem has been defined.

Dr. BRIANT: I think it is true, Mr. Mackasey. I do not personally want to be in the position of singling out pharmacy. I think that when we speak of costs in Canada, from the economic viewpoint, we have to recognize that the costs which are increasing most rapidly in the country are distribution costs, for a number of reasons. This is where one should look to reduce the delivered price of any

goods and services to the Canadian people. We need a royal commission on distribution, I would say.

Mr. MACKASEY: The point I am trying to get at, Mr. Chairman, and I think Mr. Howe has brought it out too, is there are three people involved. There are three segments here; there is the manufacturer, the distributor and eventually the retailer. One seems to apologize for the other all the time. I would prefer each segment to stand on their own legs and forget the other fellow's problem because we will get to the other people. The point that Professor Briant has emphasized, presuming his figures are accurate, is that the trouble does not lie at the manufacturing level—at least this is the theory he has been bringing up, in view of the relative closeness between the two figures, 4.4 and 4.6. But obviously we can all see a tremendous difference at the consumer level, from 7.5 to 12.5 and if it does not lie with you it must lie either with the wholesaler or the retailer. This is the point I wanted to make.

Dr. BRIANT: And it does not means to say they are making astronomical sums of money but there are inefficiendies in the distribution system.

Mr. MACKASEY: Fine.

Dr. BRIANT: That are inherent in the nature of the country as well: large land areas, small population; but it is happening in the United States as well. All distribution costs are going up, for all produits not just for pharmaceutical.

Mr. PRUD'HOMME: You mentioned the United States. I will not bother with the earphone so I will ask my question in English. I think we can see the picture quite well now as far as your case is concerned since Mr. Howe raised the question. But how does this, again, compare to the United States? Would you say it is much cheaper in the United States compared to Canada?

Dr. BRIANT: In Appendix "F" you see there the index for our 17 drugs and I think if we were to take 100 drugs we would come to pretty much the same answer, that the real cost of drugs in the United States is lower than it is in Canada because Americans are more productive than Canadians and I do not say that to be degratory to Canadians. It is just an established fact. They have a more productive economy; their wages are higher and they therefore spend a smaller per cent of their income on drugs.

Mr. PRUD'HOMME: I accept what you just said but if many pharmaceutical manufacturers are subsidiaries of United States parent companies I do not see why the price could not compare with those of the United States?

Dr. BRIANT: Well they do compare reasonably favourably in terms of our productivity. We are about 25 per cent less productive in Canada than they are in the United States. Our income per capita is the measure. I do not have a precise figure.

Mr. PRUD'HOMME: At the moment I am doing my homework.

Dr. BRIANT: On the United States?

Mr. PRUD'HOMME: Yes, compared to elsewhere.

Dr. BRIANT: Well, is that about right, 25 per cent?

Mr. PRUD'HOMME: Well I did not finish. It is quite difficult for us not being as knowledgeable as you are. My main concern again, I repeat, is the question of subsidiaries in Canada.

Dr. BRIANT: I would say their prices do compare favourably given the fact that they are conducting their business in Canada. Now the same arguments apply if you say why not close them down and import from the United States. Do we want to become an importing nation? Is this really what we want for our people? We have governments trying to build up secondary manufacturing. I remember some years ago doing some work for Manitoba—

Mr. PRUD'HOMME: We could not afford the United States pharmaceutical producers. It would be very difficult.

Mr. BRAND: Mr. Chairman, I wonder if Professor Briant could explain something to me about butazolidin. What do these prices you started out with represent?

Dr. BRIANT: This is the price to the consumer. This is the suggested list price.

Mr. BRAND: For what, for how many pills?

Dr. BRIANT: Dr. Howe's list.

Mr. HOWE (*Hamilton South*): Two hundred and fifty.

Dr. BRIANT: Yes. I did not pick one from our own list. As I say, this was picked purely at random, I can assure you, from the 16.

The CHAIRMAN: Yes, it is a good seller.

Mr. WHELAN: Have you any figures in dollar value of how much we import from the United States in drugs and much we export to the United States.

Dr. BRIANT: I do in my files but it would take a little time to find the exact figures.

Mr. WHELAN: This afternoon would be fine.

Dr. BRIANT: I will try and get the figures over lunch.

Mr. HYMMEN: Mr. Chairman, I just want to ask another question for clarification, Professor Briant mentioned this figure of 37½ per cent and that has come up before, which is the ratio of the prescription dollar related to the manufacturer's price.

Dr. BRIANT: Could we put it this way, that it is the proportion of the prescription dollar that the manufacturer receives out of which he meets his own accounts.

Mr. HYMMEN: I wanted to tie down that prescription dollar rather than the retail price of drugs plus dispensing. Now, when we talk about dispensing we are getting into the pharmacists association and out of your area.

Dr. BRIANT: Oh yes.

Mr. HYMMEN: You used a 50 per cent mark by the druggist and yet in other submissions we have had there was shown a 25 per cent wholesale mark up and a 66 per cent retail mark up. I know you cannot regulate these things.

Dr. BRIANT: I have all these books over on the other side of the table.

The CHAIRMAN: I think in the brief of the Pharmaceutical Association themselves for prescription dollar they said 50 per cent mark up; whichever way you look at it, 100 per cent mark up or 50 per cent of the price.

Mr. HYMMEN: We are tying down here in all the submission of the pharmaceutical manufacturers this 37½ cents on the dollar and I just wonder if that is what it is or it is not.

The CHAIRMAN: We will get into this in more detail later but this is what they use in their large brief, 37½ cents.

Dr. BRIANT: I have it right here. Mr. Brand, I think, produced a survey from the pharmacists last time to talk about Saskatchewan. I have a copy of the same survey and for Canada as a whole for the 1964 survey they have a little footnote, "the average gross margin is 50.10 per cent." Now they also point out that 24.85 per cent of all prescriptions are dispensed at a loss. But they published the fact that the gross margin is 50.1 per cent, I could table this if you are interested in having it.

Mr. BRAND: It has already been tabled.

Dr. BRIANT: Has it already been tabled? It is on the record then. I am not producing a figure they have not presented themselves.

Dr. WIGLE: Mr. Chairman, I do not know whether Mr. Hymmen understands but starting at that 50 per cent figure that was left there we took off the sales tax and the wholesalers cost and there is 37½ cents left for the manufacturer to account for.

Dr. BRIANT: Yes, right here is 8 cents and 4½ cents. We can do it other ways. I checked this out, taking the total sales of drugs through pharmacy. In fact, if you take Mr. Turnbull's submission, last time, I think he said prescription sales were $9.95 per capita. That is about $195,000. We can work back—we know what the manufacturers sales are approximately—for drugs that are sold on prescription to retail stores. We can check all these out and I am reasonably confident it will be about 37½ per cent.

Mr. HOWE (*Hamilton South*): Mr. Chairman, in the 37½ cents there is a figure there called earnings which I presume is profit.

The CHAIRMAN: Before we get on to that, Mr. Howe, we spent all morning getting an answer to a question you asked and obviously it was an important question. But let us finish it before we get into the question of breaking down the manufacturers' dollar. There are other questions relating directly to what Dr. Briant has said in his answer this morning. May we do that first. Once we dispose of the question I think we can adjourn for lunch and have a sitting again this afternoon.

Mr. BRAND: I would like to ask Mr. Briant, regarding butazolidin which is the best example you have used from Mr. Howe's list, you made quite a thing about not importing drugs because of the damage to our industry and so forth. Now, tell me is butazolidin manufactured in Canada or is it imported from Geigy in Switzerland.

Dr. BRIANT: That is a very good question. Can any manufacturer answer this?

Dr. WIGLE: I do not think we have anybody from that company here, Mr. Chairman. It might be improper for us to presume to know. I do not know personally.

Mr. BRAND: The reason I asked that question is that I asked why phenylbutazone was higher in British drug houses, which is the same drug, and they told me they had to import the drug so it is rather interesting to me if you are making a case for the non-importation of drugs that you would use as an example a drug which was, I presume, being imported.

Dr. BRIANT: I can only say that it was a grievous slip on my part based on ignorance. I did this last night in the hotel. I thought I would take one drug. Had I not run out of time I would have taken more just to see how the 16 large selling items compared.

The CHAIRMAN: Did you care to comment, Mr. Larose?

Mr. ROGER LAROSE (*Vice-President, CIBA Company Limited*): I cannot speak for Geigy but I know they actually import the raw material, that is the chemical substance, but all of the rest is done in Canada.

The CHAIRMAN: Fine, thank you.

Mr. ASSELIN (*Richmond-Wolfe*): Mr. Chairman, I am not a member of this committee but I would like to find out the procedure of pricing. Are drugs priced on the manufacturers selling price or are they discounted from a manufacturers suggested list?

Dr. BRIANT: Well, sir, I will have to field that question; in fact, I would like to defer it so that I can finish my point.

The CHAIRMAN: Yes, I think we should leave that question also and see if we can finish this point we have been discussing this morning.

Mr. A. M. LAIDLAW, Q.C.: Mr. Chairman, I would like to ask Mr. Briant the real basis of his method he has introduced now. I do not believe this particular method was introduced before any hearings of the Restrictive Trade Practices Commission or the Hall Commission. This is a new economic development, perhaps. Are you not in fact saying, Mr. Briant, that costs of drugs should be related really to the income capacity, the earnings, our level of income and, therefore, we are not out of line with these other countries mentioned. I would like to quote an analogy if I may; suppose it takes a Canadian one year to earn and pay for a car. And suppose in India it takes an Indian 20 years of work to pay for the identical car. Are you not really saying, does it really matter if it takes a Canadian two years to buy the same car.

Dr. BRIANT: Well, if you compare Canada with India then we probably would say it does not matter if it takes two years, but if we find the Americans can buy an automobile, say, with 9 months of income, then there would be something wrong with the price of automobiles if it took a Canadian two years to buy a similar automobile because we know roughly the relationshp between income per capita and productivity between the United States and Canada. What I am suggesting here is that when we look at the Canadian level of earnings and recognize they have a bearing on the costs at which the manufacturers do their business at the manufacturing level anyway, our prices are

reasonable in relation to prices in other countries of the world. The discussion this morning was just focussed on the U.K. but in our submission, appendix F, we show that you can take many other countries and our prices in real terms are much lower than, say, prices in Italy where we are told Italian prices are low because they have no patent protection. They are low but it takes an Italian a tremendous amount of time to earn the cost of the drugs he buys.

Mr. LAIDLAW: Following Mr. Howe's questioning and Mr. Mackasey's questioning in particular, it seems to me that your hypothesis is—I do not profess to be an economist—entirely wrong. If butazolidin reaches the consumer in the United Kingdom at a special price, it reaches the consumer in Canada at three times that price what has the Canadian earning capacity to do with it? It is the consumer which I assume this committee is interested in. Now if the patent laws allowed it and the trade mark laws allowed it, if we could import butazolidin from the U.K. at the U.K. price would this be helpful to the consumer? I suggest that it would. I think I should add there are two other elements that come into it. You have spoken about them. Quality control is essential, and we can understand that I am quite certain. I think the committee also recognizes it is not going to do anything damaging to the industry by wild importing procedures, if you want me to express it that way. There must be a proper balance drawn and I only question whether this particular method is not drawing sufficient balance between the drug industry and the consumer which is what this committee is studying.

Dr. BRIANT: Well, this question, Mr. Laidlaw would take a long time to answer because, in fact, the answer was contained in almost everything I said up to now. I did not really start out with the hypothesis that this is the proper way to measure comparative costs. I did start out with the assumption that we are interested in maintaining a pharmaceutical manufacturing industry in this country and that one measure of the economic performance of the industry is how its prices compare with prices in other countries, not just making a money comparison because if you were to pick India again, if they had a pharmaceutical manufacturing industry, you might find our prices are 20 times higher than theirs, but to look at it in terms of real cost, if we assume we want an industry. Now, if we do not want a domestically based manufacturing industry then we should go ahead and import as much as possible. So you might say well let us import where there is an advantage to import. Now I showed, I believe, that the 42 products on Mr. Howe's list that it would be to our advantage to import are very low volume items in the Canadian market. There is some question as to whether importers would want to import just those low volume items. They would want to import as well some of the high volume items and if you bring those in as well you will find their prices do not compare all that favourably with Canadian prices. If we take butazolidin, the delivered price in Canada would be something over $5. Then there is still Canadian distribution which is shown as 62½ per cent. So take $5. at 37½ per cent—I do not want to do the arithmetic—you are going to come up with a pretty high price again, for the British drug at its delivered price to the Canadian consumer because the major selling items in Britain are selling on a labour hour basis at about the same rate that they are here. I suggest from that that our prices for the products we produce as major products compare favourably with the real

cost in other countries, not so much at the price to the consumer but this is because of inefficiencies in the distribution of the products.

Mr. GORDON F. HENDERSON, Q.C. (*Patent Attorney, Gowling, MacTavish, Osborne & Henderson*): Mr. Briant, is there not a short answer to Mr. Laidlaw, that by focusing on retail price he is focussing on the wrong price because the price at which the goods will be imported, the fair market value would have a closer relationship to the price you are pointing out and you are relying on rather than that which Mr. Laidlaw is relying on. So he is focussing on the wrong price. Is that not the short answer to the question he put?

Dr. BRIANT: Yes, very true.

Mr. HOWSAM: May I add one point, Mr. Briant. On your point of the 4.66 figure and I have just done the arithmetic that you requested, if you take it back and assume that 4.66 came in at 37½ per cent and allowing nothing for the transportation and assuming abolition of duties and revert the thing back up it comes out to exactly $8 which is $7.97 so the distribution spread is almost the same, which is your point, I think, whether it is here or not the distribution process has to be covered in both markets.

Mr. BRAND: That is still cheaper though is it not than the Canadian price as illustrated?

Mr. BRIANT: There is something wrong with Mr. Howsam's arithmetic.

Mr. HOWE (*Hamilton South*): If the 37½ per cent was to be your $4.66 then your prescription dollar would still come out somewhere around $12 instead of $25 so the drug would sell for half the price to the Canadian consumer compared to what it does today at $25.

Dr. BRIANT: This is quite true. If you want to bring in drugs from other countries at lower prices you can find them, but if that is so why do we not bring in refrigerators from other countries at lower prices. Why do we not bring in any product?

Mr. WHELAN: May I interject here, we do it with a tremendous amount of agricultural products.

Mr. MACKASEY: Could I ask Mr. Whelan, through the Chairman, to give him his opportunity to espouse his favorite theory. Do you approve of the importation of lettuce from what you call starve labour wage areas to the detriment of the Canadian farmer?

Mr. WHELAN: No, I do not. That is why I am trying to get across the point we have no protection. They do not have to have any import permit at all; they just railroad the stuff in here by train, truck and everything else and we only wish we had half the protection that the pharmaceutical industry has.

Mr. HOWE (*Hamilton South*): This is part of my other question. As a non-economist, are there not other factors than the wage hourly rate to be taken into the consideration in the purchase of drugs. Do you not have to take the over-all purchasing power within the economy as to what that dollar will buy in other things than just drugs to determine how much of the dollar would be left over to buy drugs with. You cannot just take the labour hourly rate as your only factor in determining the price of drugs. For example, they might

buy milk for half the price we do so they are going to have 12½ cents left over every time they buy a quart of milk that they could put toward drugs.

Dr. BRIANT: Yes, but their wages are only half as much.

Mr. HOWE (*Hamilton South*): Well, all right, so it sells for a quarter the price. My point is that you cannot just take that. There must be other factors as well as just that.

Dr. BRIANT: Well if you wanted to take the total expenditures on drugs in relation to the consumers disposable income and say "if we were to import all the drugs that we now have what would the bill be"? You would be dealing with a fractional percentage saving of the consumer income, a fractional percentage. But I said while I was talking that a basic policy question that had to be answered is: Do we want an industry in this country? I would think that we do if for no other reason than that we do not want to expose ourselves to total dependence, in the case of drugs, on products coming from other countries. Now we might want to do this with lettuce; perhaps we should not.

Mr. LAIDLAW: Mr. Briant, you want this industry to be a completely protected industry?

Dr. BRIANT: I beg your pardon?

Mr. LAIDLAW: You would like this industry to remain a completely protected industry? I say that because I am going to ask another rather rough question but in your business you would appreciate it. Do you not believe, generally speaking, in the competitive system in this country?

Dr. BRIANT: I do, Mr. Laidlaw; as a matter of fact I teach a course at McGill University in industrial organization and public policy and I hope that I am producing a number of Canadians who believe in the competitive system. But I am prepared to argue—not because I represent the association here; if I were not prepared to I would not represent the association because my morality would not allow me to—that open competition in the case of drugs is not the proper mechanism. I know that the easy answer, and I have been given it by some people in Ottawa, is that one way to reduce the price of drugs is by open competition. This probably would be so but we would be playing around then with the nation's health. This is quite different from talking of open competition in producing automobiles, toys, or pulp and paper. Generally, I would say, Canadian industry is not competitive. Now it happens that the last point I wanted to make in my submission here touches on that. To my mind one of the problems in this industry is that there are too many manufacturers and too many retailers. If we talk of importing and importers, we would add to the number and I do not think adding to the number in this particular industry is the proper solution.

Mr. LAIDLAW: If I might follow that up with one question, Mr. Chairman; if you did open up the competition slightly or in fair measure, would this not result, in your opinion, of the inefficient parts of the industry being wound up and certain other parts of the industry getting more monopolistic?

Dr. BRIANT: I suppose it would; it would have to, that is quite right. But we come back to the point again, that if any one of the manufacturers were wound up then for the product of that manufacturer we would be completely depend-

ent on products coming from other countries. Now I am prepared to say this is fine if we are talking of shirts, textiles, almost any other product but I am not prepared to say so when we are talking of drugs. There are instances where drugs are needed in a hurry, and it seems to me, in terms of protection of the nation's health that while there may be a cost attached to having the industry here this is a cost, perhaps, that we should bear. I would be very reluctant as a public servant, if I were a public servant, to propose a remedy to the organization of an industry that contained within it, even to a small extent, some danger to the health of the people of Canada.

Mr. BLAKELEY: Well, Mr. Chairman, I did want to ask a question earlier on this 37½ cents proposition. I do not know if you would care to go into it now or this afternoon.

The CHAIRMAN: If it is a breakdown of the 37½ cents, I think we might leave it until later.

Mr. HYMMEN: Just to comment, Mr. Chairman, I would suggest the public is very much concerned about the $25 drugs and I would be interested, at another time, in seeing Mr. Briant work up this $7.97 or break down the $25 just to see actually where it went because, with all respect to the industry, in the $7.97 price in the U.K. I presume all the research and everything else has been taken care of so far as the firm bringing in a drug from the parent company and so on is concerned. One possible solution might be for the government, through their tariff regulations, to provide some relief in limited quantities to drugs that are not used to a very great extent in order to provide the public with this differential and the lower price. It seems to me that if the public is screaming, and I know they are, about the cost of drugs, and while the association has tried to justify this as part of research and everything else, it is the price of drugs in the $25 range that I think is causing a great deal more concern than the drugs in the $3.97 range.

• (12.57 p.m.)

The CHAIRMAN: If there are no other questions I think we probably have answered Mr. Howe's question and possibly Mr. Brand's question.

Mr. BRAND: We have 30 seconds left, I see, before one o'clock but I wanted to ask Mr. Briant apropos this import business, and I can see his point there, but if I understand these things correctly—I probably do not because I am thoroughly confused—I take it there are some drugs here that are cheaper in Canada than in the United Kingdom. Is that correct?

Dr. BRIANT: In dollar terms?

Mr. BRAND: Yes.

Dr. BRIANT: Not on Mr. Howe's list and I do not recall whether or not they were on our list.

Mr. BRAND: Is the cost to retailer you have here based on the labour hours too?

Dr. BRIANT: No. If you look at appendix F.3, international drug prices in Canadian dollars, for these 17 products, anyway,—let me see; are there any?

Mr. BRAND: Yes.

Dr. BRIANT: Which ones?

Mr. BRAND: Hydrodiuril.

Dr. BRIANT: Hydrodiuril and Diuril have a lower Canadian dollar cost to the retailer than they do in the U.K.

Mr. BRAND: The only reason I asked that question was I was wondering about exports to these other countries. Trade is usually a two-way street, you know.

Dr. BRIANT: Well, of course, I am not equipped to answer that question for the manufacturers.

Mr. BRAND: You talk about imports so conversely I assume you would be prepared to talk about exports.

Dr. BRIANT: I am prepared to say that the exports of the industry are quite low but one reason for that is that many of the manufacturers have manufacturing plants in the major consuming countries of the world.

Mr. MACKASEY: This is an area I think we ought to get into, Mr. Chairman, with the Department of Industry, trying to stimulate research and exports. We should find out while we have these gentlemen here how we can get to a point where we can export, as Mr. Brand has suggested. It may be time to take a look at our patent laws and see if perhaps we should reverse the trend and stimulate production in this country to a point that we can export to the North American market in certain fields.

The CHAIRMAN: Ladies and gentlemen, the meeting is adjourned until 3.30 this afternoon, in this room; and we will revert again to our general questioning.

AFTERNOON SITTING

• (3.30 p.m.)

The CHAIRMAN: Gentlemen, it is now a quarter to four and I think we should go ahead with the presentation of the brief and the questioning.

Mr. MACKASEY: What time do you contemplate sitting on Thursday?

The CHAIRMAN: On Thursday, it is my hope that the Pharmaceutical manufacturers will be back. The only sitting planned for Thursday is at 3.30 in the afternoon.

Mr. MACKASEY: No sitting in the evening?

The CHAIRMAN: It was established by the Committee last time that there would not be enough members present at that time to make a quorum. We will sit now until the Committee wishes to adjourn. Then we will meet again this evening at eight o'clock and sit until perhaps nine thirty or ten. We are hoping by that time we will have covered the majority of the brief. I just have one suggestion to make, if it becomes obvious that we cannot contemplate the whole brief within the required time we might consider going into the question of patents, as one complete subject, later on rather than break it up. I think we should revert to our original consideration on the preamble, summary, contents, introduction and recommendations, which were the areas we were covering.

It was suggested this morning that we might start off with counsel asking a few questions for perhaps the next few minutes.

Mr. LAIDLAW: Mr. Chairman, I had intended to call the attention of the Committee to certain implications that seem to arise out of this preamble that Dr. Wigle has prepared. In view of this morning's discussion I think that perhaps it is not altogether necessary now. I feel, however, that it would be helpful to the Association to show the line of questioning that may develop either during these hearings or later in the Fall and I will just indicate these very briefly. There is the economic problem, of course, that we had this morning. The second, the high cost of quality control, and questions arising from that implication, particularly if brand name drugs were imported. The third implication regarding patent protection and if this is reduced that research activities would stop—this will be taken up as a separate entity. The next implication in that preamble, that Canada cannot have a free ride, as it was expressed therein, or we must pay our own way. To the best of my knowledge, royalties have always been paid to patentees and licensees. Questions will arise when the patent situation develops about this. And the last implication in the preamble was that the drug industry would be "damaged" which was the word that was used, if more than a few token recommendations as set out towards the end of that preamble are carried out. And the only real important recommendation there was the abolition of the federal sales tax.

I would like to make this suggestion to the Committee and it may be also helpful to the Association, that the recommendations have been made by the Restrictive Trade Practices Commission's report, the Hall Commission report on Health Services, and it seems to me that the onus, Mr. Chairman, is placed on the drug industry to show why these various recommendations should not be implemented. I think that perhaps this is the basis from which the drug industry should consider that questions by members of the Committee will develop. It might be helpful to the Committee if your Association, Dr. Wigle, could provide a list of the various recommendations from the two commissions with a brief statement—this need not be done right away, of course—why these recommendations should or should not be implemented. When the Committee sits to consider the report and the recommendations, I am certain that such a schedule would be very helpful to them.

I would like, if I may, merely to start the questioning in section 1 of the report, to refer to page 5, section 1 (5), the last paragraph. This particular paragraph stresses the increasing costs of research and development in the drug industry, and the mounting expenses. The brief indicates toward the end that this is so. I think that the Committee would appreciate hearing just how much research is expended in Canada in the drug industry in comparison to what is also referred to in the brief as international research. I wonder if the Association could make available to the Committee any breakdown in this research; how much is spent, for example, in trying to work around a competitor company's patent on a valuable drug that is in demand—this could be dealt with at a later date; how much is spent of the $6½ million mentioned in the brief, in Canada; how much is spent on so-called clinical testing; is clinical testing included in research and development costs; how much of this research and development expenses or costs are spent in fact on trying to isolate new drugs that eventually could result in patent protection?

Now this is quite a large order, but I think I could say simply this, it is very easy to talk about research but there are various kinds of research, kinds that are helpful to the Canadian public and in the public interest, other kinds which are basic, and other kinds which are merely practical. I think it would be very helpful to this committee if we were able to be supplied with a breakdown of research figures.

Mr. HUME: Mr. Chairman, may I just ask Mr. Laidlaw a question so that we understand the ground rules. The Association, of course, does not manufacture pharmaceuticals. In Appendix E there is a result of a survey made of 41 companies which responded in 1964 and that is the only information that the Association has at the present time. Now, as I understand some of the outlines that Mr. Laidlaw has given, I am wondering whether this implies a new questionnaire to be sent to the companies, to be processed and collected, and so on, in the same way that we have done Appendix E, in which case I would say this will require a considerable amount of time. I just want to make sure that we understand what Mr. Mr. Laidlaw is asking us to supply.

Mr LAIDLAW: Well, I can quite appreciate, Mr. Chairman, that perhaps this Association has not the details of their individual members. It may be better and of more interest to the Committee that when actual manufacturers appear before us this question be directed to them singly.

Mr. HUME: All I want to be sure of is what is being left in abeyance for us to do as an Association, Mr. Laidlaw. It is not to avoid anything; it is just to be clear what you are asking the Association to do, and pointing out that we have compiled certain statistics and that is the only information—Dr. Wigle can correct me—that we have with respect to some of these things like research and the cost of it, as set out in Appendix E. If you want something different than that we have to start in again, circularize, get questionnaires back and compile the statistics and put them in some form.

Mr. LAIDLAW: Well, this would not be a matter for me to say, Mr. Chairman. This would be for the Committee to determine.

An hon. MEMBER: Is that kind of information available to the Association?

Mr. HUME: If you look at Appendix E (6) we have research and development expenses reported to us by 37 companies of our membership. That is for the year 1964, and that is available to us because we set about and collected it. I do not think we have anything more current than that. If that is not sufficient, if you could indicate what more we can do, I am sure the Association will do everything it can to assist the Committee. I just want to be clear as to what you are asking us to do.

Mr. LAIDLAW: My only feeling, Mr. Chairman, is that research is a very large and broad word, and I am one of those who heartily endorses it. I think it would be interesting to know whether this was in fact basic research for the creation of new drugs in this country or is the name "research" used in a different manner which would be clinical testing, for example.

Mr. HUME: There, of course, Mr. Laidlaw I would have to know how each one of the 37 member companies interpreted the questionnaire to be able to be clear as to whether they were talking about initial research, modification of products or other things. Dr. Wigle can perhaps speak on this with more

authority but, as counsel, I felt that we should know just exactly what you want because we have the best and the latest statistics we could get together. But we can go back again and get 1965 or other years, if there is something here that is not sufficient.

Mr. MACKASEY: On E (6) which was referred to, total for research and development, there was $5,504,323 spent in Canada. Perhaps Dr. Wigle would like to expand on what "spent in Canada" is. I would perhaps touch, Dr. Wigle, on that area that is obligatory by law under the Food and Drug directorate. I am talking about new drugs coming into Canada.

Dr. WIGLE: Well, Mr. Chairman, first of all, just so that we do not be remiss in our recognition of the health that Mr. Laidlaw has indicated to us, by indicating that in the future we will be questioned on these five or six items of which I have made note, quality control, patent protection in Canada, no free ride, damages to the drug industry if certain recommendations are carried out. But specific reference was made to the recommendations of the Restrictive Trade Practices Commission and the Hall Commission. I believe that we made a serious effort in our total brief to handle many of the recommendations which were made by the Restrictive Trade Practices Commission and the Hall Commission, and in many different places have referred to those recommendations and tried to point out for the information of the Committee just where they might jeopardize the health of a pharmaceutical industry and the provision of drugs on a safe basis to the people of Canada if they were implemented. But we will be happy to do as he has said, prepare a separate document which looks at those recommendations and specifically pulls out the item referable to them.

In so far as research, which I understand is the topic that you would like to open up for discussion at the present time, Mr. Laidlaw has made reference to the fact that there are different types of research, and this is true. However, our basic position, as in industry, is this. People interested in the development of drugs from the time that they explode in some type of canister to make a new chemical formulation or until they have the adverse reaction reported back by the physician from the bedside is to us, as a responsible industry, all research. Some people are inclined to look at the purest basic type of research that is inclined to discovery of some new chemical entity. We feel that the total picture throughout the world has to be taken into recognition and that the people of Canada benefit from every bit of research that is done throughout the world whether it is done here or elsewhere on behalf of the pharmaceutical industry, some of it by the industry, some of it very justifiably by universities and government laboratories, those areas I think which are recognizably, probably more justified in searching out what we call basic research which is a better understanding of nature. But once there is a better understanding of nature, I think that the history of the industry and of other industries has proven that the better understanding and its application to the benefit of mankind has been best handled by industry. So that we feel that governmental research, basic research so called, the better understanding of nature is well handled and must have the co-operation of government and universities and others, but the applied aspect so called is also fundamental before it gets to the bedside, and then the research continues because the reports must come back from the bedside to the manufacturer so that he picks up his responsibility and either alters his approach or discontinues it.

Mr. MACKASEY: Dr. Wigle, I think what Mr. Laidlaw was referring to, without stating it, was the magic formula that is built into your costs, how the international research to which you have access is evaluated in your Canadian operation, and how is it reflected in the costs of the specific drug that gets to the people?

Dr. WIGLE: Well, Mr. Chairman, I think that in E (6) we have made an attempt to move into an evaluation of research generally and I would be prepared to have some other members of the delegation, perhaps Dr. Brian Stewart or Professor Roger Larose, to speak to this item if they have anything further to contribute.

Dr. BRIAN STEWART (*Director, Pharma-Research Canada Limited, Pointe Claire, Quebec*): Mr. Chairman, I would like to say just as a preamble or general statement on research that in section 7 of our brief it speaks of this in the context of how we set it out here, called the sequence of research, but it was all part of the task facing research directors like myself and others who were interested in introducing new compounds. It follows that not all countries can do all research and Canada can contribute, I do believe, by doing everything and that can only happen if the research grows to the point where it can be supported, or it does equally, and many companies I believe in the association do help significantly by taking a section of this sequence and evaluating it for the benefit of other companies throughout the world. For instance, toxicology, if you strictly take it academically, is not a productive form of research, or a creative form of research but no one in this room I would think would agree to introduce any drugs without some of this research. Similarily, I detect in Mr. Laidlaw's approach that he was sort of grading research into first class, second class and third class types. He was interested only in the so-called first class research. Let me state right from the beginning that each of them are essential before a drug can be introduced and clinical testing is as essential a form of research as synthesizing a new compound. One without the other or any of these sequences is not a viable entity. I think with that preamble I will wait for specific questions, Mr. Chairman.

The CHAIRMAN: I was going to suggest that this might be a useful time for any questions at all on research with regard to section 7.

Mr. LAIDLAW: Mr. Chairman, is this tied up with patents or patent protection or is this on the subject generally, because I am afraid it is undeniably and irrevocably corelated with patents, and I do not want to start that, I do not believe, today.

Mr. MACKASEY: Mr. Chairman, as member of the Committee I feel like I am out in left field. I am not too sure which direction Mr. Laidlaw wants to go, even though he is our counsellor. I think perhaps we should have an in camera meeting with Mr. Laidlaw and our accountant, in all fairness to these two gentlemen, so we will know what direction we should be pursuing because we are jumping from research to patents and back again. I do not want, on the other hand, Dr. Wigle to lead me down a path that I am not interested in. I have a hard time, being a layman, and when I refer to drugs I refer strictly to aspirin because that is the only word I can pronounce, Mr.Chairman. What I am interested in, being pragmatic, is this. In section 7 of research I think it is calculated that $5 million is the price placed on research behind a new product

in the United States and whoever prepared the brief can correct me if I am wrong. I want to know how and what proportion of that $5 million was for pure research or total research, pure or not so pure, is allocated to the Canadian operation? Did the Canadian operation have access to the research prepared in the United States? What is the magic formula and how does it reflect on the cost of drugs in Canada?

Dr. WIGLE: Mr. Chairman, I always have to boil things down to a very simple sort of an understanding for myself because my qualifications as an economist and so on are very limited. My basic understanding as a physician of how the allocation of costs of research is done by the industry throughout the world is that a pharmaceutical manufacturer who is research oriented and who does participate in research for the benefit of the total world and prepared to have it supplied to them when there is a discovery, allocates that cost on the basis of all his products to all the people throughout the world that he can spread it over.

Mr. MACKASEY: May I interrupt a moment. Is it on the per capita or, in other words, world population, or is in the products sold in each country, being the fundamental difference?

Dr. WIGLE: My understanding is that it is over all his products to all the people he can supply them to and that one specific product does not attempt to pay for the research that was done on behalf of that product. I would be happy to have Dr. Stewart say something further to it. Our Chairman is pointing out some reference.

Dr. STEWART: Mr. Chairman, all I can say is that research is a very uncertain field. In our company we started two years ago, for instance, with synthetical gynochemists and pharmacologists and we think we will be doing well if we get a compound in ten years that could be introduced into the world market. I refer you to page 71 of the brief on research and the Hinchcliffe committee's report to the British Minister of Health which states that really outstanding drugs are still very few in number and if a firm makes one major advance in ten to twenty years it is doing well. Now, it is hard, as a research director to say how do we justify existence. Well, of course, if we get one major advance in ten to twenty years obviously I think it is only rational to believe that that one must carry those ten years we have been working away. We do not sit around doing nothing. We have to keep paying.

Mr. MACKASEY: May I ask a question at this point. I believe you represent an independent research laboratory.

Dr. BRIANT: Yes.

Mr. MACKASEY: Presume that under contract or in co-operation with a company, Ayerst McKenna which does a lot of research—

Dr. STEWART: Well, we are not independent. We are a research division of a European firm. We do not do research for outside firms.

Mr. MACKASEY: Well, presuming there was an independent firm in Montreal, working in conjunction with Mr. Gregory's Ayerst McKenna, and presuming that tomorrow, after years of research there was developed a product here in Canada, and presuming that as a result of this new discovery it will be

reproduced in manufacturing plants in other parts of the world, how is the initial cost of research which Mr. Gregory's firm incurred in co-operation or collaboration with your firm in Canada apportioned throughout the world? This is what I am interested in.

Dr. STEWART: Mr. Mackasey, I can only say that, first of all I have no experience in this, but there is a firm just like this called the Ontario Research Foundation, and I suggest that perhaps these people would give you exactly the right answer on their financial operation.

Mr. GORDON F. HENDERSON, Q.C. (*Patent Attorney, Gowling, MacTavish, Osborne & Henderson, Ottawa*): If I may perhaps give you a reference which will give you some guidance on how it was calculated in a court into what was considered a reasonable research ratio for an allowance by way of royalty. You may get some guidance in a case in England called geigy's patent. It was a compulsory license case. I propose at a suitable time to commend it for the consideration of the Committee. It is reported in the 1964 Reports of Patent Cases at 391. You will see how they worked it out. They took the current total annual expenditure on drug research and development over current total annual income from sales of patented drugs in that year and multiplied by 100 to determine the research ratio that gave the ratio of what should be recovered on a dollar or enabled one to determine what amount should be recovered on a dollar sale. It worked out, I may say, in the one case I had something to do with on this side, in the order of about 16 or 17 per cent of the actual sales dollar.

Mr. MACKASEY: Well, Mr. Chairman, on section E (6), Dr. Wigle, do these figures indicate that only $1½ million went out of Canada under this—I should not say under the guise of supporting international research?

Dr. WIGLE: Dr. Briant has gathered these figures and he could answer more quickly than I could, Mr. Chairman, if he may.

Dr. BRIANT: We have data similar for 1963, Mr. Mackasey; it is in much the same form. I think I could transfer the argument to these figures. Appendix E (6) shows that the people of Canada benefited to the extent of $12½ million from international research; that is the total there. Of this sum, the actual out-of-pocket costs to the Canadian people in 1965 was $7 million. The balance of $5,439,000 although not charged by the parent companies represents the extent to which the parents estimated that their Canadian operations benefited from the product of the international corporation's total research effort.

Mr. MACKASEY: Professor, I am always wary of philanthropists and I have come to the conclusion that the drug industry is in business to make a profit and for no other reason. When you tell me they are giving us $5 million out of the goodness of their hearts I am not impressed. I am more impressed by the fact that there is only 1½ million going out of the country to support international research. I would like to know what relationship $1,579,000 has in proportion to the total volume of the business which I do not think is on that page and which I have not been able to find.

Dr. BRIANT: All those companies, producing packaged human pharmaceuticals, 37 companies on page E (6) and 41 on page E (2) so that the particular figure is approximately 1½ per cent. I would round it out to about 1½ per cent.

Mr. MACKASEY: In other words, there is only 1½ per cent of your manufacturing dollar, what you charge to manufacturing expenses, goes out of the country.

Dr. BRIANT: As out-of-pocket cost.

Mr. MACKASEY: Supporting what you might call international research.

Dr. BRIANT: Yes.

Mr. MACKASEY: You are also saying that if you did not support international research to the tune of $1½ million, to duplicate this information available to you because of the relationship with an international concern, you could conceivably be expected to pay up to $12 million.

Dr. BRIANT: Actually the total would be $12 million but there is $5½ million spent in Canada, so subtracting that there could be $6½ million paid out.

Dr. WIGLE: Mr. Chairman, just for the record, in case there is any misunderstanding, these figures that are on this page are not by any means indicative of the research expenditures from which the Canadian people as such benefit. The Canadian people benefit from the total research that is done in the world which is in the nature of $450 million a year, I believe, Professor Briant.

Dr. BRIANT: It is $450 million.

Mr. MACKASEY: But Professor Wigle, the $1,579,000 goes into the cost of producing the pill here in Canada, not the particular pill but pills. It has to be recovered or regained from the population, from the people who buy your products. Am I right in that?

Dr. WIGLE: Yes, that is right. That is correct, to pay it out.

Mr. MACKASEY: I was under the conclusion, Mr. Chairman, that it was a higher percentage. The $5,504,000 spent in Canada, in other words, covers research done other than by Pharma-Research, and pays for the gathering of information, side effects, and so forth from doctors. Is that in that category there?

Dr. BRIANT: This is following on Dr. Stewart's point I think, that Canada plays a part in the total co-operative international research effort and the practice testing of and relaying results is of benefit to all the companies in the international complex.

Mr. MACKASEY: Is any of the $5,504,000 spent in Canada recoverable or charged to pharmaceutical companies or industries outside of Canada? If, so, does the Canadian consumer get credit for it?

Dr. BRIANT: Well, according to the statistics, the answer is no, that no companies outside of Canada are charged for research expenditures in Canada. I am basing that purely on table E(6).

Dr. STEWART: Could I say that I see what you are getting at, Mr. Mackasey, but I think what is charged is dependent on success in research. I think the research industry or the establishment of it in Canada is very recent, except for two or three companies who are old hands at the game. If I could just quote the two major Canadian advances, one was insulin, and the other was premarin of Mr. Gregory's Ayerst company, on my right.

Mr. MACKASEY: What was the second one?

Dr. STEWART: Premarin of Ayerst McKenna. Both of these—Mr. Gregory will correct me if I am wrong because I do not have any inside information—have brought rich returns in royalty I think to the Canadian operation. Certainly insulin, I think I am right in saying, allowed the government to establish from the royalties, the Connaught Laboratories in Toronto, and this had played a significant role in biologicals for the last thirty or forty years.

Mr. MACKASEY: What happened to Mr. Gregory's royalties?

Dr. STEWART: Well, Ayerst is the biggest Company in Canada, I think.

Mr. E. GLYDE GREGORY (*President, Ayerst Laboratories*): Mr. Chairman, Gregory, is my name. I would say that our laboratory is operated here in Canada, as you know, and it is financed on a project basis by other members of the Ayerst organization throughout the world. In other words, we are compensated on a project basis by our other subsidiaries or affiliates, or whatever one might wish to call them.

The CHAIRMAN: For a point of clarification, Mr. Gregory, you are saying that all of your company's research for the whole world is done in Canada.

Mr. GREGORY: This is true.

The CHAIRMAN: And that you are paid for that research on the basis of what you do.

Mr. GREGORY: For other affiliates, yes.

Mr. MACKASEY: Dr. Wigle, why are there not more companies doing the same thing as Ayerst McKenna?

Dr. WIGLE: Well, Mr. Chairman, I think that this is a matter of evolution, time, growth, the opportunity to expand to the level where they can do such; as we mentioned the other day we are only twenty-five or thirty years old in this industry, and I think that if the encouragement is continued to be given by the government, as it is presently and has been indicated by the efforts of the Lambert people who have just set up a new laboratory, the Smith Kline & French establishment, the tax incentives that are established with 150 per cent and so on to do it, that there will be—and this is a growing factor in our industry; it has increased I believe by two and a half to three times within the past five years—every reason to believe that it will continue to grow.

Mr. ROBERT F. DAILY (*Vice-President and General Manager, Smith Kline French Inter-American Corporation, Montreal*): Mr. Chairman, may I qualify this a bit. I heard my company's name mentioned. I would like to answer Mr. Mackasey's question more specifically. He asked why other companies are not able to parallel Ayerst McKenna and Harrison very worthwhile, and, I am sure, productive effort of concentrating all of their research activities in Canada. Well, this is an international industry. Now, Ayerst McKenna and Harrison, in its wisdom, and perhaps, if I might speak for Mr. Gregory, the fact that they had certain Canadian roots, decided that for this reason and perhaps other reasons, their research activities should be concentrated in Canada where the company had its origin.

Our company, on the other hand, would find it impossible to do of our research activities in Canada. We have our roots in Philadelphia south of the border, where we have a substantial capital investment and research activities. As a matter of fact, I think in our annual report we declared for 1965 that our research and development expenditures reached $22 million which is a fairly healthy percentage of our sales. However, we did decide, and perhaps this is in conflict with some policy considerations of other companies, that research to be most productive should not become too heavily centralized, and for this reason—and this incidentally was before Mr. Gordon or his predecessor—research tax incentives were brought forward several years ago which gave us some real advantage in doing research in Canada. We decided even before this development that it was in our interest to invest a significant amount in research activities. This culminated in a $1½ million research center several years ago We feel even though we are not doing all of our research activities in Canada what we are doing is a useful supplement to our activities both in the United States as well as in England where we have an even bigger investment.

Mr. HENDERSON: Mr. Mackasey, when we come to the patent section too, it will be the burden of our submission that the patent laws as they stand at the present time are not conducive to the further development of the type of thing that Mr. Gregory's company has done, that the level of patent protection in this country is of such a nature that it is not warranted and, therefore, we are discouraging rather than encouraging that kind of development. When we come to it I will give you cases of a particular nature to show why I say that.

Mr. SCOTT: I just have a couple of questions, Mr. Chairman,

Dr. Wigle, from what you have said do I take it that you consider research as a very important and growing part of the industry?

Dr. WIGLE: Well, I do on an international basis, Mr. Chairman. There is not any doubt that as a physician this is one of the fundamental reasons that I am associated with this industry. I think that the international and the world pharmaceutical industry has made such a terrific contribution to the world health of mankind in the last thirty years that anything that would hinder this research would be tantamount to slowing down the progress, as I said the other day, of people who are now suffering with diseases that are incurable. It would be tantamount to us saying, I am sorry but we cannot afford to look for a cure for you, and that has not been the philosophy of Canadians that I have met.

Mr. SCOTT: Those are laudatory sentiments. You told us that the Canadian consumer, I think it was you said, benefited by the $40 million spent in international research. I can understand how the companies would benefit by the research, but I wonder could you explain to me how the Canadian purchaser benefits?

Dr. WIGLE: Mr. Chairman, I think that the responsible research oriented manufacturer of pharmaceuticals throughout the world has proven his willingness and ability to make his products available when they are discovered and when they are given protection to as many countries as he possibly can in the world. Certainly many of the products from which Canadians are benefiting today and from which we as individuals have grown up to take for granted, have been given to us from such origins and they certainly did not all come from Canada per se.

Mr. SCOTT: Mr. Chairman, I have only been subbing for Mr. Orlikow. Have the companies filed their profit and loss statements?

The CHAIRMAN: No. The companies are going to appear before us separately as individual companies in the fall. The organization before us is just manufacturers associations representing a certain proportion of Canadian companies.

Mr. SCOTT: Perhaps this is premature but is it the intention of this Committee to obtain the financial statements of the companies? I would like to compare your profits with your expenditures in research.

The CHAIRMAN: It would be the hope of the Committee that the individual companies will be that frank with the Committee. These are private companies actually. We could ask for this information but whether we can actually obtain it is another question.

Mr. SCOTT: Perhaps you can answer this other question. What degree of co-ordination or co-operation takes place between our pharmaceutical companies in the area of research? I am perhaps erroneously under the impression that a good deal of the research is spent in needless duplication tracing the same goal. To what degree is there co-ordination and co-operation in the research field?

Dr. STEWART: Well, if you mean by that do we sit down and say will one company do this, and one company do that, as far as I am aware there is none. Let us face it. I can only give you our own philosophy, it is that we are skilled in certain areas by tradition or success in the parent company as we say and, for instance, we would avoid antibiotics or steroids or something like that, and concentrate our research in physio-pharmalogical work or cardiovascular. Now in here we have no co-operation and no collusion, if you like to put it that way, with other companies and we try our best to get some useful compound that will be an advance on what is already available. If one of our competitors happens to be working in the same field and brings out simultaneously a similar compound then, as you rightly point out, it is duplication. But experience has shown that freedom to choose your own projects and to pursue them is probably the most secure way of getting greater advances. I think the history of the industry has shown over the last twenty years that there has been real progress even though there may have been some duplication.

Mr. SCOTT: If I may make an interjection. I am just trying to ascertain the situation. Is it fair then to say that there is virtually no co-ordination or exchange of information?

Dr. STEWART: At the level of research directors and the planning of research there is absolutely none.

Mr. HENDERSON: They watch each others patents.

Dr. STEWART: The patent literature goes direct.

Mr. LAROSE: The very point I want to make is the patent—is a very wealthy source of information for research chemists and also the literature is full of information. Of course, all research chemists try to read as much of the literature as they can and, therefore, they know what the other people are doing. Now, one point about duplication; even if the purpose was simply to duplicate other people's products, this in itself would be very useful because in

research you never know what the end result is going to be. You start with an hypothesis or your start with a name, but the product that comes out of your research is an unknown. That product can be more potent; it can be more useful; it can be less toxic, in fact the history of research has shown just that, that as we progress we have been able to produce products that were more useful, more potent, less toxic.

Mr. SCOTT: One more question and then I will relinquish my time. I do not know who answered this but it relates to E (6) section 1. How do you arrive at the figure of roughly $5½ million as being the cost of research performed on our behalf for which no charge is made?

Dr. WIGLE: It is the result of our statistical survey and perhaps Dr. Briant can answer that.

Dr. BRIANT: Well I cannot say much more than that. It is the result of the statistical survey, that 37 companies have submitted responses to the specific questionnaire and the summation of the amount comes to $5½ million, approximately.

Mr. SCOTT: But is it not charged back in the price of the product anyway?

Dr. BRIANT: I really could not say. An individual company could answer.

Mr. SCOTT: That is all I have at the moment.

Mr. MACKASEY: Did we get an answer to that last question?

Dr. BRIANT: The answer is, "I cannot say."

The CHAIRMAN: He said, he cannot say.

Mr. MACKASEY: It is a long way from Christmas and I cannot see putting $5½ million in the pot. That is all.

Mr. LAIDLAW: Mr. Chairman, Dr. Wigle referred to tax incentives to aid research in Canada, and I will just read these out for the benefit of the members of the Committee. There was an amendment to the Income Tax Act in 1961 which provided for acceleration of the rate with which capital expenditures for research could be written off as expenses. There was a plan by National Research Council in 1962 providing financial assistance up to 50 per cent of the cost of some projects. In 1962 Canadian corporations undertaking to increase industrial research in Canada were permitted to deduct 150 per cent of their increased expenditures in scientific research. Now perhaps I should not address my question to you, Dr. Wigle; perhaps it should go directly to the manufacturers. I wonder if the manufacturers present here today have any actual figures as to the benefit they receive by these tax incentives because the tax incentives in fact mean, at least to me, that the taxpayer is subsidizing the drug industry to promote research and if patents presumably come out of that research the patents belong to the industry and not to the taxpayers who subsidized.

Mr. HENDERSON: There are a good many assumptions in that that do not seem to add up. First, there is no indication that any of these tax incentives have given rise to any patents that have lead to the conclusion that you reach.

Mr. LAIDLAW: This is one answer I wanted to know.

Mr. HENDERSON: You put it in the form of question rather than statement. Well, if it was put that way, at least we can investigate it. I rather thought you were indicating this to be a fact rather than an enquiry.

Mr. MACKASEY: Mr. Chairman, could I ask Mr. Laidlaw a question for clarification. This intrigues me, Mr. Chairman. Are these tax incentives and write-offs to stimulate research limited to the pharmaceutical industry, Mr. Laidlaw?

Mr. LAIDLAW: No.

Mr. MACKASEY: What would happen, if I could draw an analogy, if as a result of this research somebody came out with a new refrigerator; would it be his or the government's? How would you expect it to differ from the drug industry? Would you think that it would come in under research?

Mr. HENDERSON: As I understand it, and I think Mr. Laidlaw will confirm it, it would belong to the manufacturer.

Mr. MACKASEY: You see the point that I keep coming back to, is that I have no allusions as to why you people are in business. You are in business to make money I presume. Whether you make exorbitant profits or not is what we are here to find out. I think periodically we lose track of the fact that the drug industry does not differ, in my opinion, from the bread manufacturer, or the man making the refrigerator. You are here to make a profit on a product that you are producing. That is why I asked. I thought perhaps from Mr. Laidlaw's remarks that this reserach was placed exclusively at the disposal of pharmaceutical industry.

Mr. HENDERSON: To carry that one step further into the patent field, the patent protection, however, in this field is discriminatory.

Mr. MACKASEY: That is a matter of opinion.

Mr. HENDERSON: Well, let us put it this way. I do not think it is a matter of opinion that the scope of protection is far less in this field than in any other. That is not a matter of opinion; that is a fact. That we can get into in detail.

Mr. MACKASEY: That we will establish when we get to the section on patents.

Mr. HENDERSON: Yes, this will be the burden of our submission when we get to patents, but I do not think that there will be any dispute about the fact of difference. Whether there is justification for it, is another matter. There is no doubt as to the fact.

Mr. ISABELLE: I have one question. Maybe the question is silly but could we have the definition of a drug manufacturer. If I understand correctly, some manufacturers are doing research and others do not do any research. What is the exact definition of a drug manufacturer?

Dr. WIGLE: Mr. Chairman, we have had many definitions of manufacturing, including those that were put down by the Trade and Commerce people, those for our own purposes and those for other people's purposes but I would like to give Professor Larose an opportunity to define a pharmaceutical manufacturer.

Mr. ROGER LAROSE (*Vice President CIBA Company, Limited, Dorval, Quebec*): I could give you a definition but there could be many; mine would be

that a drug manufacturer is one who transforms a substance into a pharmaceutical product.

The CHAIRMAN: I should point out that is not the definition under the Food and Drug Act.

Mr. LAROSE: Well, I do not think the drug manufacturers are defined in the Food and Drug Act, a drug is.

Mr. HENDERSON: It is in the regulations.

Mr. LAROSE: Well, I will keep mine, Mr. Chairman.

Dr. WIGLE: So far as our Association is concerned, Mr. Chairman, I might just say for the record that a full member of this Association as a pharmaceutical manufacturer are those corporations or firms which manufacture and distribute or distribute under their own labels in Canada under proper conditions for control of quality and standards pharmaceutical preparations dispensed or prescribed by physicians.

Mr. ISABELLE: There is no question of research at all.

Dr. WIGLE: No, it does not mention it.

Mr. SCOTT: Do you classify under research the testing of the drugs before they are given out to the public?

Dr. WIGLE: Oh yes. Do you mean the testing before they are put on the market?

Mr. SCOTT: Is that classified under this research you are talking about now?

Dr. WIGLE: Indeed, and it is fundamental in my opinion, to the safety of the Canadian public.

Dr. STEWART: Mr. Chairman, I would just like to turn to Appendix H which gives you the stages which a drug goes through from the time it is first synthetized to the time it is sold to the Canadian public. I think properly all of these steps are in large measure part of research development.

Mr. HOWSAM: Mr. Chairman, with respect to Mr. Scott's comment I might mention that the question of testing was important, as witness the case of thalidomide in Canada where inadequate testing was the key problem.

Mr. SCOTT: Have you any self-criticism to offer in that field?

Mr. HOWSAM: No, sir, I do not.

Mr. SCOTT: I did not think so.

Mr. HUME: Mr. Chairman, there is a definition for Dr. Isabelle on page 33 that is adopted in the brief.

Mr. LAIDLAW: On that question, Mr. Chairman, are there any actual therapeutically active substances made in Canada, or are these all imported?

Dr. WIGLE: Well, Mr. Chairman, my actual knowledge is limited but offhand I can think of one therapeutically active substance, tetracycline, one of the broad spectrum antibiotics, as I understand it, is treated right from the stage of fermentation in Canada by the company that provides a good portion of the market.

Mr. LAIDLAW: But by and large would most of the actual active ingredients be imported into Canada?

The CHAIRMAN: Mr. Beauchemin, do you have something to contribute that is pertinent?

Mr. BEAUCHEMIN: I understand that 20 per cent of therapeutically active substances used in Canada are manufactured here. I understand also that the Department of Industry has a great interest in seeing that there is an increase in this production. We are certainly increasing it all we can, but we are not essentially in Canada in the fine chemical field which the therapeutically active substances are.

Mr. O'KEEFE: I have just one question, Mr. Chairman. The end result of all drugs and all chemicals is the effect it has on the patient, whether the patient is cured, killed or improved.

An hon. MEMBER: In which order?

Mr. O'KEEFE: That is the very point. How is that research paid for? I presume that is supported by the doctor, by the attending physician. Is the research carried out by the doctor or his report on each individual case given to someone and, if so, whom? And how is it paid for? It is, I presume, part of the research cost.

Dr. WIGLE: Mr. Chairman, if I understand the question correctly, you are referring to that portion of research which is of a continuing nature after a product is placed on the market?

Mr. O'KEEFE: Yes. When the doctor prescribes the prescription he also observes its effect, I presume, on the patient. If the patient dies—may be it is not from the taking of drugs but possibly from its side effects—does that report go back to you people? Is that doctor paid for that, how, and how much?

Dr. WIGLE: I think that these are part and parcel of the total pricing picture that takes into mind distribution and professional information, and I think that professional information is a two-way street, and part of the cost is getting this information back. Most of the responsible manufacturers encourage their representatives to be continually seeking return information from the practising profession as to what the effect has been. In addition, the Food and Drug Directorate are working on an adverse drug reaction program which the Association has offered support to whenever we have the opportunity.

Mr. O'KEEFE: And you get that result from the attending physician.

Dr. WIGLE: Yes, that is right.

Mr. O'KEEFE: Always.

Dr. WIGLE: Well, the adverse reaction, as I understand it, would be the assessment of the attending physician. It would have to originate there unless I misunderstand the question, Mr. Chairman.

Mr. O'KEEFE: But I am not quite clear on who pays for this. Who pays the doctor who reports?

The CHAIRMAN: There would be no fee attached for such service.

Dr. WIGLE: That is right. Part and parcel of the service which a responsible manufacturer offers when he puts a product on the market is to get the information out and be prepared to get the information back.

Mr. O'KEEFE: The only way he can get it back is from the doctor who prescribed it.

Dr. WIGLE: Of course, that is right, but he sends a man into the field to give the doctor the opportunity to report that information back and, in fact, it has been on several occasions proven that this has been the facility which the responsible manufacturer has offered which has made a great difference in the arresting and recall of a product from the market when it was a responsible manufacturer.

Mr. O'KEEFE: Is this particular doctor paid a fee for that report?

Dr. WIGLE: No, not at the present time.

Mr. O'KEEFE: Then who is?

Dr. WIGLE: The manufacturer carries the responsibility and the cost of it through his representatives that interview the doctor.

Mr. O'KEFFE: But if there is no fee, how can there be a cost?

Mr. LAROSE: Actually we would have to explain that we have in our company medical department physicians who are working full-time for us—for instance, I have three—and one of their jobs is to keep in constant contact with the physician, and side effects are being reported directly to us by the physician when they occur, or they are reported to us through our medical representatives. In turn, we have to report to the Food and Drug Directorate the moment we have sufficient information about the side effects reported by the physician, so we will either enter into correspondence or in telephone conversation, or we will send a medical representative or one of our physicians will go and visit the physician and get all the facts from him and, in turn, all of that information is given to the Food and Drug Directorate. In turn, they might take action themselves in which we will have to participate, for instance, in sending a letter of caution to the physician, to all the physicians of Canada. This is a cost which we incur. We pay these physicians; we pay their time; we pay their expenses and so forth. This is part of our operating costs, that is what we call the cost of doing business in the pharmaceutical field.

Mr. O'KEEFE: I thought I understood Dr. Wigle to say that those physicians were not paid. You say they are paid.

Mr. LAROSE: The physician who is treating the patient, witnessing the side effects and reporting it to us, is not paid, but the physicians on our staff are full-time employees of our company and, therefore, are paid by us, and this is our way of doing business. This is the cost of doing business.

Mr. O'KEEFE: Do you have any idea of how many physicians in Canada are paid on the basis you mentioned.

Dr. WIGLE: On page 87, there are 71.

Mr. LAROSE: I do not want to offend but we figure it is about 60.

Dr. WIGLE: 38 companies and 71 doctors in 1964.

Mr. O'Keefe: In all Canada?

Mr. MACKASEY: Mr. O'Keefe wants this information, and so do I. What obligation is there at the present moment, other than a moral one, on a

practising physician to notify the drug companies or the Food and Drug Directorate of some side effects or something abnormal that he sees as the result of administering a prescription to a patient.

Mr. LAROSE: I would say it is a legal obligation on the part of the physician.

Mr. MACKASEY: Legal or moral?

Mr. LAROSE: I think it is legal. Mr. Allmark from the Food and Drug Directorate could answer that, I am quite sure. I think it is a legal obligation.

Mr. M. G. ALLMARK *(Food and Drug Directorate):* For an old drug it is not a legal obligation but for a new drug it is.

Mr. LAROSE: For a new drug it is.

Mr. SCOTT: Do doctors act as research people for you in this way?

Dr. WIGLE: Mr. Chairman, if I might attempt to answer that I think that the medical profession agreed to co-operate in the reporting of adverse drug reactions as a moral responsibility; the legal application has come out with the development of this new program, trying to get the reporting of it. My impression is that so far the medical profession are co-operating very well with this program. Does that answer your question?

Mr. SCOTT: I am curious about what has just come up. I can recall some allegations in the United States about doctors administering drugs to patients which were almost in the category of experimentation without the patient's knowledge. Is there any of this going on in Canada?

Dr. STEWART: Mr. Chairman, if I might respectfully say, I do not think this is part of our brief here at all. I am talking now as an individual, but this is an ethical problem which is exercising the medical profession in most countries now. We in the pharmaceutical industry can only make it plain in research that we do not actually do the research on the patient. In other words, our medical department that Mr. Larose was talking about or our clinical pharmacologists are not the people who actually give drugs to patients. These people are skilled in the fields of statistics and experimental design and they are also knowledgeable and make it their business to get to know all the facets of this particular compound, so that he can advise investigators whose full-time profession is treating patients in different specialties. The ethics to which you refer really is a problem for the medical profession and not for the pharmaceutical manufacturers. We go along with them. If they say no, they will not do it, we say fine.

Mr. MACKASEY: But you supply these to them.

Mr. STEWART: Only if they consent; they ask us as a rule. We put the picture to them and if they find that it is beneficial to their practice, they agree to do it. But it is not our decision as to whether the drug is given to humans or not.

Mr. SCOTT: Do you supply the drugs to the doctor free of charge?

Dr. STEWART: Well, I think again, it varies. The regulations allow us to sell them. When we get permission from the Food and Drug Directorate, we do; but I think the general policy is that we supply them free of charge for these investigations. Let me put it this way, Mr. Scott; you realize that we cannot get permission to introduce a drug for commercial sale in the country without clinical work or, in other words, experience in patients. The pre-clinical permis-

sion to test drugs in patients, we have to submit the toxicology, animal experimentation to the Food and Drug Directorate and we receive specific permission back from them to test it in humans. I believe, Mr. Allmark will correct me if I am wrong, with the pre-clinical permission we are allowed to sell; that specifically spells it out. But it is usually the practice of the pharmaceutical manufacturers, at least most of them, not to sell until they receive what we call the permission to release a new drug. When we receive permission to sell, that is the time we start to earn money on the drug.

Mr. SCOTT: It was my understanding that before you can sell the drug commercially you have to experiment on people?

Dr. STEWART: No. We can sell the drug if we get permission to test it on humans.

Mr. SCOTT: Do you do this by using the doctors to administer it to their patients and report back to you the effects.

Dr. STEWART: Correct.

Mr. SCOTT: Are the patients told that this is the arrangement?

Dr. STEWART: I am sure they are.

Mr. SCOTT: Do you know whether they are told?

Dr. STEWART: In all the trials I have been associated with they have been told.

Mr. LAROSE: Mr. Chairman, if this is relevant I think you should invite a clinical investigator to answer these questions because this is really not in our field.

Mr. SCOTT: Well, I am only asking for whatever knowledge you have on the subject. If you do not have it, just say so.

Mr. LAROSE: Yes. But I would suggest Dr. Jacques Genest, for instance, or somebody who does clinical investigation. They know, because they do it all day long.

Mr. O'KEEFE: A supplementary, Mr. Chairman. If a drug is not sold, Dr. Stewart, but given to a doctor for experimenting, may he then use it despite the fact that it has not been tried on humans before, if you give it away, as I assume some drug companies do.

Dr. STEWART: Mr. Chairman, I think we have to get this absolutely plain. The regulations are clear. We cannot give it to a doctor unless we receive written permission from the Food and Drug Directorate that it is allowed to be tested on humans. And I think responsible manufacturers would not even get to that stage without that permission.

The CHAIRMAN: We are getting a little lost in the field of safety which I think the Committee has already gone into.

Mr. ISABELLE: I have just another question and then I think I will be finished. What percentage of drug manufacturers in Canada are doing research? Is there a percentage available?

Dr. WIGLE: Dr. Brian Stewart might answer.

Dr. STEWART: Dr. Isabelle, we have a reprint here which I will send to you. It came out in *Chemistry in Canada* in November. It listed all the companies in

Canada doing research in Canada. There are nine listed here. I am talking now about animal experimentation or, in some way, some form of pharmacology, but all companies in Canada are doing clinical research now, at least all I think associated with the pharmaceutical manufacturers association. And we come back to that big list I showed you in Appendix H and section 7 which gives the sequence of research. But I thought your question referred mainly to animal facilities, pharmacology and so on. I say that the majority of companies in the Pharmaceutical Manufacturers Association do actual clinical research in Canada.

Mr. ISABELLE: But not all companies?

Dr. STEWART: No, no; those in the Pharmaceutical Manufacturers Association.

The CHAIRMAN: Are there any other questions relevant to research, leaving out the explanations of research as it applies to patents and vice versa?

Mr. MACKASEY: Well, Mr. Chairman, I will accept that, provided you give us a little leeway on patents if we go beyond it because the point I had in mind, getting back to costs in research is this. I should not say one of the fallacies but one of the impressions I have always had of the drug industry is that they hide abnormal profits under the guise of research. Let us phrase it another way; profits going out of the country under the guise of supporting research done outside of Canada. This is why I am a little amazed at the figure on page E (6) which, if it is accurate, I only hope that if there are 37 companies they have not 37 companies that do not send too much money out of the country. But if $1,579,000 is all that goes out of the country, by way of research, then I have got to remain silent at this point and find some other loophole.

Mr. BLAKELEY: Mr. Chairman, following on from Mr. Mackasey's point which relates to the fact that research and development costs pertain to 37 companies whereas the Schedule E (2) pertains to 41 companies and that it was, I presume, from here that the sales figure was obtained to arrive at that 1.5 per cent figure mentioned earlier, I would ask, Mr. Chairman, would the four companies that are missing be companies that would likely have a large expenditure for research going outside of the country?

Dr. WIGLE: I am not sure that we are able to answer this because this is a survey that is done in confidence; even within the Association offices we do not know the specific return from each one because it is done by an outside agency, and those companies are not identified that are in each particular portion. But perhaps Dr. Briant could elaborate on this.

Dr. BRIANT: Well, that seems to be the correct answer, Mr. Chairman. We frankly do not know the companies that do not answer the questionnaires.

Mr. MACKASEY: You know the four that are left out and, without mentioning them, are they large companies?

Dr. BRIANT: We do not know the four.

Mr. MACKASEY: You know the forty-one that were included.

Mr. BLAKELEY: We do not know their names.

Dr. BRIANT: It is not likely for this reason that so far as we know from year to year there is some change in the list of the companies that respond, and we

can tell from the figures whether there is any wide variation, say, in 1964 from previous years, and there is not. The sample is usually a fair reflection of the reality, in fact an actual reflection.

The CHAIRMAN: Gentlemen, I would suggest that perhaps we should pass on to section number 2.

Mr. HUME: Mr. Chairman, with respect I am afraid I am still left in the air with the point I made with Mr. Laidlaw. Mr. Laidlaw was kind enough to give us a list of things that he wants developed, and one of them was some sort of a breakdown of research and development. I think I stated it accurately that the only information we have is reflected on E (6). What I still do not know is, does Mr. Laidlaw want us to go back and get some further information or is he going to wait until some of the individual companies come before the committee and get some information that way. All we have at the moment is on E (6) and if we need any more we have to go back and get it, which means corresponding with these companies and attempting to persuade them to answer the questionnaires and then correlating the information. If the Committee wants it, Mr. Chairman—I am sure I speak for the Association—we will do the best we can, but I still do not know whether we need.

Mr. LAIDLAW: If I may be permitted to answer that question for the Committee, Mr. Chairman, I would say that following your explanation, sir, I think it is probably unnecessary at this time to ask you to go into it in that detail, at least until the same type of question can be addressed to each specific manufacturer.

Mr. HUME: Thank you.

The CHAIRMAN: I was going to say that specific invitations will be going out to the drug manufacturers, many of whom sit in this room under other hats, if we like to say it that way. We can include this if they give us a breakdown if possible of their research dividing it into basic research, clinical research, manufacturing research and these different areas. So I suggest that perhaps we move on to prescription dollar, section number 2.

Dr. BRIANT: Just before we leave, there is one little point that may be of interest. I looked through my records. I notice that there were 12 M.D.s in the industry in 1958, 71 in 1964. There were 61 Ph.D.'s in 1960, 106 in 1964. This gives some measure in terms of human beings employed, the nature of the increase in the industry's research effort over the years.

The CHAIRMAN: Perhaps before we get into this there was one question that I think unofficially you thought you might be able to come up with the answer. That was the question of how many drugs were actually exported from Canada. I am not suggesting that you answer it right at the moment, but perhaps if this information is available the Committee might like to have it at a later date.

Dr. WIGLE: Yes.

The CHAIRMAN: Perhaps you might just communicate it in letter form to the Committee.

Mr. MACKASEY: Perhaps it could be done when we have the patent discussion.

Mr. WHELAN: If I understood the doctor right before dinner, he said he was going to look it up at lunchtime.

The CHAIRMAN: He took time to eat.

Dr. WIGLE: We will take the question under advisement.

The CHAIRMAN: Fine. We will move on to section 2, the manufacturers portion of the prescription dollar.

Dr. BRIANT: Could I just stop a minute. I am always a little behind. I do have a figure for export sales of $1,152,000 for 1964 for 41 companies.

The CHAIRMAN: Is that the total?

Dr. BRIANT: Yes. That is the total of export sales.

Mr. MACKASEY: Have you also got on that same page the total sales for those companies regardless of where they sold their products?

Dr. BRIANT: Yes, $107,000,000, so it is about the same percentage as for research.

Mr. WHELAN: Have you got the figures on imports at the same time from the United States?

Dr. BRIANT: Those are in the brief, page E(4).

The CHAIRMAN: Section number 2, gentlemen.

Mr. SCOTT: I wanted to ask a few questions—I do not know to whom they should be directed—on the schedules at page 2.2 and 2.3. The most significant thing that strikes my eye, and perhaps you could give me some information on it, is that it seems to cost almost as much to promote or market the products as it does to manufacture them. I notice on the manufacturers portion it is 11½ cents to manufacture, 11 cents to market, 2½ cents for the important field of research, and 1½ cents for labour. I wonder if somebody could give me some information on what is involved in the 11 cents that goes into professional service, marketing, and so on.

Dr. BRIANT: Before we do, could we clarify the point on labour; the 1½ cents that has been referred to a number of times is just plant labour, that is of manufacturing labour. But in many of the other items in the professional service representation, distribution, warehousing, research and development, and manufacturing administration there is also labour included and this is answered on page 3.4. Taken from the statistical appendix labour is shown to be $29 million out of payments in Canada of $85 million, so the total labour cost in the industry is something in excess of 30 per cent.

Mr. MACKASEY: Mr. Chairman, if I might ask at this point a supplementary question, the top line, manufacturing, 11½ cents; is that direct labour.

Dr. BRIANT: Direct labour?

Mr. MACKASEY: Direct labour other than your indirect.

Dr. BRIANT: Yes.

Mr. MACKASEY: What did manufacturing consist of? What is included in the word manufacturing?

Dr. BRIANT: Do you want a statistical answer, because it is down here? Eight and a half cents for materials, 1½ cents for labour, 1½ cents for plant, 11½ cents for manufacturing.

Mr. SCOTT: I was waiting for an answer to my question about what is meant by marketing, medical and professional service representation, what is involved in that? Is that set out in detail somewhere, Mr. Chairman?

Dr. WIGLE: Yes, it is, Mr. Chairman. There is quite extensive detail under the marketing section and in Appendix B, Mr. Chairman, showing the role of the detail men.

The CHAIRMAN: Is it the wish of the Committee to reconsider section 9 now? It seems to me we will have to break down our study somewhere and if you wish to go into that that section dealing with marketing, selling, promotion, and so on, perhaps we could do it now.

Mr. MACKASEY: Now, Mr. Chairman, if you are deviating or if you are permitting us to go into another section, then I would like to reserve the right to go into the Hilliard report at the bottom of page K 10 and the beginning of K 11, which I think has a very important bearing on this question.

Dr. WIGLE: Well, Mr. Chairman, I think that this is a pretty extensive subject to open up as an interval, with respect. The Hilliard report is closely related to the problem of patents and other areas that you had thought that you would hold over.

Mr. MACKASEY: Well in all fairness to Mr. Scott and the prescription dollar, at the bottom of K 10 one of the strongest recommendations of the Hilliard report, which I thought was almost in direct opposition to the Hall commission report, goes on to say—and I am just going to abbreviate it because I realize I am on somebody else's time—that it recommended that no manufacturer shall market any drugs unless he has available a product brochure containing complete information on the indications, contra-indications, precautions, dosage and side effects, as well as a resumé of pharmalogical and clinical studies carried out on that drug, and that such brochure be furnished on request to any physician, dentist, veterinary, surgeon or pharmacist registered and entitled to practise the profession in the provinces of Canada. I just thought this had a relation to the area that we tend to criticize and that is marketing, selling and advertising.

Dr. WIGLE: Mr. Chairman, I think the comments, as I understand them, are correct. I would just like to have it recognized that when we get to this item I think that the Committee will be aware that we are in full support of the recommendations of the Hilliard Committee.

Mr. MACKASEY: I imagine you are.

Mr. SCOTT: I will reserve my questions.

Dr. BRIANT: Mr. Chairman, I do not know if Mr. Scott has appendix D, but the role of the detail men is set out therein.

The CHAIRMAN: As the breakdown of the manufacturers dollar really sums the whole brief up, I think we will come back to it at a later stage with no trouble at all. Perhaps we will move on to some of the other sections.

Mr. BLAKELEY: Mr. Briant, would you be able to tell us the percentage allocation of sales; that is, the wholesalers, retailers, hospitals? There was a

similar allocation in 1950, and there are figures for 1960; I was wondering if you have them for 1964? I am referring to the allocation of manufacturers sales amongst these various categories.

Dr. BRIANT: Do you want to write this down?

Mr. BLAKELEY: Do you have it?

Dr. BRIANT: If you write this down you can do the calculations: $23½ million direct to retailers; $23,500,000 direct to retailers by manufacturers; and $49.9 million to wholesalers, which is then passed on to retailers; hospitals $27 million; government, $3.2 million; export about $1.15 million.

Mr. BLAKELEY: If I am lucky that will add up to a hundred.

Dr. BRIANT: And, rounded out, with about $2.8 million.

Mr. BLAKELEY: Well, the reason I ask this was that I wanted to determine what the relationship was between the sales directly to retailers and to wholesalers and I think we can probably conclude that essentially all wholesalers' purchases from the manufacturers are made to the retail pharmacists. This ratio has changed somewhat from the figures I have here, but the reason I wanted to develop this, Mr. Chairman, is that in the calculation of the 37½ cents, we start off with the results of the survey conducted by Professor Fuller for the Canadian Pharmaceutical Association and you work down to this figure by deducting the full wholesalers' margin, but since the retailer will purchase a good portion of his materials directly from the manufacturers, then surely you should not deduct the full margin from this. Do you follow me? I say this because you are deducting the full wholesale margin on the basis that all sales by the manufacturer made to the retailer via the wholesaler. But this is not the case, so it seems to me that that portion of the wholesaler's margin that has been deducted in this calculation which really comes about through the sales by the manufacturer directly to the retailer should not be deducted.

Dr. BRIANT: Yes, but the point here—I think I am right; Mr. Beauchemin might know better—is when the manufacturer sells directly to the retailer he sells to the retailer at the price that the wholesaler would be paying.

Mr. BLAKELEY: Oh, this is not what was reported the other day though.

Mr. BEAUCHEMIN: Not necessarily. Actually if the manufacturer performs a wholesale function, and some manufacturers sell, by policy, directly to the retailer, he performs a wholesale function.

Mr. BLAKELEY: He sells at list less forty percent.

Mr. BEAUCHEMIN: Yes, and he is entitled by the Department of National Revenue to deduct 15½ per cent for his performance of the wholesaler function. The cost is practically the same whether its the distributor, the wholesaler or himself. If he acts as a wholesaler himself for those products, well and good. It costs him something.

Mr. BLAKELEY: He is taking the wholesaler's margin, then.

Dr. BRIANT: The point there, Mr. Blakeley, is that you might eliminate the wholesaler but you do not eliminate the wholesaler's function.

Mr. BLAKELEY: Oh, that is all right.

Dr. BRIANT: The point that Mr. Beauchemin is making is that if the manufacturer performs that function he keeps the 8 per cent of the prescription dollar to cover the costs associated with the wholesaling function.

Mr. BLAKELEY: I still believe my point to be valid. Unfortunately, all the figures I have calculated were based on the figures that are out of date but at that point it was 50/50 actually. But I still believe that in the reduction here, in the calculation of this, that you should not be taking off the full margin, only that portion which is going to the wholesaler and not remaining with the manufacturer.

Dr. WIGLE: What would be the distribution of that extent then.

Mr. BLAKELEY: Well, it is borne by the manufacturer, then.

Dr. WIGLE: Well, you have it in here.

Dr. BRIANT: Oh, no.

Mr. BLAKELEY: Do you mean to say, then, that the revenues and expenses of the wholesaling operations of these companies are not reflected in these figures?

Dr. BRIANT: Oh, I think they will be.

Mr. BLAKELEY: Well then, the costs and profits are as well.

Dr. BRIANT: Yes. But, as you can see, if you were working on the 50/50 percentage that is quite different from the figures I gave.

Mr. BLAKELEY: Oh, well, I concede that you will get slightly different figures.

Dr. BRIANT: Much greater percentage.

Mr. BLAKELEY: You would still get something more than 37½ cents as well.

Dr. BRIANT: Yes. Let us see. It would be two-sevenths of eight cents, about 2 cents.

Dr. WIGLE: Mr. Chairman, would that not be based on the presumption that the manufacturer could do the distribution cheaper than the wholesaler?

Dr. BRIANT: No, I do not think so.

Dr. WIGLE: It does not have to be.

Mr. BLAKELEY: Another point, Mr. Chairman, this resulting figure—that is, the manufacturer's portion of the retail dollar—tends to increase as the higher priced drugs are dispensed and I think it is unfortunate that the calculations I have are based on slightly outdated figures. It is too bad these were not available. However, if you were to take the same survey and take the retail prices and the average cost at the higher levels for higher priced drugs, you would find the manufacturer's portion of the retail dollar tends to increase as higher priced drugs are dispensed. I only do this to point out that the 37½, the 39½ or whatever it may be, is only an average.

Dr. BRIANT: Oh, yes, and we do not claim it to be anything more than that. If you want to work it out another way, take Mr. Turnbull's figures, for example, of per capita sales in Canada, use the figure of 20 million, and take the manufacturer's sales, and you will find that they come to about 37½ ex sales tax,

about 37½ per cent of the total sales of drugs on prescription through retailers. It works out almost the same.

Mr. BLAKELEY: So we might note that the example you used this morning had a resale price on it of $25 to which you apply the 37½ per cent back. Obviously that would not apply because I am sure if you check out the higher priced figures you will find that the percentage is much higher than that.

Dr. BRIANT: Well, I did some recalculation and I would like to make use of this opportunity, as Mark Twain said "talking of fishing", to talk of that particular drug, Mr. Howsam was using an imported slide rule and he messed up the calculations. Coming back to the manufacturer's selling price of $4.66; if that were brought in from Britain—I think these are reasonably correct—we add 17½ per cent for duty—that is 82 cents—for a figure of $5.48; transportation would have to be added, and 5 per cent of the cost in Britain is said to be a reasonable estimate for the transportation—the manufacturer has worked it out —it comes to $5.71. Then we have to remember that many of the non-manufacturing costs incurred by the Canadian manufacturer would have to be incurred by the importer, the distribution costs, for example. So I have added here as costs the equivalent to Canadian manufacturers—that is, the non-manufacturing costs. Marketing and medical information, if we take this drug as an average—all we can deal with are averages—it would be thirty per cent of the Canadian manufacturer's present selling price. This is the percentage we have down; 30 per cent of $9.37 is $2.81. Distribution and warehousing, because the importer would have to have distribution and warehousing functions performed, is 4 per cent of $9.37—I am getting these percentages from page 23 in the brief—37 cents; income tax and profits of 15 per cent of $9.37, and that is $1.41. And administration because, presumably the importer would have to have some administrative staff, I used 3 per cent—I think in the brief it is 4 per cent—for 28 cents. You get $10.58 which I was going to say was 37½ per cent of the cost to the public. And if we blow that up to 100 per cent then we get a cost to the public of $27.50, a comparison with the $25.00 that we had down.

Mr. MACKASEY: Where did you put the federal sales tax?

Should it not be included right after the 17½ per cent excise duty; if that is where it is charged it makes a big difference. If it collected at the border, it is then collected as it comes into the country.

Dr. BRIANT: I do not know what happens with importations.

Dr. WIGLE: It is collected at the time of importation.

Dr. BRIANT: Importation? And it is based on the imported price? You would have to call this about 40 per cent then instead of 37½, and that would give us a figure of $26.40, something like that.

Mr. BLAKELEY: And we just saved the Canadian public $1.10. This is important to me.

Mr. MACKASEY: The $5.48, because of the federal sales tax, increases 57 cents.

Dr. BRIANT: Oh, yes, that is quite right. It might be that following Mr. Blakeley's point, that using 40 percent here is too low a percentage to use, but the pharmacists report after the gross, so I think if we took anything more than 50 percent, we would really be stretching a point. I think 45 might be

reasonable, and when you blow this up you will get the price to the public around the price of the present Canadian drug. The point I am making here is that these costs that we omitted in our very quick calculations with the slide rule this morning are costs the importer would have to incur. It could be that if he has a small number of items in his line that these percentages would be even higher.

Mr. LAIDLAW: I assume you conclusively proved that the drug industry in Canada has nothing whatsoever to fear from the possibility of imports. You just donwstated it, so why are you worried about it?

Dr. BRIANT: Because there are other drugs, Mr. Laidlaw, as we showed, 42 on Dr. Howe's list that have a price in the U.K. that does compare far more favourably but, as you pointed out, these are old drugs, subject to the price regulation in Britain and this particular drug is a price we set at the start. Is the price in Britain comparable to the price in Canada. This the manufacturers do not have much fear of at the moment.

Mr. MACKASEY: You pointed out that the drug lands in Canada for $6.00, federal sales tax included, so with our outmoded system of distribution it gets to the gullible public at a cost of $26.00. This is a tremendous spread, and I think it is an abnormal spread.

Dr. BRIANT: There are assumptions here but it could be.

Mr. MACKASEY: There may be reasons but I do not think it is fair to the consumer that an article that is going to cost them $26.00 lands in Canada, or can be manufactured by you for $6.00. Yet your argument to Mr. Laidlaw is that you can manufacture it just as cheaply as to bring it in. If you can manufacture it for $6.00, you would have a hard time to convince me that it should be sold for $26.00. This is what the whole purpose of our meeting is.

Dr. WIGLE: Mr. Chairman, may I ask Mr. Briant if this was a finished product that was being brought in? I thought this was a basic product for manufacturing.

Dr. BRIANT: I am told that the pharmacists profit is 4.8 per cent on the average before taxes.

Mr. SCOTT: What makes up the difference?

Dr. BRIANT: I cannot answer that but, perhaps, dispensing costs, prescribing costs, and so on.

Mr. SCOTT: You have given us your figures and you say they do not lie.

Dr. BRIANT: I did not say that. Are you thinking along the line that liars figure and figures lie.

Mr. SCOTT: Well, I am not trying to put you in either category, but Mr. Mackasey has raised an important point, and I am wondering if there is any answer as to why the manufactured price of around $6.00 ends up to the consumer at $26.00? Where does the difference go and how is it allocated?

Mr. MACKASEY: $5.48 is proper and the 11 per cent charges at that particular point because it is charged as it comes in through customs; 17½ plus 11 plus transportation usually ends up around 30 per cent and I am basing this on the years when I did a little importing in other fields. You end up with $6.00,

yet that becomes $26.00 to the Canadian tax payer, which brings me back to my theory that you people represent 37½ cents on the prescription dollar, yet all other taxes, including my own, are directed at reducing the 37½ cents as the potential cost of the high cost of drugs. If I fall into this cliché which I do not like to, and we are not putting enough emphasis or we have not indicated that we are putting enough emphasis on the 62½ cent area—that is, from the moment it leaves the manufacturer's door to the time it gets to Joe Public, the biggest area, you people represent a little more than a third of the cost, other people represent two-thirds of the cost. It seems to me that we should be directing our efforts, Mr. Chairman, before this thing is over, in direct proportion to find out, not only if we can reduce the 37½ cents but what we can do to reduce the 62½ cents. It is quite conceivable that the method of distribution in this particular field is outmoded as compared to the distribution in the field of other consumer products which are not vital to health—I am talking about refrigerators, and you can name them all—where the method of distribution from the manufacturer to the consumer has gone through radical change. I might say, Mr. Chairman, that there was a day when a set of golf clubs—I will come down to something I am familiar with—went from a manufacturer to a wholesaler or to a distributor sometimes and then to a wholesaler, and finally into a store to a catalogue price which represented an awful high figure as compared to the cost. Through the years the thing has now been streamlined. You can pick up those same golf clubs at about 33 per cent or 40 per cent less than you did five years ago. Why? Because you are buying them much closer to the source of production, and it seems to me that this is the answer in the drug industry. Somewhere along the line, Mr. Chairman, we are overlooking in our anxiety to get to the drug industry which we have to, or the pharmaceutical industry, we must make sure to reserve enough time to attack the 62 per cent or that area that contributes the 62 per cent. Here is a flagrant example, if Professor Briant's figures are accurate, a $6.00 item landing in the port of Montreal being sold to somebody in Vancouver for $26.00.

The CHAIRMAN: All the manufacturers can comment on is the 37½ cents in their brief. The other 62½ can be pointed out to us but they cannot explain it.

Mr. MACKASEY: That does not prevent Professor Briant from going beyond the $6.00 to the $26.00. You cannot have your cake and eat it too. If the drug industry wants to limit us, Mr. Chairman, to discussing how they arrive at the $6.00, then let witnesses restrict their information to that area, and not volunteer information that makes them look pretty sick as this does.

Dr. BRIANT: Well, to be frank, Mr. Mackasey, I am almost sorry I went beyond the $10.15.

Mr. MACKASEY: I would too if I were Professor Briant.

Dr. BRIANT: I think the distribution problem is a problem throughout the Canadian economy. I will not subscribe completely to your argument that we distribute as quickly. It is inherent, of course, in a large country with a small population. That might be particularly so with drugs where every small town needs a drug store to supply their needs.

Mr. MACKASEY: Mr. Briant, I am not saying there is not a reason for it but I am not too sure that you are the best qualified person to give it to us. I think it

is the duty of the Committee to get the right people here to answer why $6.00 becomes $26.00.

Dr. BRIANT: Could I just make one point and then I will sit down. I should have stopped at the $10.58 figure and compared it to the $9.37 figure that we had for this drug to the manufacturer. But it is not inconceivable that in duty, transportation, the federal sales tax, and the incurrence of the non-manufacturing costs that would have to be incurred on this quality drug—it is the same as buying in areas where it is available—that even then the equivalent cost at the manufacturer's sales price would be higher or certainly not much less.

Mr. MACKASEY: What you are saying is that it is not necessarily true that you can import at dramatically lower prices.

Dr. BRIANT: Only if you buy the very small volume items from Britain that have highly regulated prices but very small markets in Canada. But I went on to grant Mr. Blakeley his point that it could be 40 or 45 per cent on some necessarily expensive drugs. It could be but I doubt whether it would ever be 50 per cent on any drug.

Mr. PRUD'HOMME: Again I come back to my question of this morning of importing from the U.K., but, if I had said importing from the United States you would give the same answer you gave this morning.

Mr. HUME: Well I think the answer is that Dr. Howe's question related to the United Kingdom and Canada.

Mr. PRUD'HOMME: I wish we could get away from Dr. Howe's questions.

Mr. HUME: But I was just trying to explain.

Mr. PRUD'HOMME: I am sure we might find ourselves all agreeing at the end of the day that U.K. or Canada, it is all right; but I am sure that Dr. Howe could easily have asked a question like I would ask about the U.S.A. Then I think it would look much different. The picture would be much different.

Dr. BRIANT: Do we not have a number of drugs whose prices are lower in Canada than they are in the States?

Mr. DAILY: If I may talk to this for a moment, Appendix F reads that there is a listing of 17 products in our survey, prices to the retailer are listed in terms of Canadian dollars for Canada as well as the U.S. Out of the 17 I calculate 8 of the prices are actually higher in the U.S.A.

Dr. WIGLE: Well, Mr. Chairman, in defence of Mr. Briant's explanation of the price right down to the consumer level, I think that it is quite true that this morning in the early questioning relevant to these prices he was asked to carry it to the consumer level. I would like to have that on record.

Mr. MACKASEY: There is no point in doing it because he has pointed out, in extension of my argument, that the problem lies in the 62 per cent area rather than in the 37 per cent area.

Dr. BRIANT: Yes, but I do not want in the process to be unfair as you understand, Mr. Mackasey, to the pharmacists. I am not expected to speak on their behalf. Their statistics show their position as an unprofitable operation in many cases.

Mr. HOWSAM: Mr. Chairman, to wind up this particular exercise that Dr. Briant has been through, the product in question came from a list provided by Dr. Howe and indicated a package size which would never normally be a prescription. I would not like anyone to be left with the impression that a Canadian would walk into a drug store and be charged $25.00 for that prescription. It was for 250 tablets. It is a bulk package size subjected to various discounts that Dr. Howe picked out in his list, and that is the reason that it was used as an illustration, but it is certainly not the kind of prescription that an individual might get on a normal day.

Mr. SCOTT: The fact still remains that you can have a prescription filled at the Sick Children's Hospital in Toronto for 98 cents if your child is in there, and the renewal is $3.95 at the corner drugstore.

Mr. MACKASEY: I think we will get into this as time goes on.

The CHAIRMAN: This brings up the point of different costs of drugs in different organizations and in different areas which I think Mr. Blakeley was getting at, hospital pharmacies and government pharmacies versus private drug stores and so on.

Mr. BLAKELEY: Mr. Chairman, one further question with respect to section 2.

The CHAIRMAN: If there are going to be a lot more questions on section 2 we could leave it.

Mr. BLAKELEY: I thought you were leaving section 2.

The CHAIRMAN: We will come to that under marketing in another section.

Mr. BLAKELEY: On page 2.3, the income tax and earnings are each indicated to represent 7.5 per cent of total sales and together they represent 15 per cent. On page 35, about the middle of the page, it says that the earnings represent 10.8 per cent—that is before taxes, how do we reconcile these two figures, the 15 per cent and 10.8?

Dr. BRIANT: I would be very happy to Mr. Blakeley. I anticipated that question. On page 2.2 we are dealing with sales on prescription through retailers. Our assessment is the end result. The figure on page 35 is derived from the profit figure in Appendix E, the total operations of the company, so if you look at page E (2) we are relating the $7.7 million net earnings to the $150 million total revenue. We are dealing with the total revenues of the companies and not just the sales of packaged human pharmaceuticals.

Mr. MACKASEY: You are going to state some income.

Dr. BRIANT: The companies in the industry do. I do not.

Mr. MACKASEY: I understand Professor they are doing pretty well.

Mr. BLAKELEY: Well, Mr. Chairman, do I understand that the 10.8 per cent is based on total revenue of $150 million.

Dr. BRIANT: That is right.

Mr. BLAKELEY: Of which roughly $16.2 million is profit before taxes. Is this the 10.8 per cent?

Dr. BRIANT: Yes, if you look at E (2) you get 8.586 + 7.735, which is 16.32.

Mr. BLAKELEY: Well, that is what I said.

The figures on section 2 though, break down of the manufacturer's dollar.

An hon. MEMBER: That is the prescription dollar.

Mr. BLAKELEY: No, not 2.3. That is the manufacturer's dollar, the sale of human pharmaceuticals, prescription drugs.

Mr. HUME: 2.3 is simply the percentage calculation of 2.2.

Mr. BLAKELEY: The figures from which these percentages were calculated are not included in Appendix E.

Mr. HUME: 2.2.

Mr. BRIANT: Take E (2) and the second column packaged human pharmaceuticals, revenue of $110 million and you will see there they have income taxes and net earnings, $15 million. That is about 15 per cent.

Mr. BLAKELEY: Do I understand then that the percentages on 2.3 are developed from the middle column, column 2.

Dr. BRIANT: That is right.

Mr. BLAKELEY: E (2), and that the 10.8 per cent is developed from column 1.

Dr. BRIANT: That is right. You should look at the third column to see that the companies report a loss on all others, including bulk human pharmaceuticals.

The CHAIRMAN: Could I make one point there. At the top of 2.3 it should really read the breakdown of manufacturers portion of prescription dollar. It is the same set of figures as on 2.2 except transposed into percentages because the Chairman asked for it that way.

Dr. BRIANT: The figures on 2.2 multiplied by 100 over 37½.

Mr. MACKASEY: This might get back to Mr. Scott's question. The third column on E (2) then would show the loss of $545,000 bulk human pharmaceuticals, is this the area that you would consider sales to hospitals?

Dr. BRIANT: I think Mr. Beauchemin can give a definition.

Mr. BEAUCHEMIN: Unfortunately, Mr. Chairman, I do not have the definition we used in our questionnaire but if I recall well, I do not believe it included this. It included bulk pharmaceuticals in chemical form.

Mr. MACKASEY: Who do you sell bulk pharmaceuticals to at a loss, other pharmaceutical firms?

Mr. BEAUCHEMIN: The loss was a result of total operations.

Mr. BRIANT: Some of them make money but others are losing on it.

Mr. BEAUCHEMIN: This area of sales, of course, would be included in that and other operations I presume.

Mr. MACKASEY: Let me phrase it another way. The sales to hospitals; this is going to come up whether you are selling at a loss to a hospital or whether you are selling abnormally high to other outlets.

Mr. BEAUCHEMIN: Sales to hospitals are included in column 2, human pharmaceuticals.

Mr. MACKASEY: Bulk human pharmaceuticals are also sold to Veterinarians.

Mr. BEAUCHEMIN: Others including bulk human pharmaceuticals; others would be veterinarians.

Dr. BRIANT: We do have a definition and we could advise the committee of this. I do not think I have the definition here of exactly what is included, but certainly it does not include packaged human pharmaceuticals.

Mr. MACKASEY: Would you eventually dig out for me your definition of a bulk human pharmaceutical?

Dr. BRIANT: I would be very pleased to. We could have it for Thursday, or tonight.

Mr. GREGORY: Mr. Chairman, I would like to refer to Dr. Briant's comment on exports from Canada. It is my estimation that we will export this year about 5½ million of finished and raw goods out of Canada.

Mr. MACKASEY: Who will do this?

Mr. GREGORY: My company.

Mr. MACKASEY: What is the name of it?

Mr. GREGORY: Ayerst Laboratories.

The CHAIRMAN: Gentlemen, I think this would be a good place to adjourn the meeting until eight o'clock.

EVENING SITTING

The CHAIRMAN: Gentlemen, I think it would be reasonable to start this evening's session.

When we concluded the hearings this afternoon I think we were just finishing number 2 section, on the prescription dollar.

Mr. HOWE (*Hamilton South*): Eventually, but let us not conclude it at the moment. I have some questions.

The CHAIRMAN: Are they relative to this section, or could they be relative to another section?

Mr. HOWE (*Hamilton South*): They are very definitely relative to this section, Mr. Chairman.

The CHAIRMAN: All right.

Mr. HOWE (*Hamilton South*): I have two questions. The first one is: The earnings, which, I presume, Mr. Chairman, are profits, are stated at 3 cents which interestingly, is one-half a cent more than research, but aside from this, does this 3 cents represent just dividend payments, or is this the total earnings including those which are retained for further development of the drug business?

Dr. WIGLE: Thank you, Mr. Chairman. I think that Professor Briant might answer this question.

Dr. BRIANT: The figures I have which come from Appendix E, show that this 3 cents comprises, for the packaged human pharmaceuticals, $2,182,000 interest charges and dividends, and $6,153,000 retained earnings. Therefore, for every dollar paid out in interest charges and dividends $3.00 are retained within the industry for re-investment in the industry.

Mr. HOWE (*Hamilton South*): Was this really part of the profit?

Dr. BRIANT: Oh, yes.

Mr. HOWE (*Hamilton South*): No; but it is included within this 3 cents.

Dr. BRIANT: It is not broken down. We could break it down.

Mr. HOWE (*Hamilton South*): No; but it is included within the 3 cents.

Dr. BRIANT: It is included within the 3 cents, and three-quarters of a cent are paid out as dividends and two and a quarter cents are retained.

Mr. HOWE (*Hamilton South*): Reducing this to dollars, the research at two and a half cents in most companies, or in a lot of companies, represents perhaps $5 million to $10 million according to figures elsewhere in your brief, so this 3 cents would represent, of necessity, more than the two and a half cents on research.

Dr. BRIANT: It does represent more but the figures I used—I have here the sheet of paper from which these are calculated. The research and development charges, was $7,119,529. You will find that on page E (2) of the brief under the column headed "packaged human pharmaceuticals.".

Mr. HOWE (*Hamilton South*): I did a mental appendectomy and I did not see that.

Dr. BRIANT: Well, it is there. The retained earnings after taxes plus interest charges of the $8,026,000 are shown in line 13 of the second column on page E (2), plus $309,000 of interest charges in line 10. Therefore, the profits of the 41 companies—of the 58 member companies of this association—are $1,200,000 more than the expenditures on research in 1964.

However, I will say again that, of the $8,300,000, $2,182,000 were paid out as dividends and interest charges, and the remainder, $6,153,000, were retained in the companies in Canada, to serve as an investment. In fact, I think we illustrate this point on pages 3.7 and 3.8 of the brief, where from 1960 to 1964 we show the planned additions at cost and the source of the financing of these planned additions. Twelve million, seven hundred and eighty-eight thousand were provided from depreciation charges; and $22,728,000 from equity investment, most of which was additions to retained earnings. I think it is fair to say this.

Of the sources fo funds, $35,500,000, investment was $24,700,000. On page 3.8 we point out that the excess of the sources over the uses are represented by $8,625,000 invested in inventory and $2,200,000 in accounts receivable to finance the increase in accounts and other assets associated with the rising sales, which was not provided for by trade credit and other forms of debt capital; so that it is fair to say that the earnings retained were re-invested in something other than just cash in the bank.

Mr. HOWE (*Hamilton South*): But also was shown in the earnings.

Dr. WIGLE: Mr. Chairman, I think it is also pertinent, if Professor Briant would permit me, to point out that at the bottom of page 3.8, in the last sentence of this submission, we point out that there are two interesting relationships disclosed by these figures: For every dollar earned the companies paid four dollars in taxes. Is this right Professor Briant?

Dr. BRIANT: Absolutely correct.

Mr. MACKASEY: When you said that for every dollar earned you paid two out in taxes, I thought you were playing Santa Claus again. It finally dawned upon me, but I would like you to explain that paragraph. It is very ambiguous.

Dr. BRIANT: Well, when you say "playing", Mr. Mackasey—

Mr. MACKASEY: Dr. Wigle has just mentioned, for the benefit of the Committee, that for every dollar earned you paid two dollars in taxes. It leaves a false impression that you supplemented your dollar with another dollar given to the government.

Dr. BRIANT: Yes. I can explain that. In fact, if anything, that is an understatement. In Appendix E (2) the income taxes of the companies for 1964 are shown as $8,586,000.

Mr. MACKASEY: What page is that on?

Dr. BRIANT: Page E (2) in the Appendix. Income taxes are there in the first column, line 11, $8,586,000; and then there would be sales tax which was paid and also payroll taxes and numerous other taxes; so that in the aggregate, actually, I think it would be fair to say that they actually pay more than two dollars in taxes for every dollar of earnings. We have used the conservative figure.

Mr. MACKASEY: Dollar earnings after the taxes are paid?

Dr. BRIANT: Yes, after the taxes; they are dollar earnings after taxes. Until the taxes are paid you really cannot call them earnings.

Mr. HOWE (*Hamilton South*): One other question, and it is not bearing on this at all. You state in your brief too that the companies you represent advertise or represent only to the medical profession. This is stated in the brief, and we will accept this. Therefore you are advertising ethical products to professional men on a professional basis which costs 11 cents out of the 37½ cents.

Do you have any control over the type of advertising or representations that are presented to the doctors within these 57 companies which you represent?

Dr. BRIANT: Dr. Wigle will answer.

Dr. WIGLE: There is a code.

Mr. HOWE (*Hamilton South*): There is a code, is there?

Dr. WIGLE: Yes.

Mr. HOWE (*Hamilton South*): Mr. Chairman, I would like to demonstrate some things which were sent to my office. I have a shoe cleaner; I have

innumerable prescription pads and scratch pads; I have a measuring tape; I have letter openers; I have matches of innumerable types; I even have repairing for ladies' stockings and thread; I have measuring tapes; I have tourniquets; I have Kleenex; I have a practice golf ball, and I even have golf tees; without mentioning calendars and a lot of other junk, which is sent to doctors to advertise drugs to the intelligensia, shall we say—we will give the doctors the benefit of the doubt, and call them the intelligensia.

Is this the type of advertising that is used by the drug firms to advertise drugs to be sold and written on prescription by doctors.

Mr. HUME: Mr. Chairman, may I say, through you, sir, that Mr. Brydson in the Ontario enquiry did the same thing. He dumped them all over the table and when we examined them we found that a great many of them had nothing to do with the members of this Association. These may, or may not, but it is a difficult question to answer unless we know about who he is talking. Perhaps he might put that on the record.

Mr. HOWE (*Hamilton South*): I can name the drugs as we go. One is otrivin which is Ciba's. Are they not represented by you?

Dr. WIGLE: Yes. CIBA.

Mr. HOWE (*Hamilton South*): There is putisol which is McNeil. Is McNeil represented by you?

Dr. WIGLE: Yes.

Mr. HOWE (*Hamilton South*): I have Squibbs, for repairing ladies' stockings. I have coricidin, which is Schering's, which is a drug firm which you represent. I have Hoechst. I have tenuate, and I have forgotten who makes tenuate. I have benbritin, which is Ayerst. I have forgotten who gave me the practice golf ball. On the top of my golf tee is alertonic and I have forgotten who manufacturers alertonic.

Dr. WIGLE: Merrell, I would think.

Mr. HOWE (*Hamilton South*): I have teramycin, which is Pfizer's, and I am sure Pfizer is represented by you. I have sedalton, which is Hoescht again. I have from Squibb, a rather attractive calendar for children who come to the office. I have a pen of two colours, which is for thiosulfil, and I have forgotten by whom thiosulfil is made. I have a very attractive flashlight which does not work at the moment, but nevertheless it is here, and that is by Squibb. I have many others.

I have been insulted, or at least, I like to assume that my intelligence has been insulted, when products are advertised showing a picture of a frying pan with sausages which make up the mouth and fried eggs which constitute the eyes, which advertise Abbott supplementary vitamins as an indication that you should go on a diet.

Mr. COOK: 1934?

Mr. HOWE (*Hamilton South*): No. I have had these in the 1960s, in my office. I have had many others. I have even had cut out dolls which you open out—and this is the truth. This is preludin which is a measuring tape.

To me this is an excessive amount of junk that is advertised to an intelligent profession and must represent a fairly large portion of this 11 cents. Surely this type of advertising could be cut down to logical sampling and to logical sepcifications of drugs as given and sent to doctors so that they can make up their minds what they should use.

I can cite an example of a detail man who came to my office—I will say a few years ago because I have forgotten the year—and as he detailed the product to me I said, "Is that not the same as so and so?" He said, "Yes, doctor, it is exactly the same, except for the dietary factor." I said, "What do you mean by the dietary factor?" and he said, "If you do not buy my brand, I do not eat."

The CHAIRMAN: It was a pretty frank statement.

Mr. HOWE (*Hamilton South*): I think he summed up an awful lot in that statement because a lot of this 11 cents is spent in the advertising of drugs, which is the largest single item on this breakdown of costs. A lot of money is spent advertising brand "X" against brand "Y" which is exactly the same, but with more gimmicks, more reminders to write prescriptions, and I do not think this is the proper appeal that should be made to the medical profession to write prescriptions for their patients who are ill. If doctors do not respond to this—and I am sure they do not—I think this is wasted money and it is represented in the cost of the prescription to the eventual consumer.

Dr. WIGLE: Mr. Chairman, I would only like to point out a few things.

First of all, fortunately, the examples which Dr. Howe has justifiably given to us do not contain any samples. I think that the pharmaceutical manufacturing industry can be proud of the fact that they have evolved beyond that and have agreed to a code and regulations whereby there is no sampling except when a doctor asks for it.

The pharmaceutical manufacturing industry has only one person to whom it can present its problem. It does not spend thousands of dollars on getting a tiger into your tank, or out of your liver, or any other place. It can only approach physicians. It approaches those physicians on the basis of its products. and so far the methods of marketing to physicians have been productive.

I think that the pharmaceutical manufacturing industry of the world stands ready, any day of the week, to agree with the medical profession that if there is a better way, or if we should have a symposium every three weeks, or every three months, in each city across the country, and each community will agree that their physicians must leave in rotation for three days to be indoctrinated and to learn about it from, say, university people, we will support it. If there is a better way, let us learn how to skin the cat. But the situation has improved.

Mr. HOWE (*Hamilton South*): Mr. Chairman, that is not the point at all. The point is that, in addition to all this, we still get the literature which we are perfectly capable of reading and making a logical and intelligent decision on with regard to what is the drug of choice for our patient. Gimmicks do not improve this. We still get samples from any one of these companies, and this on request. This is in addition to that.

Dr. WIGLE: The only other thing I can say, Mr. Chairman, is that it is the general policy of all the members of our association that if any physician writes

in and says that he does not wish to receive direct mail from that company, that company will respect his wish.

Mr. HOWE (*Hamilton South*): But I enjoy receiving direct mail from a company. I am not criticizing direct mail. These are gimmicks that are handed to me by a representative of the company, who comes to see me, and who discusses the drug and who should be able to point out to me the medical advantages in my use of this drug. These gimmicks must be costly.

Dr. WIGLE: Mr. Chairman, perhaps Mr. Howsam has some remarks. He is in the marketing field.

Mr. HOWSAM: I have only two comments, Dr. Howe. First of all, I thoroughly agree with you on the usage of gimmicks. This has been discussed many times at the PMAC marketing sessions.

As pointed out earlier by Dr. Wigle there is no compulsion in the voluntary association. I personally believe statements such as yours may encourage most of our members and other people in the industry to refrain from the gimmicks which obviously are not well received by people like yourself. On the other hand, I think, in fairness that some doctors must like them or these companies would not continue to do this.

The other point I would like to make, though, in terms of trying to get the costs into perspective, is that on page 2.2 it is included in the total figure of the 4 cents under advertising and promotion, which figure also includes the other types of promotion we were talking about, including the journal advertisements and other types of promotion engaged in by the pharmaceutical companies.

Mr. HOWE (*Hamilton South*): Surely it must be included, too, in field sales expenses, 5½ cents.

Mr. HOWSAM: I believe that in the way those figures were broken up, Dr. Howe, it includes the cost of salaries and travelling expenses and automobiles and things of that order.

Mr. HOWE (*Hamilton South*): Is this because part of their time is taken up in this.

Mr. HOWSAM: I think these people are going to be paid, Dr. Howe, whether they are disturbing or otherwise; but I do agree with you—and would like to repeat that I do agree with you—on the usage of that particular kind of material.

Mr. HOWE (*Hamilton South*): It is not only the expense, but I think it is an insult to the intelligence, and I hope that you presume that you are dealing with an intelligent person when you are dealing with the average doctor. Surely this is an insult to his intelligence; and the forcing of a name on him time after time after time, and putting prescription pads and calendars in front of him and these various gimmicks of which these are only a small sampling, is an insult to his intelligence, as well.

Mr. HOWSAM: Doctor, at the risk of being offensive—and I agree with you— I can only say that I think a good number of physicians do find that these are attractive or that they are a change of pace from an other wise busy day, or whatever it may be.

The cost is not nearly as high as I think you estimate it.

The CHAIRMAN: I was going to say that we had briefly touched on this subject and decided that we would leave it until we got into marketing on section 9.

Mr. Scott has some questions that he wanted to ask relative to that, and we seem to have opened up this area. If the Committee want to go on and discuss this particular area which is this portion and section 9, this would be fine.

Mr. SCOTT: I was interested in finding out how the detail man works.

Mr. HUME: Excuse me, sir; I wondered whether, before we get on to that, Dr. Howe could indicate over how long a period these things to which he has referred were received? Are these what you have got in the last two or three months, or have these been saved up for some years?

Mr. HOWE (*Hamilton South*): No; they have not been saved up for some years, Mr. Chairman. These have been received within the last two or three months.

Mr. HUME: Within the last two or three months.

Mr. HOWE (*Hamilton South*): Yes; and these are only a sampling of those that I could muster together in my absence this afternoon to bring in for display tonight.

An hon. MEMBER: You mean, you have more?

Mr. HOWE (*Hamilton South*): There are many, many others that I have thrown away.

Mr. MACKASEY: Mr. Chairman, before we get into detail men, which I think is a very important topic, may I put a few questions to Mr. Howsam?

Mr. Howsam, I have forgotten your firm. Would you repeat the name of your company?

Mr. HOWSAM: Warner-Chilcott Laboratories.

Mr. MACKASEY: Are you one of the big companies, or one of the medium companies?

Mr. HOWSAM: We rank among the medium.

Mr. MACKASEY: As marketing manager I would imagine that advertising and promotion come directly under you?

Mr. HOWSAM: Yes, it does.

Mr. MACKASEY: Would you care to tell the Committee, in your own particular company, which you may consider representative—perhaps it is, and, perhaps it is not—what percentage of your advertising and promotion dollar would go to gimmicks? Could you tell us what comes under your advertising and what percentage is promotion?

Mr. HOWSAM: My first comment, Mr. Mackasey—and I would like to ask the Chair for an opinion on this—is that today we are representing the Pharmaceutical Manufacturers Association and I do not have any data on our particular companies' operations. I would have to be drawing from memory, which I think would be not proper at this time.

The CHAIRMAN: No.

Mr. PATTERSON: Dr. Howe has made a deep impression upon me.

Mr. HOWSAM: I can answer the question in a general way, Mr. Mackasey.

In terms of our particular budget and the company for which I now work, there is no money allocated for this kind of a gimmick.

I have spoken on public platforms on the subject and I feel that this is not a necessary way to promote drugs, although obviously some companies feel that it does pay. Therefore, this is a matter of personal opinion, and it is a free country.

Mr. MACKASEY: You say you have spoken on public platforms on this particular topic. Have you ever had any occasion to talk to an audience of doctors?

Mr. HOWSAM: Not recently.

Mr. MACKASEY: In the past?

Mr. HOWSAM: Yes.

Mr. MACKASEY: And what was the general theme of your—

Mr. HOWSAM: You would not talk on the subject of gimmicks in front of doctors?

Mr. MACKASEY: Have you ever made a survey? I am sure you have made a survey, as a marketing man, on the response from doctors with regard to these types of gimmicks. I cannot imagine—

Mr. HOWSAM: My own personal opinion, Mr. Mackasey, which is all it can be, was that this kind of gimmick was not suited to the kind of drugs that we were trying to promote.

Mr. MACKASEY: What would you base this on?

Mr. HOWSAM: I think, on hunch, and partly on survey and the attitude of people like Dr. Howe.

Mr. MACKASEY: I have to accept your answer, but it does not convince me. I cannot visualize—

Mr. HOWSAM: Because, I think, in the long run, we will sell more without doing it that way. Does that convince you?

Mr. MACKASEY: I cannot visualize the marketing manager of an important firm defining policy on hunch. I would imagine that if you do not include gimmicks in your sales promotion, it is because you have a little more valid reason than a hunch.

Mr. HOWSAM: I happen to share the personal convictions I think that Mr. Howe shares.

Mr. MACKASEY: Let me put it another way. Regardless of your personal conviction, would not your company use gimmicks if they were productive?

Mr. HOWSAM: I think for certain types of products, yes.

Mr. MACKASEY: It would use them.

Mr. HOWSAM: For certain types of products; and I think Dr. Howe might concede that there is a difference in the types of medication that are promoted, and that at times a little levity, or a little amusement, would be well received by the physician, without ever engendering displeasure, or a bad misrepresentation.

Mr. MACKASEY: Dr. Wigle, could you find out in the next few days, if possible, the percentage of the four cents in advertising and promoiton of your 37 or 41 members that would go to gimmicks, as opposed to what would go to serious material?

Mr. WIGLE: Mr. Chairman, I am sure that I could not find out within the next few days what percentage goes to gimmicks.

I share the same sentiments as Dr. Howe does on this. This is not a sensible approach to me, as a doctor, or to him, as a doctor, but some people are doing it, and capital is made of it. It is presented to you here.

I do not think it is a fundamental approach of the 57 companies in PMAC.

Mr. CÔTÉ (*Dorchester*): May I ask a question here? Do those gimmicks go to druggists and other merchandisers as well as to doctors?

Mr. HOWSAM: Occasionally they will go to pharmacists, yes.

Mr. CÔTÉ (*Dorchester*): It is not only doctors who receive them?

Mr. HOWSAM: That is correct. That kind of promotion material would be sent, I would think, to pharmacists, as well.

Mr. HOWE (*Hamilton South*): Mr. Chairman, it has been said that there are certain types of drugs. Let us grant that, for example, a nasal spray could come under this, but we get into such things—and I hate to use the word—as "butazolidins". Two of my most expensive gadgets are butazolidin advertisements; and there is penbritin, which as we all know is an antibiotic. I do not know how serious one must get, or that you get into some sort of an anticarcinoma agent of some description before you consider that these are serious things.

This is another box of Kleenex for people who require an antibiotic known as terramycin made by Pfizer. I suppose this is to blow your nose on until you get rid of the infection.

I cannot see that there is any drug that is any less or more serious than another. I think it is all in the attitude of the drug company which does the advertising, and more credit to those that do not insult the intelligence of every practising physician; because I think that the average practising physician has certainly average intelligence or better, and I do not think that this appeals to him. But, regardless of this, it still goes into the cost of the drug.

This is what I am interested in—not in a gadget, or whether I can look at something magnified, which may entertain me for a few moments, but the fact that my patient is paying more for a drug because I have got this. Surely this has some value that is represented in the eventual dollar that the patient pays. I do not know how much it is, but it is certainly a portion of this 11 cents.

Dr. BRIANT: According to page 2.2, Dr. Howe, it probably would not be more than 2 cents on the prescription dollar.

Mr. HOWE (*Hamilton South*): It is an average for all the companies.

Dr. BRIANT: And this would be absolutely—

Mr. HOWE (*Hamilton South*): Therefore, some of the companies which are not doing it are also paying for some of those who do it. In other words, some company may be 4 percent and the company that is not doing it is suffering a 2 per cent because another company does.

Dr. BRIANT: I am told that the figure is much less than the 2 cents.

Mr. HOWE (*Hamilton South*): Well, this is only arbitrary, but my point is there.

Mr. SCOTT: Mr. Chairman, one of the ones that Dr. Howe has produced is put out by Ayerst Laboratories. We might get some firsthand information tonight on the efficacy of matches.

Mr. GREGORY: We have a saying in our company that I have been a long time off the road.

Mr. HOWSAM: We do not want to impugn other people who are trying to promote their drugs, as is well pointed out in the brief, but we have two responsibilities, and one of them, if we are going to hold our jobs, is to sell our products.

I would like to point out it is our position that information that is proffered by an uncommercial, purely scientific source does not necessarily induce awareness; and, secondly, that the awareness, no matter what its source, does not necessarily induce trial. A vital function of our marketing is to create this awareness. An awareness, even if it is done in this fashion and the trial and disposition to try are separate phenomena of marketing.

I must say, in response to Mr. Mackasey's remarks, that I would presume that the companies have done enough work on this to feel that there is an inducement to try with this sytem or they would not continue doing it; and they must feel that there is value in it, or they would not continue doing it.

I think that I respect your particular position, and I am sure our member companies will respect it when they hear about it on the record.

The CHAIRMAN: Mr. Gregory, I think you were interrupted before you got started.

Mr. GREGORY: Yes. I think that probably Mr. Howsam summed this up as well as anything that I could say.

It is one thing to have in your laboratory a very useful therapeutic tool such as penbritin. It is another thing to make sure that the people who need to use it, the physicians of Canada, are thoroughly aware of its capabilities. I think that probably the use of these penbritin matches arouses interest in the physician's mind and he goes and read our literature more diligently, and perhaps discusses the product with his confreres in the community, and they alone make the decision. It is not the matches that encourage them to use the product, but rather it encourages, or increases, their awareness of the capabilities of this compound.

Mr. HOWE (*Hamilton South*): Do you not consider that the doctor likes to think that he makes his own decision, rather than be influenced by a box of matches?

Mr. GREGORY: I agree with you, sir. I did not say that the matches helped doctors to make their decision, but that it increases their awareness of the availability of these compounds, and they discuss these things with their confreres and with our medical people and with the medical literature. I think that is the basis of the use of these—

Mr. HOWE (*Hamilton South*): As a doctor, I want to make it clear that I have no objection whatsoever to penbritin. I think it is an excellent antibiotic. I am not promoting this drug at this moment—that is not my point—but this tends to turn me against it rather than make me for it. That is a personal opinion.

The CHAIRMAN: Thank you very much, Dr. Howe.

Mr. MACKASEY: I have an idea you are not going to get any more matches!

Mr. HOWE (*Hamilton South*): That is all right. I have a lighter, and I have got an electric shoe-polisher at home!

Mr. HARRY D. COOK (*President, Abbott Laboratories Ltd.*): I wanted to say, Dr. Howe, that you touched me on a sensitive spot when you talked about art, because we have tried to identify ourselves with art. I think, sir, you have defeated your own argument because you are remembering something which we published at least fifteen years ago, which had not a word on it, really, which related to the name of my company or the name of my product, but which was so popular with the medical profession that they decorate many homes today, particularly play rooms. These were a series of illustrations indicating, in a humorous fashion, the effect of poor dietary habits. I cannot recall the one with the two sausages or hot dogs on the fried egg, but this was the point, doctor. At the moment we have another series on medical costumes over the past 2,300 years on which the name of the company does not appear and the products do not appear but the demands by the medical profession for copies of these prints are reaching astronomical proportions.

Mr. HOWE (*Hamilton South*): Are you with Abbott, sir?

Mr. COOK: Yes, sir.

Mr. HOWE (*Hamilton South*): Well, I will be honest with you. Actually I resented these particular portraits so much that during the series and since, I have not prescribed an Abbott product, as a result.

Mr. COOK: Perhaps something in art that we did might please you. They did not please me either, but some of them, I think, are attractive.

Mr. HOWE (*Hamilton South*): But they all cost money.

Mr. COOK: The cost of doing business.

Dr. ISABELLE: Mr. Chairman, I do not know where we are going. Dr. Howe has just mentioned that it is an insult to doctors to receive these kinds of gimmicks, but this thing has been going on for many years. It proves that doctors like to be insulted. Another thing is that I am sure that Dr. Howe knows that many doctors have been selling these samples for many years.

Those companies are in business. They are private organizations who want to live. I do not blame them for trying to attract the medical profession with something that will make them think that they have to prescribe Abbott, Ayerst, Hoffman-Laroche, or any other company. These are only the minor things, and I do not think they affect the price to the consumer very much.

This is very important, because if the salesman does not come to our office we forget the good brand he represents. From my point of view, I am lost at this discussion, because I do not think this will achieve very much within our terms of reference which are to recommend a program to lower the price of drugs.

As I said before, there is only one way out of it. If we cannot implement the Hilliard report, which comprises practically everything that we have been discussing here, we are wasting our time again.

Mr. SCOTT: I have a couple of questions for information. I gather that as a complete newcomer—

Mr. HOWE (*Hamilton South*): Incidentally, does the Association give grants to universities?

Mr. HOWSAM: Mr. Chairman, the Association, as such, has not been in the habit of running a benevolent fund from the Association for co-ordination of all the efforts, but many of its member companies do indeed give grants to universities for specific research investigation.

Dr. BRIANT: I have some figures here which show that grants by companies for research were twice as great in 1963 as they were in 1960.

Mr. HOWE (*Hamilton South*): Are they sprinkled across the various universities, or do one or two get more than others?

Dr. WIGLE: Mr. Chairman, this might be of interest. I am sure that Dr. Brian Stewart could elaborate it more than I can, but the Canadian Foundation for the Advancement of Therapeutics is a foundation which was fundamentally founded by the PMAC, the Pharmaceutical Manufacturers Association of Canada, which we represent here today. This is a foundation which is directed at clinical investigation in Canada, and is at the present time totally sponsored by the members of PMAC. Therefore, in an indirect fashion, through the Canadian Foundation for the Advancement of Therapeutics, the Pharmaceutical Manufacturers Association of Canada does sponsor research.

The CHAIRMAN: Did you wish to say something, Dr. Briant?

Dr. STEWART: Mr. Chairman, I was just going to make that point. It was a need that was not filled by universities or hospitals. This is the training of investigators due to this great explosion of drugs and so on, and the Pharmaceutical Manufacturers Association sponsored this foundation, which is of the order of about $80,000 a year, to try to train M.D.s and give them time to go to special centres to get the skills to do clinical investigations in Canada. That, I think, was a very laudable aim on the part of the Association.

This is in addition to the grants which Dr. Briant was talking about, which were product-related. In other words, companies will usually give out-of-pocket expenses, that is, equipment or some secretarial aid, where it is necessary to do investigation. This particular Canadian foundation for clinical research was

in addition, and quite unrelated to any product. The chairman of this committee was the late Dr. Farquarson, I think, and Dr. Bryen of London.

Mr. SCOTT: I gather, then, that your contact with the medical profession is through the detail men. Is that right?

Dr. WIGLE: Only in part.

Mr. SCOTT: In a large part; that is, he is the liaison between the company and the physician.

Dr. WIGLE: Mr. Chairman, this is not in relation to the research activities that you are speaking, I hope, Mr. Scott?

Mr. SCOTT: No, this is the promotion part.

Dr. WIGLE: That is fine. I thought that we were talking about research in the Canadian Foundation.

Mr. SCOTT: No; I digressed there for a moment and I wish I had not—not because the information was not useful, but because it starts me thinking.

The detail man's main duty is to acquaint the physician with the quality of the particular product and to encourage him to prescribe it. Is that the idea?

Dr. WIGLE: You have read Appendix D?

Mr. SCOTT: Yes, I have.

Dr. WIGLE: Yes. I think it is true to say that the detail man is a representative of the responsible pharmaceutical manufacturer, who is charged with the chore of going out to give information relative to the products which that manufacturer has on the market, and to introduce any new ones which they might have out, as well as to refresh minds about the old ones. He also carries back any information that the physician might have about adverse reactions, or something that he sees in response to the utilization of these products, and this has proved a wonderful two-way street.

Mr. SCOTT: I understand that the detail man, or the agent, or whatever you call him, supplies the doctor with various free samples which the doctor then gives to his patient. Is this right?

Dr. WIGLE: At the present time, under the regulations for sampling in Canada, to which our Association contributes—and we helped with the development of these regulations—a physician must request a sample, and if a medical service representative—which is a term we like to use for our so-called detail men—visits a doctor and leaves a sample with him he is required to carry back with him to his responsible employer a card signed by that physician saying that he asked for those samples or that he requested them, that he wanted them. By the same token, samples are presently mailed in Canada only to physicians who request them.

Mr. MACKASEY: Could you table a sample or this card?

Dr. WIGLE: Can I table a sample? I am sure we could.

The CHAIRMAN: I think we could get that. I am sure any doctor here will be glad to give you a sample.

Mr. ISABELLE: This has not been the policy of companies for many years back; it is only for the past year or two.

Mr. HOWE (*Hamilton South*): Bill C-3.

Mr. Chairman, I have a supplementary question. Is this 11 cents decreased now as a result of this requesting?

Dr. WIGLE: No. There is no wholesale handing out of samples. I would like to make a comment that no ethical doctor ever sells a sample to a patient.

Mr. SCOTT: I was merely repeating what my doctor says to me.

Dr. WIGLE: I know you were but I am—

Mr. SCOTT: There is no news there for me because the doctor used one word, and that was ethical.

Mr. WIGLE: I qualified that by saying ethical.

The CHAIRMAN: I might say that the medical profession is not before us today. They will be here next week.

Mr. HOWE (*Hamilton South*): The comment was made, Mr. Chairman.

Mr. HUME: The question was asked: has it affected the price? I do not think you have had an answer.

The CHAIRMAN: Yes; the answer was: Not appreciably.

Are you finished, Mr. Scott?

Mr. SCOTT: I had not even started before the circus started going! I am just on the merry-go-round! I know what you are going through now.

Is there any estimate available of the value in terms of dollars of the free drugs, or free samples, supplied to the medical profession in this promotion and marketing?

Dr. WIGLE: I am sorry, Mr. Chairman, but personally I do not have any knowledge of it. The amount of money that is spent, or has been spent, in sending samples to physicians? Is that right?

Mr. SCOTT: Yes. How much of the expenditure on promotion could be labelled as cost of samples?

Dr. BRIANT: Looking at page 2.2, 1 cent on the prescription dollar; and if you take Mr. Turnbull's figure—I think it was in his appearance before this Committee—he gave a figure in cents . . . per capita—nine ninety-five; that is $190 million; that is, one per cent of $190 million, or of $1,900,000.

Mr. SCOTT: In free drugs?

Dr. BRIANT: Samples.

Mr. SCOTT: All right; samples. I just wanted the information.

Dr. WIGLE: Many of which are given by doctors, as Dr. Howe did, and as I did in my practice, to people who needed them.

Mr. SCOTT: Do you supply drugs at any special discount rate to doctors who do their own dispensing?

Mr. HUME: The difficulty, Mr. Chairman, is that, as an association, and by reason of the requirements of the Combines Act, this association has not interested itself in the pricing practices, or the sales practices, or the discount practices of its members. It cannot.

We asked certain questions on a questionnaire to try to be helpful to the Committee, but when you get to a specific question like that, I am afraid, sir, with respect, you are going to have to ask the company because—and I think Dr. Wigle will confirm it—we do not know, and we have not asked.

Dr. WIGLE: This is the only way that Wigle stays out of jail!

Mr. SCOTT: You do not need to feel sensitive about it. If you do not have the information—

Mr. HUME: No. I am just explaining why we have not got it here, because this is an area that an Association, strictly speaking, should not be concerned with.

Mr. SCOTT: Do the retail men visit druggists or pharmacists? Is this very widespread today?

Dr. WIGLE: It is my understanding, Mr. Chairman, that most of the detail men—certainly those who visited me—visited the pharmacists in my same community.

I think Mr. Howsam, if he has anything to elaborate on, might say something else, but this is my understanding. They visit both.

Mr. HOWSAM: They visit both, yes.

Mr. LAROSE: Mr. Chairman, I think I should add that pharmacists must be informed about our products to the same extent as we inform physicians.

Mr. SCOTT: Do they have much discretion in choosing between—?

Mr. LAROSE: They must know about the product. It is their life, actually. That is what they study four years for.

Dr. WIGLE: Mr. Chairman, in this regard I think it might be worth while for the members of the Committee to know, and I am sure Dr. Howe could explain it as well as I could, that there is a lot of times when you want your neighbourhood pharmacist to talk to you about what he has got and what is available and what is not. I certainly did in the small community in which I practised. I think that it was a benefit to me and to the people of the community that he and I could talk about what was available and what he had and whether we could use this one or that one.

Mr. LAROSE: It is more than that. By law, by every provincial pharmacy act in Canada, when the pharmacist receives a prescription he must know the age of the patient, whether it is a man or a woman, and must decide whether it is an overdosage or not, for that particular patient. He has a legal responsibility—a criminal responsibility, actually—if he does not fulfil that function.

Mr. HOWSAM: If I might add to Mr. Larose's comments, in relation to Appendix D, paragraph 1, in general, forty per cent of the detailing time of our association members' medical representatives is spent on calls to hospital staffs and to pharmacists, and is not split between the two. About sixty per cent of the time is spent on physician calls and about forty per cent on hospital and pharmacy calls.

Mr. HOWE (*Hamilton South*): It is my understanding that when a detail man comes to a doctor he has been to the druggist and hospital first so that this drug is available to the doctor when he writes the prescription.

Dr. BRIANT: Could I just correct one figure for the record? The breakdown of the prescription dollar is rounded, of course. An actual figure for sample expenditures is given on page E(5), item 2 (a).

Mr. SCOTT: May I ask this question, and then I will keep quiet? It seems to me to be quite a promotional thing that you have these medical service representatives who really are there to push their particular brand. Some of these things are used, and perhaps legitimately so—I do not know, and I am not offering a judgment on it. Is this the general way in which drugs are marketed? Are there other jurisdictions which use methods different from the service men going to the doctors and pushing and trying to build up support for their drug, or are there other systems or marketing and distribution that have been tried elsewhere?

Dr. WIGLE: Well, Mr. Chairman, in some of our preamble and in some previous statements we have pointed out that this is the method that has evolved through the last 25 to 30 years, which is truly the history of the pharmaceutical industry.

As a physician, I have said that if there is a better way then let us know about it. This has evolved, and the pharmaceutical industry, I think, has filled a great need. Mr. Scott, I think, made a little fun of my laudatory sentiments in this regard earlier today, but I still feel this need and to inform the physician about the products which have developed during thhose thirty years.

There has not been a better method developed. If there is a better way I am sure that the industry will be the first to join hands with the medical profession in developing that better way.

Mr. HUME: Mr. Scott is asking whether or not in any other jurisdictions we know of any other method. Is that not the purport of your question?

Dr. WIGLE: That has been answered.

Dr. BRIANT: Mr. Chairman, I have some figures here on the United Kingdom, showing that they spend 5.4 per cent of their sales on medical representatives. That is lower than the expenditure in Canada, but quite possibly the main difference here can be accounted for by the geographical differences between the two countries. The fact is that "the tight little island" still spends 5.4 per cent of their sales dollars on medical representatives, and that with their national health service they have not found a superior way of informing the physician.

Dr. WIGLE: I am sure, Mr. Chairman, that Mr. Scott has probably seen it, but just in case he has not, Appendix "C" deals with the standards by which we promote our products, and we hope that our members in PMAC are living up to these methods of promotion. We are trying to elevate the methods of promotion every year.

Mr. SCOTT: Are there very many drug companies not in your Association?

Dr. WIGLE: I think that probably it would be a "guesstimate" to say how many, because I do not think, with respect, that even the Food and Drug Directorate of Canada knows at the moment. They are making a sincere effort, through the notification of products, to find how many people really do sell pharmaceuticals in Canada. At the moment, I believe I am right in saying, Mr.

Allmark, that nobody knows exactly how many people market pharmaceuticals in Canada. It has been "guesstimated" at somewhere between 350 and 480. We have 57 members in our Association whom we feel are responsible research-oriented individuals who try to promote products of the highest quality and safety for the people of Canada.

• (9.00 p.m.)

Mr. HOWE (*Hamilton South*): Mr. Chairman, part of this promotional sales is the selling of one identical product over another of a competitive firm, which is actually the same drug.

Dr. WIGLE: Which examples is Dr. Howe speaking of, Mr. Chairman?

Mr. HOWE (*Hamilton South*): I am not specifying. I am saying that there are identical products sold under different trade names, which are promoted. I have had the occasion myself where a detail man has come to my office and has specifically detailed me and talked against another form of drug, specifically penicillin, and I found out, through enquiries, that this detail man had been through prescriptions at drug stores in the district in which I practised in Hamilton and found out that I was writing a certain product and he spent his time promoting his particular brand of the same product and trying to point out the efficacy of his over the other brand. In other words, there was really no basic difference. It was simply his brand over the brand I was prescribing.

Dr. WIGLE: All I can say, Mr. Chairman, is that I have not had a similar experience from ethical pharmaceutical manufacturers, members of the PMAC, one against the other. I have had imitators who have brought to me a product while I was in practice, who have attempted to impress me with the fact that it was just as good, and certainly, as a practising physician, I was not sure how I could see that they were not; but I am sure that within the last two years I have developed considerable conviction which I could have used if I had had that opportunity again to say what the difference was, because there was a difference.

Mr. HOWSAM: I would like to reiterate one of the points that you made before, that no better way has yet been found to promote products to the physicians.

Also in the brief, in section 9, you will notice that there is a balance of the new products and the difficulties that come up. We have a sort of dual responsibility. It is not always new; it is not always something which you would call medically significant; but there is the problem of the promotion side. This is the fine balance, and we got into it a little earlier.

I would like to point out, too, which was mentioned the other afternoon, that in Russia, where they took a very esoteric approach and said, "We ought not to have all of these things", they developed a system of drug information with an official pharmacopoeia and a limited selection of drugs in one page leaflets and no proper communication system with the doctors, which ended up by being quite a travesty. A fairly large report was published in the Harvard *Business Review* on this subject.

It was requested, I think, by Dr. Brand that this be tabled and I do not know whether we brought this, Dr. Harley, which does answer this question as an alternate method.

Dr. BRIANT: I have a copy of this with me now if you would like to—

An hon. MEMBER: We would like to get the one that appeared in *Fortune*, too.

Dr. BRIANT: There is another one I have here from the Journal of Marketing Research, February, 1966, entitled "Doctor's Choice—The Physician and his sources of information about drugs." This is an American publication.

On Table 1, the physician's preferred sources of information, 68 per cent of the physicians report that the detail man is the most useful source of information to them.

Mr. HOWE (*Hamilton South*): Mr. Chairman, there is the *Vade mecum* that we get annually, on a percentage of decision choices. There is another one, unfortunately—

Mr. HOWSAM: I can go through these.

Mr. HOWE (*Hamilton South*): That is an American list.

Mr. HOWSAM: No. No. But detail men: 68 per cent of the physicians find that the most useful source; journals, papers and articles, 40 per cent; medical journal advertisements, 32 per cent; direct mail, 25 per cent; doctors' conversations, 22 per cent; drug samples, 22 per cent; staff meetings in hospitals and clinics—where I would have thought there would have been some useful information—16 per cent.

Mr. HOWE (*Hamilton South*): This does not answer my question. Does it not list any?

Dr. BRIANT: The "*Vade Mecum*" is not taken as being—

Mr. HOWE (*Hamilton South*): I have always used that myself as the most reliable source of drug information.

The CHAIRMAN: I was going to say before we finish that you will find the information that has just been given to you, but from the Canadian point of view, in the brief that you now have in your possession, which is to be presented next week by the Canadian Medical Association, and they will, I am sure, give us a great deal of debate on this.

Mr. CLANCY: I just wanted clarification to make sure that I understood Dr. Howe right when he made the statement that, as a practising physician, because he did not like Abbott's advertising, he would never use an Abbotts product?

An hon. MEMBER: He is not a witness, anyway.

Mr. HOWE (*Hamilton South*): I would be glad to answer it. Perhaps I said that.

Mr. CLANCY: Why not?

Mr. HOWE (*Hamilton South*): Well, I am not—

Mr. CLANCY: You made the statement. Did you say that, or did you not?

Mr. HOWE (*Hamilton South*): Yes, I said that.

Mr. CLANCY: That is fine. That is all I want to know.

Mr. MACKASEY: Mr. Chairman, I am under a terrible disadvantage on this Committee in that I am not a doctor—

The CHAIRMAN: It may be an advantage.

Mr. MACKASEY: —nor a pharmacist.

I have the naïve opinion that in a free enterprise system the drug industry is in there to make a profit, and I presume, because of the watchdog that the government is, that they are in competition with each other. I imagine this is why periodically the legal advisor reminds Dr. Wigle that at no time should he create the impression that there is collusion between the companies, because it is a free enterprise system.

What is basically wrong with a detail man coming in to a doctor and saying that his product is better than that of the fellow down the street, any more than one brand of gasoline claiming to be better than another? What is basically wrong here?

Dr. WIGLE: Mr. Chairman, I do not think this is any peculiar attitude of the pharmaceutical industry. I think that most responsible industries which have attempted to set themselves up in a responsible position in the eyes of the public have professed to say, "Look, I am not going to sit down here today and run down the guy that sold you the radio which you got last week. I am not going to sit down and run down the fellow who is trying to sell you insurance. I am not going to tell you that the insurance company that you saw last week is a worse one than we are."

Likewise, I think this is an effort on behalf of private enterprise, of responsible industry, to prove their responsibility, and it is my sincere hope that eventually the pharmaceutical manufacturing industry of the world will prove its responsibility to the extent that they will be like a profession. I think the medical profession, the legal profession and the pharmaceutical profession have proven their responsibility to such an extent that eventually government will give them laws to administer because they believe in their responsibilities. This is the first step towards such responsibility.

Mr. MACKASEY: I do think that when you are out selling, no matter what product you are selling, it is poor salesmanship to "knock" the other man's product. This does not prevent you from saying that your product is better than another product which is also an excellent product. It seems to me that there is a lot of emphasis on the detail man's not making statements for his product because they may infer that somebody else's product is not quite as good.

If there is an element of competition—and I hope there is—I cannot visualize a situation where a detail man cannot go into Dr. Wigle's office and say, "My brand of antibiotic is a little better than the other man's because (a) it has fewer side effects", or "It does not have the same side effects as the other man's." I do not quite understand what this has got to do with costs. What I would like to know from you Dr. Wigle, however—

Dr. WIGLE: But I should question—

Mr. MACKASEY: I listened for fifteen minutes, Mr. Chairman, quite peacefully. I have learned something. A detail man is not supposed to say his product is better than the other fellow's.

Dr. Wigle, what is the degree of intelligence or educational background that is expected of a detail man, in general?

Dr. WIGLE: I think there is an item in our Appendix, Mr. Chairman, which delineates the qualifications of the detail men in this regard—Appendix D(3).

Mr. MACKASEY: I always like to hear Dr. Wigle outline it, rather than read it. It is more interesting that way.

Dr. WIGLE: But every now and then you confound me, Mr. Mackasey.

Mr. MACKASEY: Yes; I agree with you, Dr. Wigle!

Dr. WIGLE: On page D (3) it is pointed out that the education and training of detail men is as follows: Just over 40 per cent of those working for members of our association have university degrees, predominately in pharmacy, and 72 per cent have had some university training. The breakdown by academic background for those with university degrees may be summarized as follows: pharmacy, 40 per cent; other science degrees, 26 per cent; bachelor of arts, 20 per cent; bachelor of commerce, 8 per cent; post-graduate degrees, 2 per cent; other degrees, 4 per cent.

Mr. MACKASEY: Dr. Wigle, this may be in the brief, but I have not read this section of the brief; I am still on one of the earlier sections. Are these people paid a salary, or a salary and commission?

In other words, is there any—I should not use the word "unholy"—but is there any added incentive for them to unload drugs beyond what you might say is their normal responsibility to their company?

Dr. WIGLE: As far as the association is concerned, we do not have this specific knowledge, but there is some additional information in D(4).

Mr. MACKASEY: The average salary.

Dr. WIGLE: The average base salary, average gross compensation, the commission, etc., because the practice, as I understand it, varies from company to company. It is not any fixed policy. It is whether I decide for my particular company, or you for your particular company, that the men we have got might do better in this regard—whatever way we chose.

Mr. MACKASEY: I think it mentions that there is one company which pays by commission only. I can imagine if that man got hungry enough he would be tempted to be perhaps a little enthusiastic, to put it mildly, not unlike the medicine man of carnival days.

Dr. WIGLE: But he just talks to doctors, and he would have to find a lot of stupid doctors in order to put it across.

Mr. MACKASEY: You said that, doctor!

Dr. WIGLE: That is right, and purposely so.

Mr. MACKASEY: I do not think any particular group of people has any monopoly of any particular vice. In all seriousness I think that it is not good practice to put a salesman strictly on commission, if you are expecting that man to maintain a certain degree of integrity.

As you try to represent, and as your brief points out, the detail man is more than the letter carrier of gimmicks that Dr. Howe has shown us. It is a

little more than carrying along with him in a brief case some well prepared direct mail, or literature. If he is supposed to be knowledgeable and impart to the doctor some factual and objective information I do not think that he should have the added burden of having to meet a quota per week, which is basically what the commission system is.

Dr. WIGLE: There is this one case in the many that we are speaking about.

Mr. MACKASEY: Well, it is one too many.

Dr. WIGLE: In the first paragraph—

Mr. MACKASEY: If you go to the top of the page, there is one paid by commission.

Dr. WIGLE: One paid by commission.

Mr. MACKASEY: Let us keep this together; it makes interesting reading: The compensation of a sales representative of a pharmaceutical company is normally divided into two parts: a base salary and, secondly, a commission or bonus over and above the base salary. I can understand the bonus. The combination of salary and commission was the manner of remuneration in three of the 45 companies included in the survey; salary and bonus in 26 companies; salary, commission and bonus in 8 companies; and of the remaining 8 companies, one paid a commission only, 6 paid by salary only, and one by salary plus prize points—I imagine he gets the gimmicks left over at the end of the year!

What I am trying to get at is that I think that if the detail man is to do a proper job and impart information—and you keep coming back to the role of the detail man as a communication between a pharmaceutical industry and the doctors—he has tremendous responsibilities, and one of them is not to distort the facts. I would imagine that if his remuneration depended strictly on volume the tendency would be there to distort the facts, or to unload something on a busy doctor—not necessarily a stupid doctor—but a very busy doctor with a roomful of patients, who has taken fifteen minutes of his day out to listen to a detail man—that he could be prone, in a moment of absentmindedness, to buy a case of something he should not be buying.

Dr. WIGLE: Mr. Chairman, I hope Mr. Mackasey is really meaning that we should be commended that only one of our 57 companies uses this method.

Mr. MACKASEY: And you should promptly have a talk to that one.

This is an important point, however. If you are going to sell this Committee the fact that the 11 per cent is broken down into different components, not the least significant of which is the detail man—and you have devoted a whole area here, well documented, and sold us on the man's education, etc.—I think you have got to build into his duties every precaution to ensure that he is not anything more than a communicator of factual information, which, it is in the best interests of the doctor to have at his disposal.

Mr. BEAUCHEMIN: I might say, sir, that since that survey was conducted that one company has left the association. That one company was leaving the ethical drug field and going into the proprietary business, and had to leave the association, because we do not represent companies in patent or proprietary drugs.

Mr. MACKASEY: Why do you not make it one of the conditions for membership, and I mean this in your Association, a voluntary association? You talk about the code of ethics and at least one of them should be that your detail men should be free of this type of worry if you are going to attract people of higher education and eventual university education, Bachelor of Arts degrees. It seems to me that he should not have the financial concern of selling so many bottles of cough syrup or whatever he sells.

Mr. DAILY: Mr. Mackasey, we could do two things. I think it is a very good suggestion. I think we could consider including it in our code of ethics governing the standard of conduct for medical service representatives outlined in Appendix C (5), and we could also refer it for serious consideration to our by-laws committee at our next meeting.

Mr. HENDERSON: Mr. Mackasey, I get the impression that the detail man is acting in a legal vacuum, distorting facts and doing all kinds of things that he is not able to do. He does not operate in a legal vacuum, and he has certain legal requirements that he must meet. This, of course, applies generally, not just to this industry but he has to operate within the laws of injurious falsehood, which still are with us. That I admit has the element of malice, and it is not always easy to prove. In addition to that there are the laws of unfair competition, which are found in the Trade Marks Act, and misleading statements relating to the products of the competitor will give rise to liability.

I do not think one should get the impression of detail men that we seem to be getting. They do not operate in a legal vacuum, and they just do not operate in the sense of distorting the facts.

Mr. MACKASEY: On the other hand when the doctors come before us many of them will tell us it is just the opposite to what you have said.

Mr. HENDERSON: I have heard it today.

Mr. MACKASEY: Yes, and I heard it last year at some of the thirty meetings we held. I think where there is smoke there is fire.

I can document, if you want me to, some of the experiences that doctors have had with unscrupulous detail men who have misrepresented their product, and who have downgraded the competitor's product. You wonder what type of screening process resulted in their being hired in the first place.

Mr. HENDERSON: What I am suggesting is we should not judge the industry by that example.

Mr. MACKASEY: On the contrary, I am not. I am not running down detail men in general. I am suggesting that they be taken off a commission basis. I am just trying to make it a little more difficult for those types of people to get into the pharmaceutical industry.

Mr. HENDERSON: From that point of view there is unanimity.

Mr. LAROSE: Perhaps, Mr. Chairman, we could say, in a general sort of way, that we fire men from time to time.

Mr. MACKASEY: That is kind of you, too.

Mr. LAIDLAW: Getting back to section 23, 36 cents, we know now, of the manufacturer's dollar goes to professional service representation marketing and

medical information. I would like to ask the association this question: Is the competition at this particular level so intense that it would be impossible for your association to exercise voluntary restraint and keep these costs low. That is my first question. If each member of your association cut their costs in half, everybody abided by the rules, your competition would remain the same, and the consumer would benefit. Is that an impossibility?

Dr. WIGLE: Mr. Chairman, if I understand the question correctly, it is that you would suggest that the members of our association, the 57 companies which are in PMAC, would collude to cut down their competition and their promotion within a certain area to reduce the cost of drugs generally. My answer to this would be that I do not know how we could do this at the present time, with the attitude of the Combines Act and the controls that are imposed, without any going to jail. I believe that is the correct answer, unless someone else—

Mr. LAIDLAW: No; this has nothing to do with setting prices, Dr. Wigle. This is a voluntary—

Dr. WIGLE: Restriction of promotion?

Mr. LAIDLAW: Restricting your expenses?

Dr. WIGLE: And what would be the purpose of restricting that promotion, Mr. Chairman?

Mr. LAIDLAW: To bring down the ultimate cost of drugs to the consumer.

Dr. WIGLE: I would ask Mr. Hume to answer.

Mr. HUME: All I can say, without a great deal of study, is that you are getting into an area where you are affecting price; and in any area, I suggest, where you are affecting price you are on very dangerous ground under section 32 of the Combines Act. I personally would advise this association, as an association, to have nothing to do with it.

Mr. LAIDLAW: When price is reduced thereby?

Mr. HUME: Under the Combines Act, as you know, in some of the prosecutions the fact of prices being reduced, or the public interest being served, does not make any difference. It is an offence to agree to do certain things affecting price. You are into an area that is very difficult.

May I also just say, in passing, in answer to your question—and this is a matter of public record—that I recall being present at the hearings of the Restrictive Trade Practices Commission in Montreal when a pharmaceutical manufacturer, who was not a member of the association, was asked on this question about voluntarily reducing his promotion—I think his name was Antoft, and I am speaking from memory and it goes back some years, but it is a matter of public record before that Commission—and he said he did reduce that and that his product nearly went off the market and he had to get back into it with both feet or he would have gone out of business. That is a matter of record before the Restrictive Trade Practices Commission. It is of some significance, I think, in this general discussion about what is, and what is not, a matter of business judgment.

I just mention this in case the Committee, or you, sir, as counsel to it, want to follow that up. That is evidence given to that commission.

Mr. LAIDLAW: Are you sure the reason you are coming to that conclusion is not because the competition at this level is in fact too intense for the members of this association to get together and see if, voluntarily, they can cut down these expenses so that none suffers and the consumer benefits?

Dr. WIGLE: Mr. Chairman, I think that this has been discussed very vaguely within our Association, and the only feeling there has ever been is that if we could have permission from the people who control the Combines Investigation, etc., if we could discuss such a thing and we would have permission to do so, we might indulge in this area; but otherwise our association has not indulged in such activities.

Mr. MACKASEY: Mr. Chairman, I would like to ask a question arising out of Mr. Laidlaw's. I presume, Mr. Laidlaw you are referring to the 30 per cent on the breakdown of the manufacturing dollar?

Mr. LAIDLAW: Yes, sir.

Mr. MACKASEY: And the advisability of cutting back on the promotional material which I think is the area that is obvious in all the reports, and the one that is most obvious to me.

This is why earlier today I made reference to to the Hilliard report, Mr. Chairman, and before you rule me out of order I want to emphasize that I am in order. I would like to refer—

The CHAIRMAN: Thank you for the information!

Mr. MACKASEY: I learned that from Mr. Herridge.

I think this is important, Mr. Chairman, if you turn to K10 of the Hilliard report.

I would like to pay tribute at this moment, if I may, to a member of our Committee, who is no longer with us, Mrs. Jones, who was a very active member last year, and, even if she was a Tory, a good one. It was her questioning in the House that prompted the Hilliard report.

Section 7 seems to refute the arguments that appear in the Hall Commission report and other reports about the advisability of cutting down promotional material. It emphasizes that there must be an availability of information. I have read it once into the record today, Mr. Chairman, and you have stated that this information should be made available to the doctors, to the hospitals, to the pharmacists. It emphasizes that no manufacturer shall market any drug unless he has available a product brochure contining complete information on the contra indications, precautions and so forth.

This is the very area that we have discussed at length tonight about cutting out, or cutting down. It seems to be running contradictory to the strong recommendations of the Hilliard report.

I would like the comment of some people because if I recall certain areas of the Hilliard report it now enlarged the responsibility of the drug companies in so far as concerns import goods coming into Canada—to treat them as new drugs in the promotional ventures. It would seem to me that recommendation

7 in the Hilliard report, if anything, is going to put a greater strain on your promotional dollar. I do not know what you think of that, Dr. Wigle, or whether you have studied this at all? You have read the report, I presume, Dr. Wigle.

Dr. WIGLE: Yes. I have had considerable exposure to it.

Mr. MACKASEY: I thought perhaps you were just catching up right now.

Dr. WIGLE: I am trying to catch up on three other things ahead of me at the same time, with respect, Mr. Chairman.

I do not believe that the recommendation of the Hilliard report is necessarily aimed at increasing the information which the originator of the product would have to supply. It is that the compulsory licencee, who is now moving into the area, should be obliged to give the same information, unless I have misread the section that you are referring to. I think that this is so; and I think that we feel that a new manufacturer and supplier of a product to the physicians of Canada should have the same responsibility to prove that his product is as clinically safe as the original patentee has proven.

Is this anything of—?

Mr. HUME: I do not think that is the point. Mr. Mackasey, your point, as I understand it, is that this recommendation 7, in addition to any other thing the company feels it must do, places an additional burden—I do not like to use that word—an additional responsibility to have a product brochure which presumably will cost money to produce, and this, as you say, will place a greater strain on the promotion dollar. That is your point?

Mr. MACKASEY: Yes; because it is not only the brochure; there is the information that must be gathered—

Mr. HUME: Yes; contained in it.

Mr. MACKASEY: —and obtained and researched and dug out of the original country—if you are importing from Italy, for instance—and then wrapped up into a bilingual brochure and sent across the country. This will, I imagine, on your balance sheet be classified as promotional literature.

Mr. HENDERSON: It makes the point that medical information is a necessary function.

Mr. MACKASEY: Yes; but, nevertheless, it seems to me to have a direct bearing on the possibility of reducing the dollar going to promotion.

Dr. WIGLE: Mr. Chairman, I would like to submit that I do not think that the Hilliard Committee at that moment was concerned about the cost of promotion. I think that they were concerned about the item of safety and about the drugs that were promoted to the medical profession after somebody had received a licence to put this drug on the market, and that thereby this new licensee should be compelled to provide adequate information. I am sure that Professor Larose could elaborate on this. Is this not the right interpretation?

Mr. LAROSE: That is exactly it, yes. Mr. Mackasey leads us to another point, which is that when we are discussing information and promotion I think we are always thinking about it in a very static way. If we could hold a physician as a captive audience all the time and give him all the information about all drugs and he would remember all this for the rest of his life, then I think we could

eliminate a good deal of the promotion; but there are a great number of firms trying to convey that information to a great number of physicians, and that information is not static, it is renewing itself, there is more added to it all the time. It has to be conveyed all the time by a great number of firms to 20,000 physicians in Canada, and 8,000 pharmacists in Canada.

We do not know how much information material it takes to give all the physicians all the time all the information they must get. That is really the essence of it.

Mr. HOWSAM: I think, in part, this whole question started, Mr. Mackasey, on the question of the detail men and Mr. Laidlaw's question of voluntarily reducing them.

I think that perhaps the point you are making, or adding, to the Hilliard recommendations is that we have to stand ready to make information available and the detail man is the source that is used as the best one to inform doctors when problems arise.

A few years ago I was with a company and they had the problem of a drug withdrawal which was certainly unanticipated. They had a field force which was available from coast to coast, and in a period of, I think, about forty-eight hours, 65 per cent of the doctors in the country were contacted—in this instance by mass telephoning; but they had the communication link with the doctor. This is all part of this information technique and the detail men.

Mr. MACKASEY: Well, I had got off the detail men at the moment. I was wondering, if we, in theory, reached utopia and were not permitted to spend any money on what is loosely called promotion—let us say we use direct mail—how then would you carry out the recommendation of the Hilliard report which says specifically that in the case of a new drug you are responsible for the dissemination of information and I might point out that the Hilliard report touched on safety but it redefined what a new drug is. Any one of you gentlemen, importing from Italy, might have that classified as a new drug, using a different method of production in Canada than was used in Italy. Therefore, you then have the responsibility, under section 7, to promote through direct mail, or make available through direct mail, the brochures, information, to doctors, not necessarily propaganda but factual information.

Dr. WIGLE: Mr. Chairman, I do not believe that the Hilliard committee intends that they should call upon the manufacturer to deliver this to the physician. It has to be available as a responsible production by this licencee of his own information on his product, on the contra-indications, the precautions, the dosage and the side-effects.

As far as the distribution of it is concerned it would be in accordance with how he decided to distribute his product, but it must be available to physicians.

Mr. MACKASEY: In what form, Dr. Wigle?

Dr. WIGLE: I think that this would eventually be at the discretion of the Food and Drug Directorate when they decided to implement such things. If they did, they could then decide that something that was enclosed—

Mr. MACKASEY: No. The last line on bottom of page 10 tells you the form. It says "In a product brochure".

Dr. WIGLE: Mr. Chairman, I am not sure that a product brochure could not be anything from that to the folded document which is enclosed with the package that goes to the pharmacists, or to the doctors.

Mr. MACKASEY: That folded affair and this document are classified in your balance sheet under what heading?

Dr. WIGLE: Promotion, medical information; marketing information.

Mr. MACKASEY: That is exactly what I am trying to say.

The CHAIRMAN: Could the Chairman take advantage of his position and ask a question for clarification? Somebody has got me confused here.

If we are talking about a new drug, this product brochure is something you are really doing now; you are not adding anything with these, because you are already doing this right now.

What I think you are really referring to here is that if somebody gets a compulsory licence and manufactures a drug on that licence he would have to provide the same information that you are now providing. Is this not correct?

Mr. LAROSE: Yes, Dr. Harley. This was done because some firms obtained compulsory licences and then relied on the patentee, or the patent holder, to supply the information which was sometimes requested of the licencee, and there have been cases where the licencee has referred the physician to the patent holder to supply the information which was requested of the licencee, which is rather—

Mr. MACKASEY: I think Dr. Harley has made a very good point.

The CHAIRMAN: I am sorry. It was just a point of clarification.

Mr. MACKASEY: Yes; but I had not made myself too clear. The point you are mentioning, Dr. Harley, is that this does not ask the manufacturers to do something which they are not already doing, but the Committee here has inferred that they have stopped doing something they are already doing, and that is, spend so much money on direct mail and promotion.

I am just saying that in the present circumstances, let us say if this was yesterday, you have at your disposal all the ingredients and mechanism necessary to carry out the Hilliard report. On the other hand, if this Committee were to recommend a cut back in the area known as promotion it could then make it very difficult for the pharmaceutical industry to carry out section 7 of the Hilliard report when, and if, it becomes law. That is the point I was trying to make.

Dr. BRIANT: Mr. Mackasey, your point may be covered on page K-6, the second main paragraph, where it says: "any company manufacturing such a drug should always be able to provide complete informational material about the product to the medical and paramedical profession". It does not mention the compulsory licensing which is something which has entered into it. It just says "any company" and these are general conditions, and then at the bottom of the page: The responsibility of—a company marketing a potent drug—a marketing company "to be completely familiar with all the uses, effects, and side-effects of such a drug and to make this information immediately available at all times to the prescribing physician who may require it." This covers the point, I think, that you are making.

Mr. HENDERSON: Any restriction, whether voluntary or imposed by law, would be contrary to the proposal in 7. That is your point, if I follow it.

Mr. MACKASEY: It would certainly make it more difficult.

Mr. HENDERSON: It would make it more difficult.

The CHAIRMAN: Are there any other questions on that, gentlemen? If not, I thought we might move on to number 3 which is economics, which is really quite closely related.

If we can manage to get through that tonight, I think that would probably be a good place to stop. Probably a lot of the brief, in one way or another, we have already covered, because so many things are interrelated.

Are there any questions arising out of section 3?

Mr. MACKASEY: There was a lot I would like to have brought up, Mr. Chairman, but we have to consider the time.

Section 3, if I recall, without going back to it, is, I think very important. Again, I am not trying to be the devil's advocate, but it has been suggested here today—and suggested by some pretty responsible people—that the quickest way to reduce the cost of drugs to the consumer in Canada is to adopt the policy of almost indiscriminate importation. It seems to me that this would be admitting defeat. We should be able to foster a vigorous industry and at the same time to price it.

I think this section emphasizes, if I am not mistaken, the impact that the industry had on the Canadian employment market. I think we cannot skip over it, otherwise we are going to get a mistaken impression of what role the industry does fill in particular communities such as Toronto and Montreal, where it represents a substantial dollar volume in so far as payroll is concerned. I think we should give it a fair amount of treatment.

The CHAIRMAN: Does the Committee want to go on with this?

Mr. HOWE (*Hamilton South*): I would suggest that we have had enough for today, Mr. Chairman.

The CHAIRMAN: If the Committee would give the Chairman a little discretion, I think there are several areas in this brief that have been covered one way and another, and rather than go through the same order that we have been numerically, perhaps you would leave it to the discretion of the Chairman, or any other member who would like to make suggestions, for the group's next appearance before us, so that we can cover as much material in as short a time as possible.

Just for the clarification, the Pharmaceutical Manufacturers Association are invited to appear again before the Committee on Thursday at approximately three-thirty. Sometimes the members are a little bit late because we come after certain portions of the proceedings of the House of Commons has concluded for that day. That will then be the last appearance before that Committee.

We have indicated that we would like to see you again separately to discuss patents, which is a big area, and it may well be that we would like to see you

again some time in the fall to go over certain areas of the brief which Committee members would like to discuss with you again, if that is possible.

Mr. HUME: Mr. Chairman, so that those of us who come from Ottawa may have some idea, could you indicate how late you are likely to sit on Thursday? We are not suggesting that there be any restrictions, but if you could indicate those of us who have travel arrangements can make them. It is just the day before the week end.

The CHAIRMAN: Yes. That is on Thursday. It is the afternoon, three-thirty.

Mr. WHELAN: Mr. Chairman, I was just talking to Mr. Mackasey about that. I had just come from the House before coming to this meeting. I think you are aware that on Friday we do not sit.

The CHAIRMAN: Yes. That is why we are not sitting Thursday night.

Mr. WHELAN: Probably there will be the adjournment Thursday at six o'clock. This is not factual yet, but this is what—

The CHAIRMAN: I was going to suggest that we sit until five-thirty. Does that sound reasonable? We are not starting until three-thirty.

Unless the Committee is prepared to sit—

Mr. MACKASEY: Can we not sit in the morning, Mr. Chairman?

The CHAIRMAN: It is a question of time. It is possible we might be able to sit in the morning, but highly unlikely because of other committee meetings.

Mr. HOWE (*Hamilton South*): Mr. Chairman, I will move that we sit from three-thirty to five-thirty on Thursday for the sake of getting an opinion.

The CHAIRMAN: Are there any other points of procedure to cover?

Dr. BRIANT: May I ask a question, Mr. Chairman? Was I correct in understanding that you will be going to economics on Thursday?

The CHAIRMAN: Yes. Mr. Mackasey wished to talk about the economics, and from there we will go into other sections; but I think that is where you wish to start, Mr. Mackasey?

Mr. MACKASEY: I want to know why we should not throw the industry right out of the country!

Mr. LAROSE: We will have to tell him.

The CHAIRMAN: The meeting is adjourned.

THURSDAY, June 23, 1966

The CHAIRMAN: Ladies and gentlemen, I think we should now proceed with the questioning of the Pharmaceutical Manufacturers Association because this is their last appearance before us at this time, although they have said they would come back and speak to us in the fall on patents. I think it is obvious there may be more matters the committee would like to raise with them and we should perhaps change the format of the meeting a little bit today and restrict

everyone's questioning to a five minute period so that everybody gets a chance to ask whatever is most pertinent in their mind. We will not conduct the questioning with regard to any one section but you may ask any question on any section that you wish, provided that it has not already been covered. We will start the questioning with Mr. Mackasey.

Mr. MACKASEY: Mr. Chairman, as usual I will start with a little statement. It is ridiculous for us to think that we can cover this brief in two sessions or even in three. It would take about 30 if we are going to do the job with which we are charged. If there is no other alternative I suppose we will have to go through the motions of fulfilling a function which we are not really filling. We had the same experience with the pharmacists the other day. It was a very short period. We did not, I think, give the pharmacists an opportunity to present their side of the case too adequately nor did we as a committee have an opportunity of delving into some of the rather trite or pat statements of Mr. Turnbull. I would like to come back in the three and a half minutes that I now have left to the question of the detail man. I say this because of the publicity given the other evening to Mr. Howe's revelation. I am not criticizing the press; I think they were quite accurate and I commend the press for this but it could, to the uninformed, misrepresent the role of a detail man. I would like to find out from Dr. Wigle what else the detail man carries in his brief case besides gimmicks. I would like to see, as an exhibit, a kit with the type of direct mail or promotional material that you leave with the doctor and, Mr. Chairman, I would like also to make a motion that at the first opportunity we have before the committee a detail man rather than Dr. Wigle speaking for that detail man. I would like some detail man representing a company before the committee so we could question him directly as to how he carries out his functions. I notice for instance on page C.5 that he is reminded to use no profanity when he is talking to doctors, that he must be neat and must have a very professional attitude, be very honest and accurate. I would like to suggest that we have a detail man come to the committee so that we can find out.

The CHAIRMAN: I do not think this would be a function of this organization. Surely when some of the people here assume their other hats and appear before this committee as a private individual company we could ask them. When I write them later this month, would they consider bringing a detail man with them if this is what you wish, and a kit. Perhaps some companies would undertake to send us one in the summer so that we might study some of your promotional materials.

Mr. CLANCY: Perhaps we could see some of his samples?

The CHAIRMAN: A detail man is not supposed to carry samples any more.

Mr. MACKASEY: Mr. Chairman, this is another point which I think is very important. I share Mr. Howe's concern with gimmicks that add to the cost of drugs. I would like to be specific as to what effect it does have on the price to the consumer. I would like to see not only the direct mail or the educational material, as you call it, the informative literature, but I would like to see also some of the forms, some of the literature that is put at the doctor's disposal to induce him or to suggest to him that he request samples. I see nothing wrong with samples, Dr. Wigle. I know of no other way you can make your product

known but I understand of course according to the present rules and regulations the doctor must ask for these samples.

Dr. Wm. W. WIGLE (*President of PMAC*): That is right, Mr. Chairman. I am not too sure whether I will take up any of Mr. Mackasey's time when I talk. I would hate to. Well, I would like to say that we were concerned about the great attention that was paid to the gimmick item in the press as a result of our last meeting and so we did a couple of days of quick research as fast as we could; the only estimate we have at the present time is that this gimmickry as carried out by a few of our companies might represent somewhere around 1/2000th of a prescription dollar in Canada. Now, we would be very pleased to bring you specimens of the other type of information which is supplied to the medical profession and indeed, I think, if I might suggest this, perhaps some of the responsible scientific and medical journals in Canada might be asked to give their comments to this committee as to the value of pharmaceutical information being utilized by those scientific academic journals to carry other scientific technical articles because they are sort of the vehicle by which these messages are carried. We would be happy to take this under advisement, Mr. Chairman, and try to bring you more evidence.

The CHAIRMAN: Yes, I am sure we could ask this question of the medical association when they are before us on Tuesday.

Mr. MACKASEY: Mr. Chairman, are my five minutes up?

The CHAIRMAN: Yes.

Mr. CLANCY: Apropos my friend's recommendation that he brings in a detail man I think, at the same time, we are overlooking one big factor of the drug industry, the independent retail pharmacist. I think it would be good to have them both here together because there are a lot of questions to be asked on both sides.

The CHAIRMAN: This would be the pharmacist who is represented by the pharmaceutical association but you would like to bring a practising pharmacist.

Mr. CLANCY: One who is independent and running his own business, dealing with all companies, the doctors and the government. Let us see where the squeeze is.

The CHAIRMAN: Well we could ask the pharmaceutical association if they would know of any pharmacist who would like to volunteer, and I think that is all we could do. Did you have any questions you wanted to ask, Mr. Clancy?

Mr. CLANCY: No. Basically, I think the main thing is that we are here on the price of drugs and where does it fall, in which part of the industry?

Mr. BRAND: If I may get back to the detail man for a moment. You would then say that these gimmicks were given too much attention by the press with a cost of 1/2000th, is that correct?

Dr. WIGLE: That is the estimate from the information we were able to gather. Certainly not more than 1/2000th of a prescription dollar.

Mr. BRAND: Would you agree then that an inordinate amount of publicity was given to this in view of the very small portion of the prescription dollar that was involved with this type of advertising?

Dr. WIGLE: This would be my personal impression, Mr. Chairman.

Mr. BRAND: As a one-time practising physician, Dr. Wigle, what was your personal response to this type of advertising, when you received it? We have heard one view from a member of the committee.

Dr. WIGLE: Mr. Chairman, this is a question that I think is a very difficult one for physicians to answer and I will try and be as truthful as I can in my assessment of it. I think that when I received this sort of gimmickry I probably as an individual got a kick out of getting the gimmick. I was glad to take it home and give it to my wife to use as a paperweight or for our children to take to school if it was a model of a heart or something like this that they could utilize in this fashion. But as a member of the medical profession who is supposed to have a professional line and a good policy that is in the interest of the promotion of drugs on a highly ethical plane, I felt a little obliged to be against such things. I do not think I ever got around to where I got up and spoke against them but I think that generally, even within this association, it has never been written as firm policy, but the same thing applies. A lot of the companies in our association do not do this. Some are discouraging it. Others are exploring anew in it. I think that is the only way I could express it.

Mr. BRAND: You are making a generalization, Dr. Wigle. I wonder if perhaps you could be a little more specific if I give you a specific question with regard to those particular items which would have some bearing on the actual practice. Now, I believe some of the items tossed on the table here and photographed the other day included such things as a pinwheel by Geigy Corporation for testing the sensitivity, neurological loss or deficit or something of this nature or even tape measures which are used constantly in medical practice. Did you find these were totally useless items.

Dr. WIGLE: I was not thinking of those when I spoke or insulting them by calling them truly gimmicks. The thing I was thinking about as a gimmick was something that was not particularly useful in the practice of medicine. I must say that those items which Dr. Brand has mentioned, another tape measure, because you are continually wearing them out in practice and a gadget by which you might calculate the expected date of confinement in an obstetrical case or something to assist you with other measurements of the movements of joints or something of this nature, I welcomed.

Mr. BRAND: Would you also put in the same category such things as a handbook of neurological diagnosis which would fall within these broad general terms of giveaways, or the magazine Consultant put out by Smith, Kline and French which is in my personal opinion an excellent publication?

Dr. WIGLE: I would. I think that some of these publications, I must admit, I did utilize in practice. To my knowledge there was no easily available reference book.

The CHAIRMAN: I should point out that you are really putting Dr. Wigle on the spot here because you are asking him questions of a profession he now no longer represents really here today. We will have the medical association before us on Tuesday and these are probably the more appropriate people to ask.

Mr. BRAND: I do not think this is out of the way at all, Mr. Chairman, because in his position now, I am sure he was chosen for this because of his

experience in the practice of medicine and which he could lend to the association some of his experiences which are wide in his field.

The CHAIRMAN: But he is not speaking for the association when answering the questions you are asking him. That is the only point I am making.

Mr. BRAND: Well then is there somebody around that I could ask about the Merck manual put out by Merck, Sharp and Dome, something that has become a bible for every intern across this country for many, many years and which was put out as a promotional gimmick by the Merck, Sharp and Dome company.

Mr. Guy BEAUCHEMIN (*Executive Secretary of PMAC*): Mr. Chairman, we have brought some examples of the kind of constructive advertising which Dr. Brand is talking about and I will leave them on the table here for the committee's perusal.

Mr. MACKASEY: Mr. Chairman, on a point of order so that neither Dr. Brand nor Dr. Wigle are not misunderstood, I do not have any conclusion that the press has treated the committee meeting the other night unfairly; on the contrary I think the press has been very objective in their reporting.

Mr. BRAND: I do not think I ever made that assertion.

Mr. MACKASEY: No, no, but when we play it back you will find you can draw that inference from Dr. Wigle's remarks which I do not think he intended to portray, at least I hope he did not.

Dr. WIGLE: Mr. Chairman, I was asked a question by Dr. Brand as to whether I thought there was undue attention paid to it; I think my answer was yes because it is my impression we discussed some things that to me were much more vital about the cost of drugs.

Mr. MACKASEY: This was not the fault of the press. It was the fault of the committee in not emphasizing this part.

Mr. BRAND: My point in bringing it up now is because I think it has been weighted too heavily on one side.

Dr. WIGLE: I think the word attention was mentioned and I do not think it was specified whether it was press attention or committee attention, I am not too sure.

Mr. BEAUCHEMIN: These, Mr. Chairman, are scientific publications put out exclusively for the better information of physicians on different products which are available. They are not publicity pieces as such; they fully include all contra-indications and precautions which have to be followed when you use the drug.

Mr. O'KEEFE: Mr. Chairman, there are two statements on which I would like a little more elaboration. One is an answer given by the gentleman third from Dr. Wigle in response to a question asked by Mr. Laidlaw. I think Mr. Laidlaw's question was to the effect that could not something be done to reduce prices if you could agree to co-operate with that intention in mind. I believe, sir, your answer was that we would then be infringing the combines legislation Am I right in that?

Mr. Fred R. HUME Q.C. (*Barrister, Hume, Martin and Allen*): The question put to me or to Dr. Wigle, Mr. O'Keefe, as I understood it was that by

agreeing on a method of distribution or promotion might not this produce some results. I pointed out and I am still of the view, that any association of manufacturers who agree on any matter that pertains to price are treading on very dangerous ground. I said then and I say again that without it being clearly understood that this would not affect the ultimate price then I would advise this association to take any action as an association. I think this is a case where the manufacturers must unilaterally decide on their method of distribution, their promotion or whatever because this is the area that, in my humble submission, is dangerous under the Combines Act.

Mr. O'KEEFE: Now I am not a lawyer nor a doctor nor a pharmacist—but it seems to me that our combines regulations are there to protect the Canadian public. If protecting the Canadian public is preventing people from co-operating in reducing prices then surely that law is stupid.

Mr. HUME: Well, you will have a great deal of agreement in that statement, I am sure, because there are other industries where, for example, they would like to get together to have uniform packaging, uniform discount practices and they are not permitted to do so by the Combines Act.

Mr. O'KEEFE: Then you are suggesting that the Canadian government is preventing lower prices.

Mr. HUME: No, I am not suggesting that. I am saying sir, that the Combines Act as presently worded, and you may be aware that there are groups who are constantly suggesting to the government that this Act be amended, prevents manufacturers through an association to agree together on matters that affect price. Now, sir, I cannot go beyond that because I cannot go on to say that the legislation has a certain result. I do not know enough about it. I will just say that they must not discuss these matters as a group.

The CHAIRMAN: Perhaps I could just say here that we will get an opinion from the Restrictive Trade Practices Commission on this.

Mr. O'KEEFE: Maybe we are here infringing the Combines Act if that were so. We are trying to agree on a method of reducing drug prices. Is that not so?

Dr. WIGLE: No, we are not representing individual companies here today.

The CHAIRMAN: We will get a legal opinion from the Restrictive Trade Practices Commission.

Mr. O'KEEFE: Well, that is one problem I had in mind. The other is the theory behind the labour price in England as against the labour price in Canada. Now, I feel that all averages—necessary sometimes—are imaginary and being imaginary they are nearly always wrong. The prices you put up the other day on the board indicated the Canadian was making $2.02 an hour against an Englishman making $1.05 an hour. Well surely those figures you presented can only apply to people who are making that particular salary, and then it would have no effect on anyone else in Canada who is making more or less than $2.02 an hour. Is that so?

Dr. PETER C. BRIANT (*Vice Dean and Director, School of Commerce, McGill University*): Well, Mr. O'Keefe I would not go far as to say it would only apply, I will agree with you though that averages are meant just to give a general description. Clearly Canadians who earn, say, $5 an hour are in a

superior economic position vis-à-vis the cost of drugs from those who earn $2.02. This was in 1964 the average wage rate in manufacturing. Similarly, Canadians who earn less than $2.02 are worse off vis-à-vis the price of drugs. Of course, this demonstrates something we know. The indigents, for example, perhaps are in a poor position so far as the cost of drugs to them is concerned. This would be true in most countries except those that take care of the indigents. But the figures that were prepared were to show just a general picture and demonstate for certain drugs in the United Kingdom, even with the health service, their real cost is higher than the real cost of corresponding drugs in Canada. Dr. Howe's list, when broken down into the two components, shows that for some other drugs while the British prices are lower, they are not so much lower, and then for 42 of them, particularly old drugs, the effect of the voluntary price regulation scheme in Britain has been to reduce those very greatly, relative to the price of similar drugs in Canada.

Mr. O'KEEFE: But obviously your basis was 100 per cent less or 50 per cent less than Canadian price when you took the $1.05 against the $2.02.

Dr. BRIANT: Yes.

Mr. O'KEEFE: So that would throw the whole thing out relatively.

Dr. BRIANT: No, because the Canadian prices were correspondingly higher than the U.K. prices because cost in purely money terms in Canada for most products that we produce are higher than the cost in money terms in the United Kingdom. That is why we related the dollar cost of drugs in Canada and the pound cost of drugs in the U.K. to a figure for average earnings in each country. When you really get down to the basis of economic activity, as was also pointed out by Adam Smith and Ricardo in the 18th and early 19th centuries, the ultimate component of most of our goods and services is labour and the source of our income is our labour.

Mr. O'KEEFE: Would you say that was true about the drug manufacturers in Canada. You said it was only 1½ cents out of the 37½ cents cost?

Dr. BRIANT: I do not know if you were there when we corrected that but actually 30 per cent of the manufacturers dollar is represented by wages and salaries. The 1½ cents which we had in the table on page 2.2 is purely the manufacturing labour.

Mr. O'KEEFE: You are talking about Adam Smith's theory of labour being the only basis; surely that is not so. Brains are a far more important basis, I would suggest.

Mr. BRIANT: Oh, I would have to agree with you.

Mr. HYMMEN: Mr. Chairman, I have a question and due to the conflict with other committees I do not know whether or not this was asked at the last session. So far as I am concerned this has nothing to do with the manufacturers association but I feel that the professional retail druggist who does provide an important service in any community is entitled to some fair return for his operation; that is at the one end. At the other end I also recognize the importance of research and development and the basic cost which, is 37½ cents on the retail dollar. So, we get to this area we have already discussed of sales distribution and in the recommendations of the manufacturers association,

under section 9, you refer to this independent source. Has that been discussed in any detail, Mr. Chairman? Would that independent source be considered the government or would it be someone else, and would you be just taking the cost out of the present cost structure and putting it somewhere else, or would this, in essence, tend to reduce the over-all cost.

The CHAIRMAN: Could you tell us what portion of the brief or what page you are referring to.

Mr. HYMMEN: Page 14.2 and it refers to section 9 previously, this independent source to provide doctors and pharmacists with accurate up to date and I presume unbiased information about pharmaceutical products.

Dr. WIGLE: Mr. Chairman, if I might attempt to answer Mr. Hymmen, this recommendation was built around other recommendations which have been made in this regard. There have been several suggestions in the past two years that there might be some independent source of information relative to drugs and that this source of information would be available to physicians and pharmacists to inform them in an unbiased fashion about drugs. I think that the people who have made such suggestions, including ourselves, have envisaged that it would probably involve everyone concerned, the government through the Food and Drug Directorate probably, the manufacturing industry, the pharmaceutical manufacturer, the physicians and the pharmacists of the country and that there would be some co-operative effort whereby information would be available regarding old drugs, new drugs, for adverse reactions and all the rest of it, for a general drug information program. This is purely speculative at the present time and I do not think anybody could say for sure that in the long run the system evolved might absolutely reduce the cost of drugs from what it is at the present time. Mr. Larose has been intimately associated with the committee work in this regard. Mr. Chairman; might I ask him to assist with the answer?

Mr. ROGER LAROSE *(Vice-President, CIBA Company Limited)*: There is not very much more I can say than what Dr. Wigle has said. It is very difficult to maintain a constant and up to date source of information on drugs. Many attempts have been made over the years and we have brought together the committee to see if it would be possible and, in fact, at our suggestion the Food and Drug Directorate, has appointed the former director of the food and drug, Dr. Morrell now retired, to make a feasibility study of this question. I have not seen his report yet but it would not only transfer cost, as you ask, it would perhaps eliminate some duplication in the supplying of information. But, we do not know; it is worth studying and it is being studied at the present time.

Mr. HYMMEN: Would there be an interim report available in the fall, Mr. Chairman, or Dr. Wigle?

Dr. WIGLE: I think it is impossible to say at the present time but I think that certainly if this committee is still meeting when Dr. Morrell finishes his feasibility study it would be available and we would do our best to produce it or get it through the proper channels.

Mr. HOWE *(Hamilton South)*: I was just noticing in appendix "C" the code of marketing practices in connection with your pharmaceutical manufacturers association of Canada. What happens if one of your members does not live up to this very stringent code that is laid down there?

Dr. WIGLE: Mr. Chairman, we have a facility whereby a committee of ethics is struck for that particular case. This Committee is an anonymous committee that sits in judgment on the infringment and then action is taken according to what that committee decides and recommends to the board of directors, whether it be some form of penalty whereby they are removed from membership which, I believe, in past years has happened, or whether it be some form of reproach by the other members. These things at the present time are being strengthened but our past experience is fundamentally that.

Mr. HOWE (*Hamilton South*): What areas in the breaking of the code were they taken to task for or removed from your membership? Was it advertising or what?

Dr. WIGLE: Methods of advertising, unethical representations. Mr. Beauchemin perhaps can answer.

Mr. Guy BEAUCHEMIN (*Executive Secretary of PMAC*): Well, actually this code of marketing practice, especially the code of advertising, came into effect on January 1, 1966. The other codes of marketing practice were adopted about a year ago. Up to now we have had some cases of infringement which the companies have attributed to difficulty of application, closing times of advertising publications and things like that. The reasons have been accepted up until very recently. We are tightening it all the time. There may be one case about which I expect to have some more news in the near future which might be a case to be considered as a breach of the code of ethics of the Pharmaceutical Manufacturers Association and it will be treated accordingly. I want to correct somewhat what Dr. Wigle has said, that the companies he mentioned were not expelled because they had been blamed with a breach of sections of our code, they chose to resign from the association as a consequence of the violation. The association did not ask them to resign.

Mr. HOWE (*Hamilton South*): Well you have not had this code too long but have you ever found that some of your members were promoting a product that you, in your knowledge, felt was not right to be put before the Canadian people?

Mr. BEAUCHEMIN: No, it is not a case of the product not being right because this is really a matter for the Food and Drug Directorate, although we would call this to the attention of the Food and Drug Directorate if it came to our attention, but there would be maybe methods of advertising which were not condoned by our code; up to now we have reason to believe that the infringements were involuntary. But, of course, this reason will be accepted less and less as the code becomes better known.

The CHAIRMAN: I should tell the committee that Mr. Blakely had some questions that are detailed in the form of mathematics and rather than go through the procedures of the board again he and Dr. Briant are going to get together to reconcile this and then he will report back to the committee. Did you have any questions you wanted to ask other than that, Mr. Blakely?

Mr. BLAKELY: Yes, I do, Mr. Chairman. At page 35 reference is made in the second last paragraph to the fact that the rate of return for the industry would seem to compare or be in line with results for other industries. I wonder if we

might be advised of the source of that information—that is, the results for other industries?

Dr. BRIANT: Well it is in the paragraph above.

Mr. BLAKELY: Well, it is cross-referencing back to CMA then?

Dr. BRIANT: Yes.

Mr. BLAKELY: Page 2.3 and also E.3, manufacturing administration as distinct from the sales administration, evidently represents 11 per cent of the manufacturers dollar. Would I be correct in understanding that this item includes the management service charges of approximately $2.4 million.

Dr. BRIANT: No, I do not think so. I can explain that.

Mr. BLAKELY: Well is this one of the matters which might come out in some of the other detail we have to check out? If so, I would defer on it.

Dr. BRIANT: It could or, if the chairman wishes, I could explain it on the board and then everyone would understand.

Mr. MACKASEY: I think, Mr. Chairman, what we need is a closed meeting with our accountant so we can be briefed on where he thinks you people are wrong. Otherwise we are just spectators.

Mr. BLAKELY: Let us pass on this one.

Mr. MACKASEY: Then I think we can go after you people properly on your balance sheet.

Mr. BLAKELY: Passing over that, Mr. Chairman, and moving on to another quick one, the association has given us the return on resources employed. Would you be able to give us the return on capital employed?

Dr. BRIANT: Yes, I could do that. You mean on owner's equity plus any loans from the parent companies to the subsidiaries?

Mr. BLAKELY: Yes?

Dr. BRIANT: Yes, I could give you that.

Mr. BLAKELY: Fine. We have the one side of the balance sheet; could we have the other side of the consolidated balance sheet?

Dr. BRIANT: Yes, I could make that available for you. I might say that the fact it was not there is attributable to me because I had taken the position—I do not want to stay and argue it now; I just want to explain why one half the balance sheet was missing—that in comparing the profitability of industries to my mind the correct approach is to compare the return on total resources employed. But different industries have different methods of financing that lead to different rates of return on the owner's capital employed. But from the viewpoint of social regulation of industry this is a less important measure so I said we should just put in the statistical appendix, the portion of the balance sheet that related to figures in the brief. But we can make the other side available to you.

Mr. BLAKELY: Again, in E.1, I think it indicates that other assets amount to approximately $9.8 million. What would be the general nature of the items

included in there. In particular, would there be any investments? If so, what would the amount be?

Dr. BRIANT: I am afraid you have got me. I do not have a breakdown of that. In fact, I do not think I could give you that.

Mr. BLAKELY: It was not part of the survey?

Mr. MACKASEY: Would it be royalties?

Dr. BRIANT: Oh no, it would not be royalties. It could be investment in subsidiaries, Mr. Blakely.

Mr. Robert F. DAILY (*Chairman of the PMAC Board of Directors and Vice-President and General Manager, Smith Kline and French Inter-American Corporation*): I would suggest that we could try to find out from some of our individual companies represented here and perhaps when we appear in the fall or else earlier than that we could supply this information separately.

Mr. BLAKELY: Mr. Chairman, I wonder if we can get a brief explanation, it can be done that way, of the reasons and explanations that would be advanced for what would appear to be a relatively high rate of return for the pharmaceutical industry compared to all industry? Now, the reason I say there would appear to be this relatively high rate of return in comparison is taken from the information included on page 376 of the Report of the Restrictive Trade Practices Commission. I am sure the percentages are probably quite familiar to the members of the association.

Dr. BRIANT: Do you want a quick answer to that?

Mr. BLAKELY: Well, it was pointed out in that particular review—granted it goes back a few years—in the period 1953 to 1960 on an average the pharmaceutical industry enjoyed a rate of return on capital invested of 19.8 per cent compared to all manufacturing of 10.9, roughly doubled.

Dr. BRIANT: Is that before tax or after?

Mr. BLAKELY: That is before tax.

Dr. BRIANT: Because I worked out a figure for return on stock equity after tax of 10 per cent. But mind you this is very complicated, I have here 36 possible measures of rates of return. This is why I really find it difficult to give a quick answer.

Mr. BLAKELY: Well, first of all, would you say that it appears to be relatively high in comparison?

Dr. BRIANT: Yes, I would say it is higher than the average of all industries. There are different explanations for that. For one thing, if you are looking to the period 1950 through 1960, this was a period when many new products in the industry were introduced. New products are typically fairly profitable products and then their rate of return declines through time. Then there are other factors such as the balance sheet of the pharmaceutical industry, as with many other industries, but I would think particularly so, in the case of pharmaceuticals, fails to reflect all the assets used in the business. This is an industry which is particularly dependent on, as Mr. O'Keefe said, brains. Well, it is particularly dependent on a high level of technical ability, a high level of education. This is not taken into account in the investment of the industry as such and this tends

possibly to lead to a higher rate of return because you are leaving out some important items.

Mr. MACKASEY: Mr. Chairman, may I ask a question. On page 5 you list quite a few industries which, according to your figures, have a higher rate of profit than the drug industry. If I was interested in playing the stock market I would be interested in these statistics. You mentioned soft drinks, alcoholic beverages, pulp and paper mills, engraving, stereotyping, allied industries, offices, storage machinery, fertilizers and industrial chemicals. You claim that all these companies in 1962 earned more money than the drug industry. Now which drug companies are you basing this on, some or all or an average?

Dr. BRIANT: We are basing this, Mr. Mackasey, on the 41 companies in the association's statistical survey, so it is 41 of the 57 members.

Mr. MACKASEY: There could be some drug companies earning more money than Coca Cola, say, or Seagram's?

Dr. BRIANT: Oh, I think this is true.

Mr. MACKASEY: Then, of course what you are saying is the average is less.

Dr. BRIANT: Yes. To some extent this depends as well on how they choose to capitalize themselves. If the company uses a great deal of debt then it can increase the return on the owner's investment but by doing so it has added to the risk the owner's are willing to accept, over and above the risks in the industry they have imposed on top of this financial risk inherent in using other peoples money.

Mr. MACKASEY: You say the profit after taxes amounted to 5.2 per cent.

Dr. BRIANT: That was on the sales dollar, so that out of every dollar of the company's sales they were left with 5.2 cents.

Mr. MACKASEY: Would this be on the corporation tax returns of the 41 companies?

Dr. BRIANT: Yes, it would, unless their measurement of income for tax purposes is different from their measurement of income for purposes of the annual survey, which can happen. There are numerous adjustments that can be made from what they think their income is to get their taxable income.

Mr. MACKASEY: I do not know if I am on my second five minutes but I am only on a supplementary question. The royal commission suggested that the $5½ million which you people consider on your balance sheet as royalties, management services, dividends and so on should be considered a profit. What stand are the income tax department taking in this regard?

Dr. BRIANT: I beg your pardon?

Mr. MACKASEY: How do you justify this $5½ million to the income tax department as not pure profit, as a legitimate expense?

Dr. BRIANT: Well perhaps one of the attorneys might be able to answer that but I presume that it is a deductible business expense for tax purposes.

Mr. MACKASEY: It is considered by the government as a legitimate deductible item?

Dr. BRIANT: Yes. We state this in the brief as well as at page 3.6, that if royalties and dividends, amounting to 5.77 million—were included as profit, as the royal commission seemed to forget, it would increase the rate of return; but then we argue that these are not really profits but they are necessary business expenses that have to be incurred by the companies.

Mr. MACKASEY: I do not want to infringe on our accountant's five minutes, Mr. Chairman.

Dr. BRIANT: Could I make one point that might help in understanding section 3. That the pharmaceutical industry, I think, is a profitable industry. This, to my view, is not something the industry should be ashamed of. Certainly we do not want unprofitable industries in this country because they would be producing output the value of which in the market place would be less than the cost of the factors they put into the production. I am certainly not ashamed of saying the profits in the industry have been good. A real test, it seems to me, is whether the investment in assets in the industry is commensurate with the rate of profit, because what we should worry about are industries with high rates of profits and a very low rate of expansion of the assets because then you wonder what barriers there are to entry and investment by new firms. Or, conversely, we should also worry about industries with a high rate of investment and a low rate of profit because more resources are being plowed into the industry than are necessary. Now, as we demonstrate on page 3.7, the investment in the industry over a five year period has been equal to the funds retained through depreciation charges and equal to the earnings retained in Canada, so that it would appear—it is relatively difficult to try and do a statistical correlation between these two—that the high rate of profits is also followed by a high rate of investment. Now, this is implicit in the operation of the market system. Profits perform different functions and one of them is to indicate possible profitable investment opportunites. Now, if they are not picked up I, as an observer of the industrial scene, would start to say, well, what is wrong with this industry. But, I believe in the pharmaceutical manufacturing industry. The high rate of profit has led to a high rate of investment and from this point of view the industry has performed in a satisfactory manner.

The CHAIRMAN: There are probably a lot of questions in Mr. Blakely's line. I think probably you and the professor are going to have a busy, hot afternoon some day. I wonder if Mr. Laidlaw might have any questions at this time?

Mr. A. M. LAIDLAW, Q.C.: On this business of dividends and retained earnings, Mr. Chairman, section 3.6—it is the same chapter—I just noticed that $1½ million were charged by the parent companies of the subsidiaries for research done in their behalf. Is this a levy?

Dr. BRIANT: I cannot answer that, Mr. Laidlaw; I do not know how the companies in Canada are charged by their parent companies.

Mr. MACKASEY: Well, you did put it in there for our perusal? If forty gentlemen represent the industry, someone should know how the $1½ is calculated? It is obviously a Canadian charge to international research somewhere along the line. I asked that question last week and got an evasive answer and I hope we can get a more factual one today.

Mr. DAILY: May we have a definition of what counsel means by a levy? Is a levy different from a charge?

Mr. LAIDLAW: I would just like to know what rate it is based on, sir; that is all.

Mr. Gordon F. HENDERSON, Q.C.: (*Patent Attorney, Gowling MacTavish Osborne & Henderson*): Oh, well I am sure it would not be a single rate. I am sure it would differ among the companies in terms of what they considered it to be worth.

Mr. MACKASEY: I understood the answer was based on a per capita of the population of the countries involved. I may be wrong.

Dr. BRIANT: I asked around once on this and I found a fairly customary way was to allocate on the basis of relative sales. This is fairly typical of the companies. If the Canadian company has 10 per cent of the world sales it is charged with 10 per cent of the research expenditures of the entire international operation.

Mr. LAIDLAW: Perhaps, Mr. Chairman, when the manufacturers appear before us they would have this information. I will not press any further. I have one question on the same section though. At the bottom of page 3.8 I notice that $21 million were paid in dividends. I assume that the balance of the $43 million mentioned as net income is retained earnings, which follows out Dr. Briant's statement that they are keeping a balance between paying out dividends and retained earnings for expansion. My question, however, is this: Does the majority or most of that $21 million paid out in dividends go out of the country?

Dr. BRIANT: Yes, I think the answer would have to be that it does.

Mr. HUME: It would depend, surely, where the shareholders were but I think it is true to say, is it not, that most of these companies being subsidiary companies you could assume the majority or controlling interest would be foreign rather than Canadian. There must be some exceptions where Canadians have shares in some.

Mr. MACKASEY: A supplementary question. Are most of these companies in your association on the stock market?

Dr. BRIANT: Not on the Canadian market.

Mr. MACKASEY: On any market.

Dr. BRIANT: Yes.

Mr. MACKASEY: Is there anything to prevent a Canadian from sharing in these dividends by buying shares in these companies?

Mr. DAILY: Not at all.

Dr. BRIANT: One point, if I may just follow it up, Mr. Chairman. Mr. Mackasey asked about this yesterday and I did not have the sheet with me. While $21 million or so in dividends goes out of the country unless shareholders are Canadians, we have to remember that $22.7 million does stay in the country. That is shown on page 3.7; the figure ties in. And then, I worked out for a five year period, and it is amazing the way the figures worked out, that the total of

dividends and earnings retained for a five year period were $43,781,000. The total of excise and sales taxes were $43,783,000. It is on this sheet of paper I have here. It is on page 3.8. There is only $2,000 difference between the excise taxes collected over five years and the total of retained earnings and dividends. Then corporation income taxes were $41,712,000.

Mr. MACKASEY: Surely, apart from the figures being interesting they are of no other interest to us. We are only interested in what you retain after you pay the government taxes. The coincidence may be of interest but I do not know what bearing it has on the cost of drugs.

Dr. BRIANT: Well it has a bearing in relation to the amount that goes out of the country but a tremendous amount stays in the country. This is the point I am making.

The CHAIRMAN: I can give you another minute, Mr. Mackasey.

Mr. MACKASEY: I did not know I was on my five minutes, Mr. Chairman. These were all supplementary questions. I want to get back to Mr. Hume's answer to Mr. O'Keefe, perhaps for clarification. You pointed out, as a very conservative lawyer would, that under the Combines Act the companies cannot get together either to raise prices or to lower prices. I can understand legal counsel giving that answer but presuming that it was not against the law, is it possible that if you people got together you could come up with ways and means of lowering the price of drugs?

Mr. HUME: Well, I think, Mr. Chairman, the obvious answer must be yes because the amendments that were put through to the Combines Act some three or four years ago excluded from the penalty portion of getting together, goods that were going to be exported. I think it is in subsection 5 or subsection 6. I am not an economist but I would think the reason why they excluded goods to be exported would be that they must have believed, the government or the people who are concerned with this thing, that if manufacturers could get together in these areas they could produce a better result and over the years, in connection with this and other associations that I have had to advise from time to time, I know that approaches have been made to the Minister of Justice in the past to take another look at this part of the Combines Act because it is preventing uniformity of packaging, uniformity of distribution methods on the basis that each company must make unilateral decisions and let the law of the market place govern competition. So, I think the answer must be that if they recognize benefits for domestic trade if you can get together. But, the obvious danger is that an association who may be suspect in some quarters anyway, must be, I think, if it is going to survive and perform a function, very careful not to get involved in this area at all. That is the reason I gave that answer the other day. Certainly during the wartime under emergency powers companies were brought together and they were required to produce uniform products and uniform promotion and so on and great benefits resulted. However, the minute the war was over we went back to the old system and I am sure there must be economic waste under the Combines Act.

Mr. MACKASEY: We are charged in this committee to find ways and means of lowering the cost of drugs and I think Mr. Hume's statement is very important. He has made a statement that there are ways and means by which the cost of drugs could be lowered provided the pharmaceutical industry had a

certain amount of freedom now denied them by certain laws in Canada to discuss ways and means of uniformity in packaging and distribution, I imagine, to bring the cost down. I think it would be very helpful to this committee if by the fall somebody representing the pharmaceutical industry could prepare a concise brief on precisely how this is possible. So, if it is feasible and this committee thinks it is practical and in the best interest of the consumer we can discuss this brief and recommend it to Parliament if it has the desired effect, which is, of course, to bring down the cost of drugs. This is what we are here for and we are duty bound, morally bound to investigate all avenues that could lead to the eventual reduction of the cost of drugs.

Mr. HUME: Mr. Chairman, I should be very glad to assist in the preparation of a draft memorandum along these lines. I should just like to leave you this thought too, that in the United Kingdom and the European Common Market there is a certain relaxation under the Combines Act where what would be a crime in Canada is not a crime in those countries and it is done in the interest of the public good. Here it is no defence to a prosecution under the Combines Act that you reduce to price, or you produce to better result.

Mr. O'KEEFE: Has there ever been a case in Canada where a company was charged under the Combines Act and convicted of reducing prices to the consumer? Has there ever been a case like that?

Mr. HUME: Yes. I do not know about reducing prices but the Fine Paper case—I have not got the exact citation of the Supreme Court of Canada—made it clear that it is not relevant in a prosecution under the Combines Act that any benefitted resulted. It is a crime to combine, period, good, bad or indifferent. If you agree and it affects price under the section of the Act in my respectful submission you are liable to prosecution. It is now no longer a defence for an accused to say: Well, I produced a good result.

Mr. O'KEEFE: Has there ever been a man accused of reducing prices to the consumer and convicted on that basis?

Mr. HENDERSON: It is my recollection—and I am speaking purely from recollection—without having checked this for many years, that this did arise in the retail coal distribution in the Winnipeg area. I would have to check it but it would be worth investigating. I am not stating it is a fact but it is my recollection that that did take place.

Mr. HUME: It is also my recollection in the Wire and Cable prosecution, evidence was adduced to indicate that some of the prices—not across the board—were reduced, and the court held this was completely irrelevant to the prosecution.

Mr. O'KEEFE: Well, Mr. Chairman, I would hate to be part of a government that kept that law in effect if what the gentleman is saying is true.

Mr. MACKASEY: Mr. Chairman, I might give another example at the risk of losing a few minutes. I think last year we had a case in Montreal where a company was prosecuted for lowering the cost of the sale of milk. I do not know if it comes under the same law but it definitely happened.

Mr. BRAND: Along the same line and à-propos section 3, would you agree, whichever one of the gentlemen knows something about this, that since we import most of the basic chemicals for production here and it is not feasible to

manufacture them in Canada that if we had a manufacturing industry for the constituent chemicals of some of these drugs in Canada we could as a result reduce prices?

Dr. WIGLE: Mr. Chairman, this has certainly been a serious concern of the industry and in co-operation with the Department of Industry we have had several talks about the possibility of a fine chemical industry. Perhaps Mr. Larose could give a little further information.

Mr. LAROSE: Not much more because I think you would have to study each product individually. The market is very small for the chemical substances and it is only one part of the total cost, and not a very high part of the total cost. Now, while it might be inexpensive to produce all that is required in Canada of the substance, it might require a large investment to produce an equally small quantity of another substance. So, you could not give a general answer to that. But, certainly some products could be produced more economically in Canada.

Mr. BRAND: Well let us go down to page 3.3 in the middle where the statement is made that:

> —further, the present tariff structure does not encourage the production of these chemicals in Canada.

Just what does that mean?

Dr. WIGLE: Page 3.3, relative to the tariff structure in Canada at the present time and the way that it discriminates against the beginning of a chemical industry. I think we have discussed this.

Mr. LAROSE: Yes, it only means that the tariff is 15 per cent.

Mr. BRAND: Well, it says it does not encourage the production. What does that mean?

Mr. LAROSE: Well, because it is cheaper. If it can be produced in larger quantities and if you only add 15 per cent then it is cheaper to import than to produce it in small quantities.

Dr. WIGLE: You would not be able to produce it competitively and the other fellow could still import it cheaper than you could make it while the tariff is as low as it is.

Mr. HENDERSON: We say too that there should be added to that sentence the compulsory licence provisions of the Patent Act do not encourage the production of a base chemical in this country because economically it is not advisable. That is a matter I believe we will go into at greater length but I think it should be put on the record at this point.

Dr. BRIANT: It is in the next paragraph, I think.

Mr. HENDERSON: I am sorry; it does flow, but the two should be read together.

Mr. HYMMEN: I have a related question. The government already has indicated that the 11 per cent sales tax could be eliminated if it was for the benefit of the end product. Then, by the same token if it is cheaper to bring in a product with 15 per cent duty then, for the benefit exclusively of the drug industry and the ultimate consumer, we might consider removing that 15 per cent as well.

The CHAIRMAN: Is not the point you are trying to make that the manufacturer's goods have a higher tariff?

Dr. BRIANT: The opposite point is the advantage to this country in encouraging the development of a fine chemical industry and that at the moment there is a positive discouragement in the 15 per cent tariff not being satisfactory protection.

Mr. HYMMEN: Yes, but the regulation might be on the basis of a certain volume demand of that chemical; once it reaches that volume and it becomes economically possible to manufacture it then you raise the tariff.

Mr. MACKASEY: Am I on my next five minutes?

The CHAIRMAN: Mr. Howe had a question.

Mr. HOWE (*Hamilton South*): At the bottom of that page 3.3 there is a question I would like to ask. The sentence says:

> Certainly, it would encourage exporting activity if conditions in Canada fostered a more comprehensive manufacturing operation—

What are the conditions that do not foster a comprehensive manufacturing operation in Canada?

Dr. WIGLE: Those are the items that we had actually discussed here, Mr. Chairman, the basic chemical industry plus this protection of manufacturing generally and the difficulties we have with compulsory licencing. At the present time a manufacturer is a little reluctant to set up the total processing ability to produce products in Canada when someone else can just apply for a compulsory licence under the Patent Act and start up alongside of him. Perhaps someone else could add something.

Dr. BRIANT: Well there are the related aspects of importing the chemical from another country and then processing it in Canada into a final drug. In the long run this can be more of a discouragement—

Mr. HOWE (*Wellington-Huron*): But the words are "conditions in Canada". Now, what conditions in Canada prevent the fostering of this type of industry.

Mr. HENDERSON: These are the conditions in Canada, Mr. Chairman. By way of example, the existing patent legislation in its present interpretation is such a condition. When a company is in a position of manufacturing a base chemical and then finding that it has established a manufacturing establishment which could be rendered uneconomic by someone applying for and obtaining a compulsory licence for the production of medicinals at a very, very low rate, you do not have a condition conducive to establishing and investing in this country. That is one example of what is meant by that paragraph.

Mr. HOWE (*Wellington-Huron*): In other words, the patent regulations—

Mr. HENDERSON: They discourage rather than encourage investment in the production of pharmaceuticals in this country.

Dr. WIGLE: Mr. Chairman, we had said we would go into the patent section more thoroughly at our future hearings but we would be happy to go into it now, if you wish. One of the other aspects of it, just for the quick information of the committee, is also that at the present time the patent regulations only allow patents on processes, and, not on a particular product.

Mr. HOWE (*Wellington-Huron*): I was wondering how this patent would work when opposition could start up next door to you. Would not they have to get a patent as well? Is it just licensing?

Mr. DAILY: May I give one example here; it is a personal example because our company has one of our products which we are synthesizing in Canada. By synthesizing I mean that we are involved to a limited extent in fine chemical manufacturing. I think we should differentiate here between manufacturing the formulation of our drugs, as we explain in our opening paragraph here, in extent of its manufacturing, fully 83 per cent of the prescription products sold in Canada are actually manufactured here. We mean by this kind of manufacturing, secondary manufacturing, the formulation of the active ingredients into a manufactured product. Now when we say in the last paragraph here, that there are certain conditions which do prevent a more comprehensive manufacturing operation, we mean here a more comprehensive fine chemical manufacturing operation. Now, in our situation, we have a product which we are synthesizing and it is subject to a patent. But, under the general provisions of the Patent Act—if I may just take a minute—if we were not otherwise abusing this particular product and we were working it in Canada we would be allowed protection under the Patent Act to continue manufacturing, distributing and maintaining our patent position. But, in our circumstances because this happens to be a drug, the fact we are actually manufacturing the fine chemical, the fact that we are actually working the patent under the section of the Patent Act applicable to foods and drugs, this has no consequence when the patent commissioner is approached for a compulsory licence. We will get into this in much more detail. It is a very complex subject. I just wanted to raise the point however, in view of your question.

Mr. HOWE (*Wellington-Huron*): Mr. Chairman, what disturbed me was that it said conditions in Canada prevented the encouraging of an exporting activity. Is it the patent laws that do this?

Mr. DAILY: That is one of them.

Mr. HOWE (*Wellington-Huron*): What are some of the others?

Dr. BRIANT: The tariff structure to the extent that this discourages development in Canada of the fine chemical industry to get this patent. I think in another part of the brief it is implicit that we cannot do this under present conditions in Canada, the notion that if there is some form of voluntary price regulation, if it is similar to the U.K. scheme, then there can be concessions made in the allowance price charged in Canada for products that are being exported.

Mr. HOWE (*Wellington-Huron*): Would you say the 11 per cent sales tax has something to do with the price; it prevents the possibility of exporting or competing in other countries?

Dr. BRIANT: No.

Mr. LAIDLAW: Mr. Chairman, I had not intended to discuss the patents at all this afternoon. I think all of us were in agreement that this is a technical subject and requires practically a whole day by itself.

The CHAIRMAN: We have very little time to get into it actually.

Mr. LAIDLAW: I am very disturbed that my colleague, Mr. Henderson, made such an affirmative statement which I am not willing to deny.

Mr. HENDERSON: Well I was asked specifically what are the conditions and that is a condition so I will not elaborate.

Mr. LAIDLAW: So I can get away from Mr. Henderson's pet subject, I see a remark on page 11.2 which, incidentally, is in the patent section but deals with pricing. In paragraph 2 it says:

> When it comes to pricing the product covered by this monopoly—

That is the patent on a therapeutic product of process.

> —it must be recognized that there are practically no drugs which possess a therapeutic monopoly. For almost every means of treatment, patented or not, there is an alternative or several alternatives.

Now I think this is something the committee is very interested in, but turning now to section 12.5 at the bottom of the page there seems to be a conflicting statement to the following effect:

> There is also the broader question of whether any two prescription drug products, even though containing the same active ingredient, can be considered truly equivalent. Long experience, backed by considerable scientific evidence, leads our companies to believe that this is rarely the case.

I wonder if it could be explained why those statements appear to be at odds, so to speak.

Dr. WIGLE: Mr. Chairman, I might attempt to. This statement on 11.2 is referring to a therapeutic monopoly, meaning that this would be a disease for which there was only one drug that all physicians would capably and justifiably use for that specific condition. This is a relatively rare situation where there is a complete therapeutic monopoly by one chemical agent. The other reference to whether one drug that is used for that condition alongside another one is therapeutically equivalent. This is the subject discussed at the bottom of page 12.5. The difference is that there is a tendency to look at one drug and say that the chemical content is the same as the other drug and that therefore they are equal. But, we know from experience in pharmacology, clinical studies and investigations of drugs that there are many factors which can influence the therapeutic equivalency, the effectiveness of that drug in the body for that particular condition. Those factors are such simple things perhaps as how tightly the tablet is compressed; will it dissolve in the stomach or does it pass through the bowel unaffected; what is the size of the crystalline particle; is it the same as the drug with which it is being compared, because sometimes this makes a vast difference in the reaction in the individual. There are many such factors that affect the therapeutic efficacy whereas the other statement is that very few single diseases have just one drug available for their treatment.

Mr. LAIDLAW: Thank you very much, Dr. Wigle.

Mr. BLAKELY: Mr. Chairman, at page 5.2 in the distribution and pricing section it is stated that in pricing drugs there must be a proper allocation to the company's research program. Naturally, this is quite understandable. My question actually may be one which, in all fairness, should be put to a specific

manufacturer and if so you can advise me. Can you tell us how this proper allocation is decided upon?

Dr. WIGLE: Mr. Chairman, I believe this question was entertained a few minutes ago.

Mr. BLAKELY: No.

Dr. WIGLE: The allocation of the amount that is paid to the parent company?

Mr. BLAKELY: No. This is in the section dealing with pricing considerations. I am assuming it has been the determination of the price at which you will sell a product, the mark up, one of the factors being considered in the determination of this price is an allocation of the research cost. I am attempting to determine just how this proper allocation is decided upon.

Dr. WIGLE: It would be a question a specific company would have to answer. I have no experience with this data.

Mr. BLAKELY: I can appreciate that and in that case the next question is also in the same area.

Mr. DAILY: May I just attempt to answer this. What this paragraph attempts to describe is that research cannot be allocated precisely to any specific product and, therefore, the total research cost to the company has to be distributed fairly over each of the products that the company carries in its line. Therefore, this will have to be an arbitrary allocation. Perhaps, it will be based upon the proportion of sales and the successes must also pay for the failures as well.

Mr. BLAKELY: I can appreciate all that; I just wondered what type of a formula might be applied.

Mr. Peter HOWSAM (*Vice-President and General Manager, Warner-Chilcott Laboratories*): It is normally a percentage factor which is applied and every company would have a different percentage that is carried as some kind of an overhead allocation which would include the research. It is usually a lump figure that has been used in the pricing calculation.

Mr. MACKASEY: There must be some uniformity or how does the income tax department agree to what you are charging up for research.

Mr. HOWSAM: That is correct. Part of it is on the other chart we looked at a little earlier. It has to be your actual figure but it goes againts all the products, though.

Dr. WIGLE: I would not like to imply that there necessarily has to be any uniformity. My understanding would be that one company might have a terrific research expenditure in one particular year compared to another company which had practically none.

Mr. BLAKELY: Surely they do not allocate the research charge of all of one year against the drug out that year. Surely there is some amortization basis determined.

Mr. HOWSAM: The actual cost of the year, if it was going to be $100,000 of an expense total, that is the amount that the income tax people would allow you, and you take that against all your products and you use it as a factor as percentage of sales, Mr. Blakely.

Mr. BLAKELY: On the one hand I think in this area we are talking about projection.

Mr. HOWSAM: That is right and when you first originally price a product you have to have an allocation.

Mr. BLAKELY: Well then from your reply I understand you to be saying you project your market that this drug will have. I guess you would have to project the market that all drugs would have that you expect to sell that year; you estimate your budget on research expenditure for the year and then you allocate this charge to all the various drugs that you hope to market in that year. Is this what you are saying?

Mr. HOWSAM: No, I am not saying that.

Mr. MACKASEY: Well let me ask a question. It may be a little more blunt. Let us take this mythical $100,000 the government permits you to charge to research. You have got to recover the cost of the drugs. How do you determine what portion of the $100,000 is going to be charged against your aspirin, what portion of the $100,000 is going to be charged against the pill, and what percentage of that $100,000 is going to be charged against some other products you turn out?

Mr. HOWSAM: Mr. Mackasey, first of all, every company will have its own way because accountants have different ways they wish to apply it and many systems will be used. The most simple of versions would be the total sales of all of the products, using the mythical example we are on and it is going to be $1 million and the total research program was $100,000 for the year, then you would say there would be an allocation of 10 per cent against that particular product. No attempt, normally, is made to apply the total research against any specific product. It is an ongoing program whether you have successes or failures.

Mr. MACKASEY: Well this is all very nice on paper; the only point is that you are asking me to arrive at is, therefore, it is spread uniformly over all the products. But, is it spread uniformly or is it allocated, for instance, because, after all, the cost is to the consumer. Do you charge more to us on a fast selling item and less on an expensive item?

Mr. HOWSAM: No sir. In our particular experience, and this is the question—I obviously cannot answer on behalf of any other company other than my own—it is done on an application of all the products that are marketed, equally.

Mr. MACKASEY: Mr. Chairman, I have to participate in another debate. Could I have one of my five minutes now and then I will run away?

The CHAIRMAN: Well we only have a total of 15 minutes and I think we are going to give five minutes to the manufacturers to sum up.

Mr. MACKASEY: Well maybe you could stay 20 minutes. The point I want to get at is that we have not touched differential and the price to the consumer as an individual and the cost of drugs in general to hospitals, which is a very important area because there is an opinion among people they are either selling drugs to hospitals at a loss which puts you in the philanthropist class or you are selling to them at a profit and you are gouging the public. We have to have the answer. This is one field I do not think we can investigate in five minutes. The

second one that interests me is a report that exists, suggesting or recommending that the simplest way of bringing down the cost of drugs is to make it easier to import, that is to licence importers. I think this is a true factor. What I am interested in, as a practical politician, is what effect it will have on my constituency or in the Toronto area or other areas where the drug industry is concentrated. In other words, if we help to bring down the cost of drugs by taking advantage of the low labour costs which you emphasized so well, Dr. Briant, in England and Italy and other countries, we would conceivably eliminate the drug industry as it is in Canada. I would like to know from Dr. Wigle how many people it would put out of work, what effect it would have on the brain drain and so on and what effect it would have on the economy of the community. In other words, is your industry worth saving or not. If it is not let us get rid of it and if it is let us make it a viable one. This it all I am trying to say. Coming back to Mr. Howe's point the third area I would like to discuss, how is it Mr. Gregory of Ayerst despite all the impediments of the patent laws can export $5,000,000 of a product when the rest of the industry together cannot export that amount? Did he have special permission or has he found a magic formula to circumvent the patent laws.

The CHAIRMAN: Mr. Mackasey, so far as that particular question is concerned perhaps Mr. Gregory would be prepared to answer that when he comes before this committee, and he has already agreed to do so, as an individual firm. So far as your question on differential in drug pricing between hospitals and drug store prices is concerned, perhaps this would be a good thing to leave because it does open up another whole area. I think the other question you asked could be answered.

Dr. BRIANT: In answer to your question, is the industry worth saving, we would say yes. What would be the effect, if it were not, on jobs, the figure of employment in the industry is 10,000 Canadians employed in the industry.

Mr. MACKASEY: Directly?

Dr. BRIANT: Direct employment in the manufacturing industry.

Mr. MACKASEY: Could you give us a brief idea in what capacity? You are not all chiefs, you know?

Dr. BRIANT: No. Our statistical appendix has some information on that, at page E.7 Mr. Mackasey. You referred to the brain drain. There are 1200 of the 10,000 who have university education. There are 106 Ph.D.s who might leave the country and go south of the border at present working in the industry, mostly in research. This, as I mentioned yesterday—represents a very substantial increase over the figures for employment in 1960. And that is only 38 companies, I forgot to express that.

Mr. MACKASEY: You have on that same page a total employment of 6,098 people. You have now talked about roughly 1,000 people or 1,500. It is the other type of Canadian I am interested in. There are not too many Ph.D.s living in Verdun. I am interested in what you do for the fellow who goes to work with a lunch pail?

Dr. BRIANT: I do not think we have figures on manufacturing employment. This is what you are talking about here, I guess, the number of people

employed on the assembly line, in packaging and things like that. We could come back with them in the fall. We just do not have them.

Mr. LAROSE: My plant is not in Verdun, but we employ about 100 workers in my small plant.

Mr. MACKASEY: What would be the payroll?

Mr. LAROSE: Offhand I could not say.

Mr. E. Glyde GREGORY (*Vice-Chairman of the PMAC Board and President, Ayerst Laboratories*): Mr. Chairman, for Mr. Mackasey's benefit, I would like to say that we have a young lady who has been living in Verdun for something like 50 years. She has been with us about 42 and she travels every day from Verdun to Ville St. Laurent.

Mr. MACKASEY: I know her, she votes N.D.P. Nevertheless I am still interested in her future.

Mr. GREGORY: I think we should direct you to the point that these people who are employed in our industry are not residents in one or two constituencies but they are representative all across Canada. Most of us have depots. We certainly do in Vancouver, Calgary, Winnipeg, Toronto, Montreal and Moncton, New Brunswick. We have salesmen all across Canada and our people come from all across Canada.

Mr. MACKASEY: What can you do for Newfoundland.

Mr. GREGORY: As a matter of fact Newfoundland is one of the most delightful spots that I look to go to when I get an opportunity. We have a resident salesman in Newfoundland and, as a matter of interest, I think he has done a lot to help the medical and pharmaceutical professions over there with his capabilities. He is an Irishman and his name is Dermot Begley, a very deep thinker, a sound fellow and well accepted by your people.

Dr. BRIANT: If perhaps I might just take up a point; in the 41 companies that answered the questionnaires, 22 of them are in the province of Quebec. I am sure there are some in Verdun. But, a related point is that while the figure of employment in the industry from the 38 companies is apparently 6,000, it is probably 10,000 in the industry, most of the expenditures in the industry as we show on page 3.4 of our brief, $85 million out of $107 million for these reporting companies, are paid in Canada so that very many more than 10,000 Canadian jobs would be affected if we were to import our pharmaceuticals in finished form. There are such things as packaging for example, the printing of the descriptive literature perhaps and containers.

Mr. MACKASEY: I am not concerned in what constituency you are located, in all seriousness. I am interested in what would happen to the Canadian economy if as an industry you were wiped out by some Act of Parliament which said, in effect, all drugs coming into Canada come in free of duty provided they are brought in by a respectable, reputable importer.

Dr. BRIANT: Incumbent employment generated in Canada would drop, so far as the industry is concerned, by about $150 million a year at the moment, but take a multiple of this—all the side effects—it would probably cost at least

half a billion dollars with the decline in income and employment, generated in Canada by this industry.

Mr. MACKASEY: I was interested in Mr. Howe's line of questioning which I thought was quite intelligent with regard to the possibility of forcing you people if you want to remain in Canada, if you want the dividends to keep flowing into the United States to face the facts that if you want to do like Ayerst McKenna and start exporting and if there is some impediment in our rules either in patentcy or other fields that makes it impossible for you people to export then we should do something about it. I do not blame your counsel for getting his oar into the industry so far as patents are concerned, but the most wonderful situation in the world for you people would be to have complete patent protection and then keep the savings which private industry might do. I would certainly agree to an increase in the patent laws provided it effected two things; a guaranty from your industry that you would start manufacturing in Canada not only for export but for a guaranteed market such as perhaps the whole North American market, if you are an American concern in a particular product. And if we help you in the field of research then some of the things you discover through research should be manufactured in Canada or at least its equivalent be manufactured in Canada. I do not think the drug industry in general is fulfilling its obligations to Canada in the field of exports. We have a balance of payments problem which you people aggravate because of the dividends flowing out of Canada. You do very little to help us because you are not geared up to the export field, and it is time you were. Now perhaps there is something in Canada's outmoded laws that prevents you people from exporting. If so, then I think we would gladly recommend ways and means of doing something about it. But I think that you cannot leave here with the childish assumption that you are doing your duty to Canada as long as your exports are as negligible as they are.

Mr. HENDERSON: I do not think I could agree with Mr. Mackasey without a specific example. I am faced at this particular moment with a product which is being manufactured here in respect of which the company has put a plant in this country. It is exporting, yet, having fulfilled its obligation as a Canadian citizen it then is hit with a compulsory licence; somebody who does not perform those functions gets that patent protection, lives under the patent protection, paying the patent fee, which has been described as a pittance. Now this does not encourage other companies to take the steps that you say. This is the situation in this country with respect to the patent laws.

Mr. MACKASEY: All I can say is it is time to stop apologizing for your existence and bring these facts to the public.

Mr. HENDERSON: This is what we intend to do and in the patent section this is what we intend to elaborate on.

The CHAIRMAN: We do not want to get into the question of patents.

Dr. BRIANT: Well there is one other point with regard to this exporting which relates to Mr. Howe's point. With the fine chemical industry you know there is such a thing as selling on the export market at lower prices than the prices on the domestic market, with the domestic market, to some extent, subsidizing the exports because you have to meet foreign competition when you

get outside the country. This would be a great deal easier if there were a fine chemical industry in the country to follow the differential pricing approach.

Mr. HENDERSON: Some consideration should be given to class or kind determination on customs.

Mr. MACKASEY: We will deal with that when we get to patents.

Mr. HENDERSON: Well this is customs on the basis of class of kind determination on pharmaceuticals.

Mr. MACKASEY: If I leave now, will I affect the quorum?

The CHAIRMAN: Dr. Wigle has a closing statement. It has been a very hot day and I think we should let Dr. Wigle read it or take it as read and have it printed in the minutes?

Mr. MACKASEY: What is the subject matter?

The CHAIRMAN: It really is a review of what they have told us here.

Mr. MACKASEY: I would not want to accept it without having an opportunity to comment on it.

The CHAIRMAN: Well I should say in their defence they wanted to read it at the beginning and I discouraged them from doing so because there were so many other aspects we wanted to get into.

Dr. WIGLE: Mr. Chairman, before I do so I would like to mention two brief things about the imports and exports which Mr. Mackasey is making an issue of. He asked what would happen to the industry with regard to imports. I am not sure that he was here when Professor Briant explained the other day what happened in the fish net business.

Mr. MACKASEY: I was here when he took an import at $2 and brought it up to $26.

Dr. WIGLE: Were you here, sir, when he explained what happened to the fish net business, when Canada became totally dependent on importers?

Mr. MACKASEY: Yes, sir.

Dr. WIGLE: And also the other point, Mr. Chairman, I wanted to mention again was in time of national emergency there is reason to believe we might be happy to have a source of our own.

Mr. Chairman, I appreciate the opportunity to sum up at this point and recap briefly where we are in the presentation of our costs of drugs to Canadians. I am sincere in saying I think we have made an earnest attempt to give good and cogent reasons for the present level of prices in this country. These stem from the high standard of living enjoyed by Canadians and from the economic and geographic characteristics of the country. The plain fact is that because our standard of living is as high as it is a Canadian manufacturer must pay higher salaries and wages and he must pay premium prices for all of the supplies and services needed to produce, market and distribute drugs throughout Canada. Hourly wages, freight rates, shipping charges, packaging costs, advertising rates, cars, trucks, real estate, professional fees, all reflect the high cost of doing business in a country with a high living standard.

The cost of drug distribution in a massive but sparsely populated country adds very heavily to the present level of prices. Then, too, there is a matter of quality control that adds an appreciable amount to the maker's manufacturing cost. Quality control cannot under any circumstances be eliminated, and yet because the Canadian market is smaller than those of many other countries, the quality control factor has a disproportionate impact on the final price to the consumer.

Finally, superimposed on these fixed and very real costs of doing business in Canada is the 11 per cent sales tax. This in my opinion is a most regrettable tax as applied to drugs in that it is borne by people at a time when any additional charges can often work an unnecessary hardship on the heads of families.

We do not believe that the answer to cost reduction can be found in the apparently easy out of importing from countries where manufacturing costs are lower. As Dr. Briant explained the other day, when the Canadian costs of packaging, handling, marketing and distributing are added, the consumer will find himself no farther ahead.

We believe that a flourishing Canadian drug industry is essential for both economic and national health reasons. We also believe that the industry must be composed of reputable, research-based pharmaceutical companies if Canada's growing role in the research that leads to important therapeutic advance is to be continued.

Our association is concerned about the present price level of drugs to Canadians. We would like to see drugs made available to Canadians at lower prices, but we would not want to see this essential industry damaged in the process.

We have made some recommendations. We stand ready to co-operate willingly and gladly with any and all arms of government that address themselves to the vexing problems of price reduction. Any co-operative step we can take in this important regard we are prepared to take both as practical members of the business community and as responsible corporate citizens.

We spent some little time discussing the essential nature of drug research in Canada and have indicated its relationship to costs and prices. We may be questioned further about it by the committee when we get into the area of pharmaceutical patents. Canadian drug research is on the rise and I hope it can be further stimulated in the years ahead. As a matter of interest I would like to make available to the members of this committee reprints of an address by Nobel Laureate Professor Chain on the vital role of industry in developing as well as producing new life-saving pharmaceuticals.

Mr. Chairman, these five sessions have been really very enjoyable as far as our delegation is concerned. We appreciate the tolerance the committee has shown to us; we hope that you have a nice vacation and we will look forward to seeing you in the fall.

The CHAIRMAN: Thank you very much, Dr. Wigle. On behalf of the committee, I would like to thank yourself and all the gentlemen from your association who have come before the committee to take part in your presentation. It was a most worthwhile presentation.

APPENDIX "A"

PHARMACEUTICAL MANUFACTURERS ASSOCIATION OF CANADA
1110 Gillin Building—141 Laurier Avenue West—Ottawa 4, Ontario

House of commons Special Committee
on Drug Costs and Prices
Government of Canada

June 1st, 1966.

Mr. Chairman and Members:

This submission is presented to the Committee by the Pharmaceutical Manufacturers Association of Canada, a non-profit organization founded in 1914 and incorporated under the Dominion Companies' Act in 1959.

The Association represents 57 companies engaged in manufacturing and distributing ethical pharmaceutical preparations in Canada. The term "ethical" refers to pharmaceuticals dispensed on doctors' prescription and those not advertised to the public, as opposed to proprietary or patent medicines which are so advertised. Some of our member companies also make proprietary medicines, but our Association does not represent this field of medication.

Attached to this submission under Appendix O is a list of our member companies.

Our delegation to the Committee is composed of the following persons: Mr. R. F. Daily, Chairman of the Board of PMAC; Mr E. G. Gregory, Vice-Chairman of the Board; Mr. H. D. Cook, Immediate Past Chairman of the Board; Mr. Roger Larose, Vice-President, Ciba Company Limited; Mr. Peter Howsam, Vice-President and General Manager, Warner-Chilcott Laboratories Co. Limited; Dr. Brian Stewart, Director, Pharma-Research Canada Limited; Mr. Gordon F. Henderson, Patent Consultant; Mr. Fred Hume, Q.C. and Mr. Gregory Gorman, Legal Consultants; Dr. Peter C. Briant, Vice Dean and Director, School of Commerce, McGill University, Consulting Economist; Dr. Arthur Grieve, Director—Quality Control, Ayerst Laboratories; and myself as President of the Association.

In preparing this submission, we have attempted to follow the Committee's terms of reference and, at the same time, offer the Committee as complete an understanding as possible of the role of our pharmaceutical manufacturing industry in the economy and health services of Canada. It is our hope that the contents will be of assistance to you in your deliberations.

Respectfully submitted,

Wm. W. Wigle, M.D., C.M,
President.

SUMMARY

Section 1—Introduction

The make-up of PMAC and the characteristics of the industry are described in terms of its economic challenges and social responsibilities.

Section 2—Breakdown of the Prescription Dollar

This section presents the various elements involved in the cost of prescription drugs.

Section 3—Economic Structure of the Drug Industry

Surveys carried out by PMAC among its member companies indicate the size of the prescription drug market, how the market is shared, the extent to which the manufacturing activity is primarily Canadian, the market's growth, and the industry's composition and profit picture. The survey results also demonstrate the industry's direct investment in the Canadian economy and its role as a taxpayer.

Section 4—The Cost of Drugs to Canadians

The real cost of drugs to Canadians is compared to the cost of drugs to the citizens of other countries, not in terms of translating foreign currencies into Canadian dollars, but in terms of the standards of living and the earning powers of the peoples in the countries compared. The results show that Canadians can buy their drugs with less labour than people in most other countries.

Section 5—Distribution and Pricing

Peculiarities of distribution that are characteristic of Canada are described, along with pricing considerations that are influenced by the industry's sales patterns to governmental customers, and to wholesale and retail outlets.

Section 6—The Cost of Manufacturing and Quality Control

This section employs survey figures to isolate the costs of manufacturing, and the added costs required for effective quality control.

Section 7—The Cost and Value of Research

The mounting expenses involved in the discovery and synthesis of new compounds and the steps that must be taken to bring a new drug to market, along with the cooperative and competitive aspects of research are discussed, together with considerations of the growing scientific maturity of Canada, and the expenditures necessary to bring the fruits of international pharmaceutical research to Canadians.

Section 8—Public Service Products

This is a description of the products that are vital in the treatment of rare diseases and are made available to physicians either free of charge or at factory cost. The sales potential of these products is so slight that their development and manufacturing costs could not be recovered unless they were spread over a company's total product spectrum.

Section 9—The Cost of Marketing

The costs of physicians' information are broken down and the geographical facts of doing business in Canada are outlined. The provision of scientific

information is differentiated from the product promotion associated with most industries, and the measures necessary to inform the medical profession of new indications or contra-indications are set forth. Extensive reviews are made of the purposes and costs of detailing, pharmaceutical mail and journal advertising, both in this section and in the appendices. The high cost of introducing new products is explained, along with PMAC's proposal to establish an independent and properly coordinated drug information system in this country.

Section 10—The Cost of Safety

This contains a review of the costs of safety and its overall influence on the costs of research, manufacturing, marketing and distribution.

Section 11—Pharmaceutical Patents

If quality, safety and therapeutic effectiveness are to loom larger than price alone as criteria for the purchase of pharmaceuticals, the cost of drugs in Canada must be related to the patent situation. This section describes to origin of Section 41(3) of the Patent Act and the problems created by the way it is interpreted and administered; the necessity for patent protection as a research and investment incentive; the misunderstanding on which the establishment of royalties has been based; the dangers inherent in governmental encouragement of those who seek to produce pharmaceutical imitations; the opposing trend that is now manifest in Europe; and PMAC's patent recommendations, which include the establishment of a tribunal to decide on compulsory licence applications.

Section 12—The Question of "Generic Equivalency"

This section discusses the differences beeween non-proprietary or generic names and brand names, and it presents the arguments in favor of brand names that establish the manufacturers' responsibility for their own particular drug products. It considers the broad question of whether any two drug products can be considered truly equivalent and points up the factors which can affect therapeutic efficacy.

Section 13—The Provision of Prescribed Drugs under Medicare and Welfare Programs

PMAC strongly believes that any assistance program proposed by government should enable doctors to prescribe medications solely on therapeutic considerations. The nine principles that PMAC feels should govern the provision of prescription drugs under health service programs are set forth.

Section 14—Recommendations Relating to the Cost of Drugs

PMAC has put forward seven recommendations, some of which would reduce the price of drugs generally, some of which would reduce the prices of certain products, and some of which would reduce prices to certain groups of citizens.

CONTENTS

E. PMAC's Annual Statistical Survey Results for 1964.

F. International Drug Prices, a comparison of Canadian prices in domestic currency units and hours of labour with results for seven other countries.

G. The Cost of Quality Control.

H. New Drug Submission Requirements for F.D.D. Approval.

I. The Cost of Direct Mail.

J. The Cost of Sampling.

K. The Hilliard Committee Report.

L. "Quality of Drugs." (An analysis of the section of the Hall Commission Report entitled "Quality of Drugs.")

M. What is a Generic Equivalent? (An article by three prominent physicians, reprinted from the magazine, *American Professional Pharmacist.*)

N. Pharmacare, a health service plan sponsored by CPhA to make high quality pharmaceuticals available to Canadians.

O. List of Member Companies of PMAC.

2.1

BREAKDOWN OF THE PRESCRIPTION DOLLAR

This presentation is concerned with the various elements in the cost of prescription drugs which come within the control of the manufacturer. In general, as the table below shows, these amount to 37½ cents out of the prescription drug dollar. The remaining 62½ cents are required to ensure distribution through the retailer and wholesaler, and to pay the federal sales tax.

The Canadian Pharmaceutical Journal of June 1965 carried the results of a national survey of prescription prices sponsored by the Canadian Pharmaceutical Association. This was conducted during two weeks of November 1964 by Professor H. J. Fuller of the Faculty of Pharmacy of the University of Toronto, and covered 223,000 prescriptions. It gave the average price of a prescription as $3.47, and the cost of the ingredients to the pharmacist as $1.73 when additional allowances are made for wholesale distribution and federal sales tax the manufacturer's portion of the average prescription is $1.30 or 37½ cents of the average prescription dollar.

The 37½ cents received by the manufacturer breaks down as follows (based on the PMAC annual statistical survey, Appendix E):

2.2

MANUFACTURER'S PORTION OF PRESCRIPTION DOLLAR

Manufacturing		11½ cents
Materials	8½ cents	
Labour	1½ cents	
Plant Costs	1½ cents	
Distributing and Warehousing Costs		1½ cents
Professional Service Representation, Marketing, and Medical Information		11 cents
Field Sales Expense	5½ cents	
Administration of Marketing, Selling & Advertising Functions	1½ cents	
Advertising & Promotion	4 cents	
Medical and Pharmaceutical Advertising	1 cent	
Direct Mail Advertising	1 cent	
Samples	1 cent	
Medical Exhibits, Space & Other	1 cent	
Research & Development		2½ cents
Royalties		1 cent
Manufacturing Administration		4 cents
Income Taxes		3 cents
Earnings		3 cents
Total		37½ cents

2.3

To express the same data in terms of the manufacturer's dollar, the breakdown would be as follows:

BREAKDOWN OF MANUFACTURER'S PORTION OF PRESCRIPTION DOLLAR

	%	%
Manufacturing		30.0
Materials	22.0	
Labour	4.0	
Plant Costs	4.0	
Distributing and Warehousing Costs		4.0
Professional Service Representation, Marketing, and Medical Information		30.0
Field Sales Expense	15.0	
Administration of Marketing, Selling & Advertising Functions	4.0	
Advertising & Promotion	11.0	

	%
Medical & Pharmaceutical Advertising	2.0
Direct Mail Advertising	3.0
Samples	4.0
Medical Exhibits, Space & Other	2.0

Research & Development	7.0
Royalties	3.0
Manufacturing Administration	11.0
Income Taxes	7.5
Earnings	7.5
Total	100.0

3.1

THE ECONOMIC STRUCTURE OF THE PHARMACEUTICAL INDUSTRY

The report of the Restrictive Trade Practices Commission contained quite detailed statistics about the pharmaceutical industry. These were reviewed and in part reproduced by the Royal Commission on Health Services. We will not, therefore, recreate this total picture, but rather comment on certain salient aspects, presenting our views in particular about those aspects which have become a matter of public debate.

Attached to this presentation as Appendix E are results from the latest annual statistical survey taken by the Association. It covers operations during 1964.

For the 41 reporting companies in 1964, sales of packaged human pharmaceuticals amounted to $110,465,396, not including proprietary or patent medicines. It is estimated that total sales of packaged human pharmaceuticals of all PMAC members amounted to $136,000,000. Of this amount approximately 70 per cent was distributed through retail pharmacies.

It should also be borne in mind that only part of the retail expenditure on human pharmaceuticals results directly from a doctor's prescription. Most of our products are bought only on prescription. Others, though frequently prescribed, may be bought without a prescription.

The Extent of Competition

Market surveys show that no single company holds as much as 6 per cent of the Canadian Pharmaceutical market. It is significant that in the three largest classes—antibiotics, hormones, vitamins and nutrients—no single company has as much as 21 per cent of the market, and that only in five of the 24 therapeutic classes into which the market is divided does the share of the top company exceed 40 per cent.

3.2

Writing in the Spring 1963 issue of the Patent, Trademark, Copyright Journal of Research, Education, George E. Frost, a noted patent attorney, brought out some significant facts about pharmaceutical industry competition.

> "The drug industry may be divided into a variety of product categories, the products within each category being directed to generally the same objectives and being in substantial competition with each other. The typical record for any particular product category is one of constant churning in so-called 'dynamic' competition—with dramatic shifts in market positions as existing drugs are displaced by superior products of rival houses. In cardiovascular preparations, the leading company in 1951 enjoyed about 19 per cent of the market, the leading company in 1960 had about 21 per cent of the market, and of the four leading concerns in 1951 only one was among the four leading concerns in 1960. In the case of diuretics, four different concerns enjoyed the leading market position in the 1951-1960 period, the concern with the largest sales in 1960 was not among those with significant sales in 1951, and the concerns with the largest sales in 1951, 1952 and 1953 had no significant sales in 1960. And in corticosteroids, the company that pioneered the field in 1950 had only about a quarter of the business in 1954 and by 1956 its products enjoyed less than 5 per cent of the market."

Extent of Manufacturing

Our brief to the Hall Commission, submitted in May 1962, reported that approximately 83 per cent of prescription products sold in Canada were manufactured here, the remaining 17 per cent being imported.

3.3

The term 'manufacturing' is used to describe the production of a pharmaceutical from its therapeutically active substance or substances. The processes involved are product development, formulation, mixing, compounding, tabletting, etc.

There are various reasons why it has not proved economically feasible to develop a pharmaceutical chemical industry in line with the pharmaceutical industry, itself. The first of these is the limited size of the Canadian market. According to DBS "Imports by Commodities," the total value of pharmaceutical chemical imports by manufacturers in 1963 came to about $20,000,000. This total

was made up of a large number of separate products, few of which are required in any substantial volume. Further, the present tariff structure does not encourage the production of these chemicals in Canada.

In addition, where pharmaceutical chemicals are concerned, Section 67 of the Patent Act, which generally fosters manufacturing in Canada is over-ridden by Section 41. Evidence of manufacturing in Canada has not so far been considered a valid defence against a compulsory licence application made under this section.

Pharmaceutical companies in Canada have developed primarily to serve the domestic market, and at present, few of them are exportive. Certainly, it would encourage exporting activity if conditions in Canada fostered a more comprehensive manufacturing operation, including the manufacture of the active ingredients.

3.4

Employment and Purchasing in Canada

The pharmaceutical industry, which has expanded steadily in recent years, makes an appreciable and growing contribution to the national economy. Our 38 reporting companies had 6,098 employees in 1964, and total employment is estimated at something over 10,000. It is interesting to note that of the total employees of those companies reporting, approximately 25 per cent are university graduates.

Companies are substantial purchasers of goods and services in Canada. In 1964, out of a reported final sales volume of $107,790,000, materials purchased abroad and other payments accounted for about $22,215,000, the remaining $85,575,000 being represented by payments and investments made in Canada.

The total is made up as follows: (Appendix E, page 3)

Wages, salaries, benefits	$29,059,000
Materials employed in production	14,786,000
Excise, and income taxes	7,320,000
Depreciation and retained earnings	7,381,000
Other administrative, production and marketing services bought in Canada	27,029,000
	$85,575,000

The national value of industry must be judged primarily on its fulfilment of its basic purpose: to make available throughout Canada pharmaceutical products of the highest quality, the fruit of the latest international research, at prices consistent with Canadian business costs.

Profits in the Pharmaceutical Industry

Profits in the pharmaceutical industry are consistent with the risks involved. This is a research-based industry in which progress results from vigorous and sustained competition. Companies must maintain substantial expenditures on research, both in Canada and internationally, without any guarantee that specific projects will yield results even after years of investigation and development. On this depends the continuing availability of new and better drugs.

3.5

According to a review of profit ratios for 62 industrial classifications in 1962, published by the Canadian Manufacturers Association, profit as a percentage of sales for all manufacturing before taxes came to 7.6 per cent; this included several chronically or temporarily depressed industries. Pharmaceutical preparations were listed as 11.4 per cent. Manufacturing industries earning higher profits were: soft drinks; alcoholic beverages; pulp and paper mills; engraving; stereo-typing and allied industries; office and store machinery; fertilizers and industrial chemicals. Total operating earnings before taxes reported by the 41 companies replying to our 1964 survey was 10.8 per cent on sales. The profit after taxes amounted to 5.2 per cent.

Return on sales is one indication of the profitability on an industry, but it is an unsatisfactory indicator of economic effectiveness because it fails to relate earnings to the resources employed. When the flow of earnings is so related for 1964 by our 41 reporting companies, the rate of return for industry amounts to 15.6 per cent before taxes and 7.6 per cent after taxes. This would seem to be in line with results for other industries.

If, as the Royal Commission on Health services implied, fees for management services, royalties on patents, and dividends amounting to $5.77 million for 1964 to parent companies should all be included in the profit column, it would raise the rate of return on resources employed only 2.1 per cent to a total of 9.7 per cent. But fees for management and royalties for use of patents are in no sense profits; they are a vitally necessary part of the cost of doing business; and were the Canadian companies obliged to obtain these services and pay the cost to other than parent companies, the total cost of operations could well be a great deal higher.

3.6

Research has been one area where pharmaceutical manufacturers located in Canada have been singled out by the Hall Commission. Its report questioned the value of the reported earnings of the Canadian drug industry because subsidiaries are being charged for research done by parent companies. We would like to state that although 37 of our members which answered a question on this subject reported that they spent in 1964, 5.5 million in research in Canada and were charged 1.5 million by their parent companies for research done in their behalf, our members have at their disposal the results of over $400,000,000 spent in research by the total world pharmaceutical industry.

Volume and Rate of Investment

The following figures summarize the volume and rate of investment for the members responding to the PMAC investment surveys for the years 1960 through 1964:

3.7

	1960	1961	1962	1963	1964	Total
No. of companies reporting	40 ($000's)	37 ($000's)	38 ($000's)	45 ($000's)	45 ($000's)	($000's)
Plant, January 1st	$46,775	$49,893	$53,177	$54,489	$57,747	
Additions, at cost	2,987	4,373	3,606	6,257	7,492	$24,715
Plant, December 31st	$49,762	$54,266	$56,783	$60,746	$65,239	—
Less: Dep'n in year	19,659	20,268	21,915	23,767	28,034	
Plant, December 31 (Net Book Value)	$30,103	$33,998	$34,868	$36,979	$37,205	$24,715
Depreciation charged during year	$ 2,157	$ 2,300	$ 2,404	$ 3,046	$ 2,881	$12,788
Equity investment (including retained earnings)	601	3,865	3,079	6,349	8,835	22,728
	$ 2,758	$ 6,165	$ 5,483	$ 9,395	$11,715	$35,516

As these figures show, the investment of PMAC members responding to the survey was $65,239,000 at gross book cost at the end of 1964 and $37,205,000 at net book value. Thus, gross investment increased by 39.5 per cent from January 1, 1960 to December 31, 1964, or a simple annual rate of 7.9 per cent. If anything, these figures understate the normal rate of investment, as the years 1960-1962 inclusive were relatively depressed and were not, therefore, conducive to a high rate of investment. Additions to plant in these years as a percentage of plant at gross book cost at the beginning of each year were as follows: 1960, 6.4 per cent; 1961, 8.8 per cent and 1962, 6.8 per cent. The years 1963 and 1964 were more prosperous and resulted in a rate of investment of 11.5 per cent and 13 per cent respectively of the gross investment in plant at the beginning of each year. The average annual rate of investment on this basis over the five-year period was 9.3 per cent.

It can be seen from the data that depreciation charges were just over one-half the total investment in plant during period and that, in every year, plant investment exceeded the depreciation charged during the year. The balance of funds needed for plant investment came from retained earnings and other long-term capital from ownership sources.

3.8

Investment in inventories actually increased by $8,625,000 over the period. When this is allowed for, the total investment in plant and inventories, totalling $33,340,000 over the five-year period, was closely balanced by depreciation charges, earnings retained in Canada, and new funds. The difference of $2,200,000 helped to finance the increase in Accounts Receivable and other assets

associated with rising sales that was not provided for by trade credit and other forms of debt capital.

Another test of the economic effectiveness of an industry is that the role of investment be commensurate with the rate of earnings of the industry. In this respect the pharmaceutical manufacturing industry meets the test of good corporate citizenship because, not only are all retained earnings and depreciation funds plowed back into the business, but a new flow of fresh capital is provided by additional direct investment.

Tax Payments

The members of our Association responding to the annual surveys report that over the five year period from 1960-1964, inclusive, they paid excise and sales taxes of $43,783,000 and income taxes of $41,712,000. Their net income over the period totalled $43,781,000, of which $21,053,000 were paid in dividends. Two interesting relationships are disclosed by these figures: for every dollar earned, the companies paid two dollars in taxes; and for every dollar paid in dividends, the companies paid four dollars in taxes.

4.1

The Cost of Drugs To Canadians

It has been widely maintained that the cost of drugs to the Canadian consumer is unduly high in comparison with what is paid in other countries. Notably, the "Green Book" of the Director of Investigation and Research, published in 1961, contained a number of international comparisons, based on evidence produced before the Kefauver Committee (pp. 203-217). These comparisons were made in terms of actual prices, translating the foreign currencies into Canadian dollars. They did not take into account either standards of living or earning powers in the countries concerned.

To present a fair picture of the cost of drugs to Canadians, it is, we believe, essential that these factors be related to the prices paid.

In order to present such a picture, we selected 17 drugs selling in good volume under their brand names in Canada. The selection was made according to the following criteria:

(1) They represent a broad view of the most important therapeutic classes;
(2) They are the products of a number of major drug companies;
(3) The same products are sold in similar strengths and dosage forms in other countries.

The products used were:

Achromycin	Librium	Peritrate
Chloromycetin	Equanil	Doriden
Terramycin	Stelazine	Seconal
Penbritin	Ismelin	Pyribenzamin
Gantrisin	Hydrodiuril	Banthine
Decadron	Diuril	

We selected the following countries for comparison with Canada: United States; United Kingdom; Italy; West Germany; France; Holland, and Sweden. We obtained details of the drug prices in these countries, and translated them, where necessary, into Canadian package sizes.

4.2

Wage rates of manufacturing employees in seven of these countries for 1964 were obtained from the Yearbook of Labour Statistics (I.L.O.), 1944 (p. 345 et seq.) and from the "Monthly Bulletin of Statistics," (United Nations) July 1965, (p. 128, Table 57). Wage rates of manufacturing employees in the United Kingdom were derived from the Yearbook of Labour Statistics (I.L.O.) 1964 (p. 362, Table 16) and the Ministry of Labour Gazette (London), January 1965, H.M. Stationery Office, Volume LXXIII, No. 1, "Rates of Wages and Hours of Work, in 1964," p. 9. The following figures were used:

Country	Hourly rate in manufacturing	In Canadian dollars
Canada	$2.02	$2.02
U.S.	$(US) 2.52	$2.72
U.K.	6/11½d	$1.04
West Germany	M. 3.73	$1.01
Italy	Lire 373	$ .64
France	Francs 2.86	$ .63
Holland	Guilders 2.38	$ .71
Sweden	Kroner 7.12	$1.49

We then related these wage rates to the selected drugs, and obtained comparisons of drug prices in terms of labour hours. The comparisons were worked out both for actual hours of labour and as an index of labour hours, using Canada as 100. (These comparisons and the prices used both in domestic currencies and in Canadian dollars are attached as Appendix F.) It should be borne in mind that the Canadian prices included the impact of the Federal sales tax, increasing the price to retailer by approximately 10 per cent, and the price to consumer in similar proportion.

4.3

Finally, a simple average was developed for the hours of labours indices, and this shows in general terms the relationship of Canadian drug prices to those of the other countries:

Country	Indices of Price to Retailer
U.S.	79.15
Canada	100.00
Sweden	104.31
U.K.	129.40
West Germany	168.88
France	235.08
Holland	237.46
Italy	243.00

The most significant finding is surely that most products cost less in terms of labour as the standard of living rises, and Canadians therefore can buy their drugs with less labour than people in most other countries. It is also significant that, despite the existing of a National Health Service in the United Kingdom, the real cost of drugs there is still appreciably higher than in Canada. In Sweden, a country where the standard of living is approximately the same as in Canada, the price to the retailer is in line with the Canadian prices.

5.1

DISTRIBUTION AND PRICING

Methods of Distribution

A pharmaceutical manufacturer may distribute his products in various ways. To hospitals and governments he will normally sell direct, though hospitals on occasion buy through the regular trade channels. Products for retail sales are either sold direct to the pharmacist or go first to a wholesaler. This also holds true for dispensing doctors.

Many larger companies prefer to sell direct to the pharmacist. They maintain warehouses or depots in strategically locatied cities such as Moncton, Halifax, Montreal, Toronto, Winnipeg, Calgary, Edmonton and Vancouver. In some cases, manufacturers own or operate their own warehouses; in others, a number of manufacturers use the facilities of a warehousing company.

Certain companies distribute entirely through wholesalers. They include some larger companies and most of the smaller ones, which would not find it economical to maintain their own distribution facilities.

To ensure that drugs are available in retail and hospital pharmacies immediately or with a minimum delay requires a nationwide network of wholesalers, carrying substantial stocks. In this country, with the population scattered over such an immense territory, servicing all drug outlets constitutes a tremendous distribution problem.

Individual companies choose the distribution system which will be most economical in view of the size and nature of their market. None, however, relies entirely on its own facilities; all use wholesalers to a certain degree.

5.2

Pricing Considerations

Many factors must be taken into account when pricing a prescription drug, most of them related to the particular market for which the product is destined.

The likely sales pattern has to be forecast. This will be determined by the size and nature of the market, the competitive strength of existing products, and the specific therapeutic advanges offered by he newcomer.

The type of therapy for which the drug will be mainly used is also significant. If it is likely to be taken over a long period, pricing will be worked out in terms of the daily cost of therapy. For other products the total cost of therapy, based on the anticipated size of the average prescription, will be the key consideration.

There are certain operating costs which the sales of all products must cover if they are to be commercially successful. (Some products of value in treating rare diseases or conditions are consciously sold at a loss, or provided at no charge.)

There must be a proper allocation to the company's research program. This cannot be an attempt to recover the cost of the research behind a particular product, for that can be estimated only in quite general terms; each success is built on many failures. Rather, the new product must make a reasonable contribution to the ongoing research activity of the company, an activity which is becoming increasingly expensive.

The cost of production, estimated on the basis of the expected sales volume, must be covered. This includes the cost of ingredients, labour, quality control, and a proper allocation of plant overheads. Then there are the general administrative costs.

5.3

There is also the cost of an effective program of information and promotion. The various elements of such a program and the related requirements of an adequate information service and a successful marketing effort are discussed in the section entitled "The Cost of Marketing" (Section 9). Significantly, the early years of a product are those in which marketing expenditure is heaviest; without such expenditure medical awareness and use of the product can be delayed for a very long time or even indefinitely.

Finally, there is the cost involved in the manufacturer's policy of returned goods, which we believe is unique in the manufacturing industry in Canada.

The ultimate pricing pattern will be determined to a varying degree by all these factors.

The Pricing Structure

It has been a policy of the Association to refrain from any activity in the matter of price and the pricing practices of its members.

Our member companies must unilaterally determine their own policy in this area. Until the enactment of Section 34 of the Combines Act, most companies established the resale price. Since the enactment of this section, it has been a common practice in many manufacturing industries to suggest a retail price. Most pharmaceutical manufacturers have continued the practice of selling to retail pharmacists at a discount of 40 per cent off this price.

5.4

However, some manufacturers have given up this system for "prescription only products" and have adopted a policy of quoting "net" prices to pharmacies.

In contrast to the retail market, there is no clear pricing pattern known to us for drug purchases by hospitals, institutions and government. Prices here are influenced by a number of special considerations and also depend upon the individual manufacturer's policy.

The Reasons for Multiple Pricing

Differences between the price to the retail pharmacist and the price to hospital or government have been documented by the Director of Investigation and Research under the Combines Investigation Act in the "Green Book." In some cases the difference was substantial. The industry may reasonably be asked to explain why such differences occur.

Various causes may be involved. Firstly, hospitals do not pay the 11 per cent sales tax. Secondly, these customers buy in large quantities, and the offering of discounts to bulk purchasers is a normal business practice, justified by the savings in operating costs.

In addition, other considerations can carry weight, depending on the nature of the product. It may be advantageous to the manufacturer to have his product used substantially in hospitals, so that physicians become acquainted with it, and are therefore more likely to prescribe it in their own practice.

5.5

The competitive situation will have a strong influence. There is continual competition within all therapeutic categories. However, when the competition comes from a so-called generic equivalent, the original manufacturer has to decide whether to abandon the hospital or government market, or to reduce his price to a level which will meet that of a company which has not faced the costs of either research or product introduction, and carries little or no scientific overhead. In effect, he is forced to compete for business, often based on quite general specifications, against naturally cheaper, and it may well be, inferior, products. He will do this to maintain an important market or to protect the reputation of his product; in the event of the failure of a so-called equivalent formulation doctors may well blame the drug itself.

6.1

THE COST OF MANUFACTURING AND QUALITY CONTROL

Our 1964 statistical survey (Appendix E) shows that the manufacturing cost of goods for human pharmaceuticals is estimated at 32 per cent of net sales.

Within this total there is an allocation for quality control—the maintenance of a quality control laboratory, or payment for laboratory services, combined with the many special services in the production area required to meet the proper standards of prescription drug manufacturing. To measure the real extent of these expenses, we asked our members to reply to a detailed questionnaire. This was based for the sake of convenience on the similar standards which have been developed by the Canadian Government Specifications Board. (Representatives of our Association worked with government in drawing up these standards, and a number of companies helped to train the inspectors who apply them.) The results of this questionnaire are attached as Appendix G. They show that the various activities related to the assurance of pharmaceutical quality account for about 10 per cent of manufacturing costs.

However, effective quality control must take into account a company's entire operations through a series of interlocking controls.

The Committee is again referred to the Associations previous submission, June 19, 1964.

7.1

THE COST AND VALUE OF RESEARCH

To assess the value of pharmaceutical research in relation to its cost requires the awareness of certain basic facts. First, a company must maintain its research activity at an increasing cost even though there is no guarantee of success or profitable return. In electronics, for instance, once the problem is posed a research answer can be expected; this is not the case with mankind's reply to the challenge of disease. International expenditures on pharmaceutical research now exceed $400,000,000 a year, and individual companies can, and do, spend millions of dollars on specific projects—sometimes successfully, and sometimes with no result at all apart from the knowledge of what cannot be accomplished. It is estimated that only one in every 3,000 compounds tested yield a drug of sufficient value to justify its introduction.

The Hinchliffe Committee report to the British Minister of Health states: "Really outstanding drugs are still very few in number and if a firm makes one

major advance in 10-20 years it is doing very well" (p. 73). Research money, is, of course, expended in many areas and provides, too, its quota of less important advances. Yet these advances can themselves be vital aids to saving life and easing suffering. Exploiting initial break-throughs, they may provide effective medicines for related diseases, drugs with fewer side effects, more potent drugs or products that are easier to administer. Also, research will yield drugs of great value in so limited a therapeutic field that they are not commercially profitable. Yet the responsible company will ensure that such products are widely available and physicians are fully informed about them.

7.2

The second basic fact of pharmaceutical research is that it is both a cooperative and a competitive endeavour. The industry is international in scope and activity, and nowhere more so than in its approach to research. Fostering the health of any nation requires that the fruits of world-wide research be made available to the medical profession as rapidly as assurance of safety will allow. No country, even the most advanced, can afford to restrict its physicians' armamentarium to products discovered by its own scientists. Similarly, every health scientist relies on the stimulation provided by progress in many countries.

There must also be frank cooperation among the various sources of new knowledge. This means a continuing exchange between university, hospital, government laboratory and pharmaceutical company. It would be extremely short-sighted to shut any one of these groups off from the others, or to limit its ability to communicate openly.

On the other hand, the pharmaceutical industry is intensely competitive, and in the past quarter of a century competitive enterprise has created and made available a tremendous range of life-saving and other essential drugs. Naturally, there is a certain waste; two or more companies will pursue the same objective, and products can be rendered obsolete almost as soon as they are marketed. But it is our strong contention that a research-based industry develops its potential to the maximum only under the spur of sustained competition. Government may well foster specific projects, but close direction of research will only inhibit endeavour and place barriers across what is already a hard and demanding road.

7.3

In this connection, the patent laws perform a particularly valuable service, since to obtain a patent an inventor must reveal the facts of his invention. This information in turn suggests new goals to other researchers and steers them away from work that will result only in duplication. On the other hndoiai, lack of information in turn suggests new goals to other researchers and steers them away from work that will result only in duplication. On the other hand, lack of patent protection leads to a disruptive secrecy as well as generally discouraging investment. Such a system of international research relationships, cooperative but also competitive, provides mankind's best hope for new life-saving medicines. The investigations now under way into both cause and cure are far-flung and intensive: cancer, heart disease, virus diseases, multiple sclerosis and other scourges are the immediate targets of pharmaceutical research scientists around the world.

The Need to Apply Knowledge

Basic or fundamental research can perhaps best be described as an investigation into the nature of materials and substances. Applied research, on the other hand, is concerned with the attempts to find practical applications for new basic-research findings. Appropriately enough, basic research is carried out in the universities while applied research is the province of industry. Man benefits from the fruits of important new knowledge only as industry can devise the means to make it available, at the same time often widening the scope of the benefits far beyond the initial concept of the inventor. Further, the pure research may well have been sponsored or aided by industry, as for instance, in the discovery of streptomycin by Dr. S. Waksman and much of the pioneering work that led to cortisone.

7.4

The story of penicillin highlights these principles. In 1928, Sir Alexander Fleming sought help to develop his discovery, but was unsuccessful. After thirteen years the interest in penicillin revived and the pharmaceutical industry, supported financially by government to meet the needs of wartime, developed mass production processes. Subsequently, industry, itself, has added enormously to man's knowledge of penicillin therapy, greatly reduced the cost of production, and discovered several new and more effective varieties of the drug.

Today, companies spend millions of dollars exploring areas of knowledge which may, or may not, yield marketable products. They can do this only if their revenues from existing products encourage such activity; a research-based industry, where there is strong competition in product improvement, is inevitably a high-risk industry.

The Sequence of Research

Basically, the aim of pharmaceutical research is the discovery and synthesis of new chemical compounds, followed by their testing for beneficial biological activity and their final translation into safe and effective products. Each new and potentially therapeutic substance presents its own problems and requires specialized treatment, but the following are the main steps in research and development:

1 *Synthesis of a new compound* (or the discovery and identification of compounds currently existing in nature): These require fully equipped and staffed chemical laboratories.

7.5

2 *Pharmacological testing*: The biological activity of chemical compounds can be assessed only in animals—*in vivo*, not *in vitro*. Any new compound must be screened through numerous costly and time-consuming tests.

3 *Toxicity*: Once effectiveness has been established, undesirable side effects and toxicity must be evaluated in the same way. No human trials can be permitted until there has been extensive toxicological evaluation.

4 *Dosage form:* Dosage forms must be designed to provide the active ingredient of the product in its most therapeutically effective manner.

5 *Initial Clinical Trials*: Before a new substance can be used in clinical trials, permission must be received from the Food and Drug Directorate. Toxicology and manufacturing procedures in addition to the animal pharmacology must be submitted.
Once the substance passes these tests, a period of cautious evaluation in humans can be undertaken under stringent supervision of the manufacturer and the government.

6 *Further testing and clinical trials*: Should the promise of the drug be reinforced by these first trials, the compound is subjected to a new round of intensive pharmacological and toxicological evaluations. At the same time it is tested in more extensive clinical trials.

7 *New Drug Submission:* All the evidence gathered through these various stages is presented to the regulatory authority. In Canada, a "notice of compliance," issued by the Food and Drug Directorate, is required before the product can be marketed.

7.6

These activities were reviewed in greater detail in our presentation on drug safety to this Committee. (Minutes of Proceedings and Evidence No. 7). The related administrative procedures are laid out schematically in Appendix H of this submission.

Research on the biological properties of a drug cannot stop with its introduction. Some of its actions, both useful and undesirable, may become apparent only when it has been used extensively in medical practice. Such actions will require further evaluation and laboratory work. In addition, physiciens' experience may point to ways in which the product, itself, can be improved. The originating, research-based company will devote considerable resources to this activity and make strong efforts to receive continuing clinical reports on the action of the drug.

Clinical Research in Canada

Most of our member companies maintain an active program of clinical drug before the drug is marketed, and which complements other clinical research in this country which is essential to confirm the safety and efficacy of a drug before the drug is marketed, and which complements other clinical research performed in other countries.

This activity has stimulated the development of clinical research facilities in Canada, and, in addition, members of the PMAC financed in 1963 the establishment of the Canadian Foundation for the Advancement of Therapeutics. Dr. F. S. Brien, Head of the Department of Medicine at the University of Western Ontario, accepted the chairmanship of the Foundation.

To date, the Foundation has financed nine fellowships and eight studentships as well as several research projects. A three-day symposium on human pharmacology, bringing together Canadian and American leaders in the field, was organized in the fall of 1964. About one hundred representatives of the universities, government and industry attended. The theme of the conference was the improvement of drug evaluation in Canada, and another conference is projected for this year.

7.7

The Foundation is the foremost organization in Canada devoted to the support and development of clinical pharmacology.

The Cost of Research

The expenditure required to bring a new drug to the market has been increasing sharply. The Pharmaceutical Manufacturers Association of the United States estimates that the average cost of the research behind a new drug is now $5,000,000, compared to $2,700,000 five years ago. Factors accounting for this are: the general increase in research expenses; the growing complexity of much pharmaceutical research both chemical and biological; a shift in emphasis from the treatment of symptoms to the treatment of chronic diseases. In addition, far more extensive requirements of regulatory authorities call for expensive and prolonged testing in animals which must be carried out before the drug is ever given to a human.

The accumulated data needed to satisfy Food and Drug Directorate requirements before a new pharmaceutical may be made available for limited human clinical investigation often forms a stack of documents several feet high. (See Exhibit A).

Both in Canada and the United States, the requirements of government for additional data before a new drug is allowed on the market have sharply increased companies' R&D expenditures. Chemical and Engineering News, the organ of the American Chemical Society, in a special report on the pharmaceutical industry (August 10, 1964) stated:

7.8

> "Industry research people estimate that the cost of developing a new chemical entity has increased somewhere between 20 per cent and 50 per cent in the past few years, with most of the increase due to meeting the requirements of FDA."

There is general agreement that the cost of research in all fields is rising. Dr. L. R. Thiesmayer, President of the Pulp and Paper Research Institute of Canada, in a paper prepared in June 1964, estimated that in Canada as in the United States, it costs from 5 to 7 per cent more a year "just to stand still in research."

The rate of discovery in any research-based industry fluctuates, and the past few years have witnessed a marked reduction in pharmaceutical research productivity, as reflected in the introduction of new chemical entities. In the United States, from 1954 to 1961 the annual rate ranged from 31 to 63 new products. It dropped to 27 in 1962, 16 in 1963 and 17 in 1964. However, in 1965 the number of introductions rose to 24, due in part to more rapid processing by the regulatory authorities. A similar pattern can be discerned in new product introduction in Canada.

New Avenues of Research

The Wall Street Journal of November 9, 1965, in a review of new drug developments, quoted Charles S. Brown, Executive Vice-President of Abbott Laboratories as follows:

> "While we still look for better drugs in areas where we have attained success, as in antibiotic therapy, our major interest lies in drugs of the future that will fight cancer, viral and parasitic diseases, and cardiovascular and other degenerative ailments."

7.9

This statement was amplified by George S. Cain, Chairman and President of Abbott Laboratories:

> "Current efforts are pushing us deeper into the incredibly complex machinery of the cells, tissues, and organs of the body. We are trying to unlock the roles of nucleic acids, enzymes and amino acids in life processes and looking into the maze of the body's defence mechanisms."

Such research is, in fact, an excellent example of the way that pharmaceutical companies apply the original concepts of the university scientists.

Expenditure in Canada

Expenditure on research and development in terms of net sales in the pharmaceutical industry runs at about three times the average for manufacturing industry in general. Information relating to this expenditure in Canada was provided by our member companies as part of the 1964 statistical survey (Appendix E.)

The Hall Commission is critical of the expenditure on research by Canadian companies on two counts: the amount spent in this country and the amount charged for work done elsewhere. (p. 667 and p. 678). With regard to the former, it is significant that, whereas in 1959 companies reported research expenditures of $2,500,000 in Canada, by 1965 this sum had risen to $6,500,000. There has been a steady expansion of pharmaceutical research in this country—clinical investigation and also laboratory activities. Should conditions remain favourable to such research, there is every indication that the present rate of growth will be well maintained in the years ahead.

7.10

The origin of the misunderstanding that gave rise to the second criticism is explained in Section 3 of this brief.

A Choice for Canada

Pharmaceutical firms are increasing their research investment in Canada, but it would be unrealistic to claim that we can ever be the authors of a major proportion of the prescription drugs used in this country. We can be worthy collaborators in an international venture, but this must remain an international industry, with the main foci on endeavour in those countries where the major companies have been long established.

The Expansion of Canadian Research

The members of our association are keenly aware of the factors favouring research activity in this country—notably, the availability of scientific and technical people of high calibre, and the relationships possible with a number of outstanding universities. They have responded to these advantages, and to the fiscal and other encouragements offered by government, with a marked increase in both investment and annual expenditures since their introduction in 1961. Our research facilities have been greatly expanded since the Hall Commission report was documented.

Nine of our members now operate research and development laboratories in Canada. Further growth can certainly be expected so long as the treatment of our industry does not preclude the necessary investment.

Scientific personnel employed by the industry on research and development work have increased substantially in recent years. For instance, the number of physicians employed full-time in research by members of the Association rose from 12 in 1958 to 45 in 1964. At the last count—in 1964—there were 73 PH.D's or D.Sc's working in company research laboratories, 31 M.Sc's and 108 B.Sc's or B.Phm's.

7.11

This expansion of research activity on Canada reflects the growing scientific maturity of the country. However, it takes time for a new laboratory to become productive—as much as five to ten years from its establishment to the marketing of its first compound. And even the best staffed and equipped laboratories are of themselves no guarantee of success. Indeed, the uncertainty of succes can be directly related to the significance of the potential benefits.

8.1

PUBLIC SERVICE PRODUCTS

As mentioned in the preceding section, the research laboratories of the international pharmaceutical companies have developed many products, often life-saving, that are specifics for race illnesses and conditions. These products are often available to physicians either free of charge or at factory cost. A recent survey of our members showed 18 companies listing 84 products of this type. The cost of these products cannot be easily determined but their value to Canadians is inestimable.

The products, themselves, fall into six categories.

(1) There are drugs which are used to combat rare diseases and conditions. For instance, one company provides the sole or principal source of food indicated for infants and children suffering from phenylketonuria, an inborn error of metabolism which otherwise results in severe mental retardation. Another company provides free of charge for indigent patients its products that serve to control cerebral palsy and myasthenia gravis. A third company provides an antitoxin for botulism, a rare but often fatal type of food poisoning. A fourth distributes the product to combat pseudomonas (Bacterial) infections in the eyes or bowels.

(2) A company involved in anti-cancer research makes available to physicians certain pharmaceuticals that have proved themselves partially effective in the treatment of particular cancers, but have not justified a general introduction.

(3) There are occasions when somebody in Canada suffers from a disease which is common elsewhere in the world but, happily, not in this country. Specifics are made available against leprosy, sleeping sickness and malaria as well as sera against snake or black widow spider bite. A recent addition is a drug for the treatment of Schistosomiasis or Bilharzia.

8.2

(4) Specialized forms of commercial products may be provided without charge when these are specifics for rare conditions, for instance an injectable form of a drug needed in an acute hypertensive crisis.

(5) A number of companies provide the agents for specialized diagnostic procedures. These may relate to rare diseases such as trichinosis (swine fever)

or brucellosis (undulant fever). Another example is the agent to diagnose toxoplasmosis, a rather unusual condition which results in the birth of a blind baby. The mother has no apparent symptoms, but the disease is known to be carrried by dogs, and has on occasion reached epidemic proportions. Several agents are made available to physicians for the diagnosis of rare blood and renal conditions.

(6) Products required in unusual surgical procedures may also be provided. One such product is essential to protect the cornea during a particularly intricate type of eye surgery.

9.1

THE COST OF MEDICAL INFORMATION AND MARKETING

In our introduction we stated that this presentation would endeavour to answer the question: "What are the reasons for the present level of drug prices in Canada?" Clearly, related questions of great importance are: "What do pharmaceutical companies spend on marketing?" and "Why do they need to spend so much?"

Marketing Expenses

Our Annual Statistical Survey for 1964 (Appendix E), presents the marketing expenses for 41 PMAC companies. Physicians' information, covering the provision of information and promotional material to physicians, acccounts for 23.3 per cent of the manufacturer's sales dollar. Other Marketing Expenses, primarily direct selling to the pharmacist account for 6.6 per cent. The net result is that the manufacturer's marketing expenses amount to approximately 11 per cent of the prescription dollar.

The Requirements of Effective Marketing

To secure and maintain medical acceptance must be a major part of operating costs in this industry. Companies have to ensure that every physician and pharmacist across Canada is properly informed about their products; they are in business on a nation-wide scale. The fixed cost of the necessary marketing machinery must be borne whether or not a particular product is commercially successful.

Further, companies do not benefit from the saving provided by a mass market. They handle a large number of separate products, many of them with quite limited sales volume. In fact, at present in Canada only nine prescription drug products have an annual manufacturer's sales revenue exceeding $2,000,-000.

9.2

In their marketing, companies follow a pattern of activity common to most industrial countries. We do not believe that the justification for any significant deviation from this pattern within a free enterprise economy has been established for Canada.

Certainly, the managements of pharmaceutical companies are keenly aware of the cost of marketing their products. It can surely be assumed that as responsible men in profit-making enterprises they would not make the required resource commitment if they did not expect it to be productive. In fact, it is a condition of business survival.

The Impact of Geography

The geographical and other facts of doing business in Canada have to be faced. We are operating across a vast country with scattered population. Qualified representatives must be paid salaries on a North American scale. But except for those who serve in major cities, where there may be a concentration of physicians in a small area, they cannot hope to maintain a call-average comparable with other western countries. Territories are large, and travel expenses are high. And the current rate of detailing expense prevails even though companies find there are many sparsely populated areas where they cannot afford to send representatives. In this case, they have to rely on journal advertising and literature to carry essential information and promotional messages.

9.3

The Cost of Two Languages

The cost of providing full information and promotion services in two languages is also substantial. Practically all printed material is developed in both English and French versions. This calls for highly qualified translators and the duplication of relatively short printing runs. Companies estimate that their marketing expenditure is increased appreciably because of the need to do business in two languages.

The Balance Between Information and Promotion

In its marketing acitivities, a pharmaceutical company is concerned with two related requirements—the provision of scientific information and the promotion of its products. Theoretically, it would be desirable if a company could do business successfully through the single introductory provision of objective data about its products. Were the distribution of drugs in the hands of a monopoly concerned only with the sale of *existing* products, this might be feasible. But the success of this industry in developing useful new drugs and ensuring their wide availability is founded on competition and enterprise, including effective promotion. It has never been argued that the industry has failed in this, its most vital service.

Two characteristics largely fashion our marketing practices. On the one hand, drug products are numerous, varied and, increasingly, potent and complex. On the other, the use of those products is determined by the 20,000 members of the Canadian medical profession. In fact, when those who do not practise, or who have the kind of practice which involves drugs to only a minor degree, are eliminated, the determining group comes down to about 15,000. The result is the direction of extensive information about a large number of products to a rather small number of professional people to whom the system seems acceptable and effective. (See Appendices I and J)

9.4

Marketing Standards

An established pharmaceutical company knows that its greatest asset is its reputation with the medical profession. This reputation is based on the reliability of both its products and the information it provides about them. Further, both are subject to control by the Food and Drug Directorate. The FDD not only passes judgment on safety and efficacy; it must also approve the basic circular about a new product on which all promotion is based, and has lately established in cooperation with the industry definite requirements and stand-

ards for advertising material. These have been incorporated by our Association in its own more extensive code of marketing practices (Appendix C).

An established company is not going to jeopardise its standing with the medical profession by wilful misrepresentation or exaggeration. There is too much at stake for the patient and his physician, as well as for the company itself. If there are side effects and contra-indications associated with a particular drug, the company will make sure these are properly presented. But at the same time a company is going to place before the doctor the advantages of its particular products.

The Purposes of Promotion

The first purpose of pharmaceutical promotion is to arouse interest in a new product. The product has demonstrated its therapeutic value—otherwise it would not have obtained a notice of compliance from the Food and Drug Directorate—but it is most unlikely to be the only effective medicine in a particular field. It will present definite advantages for patients with certain conditions. But it cannot come to be widely used unless physicians are properly informed about it.

9.5

The requirement is not merely commercial, but is directly related to the social responsibilities of the pharmaceutical industry. Delays in informing doctors about new drugs, once these have received a notice of compliance from the Food and Drug Directorate, can well cause unnecessary loss of life and suffering.

If we assume, as we must, that doctors have the education and experience to judge the value of the new product in their own practice, then company promotion is a means of assisting them to serve their patients. It is an Association policy to respect the wishes of the physicians with respect to his receipt of product information, either by direct mail or by professional representation. The doctor under our present system is a free, responsible professional; he can accept or refuse the products available to him. One of the standards by which his professional standing is judged is whether he does this wisely.

Pharmaceutical marketing activity—information, promotion and advertising—cannot be limited to new products. New information may become available about existing products, new indications may develop or new contraindications. And companies have repeatedly found that the market for even well-established products depends on the maintenance of the promotional flow—a fact of competitive enterprise in a dynamic industry. There is continuing enlargement of knowledge and shifting of preference, and each company must do its best to influence the patterns of use which emerge—within the limits set by scientific reliability and responsibility.

9.6

The Results of Pharmaceutical Marketing

It is important to visualize the total effect of the marketing and distribution operation. Today there are approximately 8,000 prescription preparations available in this country. This includes the various brands, formulations and dosage strengths, (Hall Commission Report, quoting Canadian Pharmaceutical Association, p. 347). These products are immediately, or very rapidly, available

through any of the 5,000 pharmacies across the country, with the pharmacies stocking, themselves, all those for which there is a significant demand. All required drugs are equally available in all hospitals. At the same time, physicians, dentists and pharmacists are kept informed about these drugs—advantages, prescribing information, side effects, contra-indications—and new knowledge about them, once validated, is brought rapidly to their attention.

In these circumstances—the need both to be geared up for new product introduction and to maintain the flow of effective promotion—marketing becomes a rather rigid cost for a pharmaceutical company. The investment in good representatives and other marketing personnel must be protected just like the investment in good research workers. A company cannot hire and fire to match an irregular course of new product introduction.

9.7

Attached as Appendices D and I are more extensive reviews of the purposes and cost of detailing and pharmaceutical mail respectively, the major elements—together with journal advertising—of pharmaceutical marketing programs. The practice of sampling is discussed in Appendix J. How these various elements are combined is, of course, a decision for the individual company, influenced by the nature of its products and its past experience.

A Drug Information Service

One feature of the present system of drug information is that practising doctors receive most of their basic information about prescription drugs from the companies which manufacture them. While medical journals carry reports of clinical investigation and unusual cases, these will likely appear some time after a drug has come onto the market and be limited to particular aspects of therapy. Also, relevant articles will be scattered through many journals which the busy practitioner does not have the time to check and peruse.

The need has been recognized in Canada by doctors, pharmacists and manufacturers alike for objective, independent reporting on new products. The same need has been felt in the United States, where the American Medical Association has decided to set up a well-staffed service to provide information to its members through regular bulletins about new drugs and an annual publication collating its findings. At the initiative of our association, a committee has been set up to investigate the development of a related drug information system in this country. Represented on it, too, are the Food and Drug Directorate, the Canadian Medical Association, the Canadian Pharmaceutical Association, and the Canadian Society of Hospital Pharmacists.

9.8

It is our strong opinion, coinciding, we believe, with that of the medical profession, that this is a task for an independent professional body, composed of representatives of medicine and pharmacy, operating with the support of government, not a responsibility of government, itself. There is, we believe, a marked danger of the views of an official body being treated as a seal of official approval or disapproval, and so becoming an undesirable limitation on the professional freedom of the physician.

What impact such a service would have on the cost of pharmaceutical promotion cannot be forecast accurately. If the profession should show by its

prescribing patterns that reliance was placed on the service, companies would naturally revise their promotional programs to take account of such reaction.

Non-product Services

As noted in the survey reproduced as Appendix E, companies include in their marketing expense the cost of a number of activities which are not directly related to product information or promotion. Such activities have, of course, a general marketing purpose—establishment of the company in the minds of doctors as a responsible, scientifically-oriented organization. They provide valuable services to post-graduate medical and pharmaceutical education not available from other sources. Among these are: the organization of symposia relating to particular diseases; and distribution of the record of proceedings; and the support of professional meetings in various ways, including closed

9.9

circuit coloured television facilities, setting up of international telephone links, and the recording and distribution of proceedings.

10.1

THE COST OF SAFETY

The cost of safety pervades all sectors of our business; it is a growing cost, deriving from the awareness of government, industry and the medical profession of the toxic potential of modern pharmaceuticals.

Impact on Cost of Research

During the early years of the "wonder drugs" the exciting benefits of these newcomers tended to obscure the risks involved. Delays which companies now encounter in getting new products approved—whether for clinical testing or market introduction—have markedly increased research and development costs along the lines reported in Section 7.

The chart attached as Appendix H shows the current course in Canada of a new drug application, including the toxicological and clinical studies required, with their related paperwork.

Physicians on the staffs of member companies direct clinical research activity and provide an information service to practising colleagues, a service backed up by extensive scientific libraries, here and abroad. Much of their work relates to patient protection.

Impact on Cost of Manufacturing

Maintenance of responsible standards of quality control, referred to in Section 6 is another aspect of the expenditure on safety.

Impact on Cost of Marketing

Safety has also had its impact on marketing expense. As mentioned in Appendix J, the present sampling regulations, designed primarily for reasons of safety, have increased the cost of sampling for most manufacturers.

10.2

So does responsible promotion in general, with its awareness of the need to ensure that full information about side effects and contra-indications is widely

disseminated among physicians and pharmacists. To increase substantially the supply in Canada of imitative and inferior products handled by firms who do not share this attitude or the originator's intimate knowledge of the drug would seem at best a false economy. A glance at the Vademecum International in which manufacturers list and describe their products—and pay for the space they use—will show how consistently members of our Association include the relevant warnings. So far as we know, there is no other sphere of advertising with the same requirement for the regular inclusion of cautionary technical information.

Another example of the cost of safety is the effect of the Schedule G regulations. These provide for stringent controls on the distribution of barbiturate and amphetamine products. They require much more detailed supervision of distribution than with other prescription products—except, of course, narcotics—and more extensive record-keeping.

10.3

Some of these and other costs of safety would have to be met by any company handling the products concerned—notably, those costs which result from government regulation. However, there are others which reflect the sense of responsibility and enlightened self-interest of the research-oriented manufacturer. To increase substantially the supply in Canada of imitative and inferior products handled by firms which do not share such an attitude would seem at best a false economy. In the present developing state of our knowledge about the impact of chemicals on the human body, it could well impair the quality of health care in this country.

11.1

PHARMACEUTICAL PATENTS

The Purpose and Value of a Patent System

The three principal purposes of a patent system have been defined by Dr. Vannevar Bush, noted scientist and Nobel laureate, as follows:

> "First, it seeks to stimulate invention and the search for new applications of knowledge. Second, it seeks to promote the introduction into public use of the new devices or processes. Third, it seeks to eliminate secrecy and to make available to others skilled in the field full disclosure of the new ideas."

The value of a patent system in respect to pharmaceuticals can be assessed within two broad categories of function—economic and social. The former relates to the contribution made to economic development, the latter to the therapeutic value of the goods and services that result from the granting of a patent. We propose to consider both these aspects of pharmaceutical patents; to review the impact on them of the present character and administration of the Canadian Patent Act, with specific relation to compulsory licensing under Section 41(3) of that Act; and to suggest certain changes that will, we believe, ensure that patent legislation in this country meets more effectively the true needs of a period of vigorous scientific advance.

Two recent reports, those of the Restrictive Trade Practices Commission and the Royal Commission on Health Services, criticized even the present

scale of patent protection for pharmaceuticals. They maintained that either the abolition or emasculation of this protection was a prerequisite for reducing the cost of prescribed drugs. They appear to have based this position on the belief that the consequent wide-open competition in pharmaceutical would best serve the national interest. (Royal Commission on Health Services report p. 701 et. seq.)

11.2

An effective patent, it is true, confers a temporary monopoly. Thus it rewards the industrialist who makes public the invention, and stimulates working of the patent, which can be assumed to be in the public interest. Introduction of new and effective medicines certainly serves the public interest powerfully and continually. However, when it comes to pricing the product covered by this monopoly, it must be recognized that there are practically no drugs which possess a therapeutic monopoly. For almost every means of treatment, patented or not, there is an alternative, or several alternatives. The existence of these alternatives has a major influence on price levels.

Further, the public interest is not limited to the provision of drugs at the lowest possible price. Quality is extremely important, as is the assurance that these are the safest products which can be devised and manufactured. In addition, physicians should have available a full range of drug preparations for both frequent and rare diseases and conditions, and be well-informed about how and when to use them. The public interest is also far-reaching in time; the flow of therapeutic advances must be stimulated and maintained, progress in pharmaceuticals is at least as important as immediate efficiency. Finally, there is a specific national interest in the growth of a research-based Canadian pharmaceutical industry, making large-scale investments in Canada and offering good employment opportunities.

These are all purposes which can be fostered by a strong patent system designed to encourage the development and working of inventions in this country.

11.3

The Fostering of Industrial Development

A major justification for a patent system is that it fosters industrial development. Canada has recognized that it can enhance its industrial status only if it encourages innovation through research and development. C. M. Drury, Minister of Industry, addressed the Second Ministerial Meeting of Science of the Organization for Economic Co-operation and Development in Paris on January 12, 1966, on "The Role of Government in Stimulating Technical Innovation." He made the following pertinent comments:

> "Our basic premise is that 'technological investment' is the great progenitor of economic growth. Technology enters the economy through the process of innovation, which is one of the most important driving forces of a modern industrial economy. The task facing governments then is to stimulate the innovation process so as to ensure the rapid and effective exploitation of new scientific and technological advances. The solution involves the creation of a favourable climate for innovation and the devising of techniques to promote research and development in industry, where it can be applied for economic purposes...

"It is sometimes argued that the ready availability of imported technology makes it unnecessary for the smaller nations supporting any substantial R and D activity. A policy of reliance on licensing or imitation is of course much less costly in the short run but carries with it serious limitations on the future viability and growth potential of the dependent industry which thus becomes vulnerable to competition, (both domestic and international). Active engagement in R and D seems the best way of avoiding obsolescence and enabling a firm to successfully assimilate and exploit new technology."

In both its annual reviews published so far the Economic Council of Canada has underlined the need for increased expenditure on research and development. The Second Annual Review of the Council contained the following passage:

11.4

"In our First Annual Review we pointed out that, in order to achieve a satisfactory rate of improvement in productivity and to enhance our competitive position in the world, Canadian industry must be in a position to make adequate use of the rapidly expanding resources of science and technology. In order to do this, we must greatly increase our own efforts in research and development. These greater efforts are necessary so that Canadian industry may be equipped to make the best use of available foreign technology and also to expand considerably its own contribution to new technology to provide a basis for profitable innovation and specialization."

A patent system provides industry with an incentive to innovation. It thereby encourages investment both in research and development and in production facilities, and also fosters the introduction of new products. Patent protection has particular importance for modern research-based industries, of which the pharmaceutical industry is an outstanding example, since their future depends on the ability to incur the high cost of continuing, complex research.

In this connection we quote from a memorandum submitted by the Association of the British Pharmaceutical Industry to the British government on this subject (The Pharmaceutical Journal, January 16, 1965, pp. 52-55):

"A patent is granted to an inventor by the Crown in exchange for benefits conferred on society by the inventor. If one is to diminish the monopoly granted to a particular group of inventors the group selected should be one that confers upon society a smaller than average benefit. We believe that the pharmaceutical inventor deserves as well of public esteem and reward as does the inventor of any other kind of invention. Yet the inventor of a new drug that for the first time would effectively treat coronary thrombosis is subject to the particular severities of Section 41, whereas the inventor of a new hair curler, machine-gun, whistling top or mouse-trap is not subject to the special provisions of that Section..."

The Nature and Extent of Pharmaceutical Research

We are aware at this point of two counter-arguments relating specifically to the research activity of the Canadian pharmaceutical industry. (1) It is claimed that the abolition of Canadian patents for pharmaceuticals would have

little effect on the expansion of research and development activity within Canada. (2) It has been suggested, notably by the Hall Commission in Recommendation 80, that pharmaceutical research can, and should, be directed and financed by government.

11.5

Certainly, the pharmaceutical industry is among the most international of industries, with people throughout the world dependent for life-saving products on the research achievements of other countries. However, expenditure on prescription drug research and development in Canada has been rising steadily. Surveys of our Association members report an increase in R & D expenditure from $2,500,000 in 1959 to $6,500,000 in 1964, and nine companies now have research laboratories in this country.

This expansion is due in part to the research tax incentives offered by the Federal government, and a few companies have been given direct grants for specific projects. An inhibiting influence, however, has been the increase in the past year or two of applications for compulsory licences under Section 41(3), and the apparent ease with which such licences have been obtained.

A company's decision to increase, or even maintain, research expenditure in Canada can be influenced by many factors. An important one is certainly the quality of the scientific community; the relationships the research establishment can develop and the personnel it can employ. Tax incentives and the possibilities of government grants will be taken into account. But attention will also be paid to the climate in which company, laboratory and staff will operate, and here the state of patent protection is a major influence. In all these matters the advantages in one country will be carefully weighed against those of other possible locations.

11.6

If the development of pharmaceutical research is held to be a national interest for Canada, together with the growth of a research-based pharmaceutical industry, the denial to the industry of reasonable patent protection calls for the closest scrutiny. Canada can ill afford decisions that could endanger its long-term interests as a rising industrial power.

The second argument—that pharmaceutical research should be financed by government—ignores the realities of industrial, and notably pharmaceutical, research. This is an increasingly complex and costly activity; several international companies each spend more than $20,000,000 yearly on research and development. Their activities are carried on in close cooperation with universities and hospitals, they form part of an interwoven pattern of scientific exchange, and they are devoted to a specific and essential purpose—the application of scientific and medical knowledge to the development of pharmaceutical products of direct benefit to mankind. But, the fundamental objection is that government-sponsored research is usually isolated from the practicalities of therapeutic necessity and this research therefore cannot be directed economically or effectively without industry cooperation.

Patents, Information and Product Availability

There are significant services performed for Canadians by a research-based international pharmaceutical industry, services intimately linked with the research orientation of that industry, which would be seriously endangered if the treatment of pharmaceutical patents discouraged an orderly pattern of drug

development and control. Indeed, on the maintenance of this pattern depend both the availability and safety of the potent pharmaceuticals used in this country.

11.7

Genuine patent protection encourages a company to devote considerable resources to the introduction and marketing of its products. It does this through a carefully planned program of scientifically based information. An imitating company merely takes advantage of the medical information provided by the originating company, and is probably incapable of either maintaining or advancing it.

The activity of the research-based company is a total operation; its professional and experienced personnel are concerned with all its products. The cost of their employment is met largely through the success of a few products, yet their services to the medical profession relate to the totality. There are, indeed, many life-saving and otherwise valuable products enjoying a limited market that a company makes fully available and fully services only because they are part of the total operation. (They are described in Section 8 of this brief). Without reasonable patent protection for its main products, a company might well decide that it could not afford to give this kind of treatment to other important drugs, or, indeed, to introduce new products of however great therapeutic value if they were only used for rare diseases or conditions. Conversely, a study of the applications made for compulsory licences under Section 41(3) will reveal that the applicants, naturally enough, are interested in products which have already obtained substantial sales. Recent licences and applications relate to: Benadryl, Chloramphenicol, Largactil, Dulcolax, Zylocaine, Librium, Stelazine, Diuril, Hydrodiuril, Stemetil, and Nozinan.

11.8

The Protection of Drug Safety

The assurance of drug safety today requires extensive and continuing work in pharmacology and toxicity beginning with assembly of the material necessary to meet the rigorous demands of a New Drug Submission. We do not believe that an imitating company will possess the scientific resources to fulfil this requirement, or that it can provide the Food and Drug Directorate with the information on which to base manufacturing standards, assay procedures, etc. If the research-based company does not carry out this work, and incur the related expenses, nobody else will. Effective patent protection is the best guarantee Canadians have that all important products resulting from world-wide pharmaceutical and medical research will be introduced in this country.

The difference between the services provided by the research-based and by the imitating company goes still further. The research-based company acquires a great deal of information about the products it markets, and this is always at the disposal of the medical profession and government. It is based upon the use of products of consistent quality. In the event of any problem arising with regard to a drug, such information is of tremendous value in determining both the significance and any remedial action. A company which has merely acquired the right to manufacture or distribute a product will not have the same resources in personnel, clinical experience or accumulated international information. There has been at least one important case where a licensee was

completely unable to meet the scientific requirements of government in this connection. This was brought out in the interrogation of Mr. L. L. Winter of Empire Laboratories Limited by the Special Committee of the Commons on Food and Drugs in November 1964. (Proceedings pp. 375 et seq.)

11.9

Crucial in this regard is the decision by the Food and Drug Directorate whether a particular product still has the status of a "New Drug." If the product is still a "New Drug," then the licensee must meet the extensive scientific requirements of a new Drug Submission; if it is not, then the controls which the FDD can exercise are very limited. Because of this technical difference, a very potent drug, one which the originating manufacturer is still subjecting to clinical tests because of significant side effects, would be treated as a comparatively innocuous substance.

The originating company is concerned to keep up-to-datê complete information about all indicated uses for all formulations of a product. At the same time, it will collect and eveluate information on negative indications, such as side effects, contra-indications and problems arising from the concurrent use of other medication. Such information is developed out of physicians' reported clinical experience as well as from studies it has, itself, initiated. Uncontrolled compulsory licensing of potent drugs will distort or destroy the validity of much clinical experience; the active ingredient alone does not determine the therapeutic behaviour; reactions can be caused by the formulation as well as the drug.

This danger, indeed the general danger to drug safety, is intensified by the encouragement that Section 41(3) offers to patent infringement. It is a fact, however undesirable, that patent-holding companies hesitate to take action against infringers because the immediate counter-measure may well be an application for a compulsory licence.

11.10

The price of drugs, it is recognized, is—and should be—a matter of public concern. But price cannot be properly considered apart from drug safety, reliability and availability. It is significant that the Special Committee of the Commons on Food and Drugs decided to put drug safety before drug cost when establishing its order of priorities. (Proceedings, pp. 7-8). The public interest is best served when the relationship between price and product or service is in proper balance. Value depends on both the price and the quality of what is purchased.

The Industrial Contribution

Out of a sales volume of $110,465,000 reported by 41 PMAC members for 1964, purchase of goods and services in this country accounted for $85,575,000.

Further evidence of the growing contribution of the pharmaceutical industry to industrial development in Canada is shown by the figures detailing the volume and rate of investment of PMAC members presented in Section 3 of this report.

There is here a solid foundation for future growth—the growth of an industry of vital interest to the people of Canada. It is our contention, however, that continued growth, the expansion of both manufacturing and research

establishments, depends on the conditions under which the industry can conduct its business in the years ahead. The state of patent protection may well prove a determining influence.

The Origin of Section 41(3)

It is with this background that Section 41(3) of the Patent Act should be studied. Section 41(3) discriminated against food and drugs. The question to be considered is whether such discrimination serves the public interest under present circumstances—not a theoretical justification, but the actual results. If, as we believe, it subordinates the real interests of Canadian users of pharceuticals to those of a small number of imitative manufacturers, making very large profits out of their licences, then effective remedies for this situation should be implemented.

11.11

Section 41(3) was introduced in 1923 (Revised Statutes C. 23 s 17 (2)), having been modelled on a similar section in the English Patent Act of 1919 (Patents & Designs Act of 1919, 9 and 10 George V c. 80). This English legislation was revised in 1949, with implications that are discussed further along in this section.

The purpose of the original English enactment was explained in the Sargast Committee Report of 1931 in the following terms:

> "During the War it became apparent that Great Britain was suffering from a lack of medicine and drugs, many of which were the subject of patent rights in this country. On the other hand, it was found that in many European countries (e.g. France, Germany, Switzerland) such substances were not capable of protection under the patent laws of those countries. In this state of things it was considered expedient to modify to some extent the monopoly consequent on the existence of patent rights in regard to such substances."

The origin of Section 41(3) was the danger of a shortage of drugs in England. Section 41(3) was enacted to meet a situation which in no way applies in Canada today. In addition, the section was enacted at a time when the pharmaceutical industry, which has become the chief target of compulsory licence applications under the section, was an entirely different industry. The products to which it is now applied are immeasurably more potent and complex, and the requirements of medical information have correspondingly increased; the research that yielded these products is far costlier; and the continuing research, which present products help substantially to finance, requires an ever greater investment in money and scientific manpower.

11.12

The Present Administration of Section 41(3)

The actual wording of section 41(3), leading to the way it has been administered and to the interpretation placed by courts of appeal on the authority of the tribunal of first instance, intensifies the problem. In effect, both the first and the final decision as to the granting of a compulsory licence are made by the Commissioner of Patents. Well qualified though he is in patent technicalities, he does not have experience either of the economics of the industry or of its medical and scientific aspects. Further, under the present

regulations, he is not required to obtain expert advice in these areas. Indeed, the covering letter of the Hilliard Committee Report to the Minister of National Health and Welfare, dated July 12, 1965, made the following observations:

> "It was a shock to the members of the Committee to find the heavy responsibility put on the Commissioner of Patents. Many of the newer drugs are so complicated in their formulae that part of the products, the isomers, might not be active therapeutically though chemically pure, and some dangerous impurities may not be sufficient in amount, in small samples, to be detected. . ."

11.13

Section 41(3) provides that the Commissioner shall grant a licence unless he sees good reason to the contrary. He is thus designated to make the decision whether the exclusive right of patentee shall become the subject matter of a licence. The courts have refused to interfere with his decision on the ground that the section provides that the decision is one for the Commissioner to make. (Parke, Davis v. Fine Chemicals, 1959 S.C.R. 219: Hoffman-La Roche v. Bell-Craig, 1966 Decision of the Supreme Court of Canada). An the courts have refused to lay down what matters constitute grounds for refusal of a licence.

Section 41 (3) is defective in that it contains no objective standard for judgment by the Commissioner. No guidance is given by the section, and no guidance has been given by the courts as to what matters the Commissioner should examine or investigate to determine if good reason does in fact exist for the refusal of a licence.

In the case of Hoffmann-La Roche v. Delmar Chemicals, the Supreme Court of Canada has stated that no decision of the Commissioner has ever been overturned. But no principle has been enunciated by the Court. And significantly, the decision of the Commissioner to grant a licence has never been overturned by the Court on appeal.

Further, both the Exchequer Court and the Supreme Court of Canada have held that the Commissioner is within his right to refuse to grant an oral hearing. It is therefore difficult to see in what circumstances the Commissioner can act without evidence, since the material before him consists of nothing more than blanket statements. The assertions of the applicant are not subject to the test of cross examination.

The problems facing a drug patentee in advancing good reason to the contrary to the Commissioner are demonstrated in the following statement in the Restrictive Trade Practices Commission report:

> "...The Commissioner has not yet been convinced that an applicant was not qualified either financially or professionally, and he has rejected all arguments to the effect that the applicant had previously infringed the patent[2] or could not produce economically in commercial quantities[3] or that the market was already adequately supplied.[4] In this respect, the

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[1] *Frank W. Horner Ltd.* v. *Sharp & Dohme (Can.) Ltd.*, 15 Canadian Patent Reporter 68; *Delmar Chemicals Ltd.* v. *American Cyanamid Co.*, 32 Canadian Patent Reporter 40; *Micro Chemicals Ltd.* v. *Société des Usines Chimiques Rhône-Poulenc*, 37 Canadian Patent Reporter 93.

[2] *Parke, Davis & Co.* v. *Fine Chemicals of Canada Ltd.*, 30 Canadian Patent Reporter, at pp. 66-67.

[3] *Delmar Chemicals Ltd.* v. *American Cyanamid Co.*, 32 Canadian Patent Reporter 40.

[4] *Parke, Davis & Co.* v. *Fine Chemicals of Canada Ltd.*, 30 Canadian Patent Reporter, at pp. 65-67; *Delmar Chemicals Ltd.* v. *American Cyanamid Co.*, 32 Canadian Patent Reporter 40; *Charles E. Frosst & Co.* v. *Carter Products Inc. et al*, 29 Canadian Patent Reporter 145.

Commissioner of Patents gave the following evidence to the Commissioner (RTPC):

11.14

'Reasons to the contrary being such as the patentee already manufacturing in Canada, public demand being fully supplied, prices being reasonable, the applicant intending to produce only the bulk material leaving to others the tableting, capsuling, compounding, etc. have all been rejected by the Commissioner of Patents in Canada and by the Comptroller General in the United Kingdom (where the law is similar to ours) and the courts have concurred where appeals have been made.' "

(p. 104)

In the light of these rejections a drug patentee may be pardoned for some perplexity about the intent of the legislation in imposing the limitation that a licence shoud be refused when good reason, to the contrary exists. Indeed, Section 41(3), as it is now administered, appears tantamount to the granting of a licence of right, even though the patentee is fully supplying the market with a product of quality at a reasonable price.

To sum up, Section 41(3) of the Patent Act, subordinates the real interest of Canadians in the availability, quality, and safety of pharmaceutical products, and in the stimulation of research in one of the most vital areas of human endeavour, to limited and temporary price advantages. This misconception of the real interest would be even more dangerous were the practice of compulsory licensing under Section 41(3) to be extended to drug imports, as recommended by the Hall Commission.

11.15

The Establishment of Royalties

There is widespread misunderstanding about the economics of the pharmaceutical industry, especially about the nature and cost of the essential functions performed by a responsible company:

1. Research and development;
2. Manufacturing, including sustained quality control;
3. Presentation to the medical profession, including the maintenance of vital services of scientific information. This requirement—based on a two-way flow of knowledge goes far beyond the promotional activities usual in other industries.

A pharmaceutical company can maintain these necessary functions only if the prices at which it sells its products cover their cost and yield a reasonable profit. However, as explained above, a company conducts a total operation, and certain overheads cannot be allocated to specific products. In particular, marketed products have to bear the cost of the ongoing research operation, its failures as well as its successes, to pay for future as well as present therapeutic advances.

Unless the holder of a compulsory licence is required to pay a royalty that covers the cost of necessary functions being performed by the patentee, the licensee is being given something for nothing. This is surely an extreme application of the phrase, "lowest possible price." An examination of the licences which have been granted under Section 41(3) will show that the

applications were made in expectation of a "free ride" in relation to certain of these functions. If, indeed, the royalties granted had borne a reasonable relationship to the cost of the functions—a contribution to research and scientific services—it is most doubtful whether the applications would have been pursued.

11.16

The Commissioner of Patents has, in fact, interpreted the royalty provisions of Section 41(3) in favour of the applicants. He, himself, made the following statement before the Restrictive Trade Practices Commission:

> "...It seems to me if the price of drugs has been so high, why is it that no more Canadian companies have started manufacturing because, after all, the royalty is a pittance as against the profit that could be made."
>
> (RTPC report at p. 111)

It should be noted that the rate of compulsory licence applications has increased substantially since this evidence was given.

In addition, there is no requirement under Section 41(3) that the licensee should supply the whole of the Canadian market or provide all the type of formulation of a medicine. If he so wishes, he is at liberty to supply only certain areas or certain types of customer, to market only the most profitable items, not, for instance, injectible or liquid preparations for which there may be only a limited demand. Yet the patent holding company, maintaining a total operation, deems it a responsibility to meet all these requirements.

11.17

In the case of Hoffman-La Roche v. Bell-Craig, the President of the Exchequer Court to a certain degree recognized on appeal the inadequacy of the royalty granted by the Patent Commissioner. The royalty had been established on the selling price of the bulk chemical. The President of the Exchequer Court allowed that it should rather be applied to the selling price of the patented drug in dosage form. His decision included the following finding:

> "I have come to the conclusion that the Commissioner fell into error in thinking that 'the finished material in dosage form, packaged and labelled' was 'outside the scope of the patent' and 'immaterial' to him. On the contrary, the drug in the dosage form, if it is made in accordance with the patented process, is just as much the subject matter of the patentee's monopoly as it is when it is sold in bulk. It is precisely the same product as it is when it is in bulk except that it has been packaged so as to be in the form in which it has value as a merchantable commodity."

In this case, the Commissioner of Patents had granted a royalty of 15 per cent of the selling price of the bulk active ingredient. This would amount to $37.50 per kilogram on a probable selling price of $260 per kilogram. The proposed selling price of the applicant for the finished dosage form amounted to $3,500 per kilogram so that the royalty is equivalent to less than 1 per cent of the patentee's selling price. Since the applicant had done no research and offered little by way of medical information, he would be enjoying substantial profits through obtaining a "free ride" on the essential functions performed by the patentee. It is clear that the scale of compensation awarded the patentee effectively destroys the value of a patetn subject to compulsory licensing.

11.18

The royalty granted by the President of the Exchequer Court amounted to $525 per kilogram or 15 per cent of the licensee's selling price for the pharmaceutical in finished dosage form. Although this sum would not begin to cover the costs of research and medical information borne by the patentee, it was some recognition of the desirability of awarding the patentee more than a mere pittance.

However, in its judgment delivered on January 25, 1966, the Supreme Court of Canada overturned the decision of the President of the Exchequer Court, returning the royalty to that established by the Patent Commissioner. There is no doubt that the Supreme Court regarded the Commissioner's award as more consistent with the "lowest possible price" referred to in Section 41 (3) than the Exchequer Court award. Specifically, it stated that the "maintenance of research incentive", referred to as a royalty criterion in the Supreme Court decision on Parke, Davis v. Fine Chemicals Ltd., had been misinterpreted in the Exchequer Court award.

In effect, recent decisions have created *de facto* a standard royalty rate for compulsory licences, basing this on a very narrow interpretation of the phrase ..."giving the inventor due reward for the research leading to the invention."

By contrast, since 1949 the British Patent Law, source of the Canadian Patent Law, has referred to patentees receiving "a reasonable advantage from their patent rights." Further, the Royal Commission on Patents, Copyright and Industrial Designs (Ilsley Commission) recommended in its report that: "Royalties are from the standpoint of the patentee to be fixed with reference to reasonable advantage to the patentee instead of due reward for research." (p. 95).

11.19

In addition, the Ilsley Commission proposed to strengthen patent protection for drugs by permitting product patents on chemical substances intended for food and medicine, instead of only patents on the process involved, the present situation (p. 93). In contrast, in reversing the Exchequer Court decision in the case of Hoffman-La Roche v. Bell-Craig, the Supreme Court of Canada came to the following conclusion:

> "The royalty payable by a licensee for using a patented process is one of his costs of production. That being so there is an obvious justification, in cases where a percentage royalty is decided upon, for using as a base the sale price of the bulk material produced by the patented process, rather than a base which reflects a variety of packaging, distribution, promotional, sales and other like expenses."

There appears here a fundamental misunderstanding of the nature of the pharmaceutical industry. The cost of production, the cost of operating the plant, is only one of its continuing and essential costs. The basic purpose of the industry is to provide the means for medical treatment; it is as much a service industry as a manufacturer of goods for retail distribution. In these circumstances, to maintain research and a proper flow of scientific information are two crucial functions.

Essentially, what the applicant for a licence under Section 41(3) seeks is the right to copy the patentee's dosage form so as to claim that this copy has a

therapeutic effect identical with the original. In so doing he is, at minimal cost and with no lasting commitment, taking advantage of a substantial market created by the patentee. Further, he relies on the patentee continuing the necessary efforts and expenditure to support that market. And he will enjoy automatically any benefits that result from any new therapeutic use the patentee may discover, having played no part whatsoever in such discovery. There is no true competition between patentee and licensee since the patentee is in effect continuously subsidizing his competitor. Further, the patentee carries expense burdens immeasurably greater than the licensee's, yet is quite unable to discard them.

11.20

The Hilliard Committee Report

Concern about the dangers resulting from the inadequacies of second manufacturers under compulsory licensing led the government to set up last summer a special committee of investigation under Dr. Irwin Hilliard of the University of Toronto.

The report of this committee, tabled May 12, 1966, in the Commons, reiterated this concern and dealt with the hazards which could arise from both compulsory and voluntary licensing. The committee made a number of recommendations, all of which this Association heartily endorses. For reference it is attached as Appendix K.

The recommendations of the Hilliard Committee Report when implemented will do much to protect the public interest so far as drug safety is concerned, but there are, in addition, other vital aspects of the situation that must be dealt with as well. For this reason, our own recommendations regarding pharmaceutical patents would range beyond those of the Hilliard Committee and are covered at the end of this section.

11.21

The Potential Role of Sections 19 and 67

In Section 67, the Canadian Patent Act contains effective provisions for action through compulsory licensing to prevent the abuse of a patent: "The Attorney General of Canada or any person interested may at any time after the expiration of three years from the grant of a patent apply to the Commissioner alleging in the case of that patent that there has been an abuse of the exclusive rights thereunder and asking for relief under this Act."

Significant in the definitions of what constitutes abuse is Section 67 (2) (*a*): "...if the patented invention (being capable of being worked in Canada) is not being worked in Canada on a commercial scale, and no satisfactory reason can be given for such non-working..."

Because of the existence of Section 41(3), no recourse has been had to Section 67 with regard to patents on drugs, yet this section would appear to be the true defender of the public interest. Further, implementation of Section 67 would provide strong encouragement for the extension of pharmaceutical manufacturing and pharmaceutical chemical manufacturing in Canada. At present Section 41(3) actually discourage manufacturers from working their patents in this country because whether they work them or not has no bearing on the granting of compulsory licences. In this way Section 41(3), as now administered, directly contradicts the normal purposes of patents legislation.

Moreover, Section 19 gives the Government of Canada the right to use any patented invention on payment of reasonable compensation. This provides additional protection for the public interest.

11.22

The International Picture

Section 41(3) of the Canadian Patent Act discriminates against pharmaceutical patents in an all-embracing way quite rare in other industrial countries, concerned as they are to make drugs of high quality widely available and also to foster research and industrial expansion. There is nothing similar in the patent law of the United States. Some West European countries have compulsory licensing provisions, but these are generally dependent on abuse of the patent.

While there is now no patent protection for pharmaceuticals in Italy, legislation to reinstate it has been approved by the Council of Ministers and is undergoing parliamentary debate. It will provide process patents of ten years' duration. Compulsory licensing in the public interest is included in the proposed legislation, with the initiative residing in the Minister of Health. Fair compensation is to be paid to the owner of the patent in keeping with the importance of the invention and the profit it is expected to yield. Decisions as to royalty are to be made by the Minister of Health in agreement with the Minister of Industry and Commerce, and there is full appeal to the courts on the matter of royalty.

The draft European Patent Law prepared by the European Economic Community would grant a patent life of 20 years, and permit compulsory licences only in case of proved abuse or where one patent cannot be used without using another. The Council of Europe has made similar recommendations.

In Britain, where Section 41(3) originated, the treatment of the patentee is notably more realistic than in Canada with regard to both the granting of licences and the establishment of royalties. Under the English statute a licence is not granted as of right to create competition but rather there is a balancing of all factors involved to determine the ultimate public interest. In the event of a licence being granted the royalty is based on the costs of research, medical information service as well as a return on the capital invested in both of these functions. The most recent decisions are J. R. Geigy S.A.'s Patent 1964 RPC 391, and the unreported decisions of the Assistant Comptroller in Farmers Marketing and Supply Company Limited's Patents, 2nd August 1965 and in Pfizer & Co. Inc.'s Patents, Feb. 24, 1966. The latter decision applies the royalty to the patentee's selling price for the product in its dosage form.

11.23

Position and Recommendations

We believe that the Patent Act, as it now relates to prescription drugs, does not truly serve the public interest. In contrast, this would be better served by the establishment of new and different procedures.

Our reasons for this position can be summarized as follows:

1. The public interest requires the continuing availability of the products of worldwide pharmaceutical research at reasonable prices. This depends upon the maintenance of invention, product develop-

ment and distribution, and the diffusion of extensive and reliable information to the medical profession.

2. The public interest also requires that a reward be given for an invention, so that further research is encouraged and the industrialist has an interest in making public the results of the invention. This is the basic purpose of the Patent Act.
3. The public interest therefore does not justify, indeed is opposed to, discrimination against pharmaceutical patents since such discrimination inhibits the fulfilment of both these purposes.
4. Section 41(3) of the Patent Act, as it is now interpreted and applied, discriminates severely against patents on pharmaceuticals, and so works against the public interest, in the following respects:

11.24

(*a*) It permits compulsory licensing of pharmaceutical patents without setting out any objective standards against which to determine whether the public interest is already being served;

(*b*) a single individual, the Patent Commissioner, holds almost absolute power to decide whether a licence should be granted, and to determine what royalty should be paid;

(*c*) it does not provide that the patentee should be adequately compensated for what he loses when a licence is granted;

(*d*) there is a clear threat to the public health in the proliferation of imitative products introduced without adequate attention to the scientific capabilities of the manufacturer or distributor, capabilities which should go far beyond the ability to manufacture to minimum standards.

5. Section 67 of the Patent Act contains full provision for compulsory licensing where a patent is not being worked or is otherwise abused. In addition, Section 19 allows for the over-riding interest of the Government of Canada.
6. Effective application of Section 67 would serve as a strong incentive to the expansion of pharmaceutical and pharmaceutical chemical manufacturing in Canada, since it treats the non-working of a patent as grounds for compulsory licensing. This incentive does not exist under Section 41(3).

11.25

In the light of these facts, we make the following recommendations:

1. The protection of the public interest requires the establishment of a properly qualified tribunal to decide on compulsory licence applications in the first instance. This tribunal should be composed of men able to pass judgment on legal matters, economic arguments and medical and scientific implications.
2. It should be clearly stated what matters this tribunal will take into account during its review of a licence application, including the elements to be considered in arriving at an equitable royalty.

3. A compulsory licence should be granted on economic grounds only if the tribunal finds that the patent is being abused or not used for the public interest.
4. There should be full right of appeal from the decisions of the tribunal, with a definite determination of the bases on which an appeal can be made, regarding both the licence itself and the royalty granted.
5. *There should be an early revision of the Patent Act, leading to the establishment of a tribunal with the composition and powers outlined above.*

12.1

THE QUESTION OF "GENERIC EQUIVALENCY"

There are two ways of designating a pharmaceutical chemical—by its lengthy chemical appellation, and by what has come to be known as the proper, nonproprietary, common or generic name. This is derived from the chemical appellation. A brand name, however, fulfils a different function. It establishes the manufacturer's responsibility for a particular drug product.

An editorial, published in the Journal of the American Medical Association of November 9, 1964, concluded its comments on "Drug Names" with the following advice:

> "The preface of the second booklet published by the USAN (United States Adopted Names) Council in February, 1964, states: 'Teaching in pharmacy and medicine requires a common designation especially for a drug that is available from several sources. Nonproprietary names greatly facilitate communication between physicians. . .' So it is that physicians should be encouraged regularly to use non proprietary names, recognizing, however, that such usage is solely for educational purposes and does not provide assurance of the quality and potency of products prescribed.
>
> "To enlarge on the latter point, the physician who prescribes meprobamate as such has no way of knowing that his patient will receive the drug in a form of highest quality and expected potency. Careful prescription writers provide the necessary assurance in one of three ways: by writing the nonproprietary name plus the name of a manufacturer known to be reliable; by writing the desired brand name; or by writing the nonproprietary name plus the desired brand name. The third method has the modest advantage of reducing the likelihood that the pharmacist will make a mistake in filling the prescription.
>
> "When a physician uses a brand name or a manufacturer's name to designate the source of supply, he is fulfilling a part of his professional obligation to his patient. Having decided that medication is required, he should assume the responsibility for selecting a manufacturer who will supply the drug in a therapeutically effective form at the lowest possible cost to the patient."

12.2

The members of our Association and most other Canadian companies market most of their products under brand names. In so doing, they follow the general international pattern of the industry. There are also a smaller number of companies which market products according to the generic name of the active

ingredient, though some, in the interests of their company reputation, find it necessary to mark the drugs with a company identification, and use advertising and salesmen to promote the products of their particular company. This was acknowledged by Mr. L. L. Winter of Empire Laboratories Limited in his evidence before the Special Committee of the Commons. (Proceedings p. 381)

Both the Restrictive Trade Practices Commission and the Hall Commission called for wider generic prescribing by Canadian doctors—in order to reduce the cost of drugs. Certain questions are raised here.

The Scope of Generic Prescribing

Only a certain proportion of prescription drugs—those containing a single active ingredient or named in a recognized pharmacopoeia—can be sold easily by generic name. Studies in this connection were presented to the Hall Commission by the Canadian Pharmaceutical Association (Brief pp. 39-40). They show that about half the prescription products available are mixtures, and only about a quarter have so-called generic equivalents. In some cases, the latter are also brand-name products. In this connection, it should be noted that in many instances—and for a variety of reasons—a pharmacist will fill a generic prescription with a brand-name product.

12.3

Experience of Purchasing by Price Alone

Hitherto, government, hospitals and other institutions have been the main purchasers of drugs by generic name, it being assumed they possessed the means to ensure quality. However, as Dr. Showalter of the Department of Industry testified before the Special Committee of the Commons, the government has had its troubles with products bought by price alone. "The practice of competitive bidding on price seems to have resulted in obtaining supplies mainly from the least competent or possibly the least scrupulous suppliers." (Proceedings p. 416) This was the origin of the decision to develop the CGSB standards for companies wishing to tender for government business. Related concern about the quality of prescription drugs available to the public led the Committee to recommend that all manufacturers and distributors be registered so that they can be inspected by the Food and Drug Directorate. The Committee also commented that, "It is known that so-called generic firms present greater problems for the Food and Drug Directorate." (Proceedings p. 517)

Highly relevant, too, is the evidence given by Dr. K. J. R. Wightman, Professor of Medicine at the University of Toronto, to the Special Committee of the Commons, describing on behalf of his hospital why "we are not buying large amounts of the generic kind of thing." (Proceedings pp. 403-409)

12.4

The Fate of Alberta Bill 107

In April 1962 the Alberta government passed a bill that enabled pharmacists to substitute generic-name equivalents for brand-name products unless specifically ordered not to by the physician. This legislation has had little or no impact. According to "Drug News Weekly" of February 15, 1964, Donald Cameron, Registrar of the Alberta Pharmaceutical Association, has stated that about 88 per cent of the doctors in the province prescribe by brand name. He is quoted as follows: "Doctors are wary of prescribing generics because there have

been too many reports of cases where cheaper drugs were used without success or with disappointing results, thus eventually increasing the overall cost."

The Limits of FDD Action

Registration of manufacturers and the strengthening of the Food and Drug Directorate—both proposed by the Special Committee of the Commons—would certainly lessen the danger of poor-quality drugs finding their way onto the Canadian market.

But it should also be recognized that government inspection can never guarantee the quality of all drugs sold in Canada. This was explained by Dr. C. A. Morrell, then Head of the FDD, in his appearance before the Special Committee of the Commons:

> "...I am loath to have people say that a drug is guaranteed by the Food and Drug Directorate. I do not see how we can guarantee it. There are many subtleties, and we have not the facilities to detect differences... You cannot put 'government approved' on a drug."
>
> (Proceedings p. 158)

A major weakness in the Hall Commission approach to prescription drug services is its failure to appreciate the inevitable limitations on governmental action. This is most evident in the section of the Hall Commission report entitled "Quality of Drugs" (pp. 366-370). An analysis of that section is attached as Appendix K.

12.5

A Sound Approach

It is our belief that open competition between qualified suppliers is the best way to serve the interests of the Canadian people where drugs or any other products are concerned. Such competition is not encouraged by the destruction of long-accepted methods of protecting the legitimate rights of the manufacturing companies. Further, safety and progress should be factors of paramount importance in the development of policies regarding the pharmaceutical industry. Special care needs to be taken to ensure that firms producing or distributing drugs do contribute to these purposes, and are capable of meeting the resulting responsibilities.

The requirements for sound drug purchasing were described by Dr. C. A. Morrell, when he was serving as Chief of the Food and Drug Directorate:

> "When it comes to buying top-quality drugs, the things to check are the ability, facilities, personnel and conscience of the drug manufacturer. Neither a brand name nor a drug's generic name is the sole reliable guide to quality. The real point is who makes the drug and how it's made—the control system that ensures careful and scientific testing for potency and reliability."
>
> (Globe & Mail, August 18, 1960)

Is there Such a Thing as Equivalency?

We have discussed the safety considerations involved in the generic drug question. There is also the broader question of whether any two prescription drug products, even though containing the same active ingredient, can be considered truly equivalent. Long experience, backed by considerable scientific evidence, leads our companies to believe that this is rarely the case.

12.6

The preponderance of brand name prescribing by Canadian physicians would seem to validate this point of view. And in his evidence before the Royal Commission on Health Services, Dean F. N. Hughes of the School of Pharmacy of the University of Toronto made this statement:

> "We believe the principle of requiring practitioners to prescribe medicine only by chemical or generic name to be entirely wrong. This presupposes that any given dosage form containing the same quantities of a drug will have the same clinical effect. It has been clearly shown that this does not necessarily follow." (p. 9945)

The many factors of product formulation which can affect therapeutic efficiency were reviewed succinctly in an article by Dr. Max S. Sadove et al. which appeared in the February 1965 issue of American Professional Pharmacist. This is attached as Appendix M.

The practising physician should certainly be informed about the cost of therapy as he is about its effectiveness, and we support the Hall Commission recommendation for more extensive efforts in this area. However, maintenance of the physician's freedom to prescribe the drug of his choice is of over-riding importance. In this connection, we would cite the forceful statement made by the Hinchliffe Committee in Britain, many of whose views have been reprinted with approval by the Hall Commission:

> "The clinical and academic freedom of the general practitioner must be maintained. The loss of self-respect consequent on any departure from the principle, which has been accepted as fundamental to the National Health Service in this country, that a doctor can prescribe any drug which he considers necessary for his patients, would lower the status of the profession and ultimately have an adverse effect on the whole medical service provided for the patient. The doctor must be the sole judge of his patient's requirements for treatment." (p. 62)

13.1

THE PROVISION OF PRESCRIBED DRUGS UNDER MEDICARE AND WELFARE PROGRAMS

There is growing interest throughout Canada in the provision of prescribed drugs as part of medical service plans, whether for the population as a whole or for people in receipt of welfare assistance. The Hall Commission recommended a Prescription Drug Benefit, which would require contributory payments and be based on a National Drug Formulary. Certain provinces have lately made new arrangements for the provision of drugs to their citizens on welfare, while others are working on broad plans for prescription prepayment or insurance.

As stated in the introduction to this brief, "we believe it axiomatic that in a country which has attained the general standard of living of Canada no citizen should go without needed medication because he cannot afford it." We would point out, however, the importance of every Canadian receiving pharmaceutical products which meet "the highest standards of safety, reliability and therapeutic effectiveness." The range and quality of the preparations doctors may prescribe, whether for patients as a whole or for a particular class of patient,

should depend solely on therapeutic considerations. (Our reasons for this position are presented in the preceding section.)

It would scarcely be logical for government to develop plans designed to assure all citizens of the physician's services they need, and then limit the means of treatment the physicians may prescribe. In view of the comparative size of the national expenditures on physicians' services and prescribed drugs as documented by the Hall Commission (this brief Section 1,) such a policy may well be described as spoiling the ship for a ha'p'orth of tar.

13.2

With these major purposes in mind, our Association has formulated and made public the following set of nine principles that should govern, we believe, the provision of prescription drugs under health service programs:

1. It is the responsibility of the pharmaceutical manufacturer in co-operation with the professions of medicine and pharmacy to search, develop and provide safe and effective drugs of the highest quality.
2. It is a co-operative responsibility of the manufacturer and the pharmacist to make safe and effective medications of high quality immediately available in all parts of Canada.
3. It is the right of the physician to prescribe the drug preparation of his choice.
4. Nothing must be allowed to interfere with the duty of the pharmacist to respect the integrity of the physician's prescription.
5. It is the citizen's right to consult the physician of his choice.
6. It is the citizen's right to have his prescription dispensed by the pharmacist of his choice.
7. It is the responsibility of any agency paying for drugs to recognize the rights and duties of the physician, the pharmacist and the citizen.
8. The respect of industrial property rights as represented by patents and trade marks is the essential foundation for progress in research and therapeutics.
9. A pharmaceutical benefits program which assists the needy and encourages the self-supporting to provide for themselves will best meet the requirements of the people of Canada.

13.3

These principles set out a general framework. We have made specific proposals relating to the provision of drugs for welfare recipients to the governments of British Columbia and Quebec. In these, we offered our co-operation in determining through survey and analysis the exact incidence of different types of drug requirement as a basis for cost control. We suggested a system for obtaining a rebate of the Federal sales tax on products dispensed to welfare patients, since such products are effectively purchased by the provincial government. Finally, we reported that, although the Association could not legally commit its members to any pricing policies, many of them had expressed a willingness to place their experience at the disposal of public health authorities.

So far as the general provision of prescribed drugs is concerned, we have worked with the Canadian Pharmaceutical Association in developing its proposals for Pharmacare, and we consider this an effective plan for meeting the real needs of the large majority of Canadians.

14.1

RECOMMENDATIONS RELATING TO THE COST OF DRUGS

In general, we consider that the prices charged for the prescription drugs made and sold by our member companies are fair and reasonable as evidenced by information in Section 4. These are products of the highest quality, the fruits of intense and continuing international research. Their proper availability across Canada depends on sustained programs of medical information and promotion, and on a nation-wide distribution network. Those who manufacture and distribute the drugs must meet the costs of doing business in Canada with regard to salaries, wages and the purchase of materials, goods and services.

In this connection, we would draw attention to the following statement by the Hall Commission:

> "We conclude on the basis of the evidence presented to us that it is the unequal and generally unpredictable incidence of heavy drug costs that have given rise to the greatest concern on the part of the public, rather than what has been described as the 'high costs' of drugs as such." (Report, p. 355.)

We have, however, a number of recommendations bearing on the cost of drugs. Some of these would reduce the price of drugs generally, or the prices of certain products, or the prices to certain groups of citizens. Others would convey to the professions concerned and the general public more extensive and precise information about the cost of particular products.

1. We strongly support the recommendation made by many groups and individuals that the Federal sales tax on prescription drugs be abolished. This would reduce the manufacturer's prices by approximately 10 per cent.

14.2

2. There is a clear requirement for much wider availability of programs for drug insurance or prepayment. These would greatly assist the relatively small number of Canadians who find buying prescription drugs a real burden, whether due to personal circumstances or to the impact of either catastrophic or chronic illness. As reported in Section 13, a joint study has been made by PMAC and CPhA of the feasibility of prescription drug insurance, and a model insurance plan has been developed. Such a program would satisfy the requirements of most Canadians, and provide an effective vehicle through which government can help those who need assistance. (See Appendix N.)

3. As mentioned in Section 9 of this brief, we support the establishment of an independent source which would provide doctors and pharmacists with accurate and up-to-date information about pharmaceutical products. The size of companies' expenditures on medical information and promotion relates directly to the effectiveness of these activities. Should such a foundation prove to have a significant influence on the prescribing habits of physicians, its activities might well modify the extent of promotional activity.

4. Recommendation 82 of the Hall Commission calls for the development of more comprehensive and up-to-date statistics relating to the cost of drugs and expenditures on drugs. We believe that the provision of more detailed and more broadly-based statistics would be helpful to all who are concerned with the development of drug benefit programs, and would generate valuable information for the general public. We would be happy to work with the Dominion Bureau of Statistics or other authorities in the elaboration of such a program.

14.3

5. We favor a cooperative program by the universities, medical and pharmacy associations, and pharmaceutical manufacturers to provide physicians with more extensive information about the cost to their patients of particular drug therapies. In fact, some companies now include information about the approximate cost of therapy in their medical literature.

6. The Association approves the action taken by some member companies to abolish suggested catalogue prices for drug products available only on prescription, leaving the retail pharmacist to assess the sum necessary for the proper compensation of his services. In this connection, we acknowledge the support given increasingly by representatives of retail pharmacy to a cost-price-plus-professional-fee system for pricing prescriptions. This system generally has the effect of increasing somewhat the price of the cheaper prescriptions but markedly reducing the price of those prescriptions most often criticized as being unduly expensive.

14.4

7. The Hall Commission has recommended that the Government of Canada, assisted by the Drug Advisory Committee, sponsor jointly with the drug industry and such provincial governments as wish to participate, a study of the feasibility of a voluntary drug price restraint program for Canada, for implementation on a trial basis for a period of five years. (Recommendation 73, Report p. 43.) The members of our Association stand willing to enter into any discussions about the prices of their products which the governments concerned should consider desirable. We would, however, reiterate our position that such negotiations must take cognizance of the nine principles set down in Section 13.

NOTE: The recommendations are printed in Issue No. 4, June 16, 1966.

24630—12½

Appendix A to Brief

PHARMACEUTICAL MANUFACTURERS ASSOCIATION OF CANADA

1110 Gillin Building,
141 Laurier Avenue, West,
Ottawa 4, Ontario.

MEMBERSHIP APPLICATION FORM

Pharmaceutical Manufacturers Association of Canada is an incorporated national association of companies engaged in manufacturing and distributing pharmaceutical products prescribed or used by the medical profession. The principal aim of the Association is to advance the interests of pharmaceutical manufacturers. Its objectives are:

To promote and encourage the inter-change of knowledge and ideas for the betterment of the pharmaceutical manufacturing industry and its services;

To foster mutually constructive and satisfactory trade relations and to maintain and improve public relations;

To co-operate with legislative committees, government departments and agencies, medical and pharmaceutical societies, and other bodies in respect to matters affecting the pharmaceutical manufacturing industry;

To promote among the members of the Association a spirit of friendly co-operation, thereby striving for cordial intra-industry relations.

Membership is by election. Applicants for membership are required to abide by the Association's Principles of Ethics, Code of Marketing Practice, By-Laws, and other rules and regulations which may be in force from time to time.

In addition, applicants are required to offer evidence to the effect that they have been inspected by and qualify under the PMAC Standards on Manufacture and Quality Control.

There are two membership categories:

FULL MEMBERS: Corporations or firms which manufacture and distribute, or distribute under their own labels, in Canada, under proper conditions for control of quality and standards, pharmaceutical preparations dispensed or prescribed by physicians.

A.2

ASSOCIATE MEMBERS: Corporations or firms which do not distribute pharmaceutical preparations under their own labels in Canada but which either manufacture pharmaceutical preparations in dosage form for others or supply the pharmaceutical chemicals for use in making pharmaceutical preparations. Firms or corporations engaged in scientific research with the intention of distributing pharmaceutical preparations under their own labels in Canada are eligible for election to associate membership on an annual basis until such time as they commence distributing under their own labels in Canada and thus become eligible for full membership.

Where the parent company is located outside of Canada, membership is open to the Canadian subsidiary or branch only; the Canadian address of such subsidiary or branch only shall be carried on the official roster of the Association.

A.3

PMAC Membership Application

NOTE: The following questions apply only to the company's pharmaceutical operations, and not to other lines of manufacturing in which the applicant may be engaged.
Please check the boxes applicable: ☐

PART I

1. Name and address: .....
.....
2. State names of principal officers or partners: .....
.....
.....
3. State addresses and types of branch offices in Canada: .....
.....
.....
4. State when business of applicant was established: .....
5. State whether this application is for:
Full Membership ☐ or Associate Membership ☐
6. Check function of your organization in Canada:
Production ☐ Distribution ☐ Packaging ☐ Custom Manufacturing ☐ Fine Chemicals ☐
7. (a) State whether your products sold in Canada are manufactured by:
The Canadian Company ☐ Parent Company ☐ Associated Company ☐ Custom Manufacturer ☐
(b) If your products are made by one or more custom manufacturers, state names of all companies doing such work for you:
.....
.....
.....

A.4

PMAC Membership Application

8. State channels through which goods are distributed: .....
.....
.....
9 State number of employees in Canada: Total .....
Production ..... Sales ..... Packaging ..... Other .....
10. (a) State whether your company qualifies for sales to government under Canadian Government Specifications Board Standard 74-GP-1a, and has passed government inspection for this purpose:
YES ☐ NO ☐
(b) If "No", explain reason in covering letter.
(c) If your company has qualified, please attach to this form a copy of the letter of compliance which you have received from the Federal Government.

PART II

NOTE: The following questions in Part II apply to the Canadian operations of a company which manufactures on its own premises in Canada, or to the parent company operations of a non-manufacturing company which is a subsidiary of a foreign corporation.

11. (*a*) State whether the following questions in Part II apply to: The Canadian Company ☐ or Parent Company ☐

(*b*) If Parent Company, state name, city and country where located:

.....

A.5

PMAC Membership Application

12. (*a*) State name and qualifications of full time employee responsible for production:

.....

(*b*) To whom does he report (executive position):

.....

13. (*a*) State name and qualifications of full time employee responsible for quality control:

.....

(*b*) To whom does he report (executive position):

.....

14. On a blank sheet, to be attached to this application, give a brief description of the Production and Quality Control administrative organization of your company. Indicate separate departments, such as manufacturing, packaging, engineering, maintenance, etc. In addition list the number of employees on each group mentioned, and indicate those who are technically trained.

15. State the type of products manufactured:
Oral ☐ Parenteral ☐ Topical ☐ Veterinary ☐ Other ☐

16. State whether you perform your own analytical work in the control of your products:

	Yes	No
(*a*) Chemical	☐	☐
(*b*) Sterility	☐	☐
(*c*) Biological	☐	☐
(*d*) Microbiological	☐	☐

17. If the answer to any part of question 16 is "No", describe the facilities employed:

.....

.....

.....

A.6

PMAC Membership Application

18. State which department in your company is responsible for each of the following functions:

Function	Company Department
(*a*) Raw materials specifications:	.....

Fonction	Company Department
(b) Release of raw materials for manufacturing use:	.....
(c) Establishment of formula:	.....
(d) Establishment of manufacturing procedures:	.....
(e) In process control of manufacturing procedures:	.....
(f) Packaging materials specifications:	.....
(g) Finished package specifications:	.....
(h) In process control of packaging procedures:	.....
(i) Release of products for distribution:	.....
(j) Disposition of returned merchandise:	.....

PART III

19. Are you willing to have your premises inspected by a special committee of the Association Yes ☐ No ☐

20. State whether you subscribe to and agree to abide by the following, and kindly place your signature opposite each item:

(a) The P.M.A.C. Principles of Ethics:	.....	.....
(b) The P.M.A.C. Code of Marketing Practice:	.....	.....
(c) The P.M.A.C. By-Laws:	.....	.....
(d) Other P.M.A.C. rules and regulations which may be in force from time to time	.....	.....

A.7

PMAC Membership Application

21. Kindly attach to this application two copies of a catalogue or descriptive list of your company's products.

Signed by: .....
Name of Chief Executive Officer.

....
Date Title

.....

FOR PMAC OFFICE USE ONLY

Received ..... Approved .....
Checked ..... Category .....
Inspected ..... Date .....
CGSB .....

Appendix B to Brief

Pharmaceutical Manufacturers Association of Canada

PRINCIPLES OF ETHICS

Every member subscribes to the following principles of ethics and undertakes to abide by them:

I

The calling of a pharmaceutical manufacturer is one dedicated to a most important public service, and such public service shall be the first and ruling consideration in all dealings;

II

The pharmaceutical manufacturer must produce his preparations only under proper conditions and with scrupulous faithfulness to required standards of quality;

III

Preparations must be labelled and merchandised only in a manner free from misrepresentation, misleading practices of all kinds and in entire harmony with the highest standards of commercial morality and professional ethics;

IV

In his dealings with his fellow manufacturers and in his dealings generally, the pharmaceutical manufacturer shall be actuated by a sense of fairness and justice and his conduct shall in every way be consistent with honourable business practice. More particularly, he shall refrain from misappropriating the trade names of others, or their formulae or the distinctive form or dress of their products. He shall also refrain from making false or disparaging statements about his competitors or their products;

V

Pharmaceutical manufacturers must constantly and conscientiously strive to advance the science and elevate the calling of manufacturing pharmacy to the highest plane of public value, to the end that it may best and most completely serve the medical profession and the public.

Appendix C to Brief

Pharmaceutical Manufacturers Association of Canada

CODE OF MARKETING PRACTICE

The PMAC Code of Marketing Practice consists of four sets of standards, which govern drug advertisements directed to the medical profession, conduct for medical service representatives, hiring and training of medical service representatives, and hospital activities of medical service representatives. These various standards are attached to this preamble.

The three sets of standards governing the conduct, hiring and training, and hospital activities of medical service representatives, were prepared by the PMAC Marketing Section and adopted by the Board of Directors on January 21, 1965.

The Standards Governing Drug Advertisements Directed to the Medical Profession were prepared by the PMAC Government Relations Division and the Marketing Section, and were submitted to the membership for vote by ballot. They were adopted by the Board of Directors on January 21, 1965, and are to become effective on January 1, 1966.

Following is a review of the principles behind these various standards.

Pro Omnibus

Pharmaceutical research would be of little value if the results of this research were not made widely known to the professions concerned. It is, therefore, essential that the medical and allied professions be promptly, fully and reliably informed of the existence and properties of the medicines which are available for them to prescribe, use or supply. The pharmaceutical manufacturing industry is an important source of information on therapeutic developments resulting from its research and, as a consequence, must be free to disseminate information on its products, based on ethical considerations as identified in this Code.

Recognizing our responsibility to the public welfare and our obligations to the medical and pharmaceutical professions, we, the members of the PMAC, pledge ourselves to the following principles of ethical drug marketing.

General Provisions

Marketing activities include the spoken as well as the written word, direct mail and journal advertising, films and any other medium used for the communication of information on medical specialties.

1. Claims for the usefulness of a product shall be based on acceptable, scientific evidence, and should reflect this evidence accurately and clearly.

2. Medical claims and assertions contained in promotional communications shall have medical review and approval prior to release.
3. Prompt, complete, and accurate information concerning therapeutic agents shall be made available to the medical and pharmaceutical professions.

4. Quotations from medical literature, or from the personal communications of clinical investigators in promotional communications, shall not change or distort the true meaning of the author.
5. The release to the lay public of information on the clinical use of a new drug or to a new use of an established drug, prior to adequate clincal acceptance and presentation to the medical profession, is not in the best interests of the medical profession or the lay public.
6. Reference to other manufacturers or their specialties shall be restricted to a factual comparison.

Journal Advertising and Promotional Literature

1. The advertising practices of member companies are based on the desire to impart product information and knowledge and are governed by provisions as stated in the foregoing General Provisions.
2. Policies of member companies with regard to direct mail advertising and journal advertising are individual and reflect the marketing practices of the companies concerned. All members agree that such promotion should in no way be offensive to the physician and should conform to the high ethical standards of the profession.
3. Guided by regulations of the Food and Drug Directorate, advertising material containing scientific and technical information should give doctors and members of allied professions as complete a picture as possible of the properties of the product, based on current scientific knowledge.
4. All member companies agree to abide by the PMAC Standards Governing Drug Advertisements Directed to the Medical Profession, a copy of which is attached.

Medical Conventions

Member companies attending any medical or allied convention shall abide by the Medical Exhibitors' Association's regulations and recommendations, to which PMAC subscribes.

Medical Service Representatives

In their desire to maintain the best relationship with the health professions, member companies of PMAC and their medical service representatives are governed by the standards comprising the Code of Marketing Practice.

C.3

Pharmaceutical Manufacturers Association of Canada

Standards Governing Drug Advertisements Directed to the Medical Profession

For the purpose of these standards "advertisement" means any representation made to the medical profession through the media of:

(1) Medical journal advertising.
(2) Books and publications directed to the medical profession where the manufacturer has jurisdiction over the material appearing, e.g., Vademecum International and similar books of reference.
(3) Direct mail advertising.

An Advertisement Containing Therapeutic Claims Must include Clearly and Concisely:

(1) The official, proper or chemical name of the drug.
(2) A quantitative list of the medicinal ingredients contained in each dose or unit.
(3) The recommended dosage, method of use and route of administration.
(4) A reference to side effects, precautions and contra-indications of the drug in the recommended dosage and a statement that detailed information of these is available on request.
(5) Any precautionary statement required by the Food and Drug Directorate relating to the pharmacological action of the drug.
(6) The name of the advertiser.

In addition:

(7) Claims for the usefulness of a product must be based on acceptable scientific evidence and must reflect this evidence accurately and clearly. A claim made within quotation must conform to the same standards as a claim not presented in the form of a quotation.
(8) In the case of a new drug or one upon which considerable clinical experience has not been accumulated, it must not be stated categorically that the drug has no side effects or toxic hazards.
(9) Advertising copy should reflect an attitude of caution particularly with respect to the use of drugs which have not been studied for prolonged periods.
(10) Statements and illustrations made in promotional material should be in good taste and should present the facts in an unequivocal manner.

C.4

Any infringment of these Standards Governing Drug Advertisements Directed to the Medical Profession will be considered a breach of PMAC Principles of Ethics and dealt with accordingly.

The above regulations do not apply to advertisements of a reminder type for an establishd product, providing such advertisements contain no recommended dosage or therapeutic claims but are restricted to a general statement as to class or kind of medication, e.g., analgesic, antibiotic, anti-depressant, etc. Such reminder advertisements must, however, include the following:

(*a*) Proper or official name.
(*b*) The statement "Full information is available on request."
(*c*) Company name.
(*d*) A brief reference to Food and Drug Directorate warnings when these warnings are directed to the medical profession. It is not necessary to repeat the warning in full and it is not necessary to refer to warnings directed to the public.

C.5

Pharmaceutical Manufacturers Association of Canada

Standards of Conduct for Medical Service Representatives

The Medical Service Representative shall by his conduct reflect high professional and moral standards at all times, so that he may be a credit to the

pharmaceutical industry and favourably influence the members of the medical and pharmaceutical professions. He will agree to maintain the standards of conduct as specified by the PMAC.

1. *Appearance*

He will be neat, clean and well groomed and will dress according to professional business standards. His literature, samples, bag, car, etc. will also reflect the high standard of neatness and cleanliness expected of his person.

2. *Attitude*

He will reflect pride in his profession and his company, and support them with facts in any dicussions which may arise during or after business hours.

3. *Reliability*

He will carry out all commitments and promises and make them only within the confines of the policies of his company.

4. *Vocabulary*

He will use no profanity but maintain the level of language of his professional customers and his voice will be modulated so as not to offend patients of customers.

5. *Honesty*

He will be honest in all his dealings and should provide professional contacts with full and factual information on his products, with no attempt at misrepresentation or exaggeration.

6. *Accuracy*

His statements must be accurate and complete and must not mislead either directly or by implication. His product knowledge should be maintained at a level which will enable him to fluently converse with the professions and supply necessary information on his products. His assertions must be scientific and backed up with medical evidence. Such professional standards of honesty and accuracy are to be maintained at all times so that a high professional stature will be accredited to the individual sales representative, his company and the industry as a whole.

C.6

7. *Deportment*

He will observe the conventions of courtesy to competitors as he would to his customers. He will not initiate discussion of a competitive product by name, or criticize a competitive product, company or its personnel. He will observe the usual courtesies such as:

(*a*) Smoking only on invitation in the doctor's office, pharmacy or hospital.

(*b*) Sitting down only when invited to do so in the doctor's office.

(*c*) Placing his detail bag on the floor only, and in a non-traffic area.

(*d*) Applying no forceful tactics to interview doctors in their offices or at hospital and convention exhibits or any other place such as hallways, etc., which could be classified as "buttonholing the doctor".

(*e*) Avoid offering inducement or employing subterfuge to gain an interview with a doctor or pharmacist.

(*f*) He should acquaint himself with office, store and hospital protocol, and adhere strictly to any special ruling which he may encounter.

(*g*) Observing the precedence principle that if a competitor is already in a doctor's office, the representative shall depart until completion of business, unless he has an appointment or local conditions dictate otherwise.

(*h*) Yielding his seat to patients in a crowded physician's office or hospital.

(*i*) His contact with patients and customers should be socially and professionally above reproach.

(*j*) Addressing the physician formally as Doctor, preferably by name (such as Dr. Jones) in the presence of other physicians and associated personnel no matter how well he knows the doctor, unless the doctor indicates otherwise.

(*k*) Refraining from walking into doctors' private offices, or prescription departments, without permission.

(*l*) Removing his hat when entering a doctor's office or a prescription department.

(*m*) Departing from competitors' exhibits on the approach of a physician.

C.7

(*n*) Observing the rules of the Medical Exhibitors Association at medical conventions.

C.8

Pharmaceutical Manufacturers Association of Canada

Standards of Hiring and Training of Medical Service Representatives

The Medical Service Representative symbolizes his company and the pharmaceutical industry in the eyes of the medical and pharmaceutical professions. To ensure that the Medical Service Representative is qualified and trained for this role, the following Standards of Hiring and Training should be followed:

1. It is desirable for a representative to be a university graduate and that he be required to submit proof of this standing.
2. It will be found helpful if the applicant for the position of medical service representative is interviewed on different occasions by two or more responsible individuals within the company and, if possible, one of these interviews is held in the applicant's home with his wife present.
3. The prospective employer should thoroughly investigate the applicant's character and personal life.
4. It will be helpful for the company to utilize various aids which are available to assist in screening applicants, e.g., aptitude and intelligence tests, retail credit investigation, etc.
5. Prior to employment, it would be desirable to have the applicant work one or two days with one of the company's better representatives, in order to field test the applicant on interest and adaptability to the job.
6. Before employment, the applicant should be required to pass a medical examination.

7. All references submitted by the applicant, particularly those of former employers should be carefully checked prior to employment.
8. An extensive period of supervised training, in both the classroom and the field should be given every representative following employment. This training will vary with different companies but should be long enough to give the representative adequate background information and training to enable him to properly present the technical aspects of his company's products.
9. Indoctrination into the principles of ethics and standards of performance and conduct should be included in all training programs.
10. Member companies are urged to implement supervised training programs in the field for all representatives.

C.9

11. Member companies are urged to implement periodic refresher courses for all representatives.
12. Member companies are asked to encourage their representatives to undertake courses of study and self-improvement, aside from the training provided by the company, such as the Dale Carnegie Course, salesmanship courses, Toastmasters' Club, etc.
13. Member companies should encourage representatives to enter into community activities.

C. 10

Pharmaceutical Manufacturers Association of Canada

Standards Governing Hospital Activities of Medical Service Representatives

Aims of the Standards

1. TO ESTABLISH METHODS WHEREBY Medical Service (Pharmaceutical) Representatives can provide information and service to physicians, pharmacists, medical staff and hospital officials in hospitals,

and

2. To establish methods whereby problems of mutual interest may be discussed and solved as they arise.

With full realization that procedures usually vary with the policy and organizational structure of each institution, the following Standards are prepared for guidance. The Pharmaceutical Manufacturers Association of Canada will endeavour to have these Standards uniformly adopted and every effort will be made to guard against infractions:

Hospital Policy

(*a*) The representative should see the written hospital policy for pharmaceutical representatives where one exists. If a written hospital policy is not available, the representative should complete the hospital's Interview Form when requested by the chief pharmacist or appropriate administrative officer.

(*b*) Representatives should be ware of the policies of each hospital and follow them carefully.

2. *Attitudes and Deportment*

(a) Representatives should conduct themselves as guests of the hospital at all times in carrying out hospital work, and no attempt should be made to attract undue attention.

(b) Every effort must be made to avoid interference with normal activities of the hospital staff. Promotional work should be carried out in a pleasant and courteous manner.

(c) A physician who does not wish to enter into conversation should not be forced to do so by a representative.

(d) Although no restrictions are placed on the normal detailing of physicians, the members of the Pharmacy and Therapeutics Committee should not be detailed *in their official capacity* without prior consultation with the Chief Pharmacist.

C. 11

3. *Appointments*

(a) Appointments should be made prior to visits if it is the custom of the hospital.

(b) Under no circumstances should an individual physician be summoned through the hospital "locating" system, unless prior permission has been obtained. In any event, the representative should always identify both himself and his company.

4. *Sampling*

(a) Representatives should be guided by hospital and Food and Drug Directorate regulations in distributing samples. Under no circumstances are samples of drugs to be given to unauthorized personnel.

(b) If investigational drug material or clinical trial drugs or samples to be used on hospital patients are given to a physician by a pharmaceutical representative, the representative should inform the Chief Pharmacists of the hospitals where the physician has privileges when possible.

5. *Hospital Exhibits*

(a) Scheduling more hospital exhibits than are allowed by existing regulations should be avoided.

(b) Notices of exhibits should be placed on hospital bulletin boards only after receiving the approval of the proper hospital officials. Residents, interns and nurses should be invited to visit the exhibit only after obtaining the permission of the proper hospital official.

(c) The assigned arrival and departure times should be followed carefully.

(d) An exhibit suitable for the space available should be used, and set up without disturbing normal routine, or calling for assistance.

(e) The representative should remain at the exhibit. The exhibit should be kept neat and tidy at all times.

(f) A physician should not be approached directly. The interview should be initiated only if the physician voluntarily visits the exhibit.

(*g*) All waste paper should be removed and furnishings returned to their original position before leaving the hospital. If at all possible, the hospital official permitting the exhibt should be thanked personally.

C. 12

(*h*) Representatives should follow the hospital policy as to products and literature to be displayed.

NOTE: These Standards have been prepared following consultation with a committee of the Canadian Society of Hospital Pharmacists.

Appendix D to Brief

The Role of the Detailman

Each year our Association undertakes a survey of the number of detailmen employed by member companies and their remuneration and conditions of service. The latest survey shows that 49 companies employed 1,799 detailmen. For the industry as a whole there appears to be about one detailman for every ten physicians. We understand that in the United States and the United Kingdom the figure is in the same range. A proportion of the detailmen employed by our member companies are, however, wholly or largely occupied in working with hospital and retail pharmacists. In general, 40 per cent of detailing time, it is estimated, is spent on calls to hospital staffs and to pharmacists.

A survey conducted by MRC Limited for MD of Canada in 1963, based on interviews with 200 English-speaking physicians across Canada, showed that 98 per cent saw some at least of the detailmen who called on them, with the average number of detail calls received being 11.5 per month, and the average length of time spent with a detailman 13 minutes. A survey conducted in England in 1964 by Research Services Limited, based on interviews with 245 doctors, showed that 73 per cent had seen all the detailmen who called on them. They reported seeing an average of 4.8 detailmen in a two-week period.

The detailman fulfils a number of functions, the emphasis varying according to company and product. Primarily he is the channel of communication between his company and the medical profession. He brings doctors information and literature about products, answers questions within the limits of his traning and knowledge, referring to the medical staff those he cannot answer. He relays back to the company any incidents the doctor may report regarding side effects or unusual reactions to his company's products. He also secures signatures for the samples which physicians request. A number of companies employ specially trained and experienced representatives for liaison work with hospital staffs.

The value of the detailman as a two-way channel of communication cannot be over-emphasized, particularly as in many instances he is acting as the representative of a world-wide organization. The information he provides will have international backing, and that which he acquires can have implications for many countries besides Canada.

The pharmacy side of the detailing job has a number of elements: provision of information about new products, so that the pharmacist will be prepared for the first prescriptions; checking on stocks and in particular making sure that any products with expiry dates have been replaced in time; promotion of over-the-counter products, and the arrangements of suitable point of sale advertising; keeping the pharmacist up to date on company developments.

Should a drug withdrawal ever be required, or a serious warning about any of the company's products, the detailman has a mammoth job to inform as

rapidly as possible both physicians and pharmacists in his territory. His activity will, of course, be supplemented by printed communications.

MD Attitude to Detailing

Physicians generally welcome the detailman system. This does not mean that they receive all the detailmen who call on them. A minority, notably specialists in the larger cities, will not receive any detailmen at all. Others are selective in the time they spend—based on the company, the product, and the man, himself. Similarly, many hospitals have strict regulations about when and how detailmen can call on the medical and other professional personnel. The MRC survey quoted above reported that 23 per cent of physicians screen detailmen in some way. As to the attitude to detailing, 60 per cent said detail calls were welcome, 16 per cent unwelcome, and 24 per cent were neutral or expressed no opinion. On a related question, 68 per cent said detail calls were informative, 14 per cent said they were uninformative, and 18 per cent were neutral or expressed no opinion.

The Research Services Survey from England asked doctors the following question: 'The range of drugs and pharmaceutical products is continually increasing. How do you yourself keep up to date with new developments?' The following were the six major sources listed:

Articles in medical journals	71 per cent
Manufacturers' representatives	36 per cent
Discussions with colleagues	25 per cent
Manufacturers' literature sent through the post	24 per cent
Prescribers Journal (an official publication)	21 per cent
Advertisements in medical journals	18 per cent

No recent similar survey from the United States has come to our attention. However, a comprehensive survey of the Attitudes of U.S. Physicians toward the American Pharmaceutical Industry was published in 1959. It was the work of Ben Gaffin and Associates, and financed by the American Medical Association. It asked these three related questions:

So many new drugs are being developed today that it is getting harder for a physician to keep current. Which two or three of the sources listed do you find most important to you personally in familiarizing yourself with new drugs?

Which two or three of those sources would you say are probably most effective with most doctors?

Which two or three sources on the list would you say are probably least effective with most doctors?

This part of the questionnaire yielded the following results:

D.3

	Most Important Personally	Most Effective Generally	Least Effective Generally
	%	%	%
Detailmen	68	65	5
Journal papers, articles	40	30	7
Medical journal ads	32	26	18
Direct mail	25	23	35
Doctor conversations	24	19	10

Education and Training of the Detailman

What are the detailman's qualifications for his work? Just over 40 per cent of those working for members of our Association have university degrees, predominantly in pharmacy, and 72 per cent have had some university training. The breakdown by academic background for those with university degrees may be summarized as follows:

Pharmacy Degrees	40
Other Science Degrees	26
Bachelor of Arts Degrees	20
Bachelor of Commerce Degrees	8
Post-Graduate Degrees	2
Other Degrees	4
	100

The proportion of detailmen with university degrees is generally higher the larger the detailing force. The following table summarizes the picture for four company categories:

No. of Detailmen	No. of Companies	Total No. of Detailmen	No. with Un. Degrees	Percentage with Un. Degrees
1-20	12	137	47	34
21-40	13	404	101	25
41-60	10	499	220	44
61 and over .	7	500	260	52

Fifty per cent of the detailmen employed by members of our Association have previous selling experience before joining their companies and 20 percent have retail or hospital pharmacy experience. Nevertheless, all of them receive pre-field training which may be for one week or may be for as long as six months. This pre-field training is supplemented by refresher training which, in 75 percent of our member companies, is given at regular intervals. The other companies provide additional training when it appears warranted by the detailman's performance in the field or by his performance in a written examination set by the company.

The basic training is designed to acquaint the detailman with many aspects of pharmaceutical operations, including medical background in the area of this company's products, the ethical presentation of the products, to physicians and pharmacies, Government Food & Drug Regulations, territory management, and

company sales policies and procedures. The refresher courses cover much the same material on a higher and more sophisticated level. Attention is also given to pharmacological and therapeutic aspects of new products introduced since the previous course and to improving the effectiveness of detailmen in presenting product information to the physician. The training covers so many aspects of pharmacy and medical knowledge that after five years with his company the detailman is a professional in his field and looks for security and compensation compatible with his level of competence and experience.

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Compensation

The compensation of a sales representative of a pharmaceutical company is normally divided into two parts: (i) a base salary and (ii) a commission or bonus over and above the base salary. A combination of salary and commission was the manner of remuneration in 3 of the 45 companies included in the survey; salary and bonus in 26 companies; salary, commission and bonus in 8 companies. Of the remaining eight companies, one paid by commission only, six paid by salary only, and one by salary plus prize points.

As might be expected, a salesman's salary is higher the longer his service with his company. Average rates of compensation, by length of service, are summarized in Exhibit 1. Also shown are the range of base salary and gross compensation and the modal (most frequent) value. From this Exhibit, it can be seen that the average starting salary in 1964 was $5378. The average salesman with over 10 years service received a base salary of $7910 in that year. Average base and gross compensation in 1964 may be summarized as follows:

Years of Service (1)	Average Base Salary (2)	Average Gross Compensation (3)	Commission etc (3)-(2) (4)	Commission as % of Av. Gross Comp. (5)
Hiring	$5378	—	—	—
Under 2 yrs. ..	5741	$6192	451	7.28%
2-5 yrs.	6394	7157	763	10.66
5-10 yrs.	7118	8067	949	11.76
Over 10 yrs. ...	7910	8915	1005	11.27

EXHIBIT I

Average Base Salary and Gross Compensation of Detailman in 1964

Period of Service	No. of Companies	Average	High	Low	Mode
(1) Average Base Salary					
Hiring	43	$5378	$ 6000*	$4380	$5400
Under 2 yrs.	43	5741	6701*	4463	5700

Period of Service	No. of Companies	Average	High	Low	Mode
2-5 years ...	44	$6394	$ 7512*	$4517	$6300
5-10 years ...	42	7118	8743	5472	7500
Over 10 years	34	7910	10180	5714	8000
(2) Average Gross Compensation					
Under 2 years	37	$6192	$ 7340*	$5199	$6300
2-5 years ...	39	7157	8885*	5700	6920
5-10 years ..	38	8067	11113	6460	7500
Over 10 years	30	8915	11401	6364	8900

*Note: One company reported average compensation as follows:

Average base salaries	—Hiring	$ 8000
	Under 2 years	9500
	2-5 years	10500
Average gross compensation—	Under 2 years	10700
	2-5 years	11400

Although these figures were the highest in their categories, they have been excluded from the above table as the company has only 4 employees and is not representative of the group.

Source: P.M.A.C. 1964 Survey of Salesmen's Compensation

Cost to the Company

The figures already cited show the average and range of compensation of the detailman. The cost to the company varies depending on the distribution of salesmen by years of service. It is clear that the long a salesman stays with a company, the higher his salary and commissions become. Accordingly, his cost to his company also increases.

The 45 companies in the 1964 survey reported a total employment of 1643 detailmen. The distribution of these men by years of service was as follows:

Years of Service	No. of Detailmen	% of Total
Under 2 years	483	29.40%
2-5 years	424	25.81
5-10 years	393	23.91
Over 10 years	343	20.88
	1643	100.00

When this distribution is applied to the average base salary and gross compensation, the weighted average cost of a detailman to the typical company becomes:

Base salary	6692
Commission	766
Gross Compensation	7458

It may thus be concluded that the average gross cost of a detailman to his company, excluding expense allowances and overhead, was $7458 in 1964.

It is important to bear in mind that these figures are only averages, so that the cost to any one company may be quite different from this figure. The rate of gross compensation may differ from the average and a company may have a preponderage of salesmen with short service or lengthy service, thereby yielding a cost different from the weighted average.

On the latter point, however, it is to be noted that only 9 companies had no salesmen with over 10 years service; 1 had none with over 5 years; 2 had none with 5 to 10 years; and 1 had none with less than 2 years service. The majority of companies had salesmen in all the "length of service" categories.

Other Costs

In addition to salary and/or commission, all companies in the survey reported that their detailmen had an expense account and automobile allowance. The average expense account was reported at $1599 for the year and the average annual cost of a car at $1653. When these costs are added to the gross compensation, the average detailman cost his company $10710 in out-of-pocket costs in 1964.

These costs may be summarized as follows:

Gross Compensation	$ 7458
Travel and other Expenses	1599
Automobile	1653
	$10710

When an adjustment for fringe benefits and other overhead is added to these figures, it is safe to say that the average detailman cost his company $16,000 in 1964.

Appendix E to Brief

PHARMACEUTICAL MANUFACTURERS ASSOCIATION OF CANADA

1964

ANNUAL STATISTICAL SURVEY

TOTAL RESOURCES EMPLOYED

41 COMPANIES

ASSETS	Total 1	Human Pharmaceuticals 2	All Others 3
1. Cash	$ 6,944,444	$ 5,532,258	$ 977,929
2. Accounts and Notes Receivable	25,945,552	18,265,033	6,909,858
3. Inventory	31,399,366	19,789,317	10,342,316
4. Land, Plant and Equipment	49,679,493	40,163,716	8,518,288
5. Accumulated Depreciation	17,286,385	13,719,936	3,332,414
6. All other Assets	9,787,109	7,847,880	1,525,120
7. TOTAL ASSETS	$ 106,469,579	$ 77,878,268	$ 24,941,097

E.2

INCOME STATEMENT—TOTAL COMPANY OPERATIONS
41 COMPANIES

	Total	Packaged Human Pharmaceuticals	All Others Including Bulk Human Pharmaceuticals
REVENUES			
1. Sales (Federal Sales and Excise Taxes not included)	$ 148,053,720	$ 107,784,504	$ 40,269,216
2. Other Income	2,806,174	2,680,892	125,282
3. TOTAL REVENUE	150,859,894	110,465,396	40,394,498
EXPENSES AND TAXES (Except Sales and Excise Taxes)			
4. Cost of Goods Sold	63,816,758	35,399,032	28,417,726
5. Distribution (Including Warehousing)	6,322,984	4,254,333	2,068,651
6. Marketing	38,536,666	32,286,618	6,250,048
7. R and D	7,269,492	7,119,529	149,963
8. Royalties	3,569,651	3,367,893	201,758
9. Administration	14,640,454	11,586,050	3,054,404
10. Interest Charges	381,058	309,435	71,623
11. Income Taxes	8,586,848	8,115,632	471,216
12. TOTAL EXPENSES AND TAXES	$ 143,123,911	$ 102,438,522	$ 40,685,389
13. Net Earnings	7,735,983	8,026,874	(290,891)
14. Dividends (Subtract)	2,127,900	1,873,374	254,526
15. Earnings Retained	$ 5,608,083	$ 6,153,500	$(545,417)

E.3

APPLICATION OF THE REVENUE DOLLAR
FROM HUMAN PHARMACEUTICAL SALES

41 COMPANIES

	Foreign 1	Canadian 2	Total 3
1. Materials	$13,680,107	$14,786,285	$28,761,662
2. Salaries, Wages and Benefits	172,266	29,058,712	30,130,268
3. Depreciation	4,002	1,822,857	1,895,904
4. Taxes	4,602	6,941,397	7,027,146
5. Interest	159,318	151,962	350,555
6. Public Services	4,394	688,817	708,585
7. (a) Management Services Charges (Net after deduction of withholding tax)	2,253,732	21,831	2,298,663
(b) Withholding Tax	36,485	62,727	99,212
8. (a) Royalties (Net after deduction of withholding tax)	2,512,928	382,882	2,965,619
(b) Withholding Tax	210,477	214,793	435,961
9. (a) Dividends (Net after deduction of withholding tax)	1,011,923	630,397	1,690,236
(b) Withholding Tax	82,389	100,999	184,138
10. Other Expenses	1,935,279	25,010,953	27,398,058
11. Earnings Retained	147,463	4,523,256	3,846,075
TOTAL	$22,215,365	$84,397,868	$107,792,082

E.4

HUMAN PHARMACEUTICALS
COST OF GOODS SOLD

41 COMPANIES

1. MATERIAL (cost including freight)	
(a) Imported from Unrelated Company	$ 2,755,956
(b) Imported from Related Company	10,983,239
(c) Canadian Purchases from:	
(i) Related Companies	1,765,538
(ii) Other PMAC Companies	2,028,248
(iii) Others	7,380,068
(d) Duties	1,656,242
2. LABOR	4,178,105
3. PLANT COSTS	4,795,567
TOTAL	$35,542,963

E.5

MARKETING EXPENSES

41 COMPANIES

	Total for year	Physicians' Information	Other
1. (a) Field Selling Expense (Including supervisory and representatives' salaries, living expenses, cars, meetings, equipment etc.)	$16,844,633	$12,176,598	$4,668,035
(b) Administration of Marketing, Selling and Advertising Function (Management and staff services, home office salaries and other expenses of the marketing department, including marketing research)	4,694,395	3,567,047	1,127,348
(c) Advertising and Promotional Expenses	11,438,533	9,980,869	1,457,664
TOTAL	$32,977,561	$25,724,514	$7,253,047
2. How much Did You Spend on the Following During the Year:			
(a) Medical Exhibits and Epace	229,357	190,958	38,394
(b) Medical and Pharmaceutical Journal Advertising	2,331,527	2,118,005	213,522
(c) Direct Mail Advertising	2,739,423	2,509,965	229,458
(d) Samples (This refers to promotional samples only and does not include assay samples, etc.)	3,939,446	3,702,215	237,231
(e) Other:			
(i) Product	1,704,459	1,299,882	404,577
(ii) Non-Product	494,321	331,645	162,676
TOTAL	$11,438,533	$10,152,670	$1,285,858

E.6

R AND D EXPENSES

37 COMPANIES

1. Of Total R and D What was the Amount Actually:	
(a) Spent in Canada	$ 5,504,323
(b) Charged to the Canadian Company by Related Company Outside of Canada	1,579,140
(c) Paid to Non-Related Organizations Located Outside of Canada	8,703
SUBTOTAL	7,092,166
(d) Give a Reasonable Estimate of the Cost of R and D, Performed on your Behalf by Related Companies, But For Which No Charge Is Made	5,439,303
TOTAL	$12,531,469
2. R and D Laboratory Expenses	4,820,833
Clinical Investigation (Including medical department)	1,917,169
R and D Grants (Exclude clinical research grants)	436,232
TOTAL	$ 7,174,234

E.7

EMPLOYMENT

38 COMPANIES

Ph.D.	D.Sc.	M.D.	M.A., M.Sc. or Equal	B. Pharm. B.Sc. or Equal	B.A.	B. Com.
106	3	71	92	884.	192	105

TOTAL EMPLOYMENT: 6,098

APPENDIX F

INTERNATIONAL DRUG PRICES [1]

IN DOMESTIC CURRENCY UNITS

Product	Strength	Pkg. Size (Canada)	Canada Price to Ret.	U.S. Price to Ret.	U.K. Pounds Price to Ret.	Italy Lire Price to Ret.	Germany DM Price to Ret.
Achromycin	250 mg. Caps	16	3.24	2.90	0.77	1,680	15.81
Chloromycetin	250 mg. Caps	16	3.96	5.10	0.68	992	18.21
Terramycin	250 mg. Caps	16	4.17	3.63	0.93	2,225	15.81
Penbritin	250 mg. Caps	16	5.37	4.40	1.29	3,180	25.86
Gantrisin	500 mg. Tabs	100	4.14	2.94	0.800	2,029	9.51
Decadron	0.5 mg. Tabs	100	11.94	9.67	3.19	—	29.33
Librium	10 mg. Caps	100	7.20	7.00	1.000	2,221	11.60
Equanil	400 mg. Tabs	50	3.40	2.90	0.315	—	6.96
Stelazine	2 mg. Tabs	50	3.75	3.93	0.875	967	9.25
Ismelin	10 mg. Tabs	100	4.33	6.80	1.383	1,412	7.58
Hydrodiuril	25 mg. Tabs	100	3.12	3.80	1.48	—	12.90
Diuril	500 mg. Tabs	100	4.38	6.00	1.600	—	22.96
Peritrate	10 mg. Tabs	100	2.50	2.50	0.258	1,200	2.82
Doriden	0.5 gm. Tabs	100	3.97	4.00	—	1,615	10.20
Seconal	0.1 gm. Tabs	100	2.85	2.16	0.300	2,389	10.75
Pyribenzamin	0.5 gm. Tabs	50	1.53	1.40	—	588	6.15
Banthine	0.05 gm. Tabs	100	5.76	4.32	—	—	8.20

[1] Canadian prices include sales tax.

APPENDIX F.2

INTERNATIONAL DRUG PRICES (1)

IN DOMESTIC CURRENCY UNITS

Product	Strength	Pkg. Size (Canada)	France Francs Price to Ret.	Holland Guilders Price to Ret.	Sweden Kroner Price to Ret.
Achromycin	250 mg. Caps	16	—	15.76	16.36
Chloromycetin	250 mg. Caps	16	9.06	7.07	7.46
Terramycin	250 mg. Caps	16	15.06	12.50	16.40
Penbritin	250 mg. Caps	16	27.88	20.06	—
Gantrisin	500 mg. Tabs	100	14.18	14.34	13.20
Decadron	0.5 mg. Tabs	100	39.53	18.09	31.90
Librium	10 mg. Caps	100	16.92	15.00	15.60
Equanil	400 mg. Tabs	50	59.3	4.08	4.33
Stelazine	2 mg. Tabs	50	—	—	—
Ismelin	10 mg. Tabs	100	24.30	7.90	12.32
Hydrodiuril	25 mg. Tabs	100	—	12.69	19.00
Diuril	500 mg. Tabs	100	—	20.14	31.25
Peritrate	10 mg. Tabs	100	4.75	2.68	—
Doriden	0.5 gm. Tabs	100	—	—	—
Seconal	0.1 gm. Tabs	100	—	9.46	9.77
Pyribenzamin	0.5 gm. Tabs	50	5.90	—	7.40
Banthine	0.05 gm. Tabs	100	—	15.12	19.32

APPENDIX F.3

INTERNATIONAL DRUG PRICES IN CANADIAN DOLLARS (1)

Product	Canada Price to Ret.	U.S. Price to Ret.	U.K. Price to Ret.	Italy Price to Ret.	Germany Price to Ret.
Achromycin	3.24	3.11	2.31	2.89	4.27
Chloromycetin	3.96	5.48	2.04	1.71	4.92
Terramycin	4.17	3.90	2.79	3.83	4.27
Penbritin	5.37	4.73	3.87	5.47	6.98
Gantrisin	4.14	3.16	2.40	3.49	2.57
Decadron	11.94	10.93	9.56	—	7.92
Librium	7.20	7.52	3.00	3.82	3.13
Equanil	3.40	3.11	.94	—	1.88
Stelazine	3.75	4.22	2.62	1.66	2.50
Ismelin	4.33	7.30	4.14	2.43	2.05
Hydrodiuril	3.12	4.08	4.43	—	3.48
Diuril	4.38	6.44	4.79	—	6.20
Peritrate	2.50	2.69	.77	2.06	.76
Doriden	3.97	4.30	—	2.78	2.75
Seconal	2.85	2.32	.90	4.11	2.90
Pyribenzamin	1.53	1.50	.84	1.01	1.66
Banthine	5.76	4.64	—	—	2.21

EXCHANGE RATES: "Monthly Bulletin of Statistics," August 1965, United Nations, Table 62, p. 173–179. 1964 Rates were given in USA Dollars; converted into Canadian currency equivalents as follows:

USA $	.93	$ Can
Canada $	1.00	"
Francs	4.56	"
Lire L	581.7	"
D-Mark	3.70	"
Guilder	3.34	"
Pound UK	.334	"
Kroner	4.79	"

(1) Canadian prices include sales tax.

APPENDIX F.4

INTERNATIONAL DRUG PRICES IN CANADIAN DOLLARS

Product	France	Holland	Sweden
	Price to Ret.	Price to Ret.	Price to Ret.
Achromycin	—	4.71	3.41
Chloromycetin	1.99	2.11	1.56
Terramycin	3.30	3.74	3.42
Penbritin	6.11	6.00	—
Gantrisin	3.11	4.29	2.75
Decadron	8.67	5.41	6.66
Librium	3.71	4.49	3.25
Equanil	1.30	1.22	.90
Stelazine	—	—	—
Ismelin	5.33	2.36	2.57
Hydrodiuril	—	3.79	3.96
Diuril	—	6.02	6.52
Peritrate	1.04	.80	—
Doriden	—	—	—
Seconal	—	2.83	2.04
Pyribenzamin	1.29	—	1.54
Banthine	—	4.52	4.03

APPENDIX F.5

TABLE I

HOURS OF LABOUR REQUIRED TO BUY SELECTED DRUGS IN EIGHT COUNTRIES*

Product	Canada Hours	U.S. Hours	U.K. Hours	Italy Hours	Germany Hours	France Hours	Holland Hours	Sweden Hours
Achromycin	1.60	1.15	2.21	4.50	4.24	—	6.62	2.30
Chloromycetin	1.96	2.02	1.95	2.66	4.88	3.17	2.97	1.05
Terramycin	2.06	1.43	2.67	5.96	4.24	5.26	5.25	2.30
Penbritin	2.66	1.74	3.71	8.52	6.93	9.75	8.43	—
Gantrisin	2.05	1.16	2.30	5.44	2.55	4.96	6.02	1.85
Decadron	5.91	3.82	9.15	—	7.86	13.82	7.60	4.34
Librium	3.56	2.77	2.87	5.95	3.11	5.92	6.30	2.19
Equanil	1.68	1.15	.90	—	1.87	2.07	1.71	.61
Stelazine	1.86	1.55	2.51	2.59	2.48	—	—	—
Ismelin	2.14	2.69	3.97	3.78	2.03	8.50	3.32	1.73
Hydrodiuril	1.54	1.50	4.25	—	3.46	—	5.33	2.67
Diuril	2.17	2.37	4.59	—	6.15	—	8.46	4.39
Peritrate	1.24	.99	.74	3.22	.76	1.66	1.13	—
Doriden	1.97	1.58	—	4.33	2.73	—	—	—
Seconal	1.41	.85	.85	6.40	2.88	—	3.97	1.37
Pyribenzamin	.76	.55	.80	1.58	1.65	2.06	—	1.04
Banthine	2.85	1.71	—	—	2.20	—	6.35	2.71

* The above hours have been computed with reference to the price to retailer.

APPENDIX F.6

TABLE II

INDEX OF LABOUR HOURS REQUIRED TO BUY SELECTED DRUGS IN EIGHT COUNTRIES BASED ON THE PRICE TO THE RETAILER

Product	Canada	U.S.	U.K.	Italy	Germany	France	Holland	Sweden
Achromycin	100.	71.88	138.13	281.25	265.00	—	413.75	143.75
Chloromycetin	100.	103.06	99.49	135.71	248.98	161.73	151.53	53.57
Terramycin	100.	69.41	129.60	289.30	205.81	255.32	254.84	111.64
Penbritin	100.	65.41	139.47	320.27	260.50	366.50	316.88	—
Gantrisin	100.	56.58	112.19	265.36	124.39	241.95	293.66	90.24
Decadron	100.	64.64	154.82	—	132.99	233.83	128.59	73.43
Librium	100.	77.78	80.59	167.08	87.33	166.23	176.90	61.52
Equanil	100.	68.45	53.57	—	111.30	123.20	101.78	36.31
Stelazine	100.	83.33	134.94	139.24	133.32	—	—	—
Ismelin	100.	125.68	185.48	176.60	94.84	397.12	155.11	80.83
Hydrodiuril	100.	97.40	275.95	—	224.66	—	346.07	173.36
Diuril	100.	109.21	211.51	—	283.39	—	389.84	202.29
Peritrate	100.	79.83	59.67	259.66	61.29	133.86	91.12	—
Doriden	100.	80.20	—	19.79	138.57	—	—	—
Seconal	100.	60.28	60.28	453.89	204.25	—	281.55	97.16
Pyribenzamin	100.	72.36	105.26	207.88	217.09	271.03	—	136.83
Banthine	100.	59.99	—	—	77.18	—	222.76	95.07
Average	100.	79.15	129.40	243.00	168.88	235.08	237.46	104.31

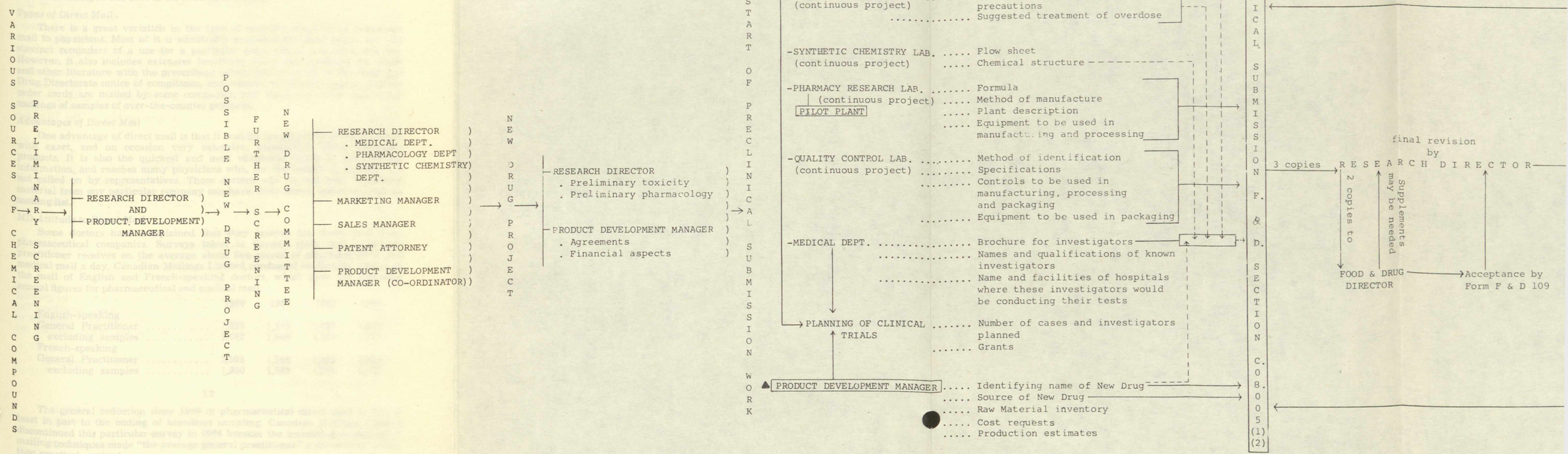
Appendix G to Brief

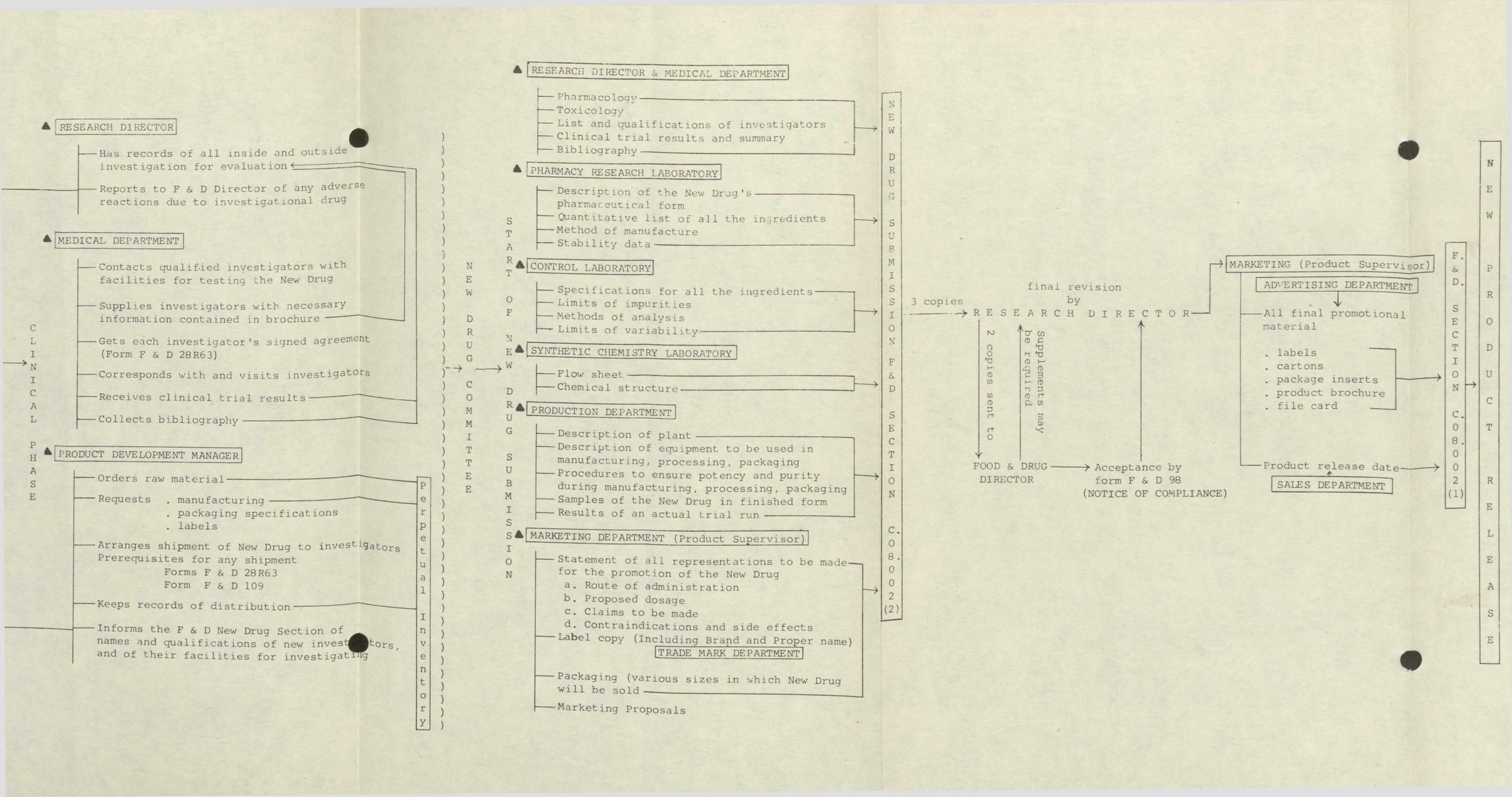
COST OF QUALITY CONTROL

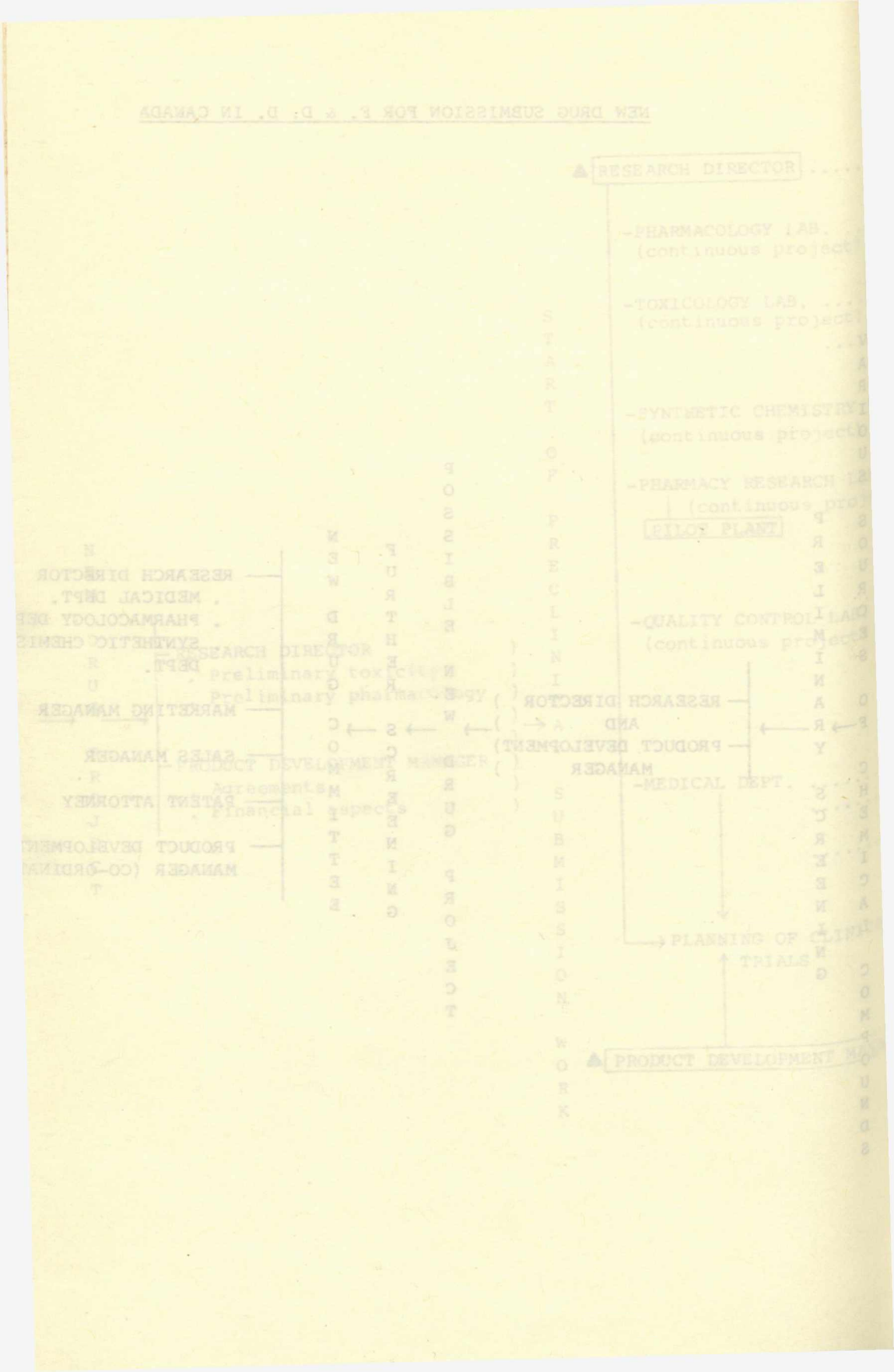
34 COMPANIES

	1963
A. Cost of operating quality control laboratories	$ 1,777,352
B. Additional quality control costs required to meet PMAC standards	1,180,108
C. Quality control costs deriving from line or in process inspections	574,655
D. Manufacturing cost of goods sold as already reported (human pharmaceuticals)	35,541,982

NEW DRUG SUBMISSION FOR F. & D. D. IN CANADA




CLINICAL PHASE
RESEARCH DIRECTOR
Has records of all inside and outside investigation for evaluation
Reports to F & D Director of any adverse reactions due to investigational drug
MEDICAL DEPARTMENT
Contacts qualified investigators with facilities for testing the New Drug
Supplies investigators with necessary information contained in brochure
Gets each investigator's signed agreement (Form F & D 28R63)
Corresponds with and visits investigators
Receives clinical trial results
Collects bibliography
PRODUCT DEVELOPMENT MANAGER
Orders raw material
Requests . manufacturing
. packaging specifications
. labels
Arranges shipment of New Drug to investigators
Prerequisites for any shipment
Forms F & D 28R63
Form F & D 109
Keeps records of distribution
Informs the F & D New Drug Section of names and qualifications of new investigators, and of their facilities for investigating
Perpetual Inventory
NEW DRUG COMMITTEE
START OF NEW DRUG SUBMISSION
RESEARCH DIRECTOR & MEDICAL DEPARTMENT
Pharmacology
Toxicology
List and qualifications of investigators
Clinical trial results and summary
Bibliography
PHARMACY RESEARCH LABORATORY
Description of the New Drug's pharmaceutical form
Quantitative list of all the ingredients
Method of manufacture
Stability data
CONTROL LABORATORY
Specifications for all the ingredients
Limits of impurities
Methods of analysis
Limits of variability
SYNTHETIC CHEMISTRY LABORATORY
Flow sheet
Chemical structure
PRODUCTION DEPARTMENT
Description of plant
Description of equipment to be used in manufacturing, processing, packaging
Procedures to ensure potency and purity during manufacturing, processing, packaging
Samples of the New Drug in finished form
Results of an actual trial run
MARKETING DEPARTMENT (Product Supervisor)
Statement of all representations to be made for the promotion of the New Drug
a. Route of administration
b. Proposed dosage
c. Claims to be made
d. Contraindications and side effects
Label copy (Including Brand and Proper name)
TRADE MARK DEPARTMENT
Packaging (various sizes in which New Drug will be sold
Marketing Proposals
NEW DRUG SUBMISSION F & D SECTION C.08.0002(2)
3 copies
RESEARCH DIRECTOR
final revision by
2 copies sent to
Supplements may be required
FOOD & DRUG DIRECTOR
Acceptance by form F & D 98
(NOTICE OF COMPLIANCE)
MARKETING (Product Supervisor)
ADVERTISING DEPARTMENT
All final promotional material
. labels
. cartons
. package inserts
. product brochure
. file card
Product release date
SALES DEPARTMENT
F. & D. SECTION C.08.0002(1)
NEW PRODUCT RELEASE


RESEARCH DIRECTOR
-PHARMACOLOGY LAB.
(continuous project)
-TOXICOLOGY LAB.
(continuous project)
-SYNTHETIC CHEMISTRY
(continuous project)
-PHARMACY RESEARCH
(continuous project)
PILOT PLANT
-QUALITY CONTROL LAB.
(continuous project)
RESEARCH DIRECTOR
AND
PRODUCT DEVELOPMENT
MANAGER
-MEDICAL DEPT.
PLANNING OF CLINICAL TRIALS
PRODUCT DEVELOPMENT

Appendix I to Brief

THE COST OF DIRECT MAIL

Direct mail, though very important, to some companies, is not a major element in the total cost of pharmaceutical marketing. Our 41 companies reported total direct mail expenses of $2,739,000—that is, slightly over 2 per cent of sales revenue, or one cent in the prescription dollar.

Types of Direct Mail

There is a great variation in the type of material which drug companies mail to physicians. Most of it is admittedly promotional—some pieces are just succinct reminders of a use for a particular drug, others are more detailed. However, it also includes extensive brochures about new products, file cards and other literature with the prescribing information covered by the Food and Drug Directorate notice of compliance, and reprints of scientific papers. Sample order cards are mailed by some companies, and there are a few unsolicited mailings of samples of over-the-counter products.

Advantages of Direct Mail

One advantage of direct mail is that it enables companies to provide doctors with exact, and on occasion very extensive, information about particular products. It is also the quickest and most adaptable means of transmitting information, and reaches many physicians who, for one reason or another, are not called on by representatives. Those doctors who do not wish to receive material from any particular company can have their names removed from its mailing list.

MD Attitude to Direct Mail

Some doctors have complained that they receive too much mail from pharmaceutical companies. Surveys taken in Canada show that a general practitioner receives on the average about five pieces of pharmaceutical and medical mail a day. Canadian Mailings Limited conducted continuing studies of the mail of English and French-speaking doctors, which gave the following annual figures for pharmaceutical and medical mail:

	1960	1961	1962	1963
English-speaking				
General Practitioner	1,825	1,343	1,397	1,332
excluding samples	1,462	1,048	1,134	1,177
French-speaking				
General Practitioner	2,503	1,766	1,492	1,562
excluding samples	1,990	1,345	1,218	1,327

The general reduction since 1960 in pharmaceutical direct mail is due at least in part to the ending of broadcast sampling. Canadian Mailings Limited discontinued this particular survey in 1964 because the increasing selectivity of mailing techniques made "the average general practitioner" a theoretical, rather than practical, concept.

Related figures developed in the United States show that the American physician receives more than double the direct mail addressed to his Canadian counterpart. The figures for medical and pharmaceutical mail were: 1960—4,566; 1961—4,089; 1962—3,893; 1963—3,636. No exactly comparable figures for the United Kingdom exist, but in 1960, a British G.P. received 2,121 pieces of direct mail, in total, compared to 2,147 for an English-speaking G.P. in Canada and 2,946 for a French-speaking G.P. In 1961, the comparative figures were: Britain 1,987; English-speaking G.P. 1,634; French-speaking G.P. 2,170.

The general American and British surveys quoted above both show that about a quarter of physicians regard direct mail as among their most useful sources of information. It is interesting that in Britain manufacturers' literature is rated above Prescribers Journal, the official publication on new drugs.

We know that even doctors who would not commit themselves to this extent do take some time to peruse their mail, and read what catches their interest. More cannot really be expected; only a small proportion is designed for permanent reference. The MRC survey conducted on behalf of MD of Canada reported that 75 per cent of the doctors interviewed said they spent some time with pharmaceutical direct mail—ranging from less than 5 minutes to over 60 minutes a day; 25 per cent said they spent no time reading it. The following figures were also obtained:

26 per cent said direct mail was welcome;
48 per cent said direct mail was unwelcome;
26 per cent were neutral or expressed no opinion.

The fact that there is a general public sentiment against this form of advertising, effective as it is, should be borne in mind when considering these figures. And we still find a quarter of all doctors welcoming a very economical means of providing them with information.

In answer to another related question:

44 per cent said direct mail was informative;
36 per cent said direct mail was uninformative;
20 per cent were neutral or expressed no opinion.

Increasing Selectivity

One development of some significance in recent years has been the growing selectivity with which companies conduct their direct mail activities. The versatility of the computer promises still further selectivity and refinement of mailing lists in the years ahead. One Toronto mailing house handles the

mechanics of this operation for the majority of pharmaceutical companies.

It reported the following trend:

January 1960	
22 companies made	33 general mailings
	27 selective mailings
January 1964	
43 companies made	7 general mailings
	103 selective mailings

March 1960

32 companies made	65 general mailings
	30 selective mailings

March 1964

51 companies made	15 general mailings
	157 selective mailings

September 1960

39 companies made	64 general mailings
	36 selective mailings

September 1964

63 companies made	19 general mailings
	156 selective mailings

Selective mailings will be addressed to specialists in a particular field or fields, general practitioners with a known interest in those fields, or, on occasion, to general practitioners as opposed to specialists.

Appendix J to Brief

THE COST OF SAMPLING

Regulations Governing Sampling

Sampling in Canada today is subject to quite strict government regulations, which were imposed primarily for safety purposes, following as they did the thalidomide experience. Previously, broadcast sampling was permitted for all drugs except narcotics and controlled drugs—i.e. barbiturates and amphetamines. Under the present regulations, drugs that are available only on prescription may be delivered as samples to a physician on receipt of his personally signed order. The order form must list the name and potency of the drug, the size of the sample, and the date of signature, or of the deliveries involved if there is to be more than one. However, the sampling period covered by one order cannot exceed six months. Also, companies must keep full records of all sample deliveries, available to government inspection, for at least two years.

MD Use of Samples

The value to physicians of the practice of sampling has been shown by the sustained volume of samples distributed under the present regulations. When a new drug comes on the market, it is clearly important for doctors to be able to obtain direct clinical experience of its qualities; they are not going to prescribe any drug extensively without such experience. But sampling is not limited to new drugs; doctors order substantial supplies of established products. A drug may be an excellent medicine for one patient, but prove less suitable for another suffering from an apparently identical condition. There is no doubt that many people would find the cost of drugs substantially higher were it not for the practice of sampling, for using samples initially helps the physician to prescribe the most efficacious drug in each particular case.

Expenditure on Sampling

Our 1963 survey of member companies asked them to report on the cost of samples as well as other promotional activities. For the 41 companies reporting, the total came to $3,939,000—less than 3 per cent of their sales.

At the end of 1964 we sent a questionnaire on the extent and cost of sampling to our members. It was answered by 37 companies, of which 34 stated they distribute samples.

Answering a question whether they were distributing more or less samples since the regulations,

7	companies replied	Less samples
2	" "	Slightly less
4	" "	Less samples, but larger sizes
17	" "	The same amount
4	" "	More samples

J.2

In answer to a question on the impact on their costs,

23	companies stated	Costs had increased
11	" "	Costs had not increased

Specific answers regarding the cost increases referred to either representatives' time or administrative work, or both.

At the time the regulations were enacted, the government indicated that it hoped they would reduce the cost of the drugs concerned as well as provide greater safety. We believe the latter purpose has been well served, but there is every indication that the additional protection to the public has increased the cost of doing business.

Appendix K to Brief

THE REPORT OF THE SPECIAL AD HOC COMMITTEE STUDYING MATTERS INVOLVING THE PATENT LICENSING OF DRUG MANUFACTURERS

also called The HILLIARD REPORT, is printed as Appendix "A" to Issue No. 4 of the Minutes of Proceedings and Evidence of the Committee (June 16, 1966)

24630—15

Appendix L to Brief

QUALITY OF DRUGS

(An analysis of the section of the Hall Commission report entitled "Quality of Drugs", pp. 366-370.)

The Section discusses the powers and activities of the Food and Drug Directorate relating to the quality of drugs sold in Canada. In so doing, it overstates the existing administrative and legal protection of drug quality—as opposed to the protection provided through the procedures of reputable brand-name manufacturers. It understates the necessary expansion of existing inspection forces to "adequately test and check drugs in Canada," in particular through the misquotation of Dr. C. A. Morrell.

The following exchange between Dr. Morrell and J. A. Macaluso, M.P., member of the Special Committee of the Commons on Food and Drugs, appears pertinent in this connection:

> Dr. Morrell: ...I am loath to have people say that a drug is guaranteed by the Food and Drug Directorate. I do not see how we can guarantee it. There are many subtleties, and we have not the facilities to detect differences.
>
> Mr. Macaluso: I do not mean the safety of the drug as to its side effects.
>
> Dr. Morrell: But you cannot put "government approved" on a drug.
>
> (Minutes of Proceedings p. 158)

The errors and misconceptions of the "Quality of Drugs" section of the Hall Commission report are reviewed against the definition above of the potential and the limits of government inspection.

Quality Control and Potency

On page 369, the Hall Commission report refers to what it calls "at least two hopeful elements in the situation." For both of these, it quotes from Dr. Morrell's evidence before the Restrictive Trade Practices Commission.

The first one is the fact that, "quality control elements for any particular company depend upon the number of products being manufactured and the danger or potency inherent in them." This is undeniable, provided the standard is high enough to ensure therapeutic quality and safety... However, since it is the cost of the more complex drugs of greater potency and toxicity that is chiefly under discussion, the relevance of the argument is not immediately apparent.

Staff Needed by FDD

The second "hopeful element" is explained in the report as follows: "Dr. Morrell further expressed the opinion that in order to adequately test and check drugs in Canada the Food and Drug Directorate would have to triple its staff of

inspectors and laboratory personnel." This appears a gloss upon the following exchange before the Restrictive Trade Practices Commission (pp. 141-143):

> Mr. Hume (Counsel to the PMAC): Is it your opinion you have sufficient inspectors and lab people to adequately test and check drugs in Canada?
>
> Dr. Morrell: No.
>
> Mr. Hume: Could you indicate whether or not this number you think should be doubled or tripled knowing the population and the demands on your staff...?
>
> Dr. Morrell: Oh maybe two or three times as many as we now have, perhaps three times.
>
> Mr. Hume: ...I wonder if you could indicate to the Commission what you would consider to be an adequate staff to be able to protect the public against any drug which might be improper, whether generic name or otherwise?
>
> Dr. Morrell: You are giving us quite a job to do. I don't know the Food and Drug Directorate should act as a control laboratory for all people who want to manufacture pharmaceuticals in Canada. I don't think that is our function. We are acting as a police agency, I believe. If you want me to analyse every batch of a drug or pharmaceutical sold in Canada, I think it would be an astonishing number. I believe we would need—when I said three times the number of inspectors I wasn't speaking of that kind of job.

In this connection it is significant that the Special Committee on Food and Drugs of the House of Commons recommends that the staff of the Food and Drug Directorate be doubled to enable it to handle effectively its present reponsibilities. (Proceedings p. 518)

Extent of FDD Inspection in Canada

The Hall Commission states that about 450 inspections of drug plants are carried out in a year by the Food and Drug Directorate, and that on one occasion the Directorate sent an inspector to Italy.

L.3

The figure actually given by Dr. Morrell to the RTPC was "300 or 400." (RTPC report p. 156) Mr. B. S. Mackasey, M.P. asked about the number of inspections when Dr. Morrell appeared before the Special Committee on Food and Drugs of the Commons.

> Mr. Mackasey: My second question is: How many drug businesses have been inspected by the food and drug offices?
>
> Dr. Morrell: We do it by calendar year. If I could give you the number that were inspected in 1963, would that satisfy you?
>
> Mr. Mackasey: That would be ideal.
>
> Dr. Morrell: The quality control regulations which are now in the Regulations of the Food and Drugs Act were introduced in March 1963, and during the calendar year 1963 there were 183 plants inspected.

Mr. Mackasey: With the personnel at your disposal, is it possible to cover all these people at least once a year?

Dr. Morrell: You mean the 485 manufacturers? No, it would not.

Mr. Mackasey: What increase in personnel do you think you would need to do this job adequately, or would you say that once a year is too frequent?

Dr. Morrell: It is not adequate in my opinion, Mr. Mackasey.

(Proceedings, p. 142)

Extent of FDD Inspection Overseas

Later in the same session of the committee, Mr. Mackasey asked the following question: "How many inspections of drug manufacturers facilities outside of Canada which supply drugs to Canadian manufacturers have been carried on by inspectors of the Food and Drug Directorate?"

Dr. Morrell: We have done none so far in the pharmaceutical field. I want to be sure that when we send an inspector to Europe he really knows his business, because I think he would have to. In terms of other drugs under the Food and Drugs Act, the biologics for example, we have an inspection scheme.

(Proceedings, p. 145)

L.4

No Notice of Compliance for Established Drugs

Certain other statements in the "Quality of Drugs" section also call for careful analysis.

At the foot of page 366 it is stated: "Not only every new drug but every new preparation of it (i.e. by another supplier) must be cleared by the Food and Drug Directorate. This requires a new submission and a new notice of compliance." This is true only of those drugs or preparations which come within the Directorate classification of "a new drug." With established drugs, a second supplier can put an imitative product on the market without obtaining a notice of compliance. The implications of this were made clear by Dr. Eloise Jones, M.P. in her statement in the House of Commons on June 4, 1965 (Hansard pp. 1977-8).

Confusion Between Federal and Provincial Requirements

On pages 367 and 368 a number of statements are made that are also only partially true:

"The provincial pharmacy acts supplement the Food and Drugs Act in providing for a listing of drugs which may be sold only on prescription." There is considerable variance between the schedules of the various provincial acts, several of which are badly out of date, and between them and the Federal schedules. The result of this is more likely to be confusion than greater safety—unless it be assumed that the Federal schedules are inadequate.

Limits of Label Information

"There are specific regulations under the Food and Drug Act also pertaining to the labelling of drugs, designed to inform the physician, the druggist and the public about their safe and proper use." This gives the

impression that all drugs and all labels are covered by such regulations, and that labels are a source of information for the general public. This may be true in its broadest sense. However, the specific regulation requires that the label bear "adequate direction for use". This will range from detailed dosage information, together with such mandatory cautionary statements as may be required by the regulations, or may be considered necessary by the manufacturer, for a drug intended to be sold directly to the public, to a simple statement such as "to be used only as directed by the physician" for a drug available only on prescription. It is not intended that every label of every drug carry information designed to inform the physician, the druggist and the public all at the same time.

Availability of Medication

"Among the basic qualities demanded by the law are that...the medication must be contained in such a way as to be wholly available to the consumer of the drug." There is no general requirement to this effect. However, C.01.012 L.5 does lay down a regulation with regard to timed release products to the effect that the manufacturer shall demonstrate that the drug is released and available as claimed when determined by an acceptable method.

FDD Inspection of Imported Drugs

"Imported drugs are also inspected on a sampling basis. In those custom ports where there are no drug inspectors, the Food and Drug Directorate is notified by customs inspectors of shipments of drugs coming into the country. These shipments are held until a release is obtained from the Food and Drug Directorate." This statement is taken from the testimony to the RTPC of Dr. Morrell. However, Mr. F. N. MacLeod of the Department of Justice then went on to ask Dr. Morrell: "Is it a fact then that your Directorate is notified of every importation of drugs into this country?" And Dr. Morrell answered, "No, I would not say it was a fact. A good many of them, but certainly not all of them." Dr. Morrell then went on to explain the reasons for this (RPTC report p. 162). In addition, the paragraph in the Hall Commission report gives the impression that a Directorate release is made only after a full analysis of the shipment in question. In answer to Mr. MacLeod, Dr. Morrell pointed out that samples were taken only from selected shipments.

Interesting in this connection is the exchange that occurred between Dr. Morrell and Mr. Macaluso at the hearings of the Special Committee of the Commons on Food and Drugs. Referring tto a distributor in Hamilton who imported drugs from the West Indies, "and has run into some trouble with the Food and Drug Directorate, " Mr. Macaluso asked: "Is there any type of inspection carried on in regard to drugs coming from the West Indies or from Jamaica, and are they checked by the food and drug inspectors when they come through customs?"

> Dr. Morrell: We would check them if we have a laboratory man available. We do not check all of it. Again, we are short of staff.
>
> Mr. Macaluso: You agree that in a case like that there is no analytical control or inspection and there is therefore a danger there?
>
> Dr. Morrell: Yes there is a danger there. (Proceedings pp. 145-6)

Concerned about "drugs that are imported into Canada and distributed without further processing," the Special Committee of the Commons made the following recommendation:

> "That inspection of quality control methods here and abroad should be carried out by the Food and Drug Directorate. If felt necessary by the Food and Drug Directorate this quality control check should be carried out by any importer before the drug is released in Canada. If this inspection is not carried out or does not meet our standards the imported drug would not be released in Canada." (Proceedings p. 515)

L.6

It should be noted that such inspection would relate only to the existence of satisfactory methods of quality control; it would not be a government guarantee of the quality of specific batches or products.

Responsibilities of Government and Manufacturer

On page 370, the Commission uses the testimony of Professor J.L. Summers of the University of Saskatchewan to support its claim that FDD inspectors could test and check drugs made abroad through inspection. Here again the extract from the testimony distorts the point that Professor Summers was actually making. (RTPC hearings p. 2254)

> J. J. Frawley: (Counsel for the Province of Alberta):...What would be the difficulty about the Food and Drug Directorate undertaking this responsibility which they don't undertake and putting the stamp of approval on non-proprietary drugs so that it could go out without those disabilities you have called to our attention?
>
> Prof. Summers: I don't think that is a function of Government. It is the responsibility of the individual manufacturer. It is the responsibility of Government to set such standards as it deems are adequate to protect the people of this country and to see that the manufacturer observes his obligations and responsibilities. Now, this can be done by inspecting these plants. No knowledgeable person in the field of pharmacy could walk into a plant and spend a day with them and not know more and learn more about the quality of the product which they produce than analytically, by testing they could learn in five years. It is the products that are produced...
>
> Mr. Frawley: Let us be very...
>
> Prof. Summers: You can't inspect quality into the product. It must be built in by knowledge and ability.

This categorical statement by Professor Summers, now president of the Canadian Pharmaceutical Association, would seem to best sum up the argument against the concept promoted in the "Quality of Drugs" section of the Hall Commission report. Government cannot inspect quality into any product, but there is much for Government to do through the inspection and, if feasible, registration of manufacturers to protect the Canadian consumer. Under present circumstances, the Food and Drug Directorate is unable to employ sufficient personnel of suitable calibre to carry out this latter task. Here is an area where immediate action is required—and where practical results can be achieved. To seek less is to fail the Canadian people; to claim more is to mislead them.

Appendix M to Brief

WHAT IS A GENERIC EQUIVALENT?

From American Professional Pharmacist

By Max S. Sadove, B.S. in Pharmacy, M.D.,
and Ronald Rosenberg, M.D., Floyd Heller, M.D.,
Morton Shulman, M.D.

Having degrees in Pharmacy and Medicine—in addition to being involved in medical practice, teaching, and research development—we have a real and often vital problem in the area of: What is a generic equivalent?

The answer to this question is especially important in that our budgets are fixed, relatively small, and frequently "in the red." Economy is a very important part of our mission, yet we must get uniform, dependable, and predictable drug results with a minimum of side actions. Basically, we represent a research and clinical department whose primary function is the care of patients (anesthesiologic), teaching, and research—with special interest in pre-operative, operative, and post-operative care.

With respect to drugs, no income accrues to individuals or the department. Any savings on drugs can be used for any of our pet projects or for research, instruments, and equipment. Economics, scientific truth, and clinical results are all vital as they relate to drugs. "Generic equivalency" is a daily problem to us.

Background

Over a period of about 2 decades, we have been using various drugs daily. On many of these, we have performed the early laboratory testing or clinical and laboratory testing. We have been an active department in clinical and laboratory evaluation. Then, subsequently, we make use of the drugs. We have studied competitive, generic equivalents, and similar drugs.

In our teachings, we use the generic terms and, where logical and efficient, we employ the generic concept. It is difficult to teach this concept. Even those dedicated to the principle find it hard and unwieldly—and also confusing and foolish at times—because everyone knows a drug by a trade name and does not know what we are talking about when we use the generic term for the drug.

Equivalents?

The principal problem we have, however, is to know what "generic equivalent" really means; also, when are 2 generic equivalents pharmacologic equivalents or "clinically effective" equivalents?

"Generic equivalents" are a continuous problem for us economically, scientifically, and socially. We have a pharmacy college as part of our structure—and personnel who are strongly dedicated to the philosophy of the truth of the "generic equivalent story."

Therefore, we will discuss our views with respect to "generic equivalents"—in that it might help others reach a conclusion and get closer to the truth.

Some of our experiences and thoughts—presented below—explain why we cannot reach a quick and easy decision on this problem of what are generic equivalents:

1. SALT

In the early days of erythromycin, we were given 2 products made by 2 of the leading pharmaceutical companies. These were to be used in our recovery room; we were also to observe any local changes as well as systemic reactions. One of the 2 erythromycin products was extremely irritating. There were many violent complaints from patients and nurses. The product that irritated was finally changed from one salt form to another. The irritancy immediately fell to a very satisfactory level.

Thus, it makes a real and definite difference to us which particular salt of a drug we get. It can change many, many factors—not the least of which are irritancy, patient tolerance, absorption, etc. If we ask for a specific drug in a specific salt form, it would be unwise to have another salt form substituted—unless one knows what difference this may make in its tolerance, uptake distribution, destruction, etc.

These 24 Factors Can Markedly Alter the Pharmacologic Action of a Drug

1. Size of crystal or particle.
2. Form of the agent—solution vs. salt.
3. Vehicle.
4. Coatings.
5. Degree of hydration of crystal or addition of de-hydrating substances to package.
6. Diluent.
7. Purity—type and number of impurities
8. Viscosity.
9. pH.
10. Sustained release forms.
11. Enteric coating.
12. Solubility.
13. Vehicle or base.
14. Container—stopper, type of glass, whether or not glass is pre-heated of impervious.
15. Package dating.
16. Quantity of active ingredient.
17. Contaminants.
18. Allergenic substances.
19. Irritation.
20. Melting point.
21. Toxicity.
22. Surface tension.
23. Storage factors.
24. Flavoring and Coloring agents.

2. VEHICLE

M. 3

We have, on several occasions, used a soluble barbiturate of essentially the same primary molecule, but in different vehicles. In many instances, the ease of pharmaceutically mixing "like drugs" prior to injection was markedly changed. The shelf life was markedly altered.

In one instance, the less expensive drug became more expensive, because of the amount that had to be discarded owing to changes in physical characteristics. There are many procedures in manufacturing trademarked products that add to their pharmaceutical stability and shelf life. It can mean that a different vehicle product is not the same as far as effect and appearance are concerned.

Thus, when are there real savings on 2 similar products with different vehicles? We really don't know without a period of testing.

3. pH

We have studied many different local anesthetics. We have found in testing them on animals and on ourselves that there is a really significant difference in local irritancy, onset, and duration—dependent upon the buffering agents. This same factor definitely affects many other drugs.

Thus, to substitute one generic equivalent drug for another, one must be sure that the hydrogen ion concentration and the amount and type of buffering is identical—or else one is getting an entirely different drug effect. Though presumably generically equivalent, the drugs may be pharmacologically and clinically different. The effect of pH on stability, compatibility, ionization, etc., is too well known to discuss, but it is frequently forgotten.

4. Containers

Containers can make a real difference in the effect of a drug. Several years ago, we were doing clinical and laboratory evaluation of a drug and were quite pleased with its effects. After a while, we felt that it would be more efficient to have 30-cc. vials of the drug, rather than 10-cc. ampules. Within days after we had received the vials, we changed our opinion of the drug. It had been non-irritating when injected in the initial study—now, it irritated. The manufacturer was at a loss, at first, as to the cause. Finally, the cause was determined. The vials were stoppered with new closures that were high in heavy metal content. This heavy metal was being leeched from the stopper into the solution, causing the tremendous increase in irritancy.

The type of glass used can also make a major difference in many solutions. Thus, differences in stoppers, glass, dehydrating agents, filling gas, etc.—can all alter the biologic difference in a drug. Many of these differences are too obvious to discuss with a professional group like pharmacists.

M.4

5. Vehicles

Vehicles make a tremendous difference in many drugs. In topically-active drugs—such as eye solutions, solutions for nose and throat . . . and also in intravenous solutions, intramuscular solutions or suspensions—the difference can be such as to render the drug completely different pharmacologically; in fact, different vehicles can change the drug from a useful drug to a very dangerous drug. Vehicle changes alter stability, compatibility, irritancy, toxicity, allergenicity, and pharmacologic effect.

On one occasion, the change in vehicle of a test drug endangered the life of one of the authors in that a thrombophlebitis developed in the deep veins of his arm which ascended well into the axilla. This caused the consulting surgeon to contemplate ligation of a subclavian vein. Prior injection of the same drug—but with a different vehicle—had not produced untoward results. Of course, this is not significant from a proof standpoint, but would be sufficient from a clinical standpoint to frighten one of the authors from ever having that drug used on himself in any form of testing. Then, testing of 2 solutions demonstrated that the author reacted to one lecithin solution—not to another.

Thus, one must realize that the changing of a vehicle can alter viscosity, compatibility, stability, irritancy, allergenicity, etc.—so that this factor must be known if one is to substitute one "generic equivalent" for another.

6. STABILIZING AGENTS

Stabilizing substances can certainly make a marked difference in compatibility, irritancy, duration of action, shelf life, dosage, and even action of a drug. The fact that a therapeutic agent has been placed in equal quantity in 2 products does not mean that there will be equal availability of the primary agent after a given time. Nor does it mean that the rate of absorption or availability of the drug will be the same for the 2 products.

This difference may be even more marked once a product has been opened, as is the case in a multiple-dose vial. In some instances, we cannot use one form of a drug—such as a local anesthetic—because the antibacterial agent or the stabilizer is contra-indicated. For example, when we use local anesthetics for epidural anesthesia, we must be sure that there is nothing in the preparation that can injure the spinal cord. It is quite possible that we may inadvertently perform a puncture of the dura while doing an epidural block—also that the solution may be unnecessarily irritating to the dura, but not to the peripheral tissues.

It becomes obvious that the preservative, antibacterial agent, stabilizing agent, anti-oxidative agent, etc., are important in the final comparison of 2 solutions, because they can markedly alter the pharmacologic effects of the principal ingredient. In many products, this information is not available and, thus, we do not know whether one "generic equivalent" may be used for another.

M.5

7. PACKAGING

The packaging of a product may make a real difference in the economy and use—as well as usefulness—of 2 identical products. Frequently, in the purchase of a volatile agent, for example, even the same company's product at 2 different periods may be so packaged as to reduce loss by 25%.

On several occasions on foreign trips, we have encountered diethyl ether that was apparently similarly packaged to American products, but on inspection many of the packages were partially empty or completely empty.

8. CONTROLS

At one time, we made our own intravenous fluids. Extreme care was taken to make these so that they would be quality products. Yet, our pyrogenic and allergic reactions were quite frequent as compared to the manufacturer's product line we now use. Generically, they were equivalent; actually, they were tremendously different.

With the present line of intravenous fluids, we find that allergic and pyrogenic reactions are almost non-existent.

9. CONTAMINANTS

A few years ago, we experienced a failure in a series of reducing regulators on nitrous oxide tanks. This was the first and only time this had happened in a period of over 15 years. Study revealed that a new contract had gone to a minor company, because they had been "low bidders" for our gas contract. It was necessary to stop using the gases of the low-bid company.

In fact, we fear all low bids when they are sharply lower than the bids of the so-called "good companies." What short cuts—what changes—have occurred to make possible the reduced price? The specifications theoretically are the same for all companies and their products, but practically the products can be very different. Sometimes a so-called minor contaminant can make a major difference in 2 products. In many instances, manufacturing know-how—gained by long experience—makes the difference in product quality.

DESIRABLE, BUT...

The desire to get the same therapeutic effect for less cost is a very reasonable one, but where can one find the data that would enable one to make this judgment? In general, it can be stated that this information is usually available only to a very few people with large laboratories, plenty of time, and a great deal of experience. Even the skilled pharmacologist frequently cannot pinpoint the difference.

M.6

Careful laboratory testing frequently does not reveal the difference between "generic equivalents" that are clinically very different. For example, tetracaine has been purchased by certain government agencies to replace Pontocaine. Generically, the products are equal, but clinically the complaints —involving shorter duration, greater number of failures, shorter shelf life, and crystal formation—were very frequent about the tetracaine. It was never revealed to the anesthesiologists involved why this was so.

Many of the anesthesiologists did everything in their power to obtain the Pontocaine solution they had been using before the material from another company had been substituted. Many of these people did not know of the same difficulties in other locations.

Did the difference in cost justify this change to a generic product from the branded product? In retrospect, it is obvious that the answer si no, but can this kind of error be prevented? We really don't know kow it can. The specifications of the 2 products were identical. The clinical results were entirely different!

There are many factors which determine the onset, duration, side reactions, and principal action of a drug. In many instances, it is physically impossible to compare 2 similar products without extensive, carefully-controlled laboratory and clinical trials. Though it is admirable to keep the cost of drugs to a minimum and it is admirable to know and prescribe drugs generically, the generically-similar product exerts, in many instances, a very different reaction from the one anticipated.

It is practically impossible for one not skilled in the area of clinical pharmacology to know what is—and what is not—a real "equivalent."

Above all, the lack of available data would preclude substitution without prior equation of the many factors which could materially alter apparent equivalency.

A FABLE

Our conclusion is that generic equivalency is frequently a fable without basis in fact; chemical equivalency of the primary agent or agents is not necessarily clinical nor pharmalogical equivalency.

Appendix N to Brief

PHARMACARE

PHARMACARE, a service program with a payment direct to the provider of service rather than a reimbursement program, is directed and operated by members of the profession of Pharmacy. It embodies guaranteed financing, guaranteed service and guaranteed fee costs with charges influenced only by the cost of the tangible ingredients of prescriptions. It may be operated as a separate entity or integrated with programs providing for other health services.

The PHARMACARE program is specifically designed to meet modern desires for a completely adequate method of financing the individual's requirements in relation to drug therapy and is in keeping with philosophies expressed by private citizens, management, labour, governments and the professions. Pharmacy's views are expressed in the CPhA Statement of Policy Relative to Health Insurance Plans. The Canadian Chamber of Commerce Statement of Policy, 1965, states: "In a free society, the individual has the primary responsibility to make provision for and pay the cost of health care for himself. . . budgeting for adequate coverage. . . with voluntary service, indemnity plans and the contribution of government to assist those who are unable to provide for themselves." Organized labour has repeatedly stated that health service plans are a desirable fringe benefit. Canada's Royal Commission on Health Services emphasizes "the individual's responsibility for personal health. . . to the extent of the individual's capabilities"; belief "that an individual family should not have to bear alone the full cost of risks. . ."; the rationale of health insurance which embodies the application of averages for the relief of millions . . . and the desirability of "necessary legislative, organizational and financial decisions to make all the fruits of the health sciences available to all our residents without hindance of any kind". Many governments—federal, provincial and local—have made pronouncements of varying degrees of specificity. PHARMACARE is adaptable to most political philosophies in that it enables the individual to assume a responsibility to provide for his pharmaceutical therapy needs while enabling the group as a whole to share responsibility to thus ensure that the services are available at a cost within every individual's ability to pay.

Features:

The PHARMACARE Plan embodies three responsibility phases, namely: a period of individual financial responsibility; the sharing of financial responsibility (co-insurance); and thereafter, full coverage ('fire insurance').

The Plan:

Health insurance, and particularly that having to do with the insuring of first class pharmaceutical services provided by community pharmacies has been the subject of many years of review and study by the pharmacists of Canada. PHARMACARE is the result of intensified study during the past eighteen months.

1. *Subscribers*

No restrictions as to age, condition of health, occupation, geographic location.

N. 2

Groups of 5 or more (i.e., recognizable groups of all types, including labour, management, professional and civic, except as organized for the purpose of obtaining health insurance and except health groups).

Welfare and medically indigent categories for whom a central authority assumes financial responsibility.

Individuals who move out of a group contract or outside of the dependent age.

Non-group individuals, in due course, according to the experience of the Plan.

2. *Benefits*

All pharmaceutical services prescribed by medical and dental practitioners—a few exceptions such as patent medicines, accessories, first aid supplies, etc.—all procedures in keeping with all usual and legal practices normally followed by the professions relative to drug therapy (i.e., prescribing habits, repeat prescriptions, long term medication).

3. *Coverage*

Combines features of prepayment and insurance—no limit as to maximum relative to pre-existing medical history and/or illness situations.

For single subscriber, after first $10 (family $20) PHARMACARE assumes 80 per cent of next $50 (family $100) with subscriber paying only 20 per cent to the provider of service, and thereafter, subscriber is 100 per cent insured for 12-month benefit period.

Features

(*a*) Enables subscriber to budget completely to a maximum amount for preescription services;

(*b*) Keeps insurance premium cost to a very reasonable level;

(*c*) Subscriber individually responsible only for normal, average expenditure;

(*d*) Subscriber's participation during co-insurance phase provides for sharing with others of his above-average expenditures;

(e) Deductible and co-insurance phases deter over-demand and/or wastage;

(*f*) Full insurance coverage protects against abnormal and catastrophic situations.

4. *Benefits period*

Any 12-month period beginning from the sugscriber's choice of date of first prescription service following effective date of contract.

5. *Identification of subscriber*

(*a*) Pocket card for reference purposes only;

N.3

(b) Personalized book of pre-punched cards serving as subscriber's receipt and cumulative record; as the pharmacist's record; and as an accounting form.

6. *Payment for services*

(a) Direct to providers of service, namely, retail pharmacies operating under the pharmaceutical legislation of the province...amounts according to a negotiated contractual agreement between the Company and a representative pharmacist organization; on basis of cost of ingredient plus a professional fee;

(b) Reimbursement to subscribers provided for where services obtained in areas where no member-pharmacies.

7. *Premiums*

(a) Group rates, annual payment structure, single subscriber and family rates (at 3X single);

(b) Pay-direct rates for subscribers previously in a group at slightly higher premium;

(c) When sold to non-group individuals, higher rate structure required.

Financial Resources:

PHARMACARE is organized as a non-profit Company capitalized by the purchase of shares and debentures by members of the profession of Pharmacy who are the providers of the services.

The ability of the Company to provide services is guaranteed by the profession of Pharmacy to the extent that if the financial resources of the Company prove inadequate, the pharmacists will agree to accept reduced fees and, where agreement is obtained, the manufacturers of the ingredients will pay in an equal amount.

Policy Direction, Sales and Administration:

Policy will rest with a Board of Directors which, in addition to the pharmaceutical profession, may include lay persons such as employers and employees and others representative of subscribing groups.

Sales and administration activities shall be the direct responsibility of the Company through its own staff and facilities or through the utilization of those of an organization with which it enters into an agreement for such purpose.

Appendix O to Brief

MEMBER COMPANIES OF PMAC

Abbott Laboratories Ltd.
Ames Company of Canada, Ltd.
Anca Laboratories.
Arlington-Funk Laboratories.
Astra Pharmaceuticals (Canada) Ltd.
Ayerst Laboratories.
Baxter Laboratories of Canada Ltd.
Bristol Laboratories of Canada Ltd.
The British Drug Houses (Canada) Ltd.
Burroughs Wellcome and Co. (Canada) Ltd.
Calmic Ltd.
Canada Duphar Ltd.
CIBA Company Ltd.
Cyanamid of Canada Ltd.
FBA Pharmaceuticals Ltd.
Fisons (Canada) Ltd.
Charles E. Frosst and Co.
Geigy (Canada) Ltd.
Glaxo-Allenburys (Canada) Ltd.
The J. F. Hartz Company Ltd.
Hoechst Pharmaceuticals.
Hoffman-La Roche Ltd.
Frank W. Horner Ltd.
Ingram and Bell Ltd.

O. 2

Lakeside Laboratories (Canada) Ltd.
Laurentian Laboratories Ltd.
Eli Lilly and Company (Canada) Ltd.
Mallinckrodt Chemical Works Ltd.
May and Baker (Canada) Ltd.
McNeil Laboratories (Canada) Ltd.
Mead Johnson of Canada Ltd.
Merck Sharp and Dohme of Canada Ltd.
The Wm. S. Merrell Company.
Ortho Pharmaceutical (Canada) Ltd.
Parke, Davis and Company, Ltd.
Penick Canada Ltd.
Pfizer Company Ltd.
Pharma-Research Canada Ltd.
Pitman-Moore.
Poulenc Ltée.
The Purdue Frederick Company (Canada) Ltd.
Riker Pharmaceutical Company Ltd.
A. H. Robins Company of Canada, Ltd.
Rougier Inc.

Roussel (Canada) Ltd.
Sandoz Pharmaceuticals.
R. P. Scherer Ltd.
Schering Corporation Ltd.
G. D. Searle and Co. of Canada Ltd.
Sherman Laboratories Ltd.

O.3

Smith Kline and French I.A.C.
E. R. Squibb and Sons Ltd.
Strong Cobb Arner of Canada. Ltd.
The Upjohn Company of Canada.
Warner-Chilcott Laboratories Co. Ltd.
Winthrop Laboratories.
John Wyeth and Brother (Canada) Ltd.

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 6

TUESDAY, JUNE 28, 1966

WITNESSES:

Representing The Canadian Medical Association: Dr. Ramsay Gunton, M.D., Professor of Therapeutics, University of Toronto, Chairman of the C.M.A. Committee on Pharmacy; Dr. Fred Fallis, M.D., General Practitioner, of Toronto, Member of the Committee on Pharmacy of C.M.A.; Dr. Arthur Peart, M.D., of Toronto, General Secretary; Dr. Donald Aitken, M.D., of Toronto, Assistant Secretary.

ROGER DUHAMEL, F.R.S.C.
QUEEN'S PRINTER AND CONTROLLER OF STATIONERY
OTTAWA, 1966

24632—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

Vice-Chairman: Mr. Patrick T. Asselin (*Richmond-Wolfe*)

and

Mr. Brand,
Mr. Chatterton,
Mr. Clancy,
Mr. Côté (*Dorchester*),
Mr. Enns,
Mr. Howe (*Hamilton South*),
Mr. Howe (*Wellington-Huron*),
Mr. Hymmen,
Mr. Isabelle,
Mr. MacDonald (*Prince*),
Mr. Mackasey,
Mr. O'Keefe,
Mr. Olson,
Mr. Pascoe,
Mr. Prud'homme,
Mrs. Rideout,
Mr. Roxburgh,
Mr. Rynard,
Mr. Scott (*Danforth*),
Mr. Tardif,
Mr. Whelan,
Mr. Yanakis—(24).

(Quorum 13)

Gabrielle Savard,
Clerk of the Committee.

MINUTES OF PROCEEDINGS

TUESDAY, June 28, 1966.
(11)

The Special Committee on Drug Costs and Prices met at 11.15 a.m. this day. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout, and Messrs. Brand, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), Isabelle, Mackasey, O'Keefe, Pascoe, Rynard, Scott (*Danforth*), Yanakis (12).

In attendance: Representing The Canadian Medical Association: Dr. Ramsay Gunton, M.D., Professor of Therapeutics, University of Toronto, Chairman of the C.MA.. Committee on Pharmacy; Dr. Fred Fallis, M.D., General Practitioner, of Toronto, Member of the Committee on Pharmacy of C.M.A.; Dr. Arthur Peart, M.D., of Toronto, General Secretary; Dr. Donald Aitken, M.D., of Toronto, Assistant Secretary.

Also in attendance: Mr. A. M. Laidlaw of Ottawa, Legal Counsel for the Committee.

On motion of Mr. Scott (*Danforth*).

Agreed,—That Dr. Gunton read the Summary of the recommendations of the Canadian Medical Association and that the brief be printed as an appendix to this day's proceedings, (*See Appendix "A"*).

Dr. Gunton read the recommendations contained in paragraph 68 of the brief. He was examined. Dr. Fallis, Dr. Peart and Dr. Aitken also answered questions and supplied additional information with reference to the brief.

Mr. Mackasey quoted from an article published in Consumer Reports of May 1966, entitled "The Doctors Who Profit from Prescriptions".

On behalf of the Committee, the Chairman thanked the Canadian Medical Association and its delegates for their submission and information.

At 1.05 p.m., the Committee adjourned to Thursday, July 5, provided the House has not recessed for the summer.

Gabrielle Savard,
Clerk of the Committee.

24632—1½

EVIDENCE

(Recorded by Electronic Apparatus)

TUESDAY, June 28, 1966.

The CHAIRMAN: Ladies and gentlemen, we have a quorum.

We have before us this morning the brief presented by the Canadian Medical Association. You have had this brief in your possession for something over one week. First of all, I think it would be reasonable to have today's brief printed as an appendix to today's report. Is that agreed? Agreed.

I would like to ask the head of the delegation, Dr. Ramsay Gunton, to introduce the members of his delegation and, perhaps, to read the summary of their recommendations.

Mr. RAMSAY GUNTON, M.D., (*Professor of Therapeutics, University of Toronto, Chairman of the Canadian Medical Association*): I am Ramsay Gunton, Chairman of the Pharmacy Committee of the Canadian Medical Association, Professor of Therapeutics, University of Toronto. Accompanying me are, on my right, Dr. Fred Fallis, on the staff of the Toronto General Hospital and a general physician in the City of Toronto. On his right and around the corner, Dr. Arthur Peart, General Secretary of the Canadian Medical Association, and on his right Dr. Donald Aitken, Assistant Secretary of Canadian Medical Association who has also previously been in practice in the City of Toronto.

As the Chairman has suggested, I will read the summary of our recommendations, and I take it, Mr. Chairman, from your remarks about the inclusion of the appendix, that the whole text of our brief will be included in the proceedings of this Committee.

The CHAIRMAN: That is correct, Dr. Gunton. This is on page 22 for those who wish to follow it in their text.

Mr. GUNTON: Summary of our recommendations to this parliamentary committee are:

1. Removal of the 11% Federal Sales Tax on all prescription drugs.
2. Voluntary adjustment of price by manufacturers on expensive products.
3. Less direct mail advertising pressure from manufacturers.
4. Approval of fee-for-service principle in pharmaceutical practice, allowing lower return on high price prescriptions.
5. No easing of restrictions on importation of foreign-made generic equivalents without some official assurance of quality.
6. No removal of patent or tariff protection for Canadian companies which could prejudice their economic survival, because of the need for a healthy pharmaceutical industry in Canada able to invest in research and development.

7. Further government assistance for persons sustaining continuous expense for drug treatment of chronic illness.
8. Insurance against drug cost should be available to all citizens under voluntary insurance programs; with government financial assistance to low income groups. Such insurance programs should include patient participation or co-insurance.

The CHAIRMAN: Thank you very much, Dr. Gunton. I should point out to Dr. Gunton and his associates that this room is equipped with simultaneous translation. If any of the members wish to ask questions in French, there is a little ear piece that you can put on your ear underneath each table.

I think the brief is straightforward. Because the brief will be presented in one sitting, I think we should just answer questions on any or all parts of the brief with no attempt to go through it in any particular form unless the Committee wish otherwise. If not, the meeting is open for questioning.

Mr. SCOTT (*Danforth*): I think on your first recommendation, you will get sympathetic response. The second one asks for a voluntary adjustment of price by manufacturers of drugs. Could you elaborate on that? I have never run across a voluntary adjustment system that was any good, and I just wondered what you had in mind, and if you could tell me a little bit more about how these voluntary systems work?

Mr. GUNTON: It would be the plea from the medical profession to the pharmaceutical firms to reduce the price of drugs for expensive items. I think our reasoning is, perhaps, laid out on pages 17 and 18, where it is pointed out that for the five per cent of the most expensive prescriptions, the saving by carrying out this principle by pharmacists would be considerable but, in addition, there is still we feel, on these items, a considerable basic cost indicated in the breakdown of the prescription costs and we suggest, without defining any systems, that the pharmaceutical manufacturers should reduce the price on these items.

Mr. SCOTT (*Danforth*): I think everybody agrees that all our investigations to date show that these prices are pretty unrealistically high, but what I am trying to get at is why do you restrict yourself to a sort of voluntary plea to them to be nice fellows and keep their prices moderate. Do you know of any place where that is done?

Mr. GUNTON: I understand there is a voluntary price restraint program which has been suggested and perhaps is in operation in Britain. I cannot tell you whether it is really effective or not. Does any other member of our delegation know?

Dr. ARTHUR PEART (*General Secretary, Canadian Medical Association*): I think, Mr. Chairman, that this is a suggestion from the pharmaceutical industry. The practicability is questionable, as you mention, Mr. Scott. We think there is some room here for the pharmaceutical industry to reduce the cost voluntarily. As doctors that is about as far as we can go. We do not know exactly how it would be carried out but perhaps you, in discussing this with the pharmaceutical manufacturers, might ask them if they know of any way it can be done.

Mr. SCOTT (*Danforth*): Do you know if the medical profession are large shareholders in the pharmaceutical companies.

Mr. PEART: I have no idea.

Mr. SCOTT (*Danforth*): There is an interesting article in *Life* this week about the large scale share participation by doctors in the United States. I just wondered if you had any information about that.

Mr. GUNTON: It was drawn to our attention just as we entered the Committee room and, speaking again for myself, I am not aware of any physicians who do own stock in either the major pharmaceutical companies or in smaller companies obviously designed for profit. Do any other members of our delegation know or have an opinion on this subject?

Mr. FRED FALLIS, M.D. (*General Practitioner, Member of the Committee on Pharmacy of the Canadian Medical Association*): We were just discussing the Canadian Medical Association code of ethics and recalling that the suggestion is made there that it is unethical for physicians to have financial interests obviously in any treatment, drugs or appliances that they are prescribing. According to the code of ethics, there is an appeal. There is no enforcement that I know of, but I would think that it would be possible for citizens to complain, if they wish, to local mediation committees. Certainly, in my own area I do not know of any physicians who would be involved in this way.

The CHAIRMAN: I was going to suggest, perhaps in keeping with what we did at the last meeting, it might be reasonable to have each one question for five minutes and then pass on to another one, coming back at a later date.

Mr. MACKASEY: Proceeding along the lines agreed, what was brought out in the article in *Life* which is certainly very disconcerting. There is an article in "Consumers Report" which I would like to table, if I can find the precise issue, Mr. Chairman, dealing with the same subject. I would like to say at the outset that any remarks I may make about the medical profession refers to a very minute segment of that very honourable profession. I am talking about the relationship between doctors and drugstores. I know that in certain communities in Canada, if it were not for the doctors setting up some type of dispensing unit, these small towns would be completely devoid of access to drugs because of the population problem. Nevertheless, in an area as big as Montreal, and I am beginning to track down one or two, there seems to be very definite relationships, in some cases, between doctors or group of doctors and drugstores or pharmaceutical dispensing units. You say, sir, that you are not aware of any such incident but, as an association, are you not morally bound to have at your disposal some medium through which or by which you would be aware of this type of finagling?

Mr. GUNTON: Do I understand you to mean, aware of the fact that physicians have an interest in a drug company?

Mr. MACKASEY: Not only an interest, but in some cases own them outright. I am referring to the fact that there are some doctors who have direct lines to certain drugstores thus preventing their patients from the right of choice; placing the order directly in the doctor's office to a particular pharmacy, again taking away from the patient the right to shop around for the filling of his or her prescription.

Mr. GUNTON: Perhaps, as Dr. Fallis pointed out, our position in this association and in a number of the provincial associations is that we do not consider it proper, as a matter of principle, for a doctor to engage in commercial

practice of pharmacy, but there really is no legal regulation which does prevent this. I do not know that there is any tribunal before which one could bring doctors with a specific charge of malpractice or unethical practice. Under laws of this country they can just own these drugstores.

Mr. MACKASEY: Are you aware of the fact that there is a law pending before Congress or being prepared by Congress along these lines?

Mr. GUNTON: No, I am not.

Mr. MACKASEY: If there is such a law, would you consider such a law desirable?

Mr. GUNTON: You have already pointed out that there are certain areas of this large country where, if doctors did not engage in dispensing—which perhaps means financial interest in the industry—people would be without a supply of drugs. I think that in this country, for reasons of geography, it would be unworkable. I would have to say that we agree with the principle of this where pharmacies are available. I do not think it could be applicable to Canada. Do other members of the delegation have a view?

Mr. FALLIS: I would like to enlarge on what I said about the local mediation discipline committee. The Canadian Medical Association Code of Ethics is a joint production with, especially in Ontario, the College of Physicians and Surgeons of Ontario, and it would be perfectly possible for a doctor to be brought up in Ontario before a disciplinary committee of the profession. Similarly, any patient who felt that wrong had been done in this area could complain through the mediation committee and have a hearing as well. I am thinking that something should be said about the new regulations under the food and drugs department that have been promulgated recently under which tab has to be kept of prescribing and of selling more than three days supply to a patient. Once this—

Mr. MACKASEY: I am not thinking of doctors selling the drug in a particular instance where there is no other alternative. I am referring to implementing a law in communities where you do have legitimate free enterprise drug stores in existence, not referring to the areas where, if it were not for the doctor looking after the dispensing of drugs, there would be no dispensing and we have got many instances where this is very desirable. I am talking about large areas like Montreal, particularly, and Toronto. I am asking, would you be in favour of such a law if it were introduced? And if not, why not?

Mr. FALLIS: One has to see the bill first and, as the Chairman says, we have not seen it.

Mr. MACKASEY: A bill, for instance, that would prevent the doctor from having a direct line to a particular drug store, a bill that would prevent the doctors from filling the prescription over the telephone in the presence of a befuddled or bewildered patient. These are some of the things I would approve of in the bill.

Mr. GUNTON: Mr. Mackasey, we have not discussed this particular point, as a delegation, so any point of view expressed, I suppose, must be a personal one. I, for one, would not be in favour of this law, but I would not be because it really would remove from this citizen, the doctor, the right to engage in a business. I think that he in a sense deserves that right as much as anyone else. We have already told you that we do object to this in principle and attempt to

persuade our profession that it is not good personal conduct but; on the other hand, the question of removing a right, in my view, would be incorrect. I would be against the law.

Mr. SCOTT: You object to it in principle but authorize it in practice.

Mr. GUNTON: Authorizing and sort of suggesting a positive approach, I do not think we have that. We have a negative one but we are sort of defending the individual right of the doctor to do this if he wishes.

Mr. MACKASEY: The judicial council of the American Medical Association, is this just a different name for the disciplinary committee that you referred to before?

Mr. PEART: We do not know what their committees do, I am afraid but I think we are making a lot out of very little, Mr. Chairman. As our friend, Mr. Mackasey mentioned, there is a small amount of this sort of thing being carried out in Canada, I believe, as he said himself. As Dr. Gunton and Dr. Fallis said, there is provision, under our code of ethics, to protect the public from the unethical. The machinery is already there through the College of Physicians and Surgeons which is the licensing authority. I think that the medical profession, certainly the Canadian Medical Association, and the colleges would be very glad to step in and control this kind of thing he talks about.

Mr. MACKASEY: If I were to bring you a concrete example of a doctor who actually controls the drugstore who is taking generic pills, repackaging them under a private brand, prescribing that particular private brand to the patient at prices set without competition because it is a private brand, what would you do?

Mr. PEART: We would like to know that.

Mr. MACKASEY: Yes, but if you did know would you remove his license?

Mr. PEART: The Canadian Medical Association is not a licensing authority. We would bring it to the attention of the licensing authority who could discipline him or remove his license. This is all we can do other than associations. But we certainly take action and we do take action on, not dissimilar things, every day, in the public interest.

Mr. MACKASEY: One final question because we are working under this five minute rule which I do not approve of because it breaks our train of thought, but I bow to the acknowledged wisdom of the Chairman from which I suffer, in comparison.

What is your opinion of prescription pads supplied with the name or title of a particular drugstore on them?

Mr. DONALD AITKEN, M.D. (*Assistant Secretary, Canadian Medical Association*): Again, this is something we have not discussed as a committee but I, personally, would say that I feel no great censure should be attached to this practice. I do not see that there is anything morally wrong in it.

Mr. MACKASEY: Are you not steering the patient to a particular drugstore?

Mr. AITKEN: The suggestion is there, that is all. He does not have to go to the drugstore.

Mr. MACKASEY: But the suggestion is there. He does not have to, but the average person who goes to the doctor once a year or once every five years receives from him a prescription and on the head of that prescription pad is the name of a particular druggist in the general area.

Mr. AITKEN: It would not be on the head—

Mr. MACKASEY: Is it not normal that the patient is going to go to that particular druggist?

Mr. AITKEN: Speaking from experience, I know that they do not necessarily go anywhere near that druggist. A very small percentage of people would actually go to the name on the prescription pad much to the displeasure of the pharmacist involved.

Mr. MACKASEY: Why would that be?

Mr. AITKEN: This is because people probably have a store that they are used to dealing with and they take all their prescriptions to whatever store they are familiar with. It is very simple.

Mr. MACKASEY: Then you have no objection if, in your code of ethics, you adopted a policy that would prevent doctors from accepting this type of prescription pads.

Mr. AITKEN: I just do not see that this would be necessary.

Mr. MACKASEY: I do, because I think it directs them to a particular drug store in which a doctor may or may not have a financial interest. One of the safeguards against this is to fill out your prescription on a blank pad and let the patient go where he or she wants to go. I think what is, perhaps, even better, is that it would remove the 99 per cent of honest doctors from the suspicions of the one doctor which is created by articles like the one in *Life* and the one that appeared in the "Consumers Report".

Mr. PEART: Mr. Chairman, I think we could get some information about this through the Pharmaceutical Association surely. We are just talking in generalities now. But, surely, there is information about this that would be available. As Dr. Gunton said, we do not have any policy on this point and maybe we should. It is common practice. I would like to see something more factual. As Dr. Aitken says, he thinks that people go all over the place. Maybe they do but we do not know what they do, quite frankly.

Mr. GUNTON: Perhaps we could hear from Dr. Fallis who has a busy practice in an area that probably has six or eight pharmacists.

Mr. FALLIS: I would like to agree with the questioner. I think that this practice is wrong and in our district we have pointed out to the local pharmacists, who have been in the habit of doing this, that if they are going to send these pads, and it is a convenience, that they should not put their names on. Several of them still have the name of the pharmacy. I keep a paper cut in the office, and I just take them off the bottom. I think, actually, I may stand corrected on this, there is something in the Canadian Medical Association code of ethics already very close to being against this. It is not actually on the point.

Mr. MACKASEY: You say in your district? What district is that?

Mr. FALLIS: Central Toronto.

Mr. MACKASEY: Thank you very much.

Mr. ISABELLE: I do not know if Mr. Mackasey is trying to put us in front of a tribunal this morning but there is one thing I want to clarify, Mr. Chairman. When we are talking about doctors who own shares in a pharmacy, or in the pharmacy industry, do we mean that if they buy some shares on the Toronto

stock market, from Robins or any others, they do not have the right to prescribe what Robins are selling?

Mr. MACKASEY: Mr. Chairman, since I have been asked the question, for Dr. Isabelle's benefit, I apologize for not having been clearer in my statement. Certainly not, I said many times that pharmaceutical manufacturing associations are on the stock market and they are there for any citizen to buy shares in them. I am referring to doctors who may own individually or collectively a drugstore and unethically direct a patient to that particular drugstore to pay out of proportion prices for drugs which he may be able to buy elsewhere by shopping around at the normal drugstore which are having a hard enough time as it is to stay alive. Again, I am referring to big districts and I am making a distinction between drugstores in large areas and those that exist, particularly in the west in under-populated areas where we can thank God that the doctor is willing to help out this community by carrying, in conjunction with his office, some source of supply. I have no objection, Dr. Isabelle, to where you place your money. If you invest in the stock market you are taking a chance whether your money goes up or down. What I am objecting to is a doctor owning the corner drugstore and directing his patients to that drugstore and giving them little or no alternative to go to the average individual druggist who may be two blocks further away and to whom he does not direct your patient.

Mr. BRAND: On a point of order, Mr. Chairman. We have been discussing hypothetical matters involving the United States. I presumed that we were here to deal with the cost of drugs in Canada. I think it is only fair that we should confine our remarks to the Canadian drug industry and the Canadian pharmaceutical industry, and not base any comments we have here on inflammatory articles in magazines, not professional journals as such, which are open to question and to interpretation. These particular articles which I have read leave out a lot of the facts. Although it may be true in the United States, this is Canada, after all, and this is the country which we are discussing. I have heard "if this happened, would you do this". These hypothetical matters have been ruled out of order before. I wonder, indeed, whether this line of questioning should be pursued at all at this time.

Mr. MACKASEY: Mr. Chairman, I am entitled to speak on the point of order.

The CHAIRMAN: Before you do speak, I would just like to say it is my understanding that Mr. Mackasey's questions were directed to an incident that has actually happened in Montreal, to be specific.

Mr. MACKASEY: Furthermore, Mr. Chairman although I am a very patriotic Canadian, I have no presumption that the morals in Canada are any higher than they are in the United States and that goes for parliamentarians as well as doctors.

As far as I am concerned if the practice exists in the United States and has been documented in *Life* magazine and in "Consumers' Report". I think I am perfectly in order, if I am going to fulfill my mandate on this Committee, to make sure that such practices do not exist in Canada; if they do not; so much the better. I think Dr. Brand is a little naive in assuming that because we are Canadians—and I am referring to research that has been done in the United States—that the possibility does not exist. It can happen in Canada. I happen to know that it does happen in Canada.

Mr. BRAND: Speaking again, to my point of order, Mr. Chairman, with all due deference to Mr. Mackasey and to his intensive research, I wonder if he could place on record the different methods of licensing in the United States for physicians and such; also the numbers who are members of the American Medical Association, comparable to the Canadian Medical Association, perhaps, and to other state licensing groups and the number of osteopaths who, too, are involved in this as well as those of the medical profession proper. I think this is all apropos of the question he is bringing up.

Mr. MACKASEY: Mr. Chairman, to accept Dr. Brand's suggestion, I would like to place on record a letter I have in front of me. If you would like to accept it, translate it and read it to the Committee, I think it will do a lot to verify exactly what I have said.

The CHAIRMAN: Gentlemen, I do not think this should be necessary. I think we should just proceed on with the questioning of the witnesses. They are only before us this one time and I think we should continue.

Mr. MACKASEY: Mr. Chairman, this is an important point, and I will read one paragraph to strengthen my argument. I will translate it as perfectly as possible. This is French and I will state it in English for the benefit of those who speak English.

The second paragraph says,

> We would like to bring to your attention a judgment rendered by Honourable Judge A. Chevrette of the Court of Sessions of the District of Montreal against two Montreal doctors—Drs. Girard and Lamothe for illegally selling pharmaceuticals.

(*Translation*)

This is the case, that in the Province of Quebec doctors are not entitled to sell pharmaceutical products.

(*English*)

This is just one of many testimonials I can bring forward. This is signed by Mr. Jacques Lamoureux who represents the College of Pharmacists.

Mr. PEART: This is what the college is doing. This is what I mentioned a while ago.

Mr. MACKASEY: I am not taking issue with the college, I am just saying there are bad eggs in every basket. I am more interested in reducing the cost of drugs, including those drugstores that belong to doctors.

The CHAIRMAN: I think we should now return to the questioning.

Mr. BRAND: I would like to ask these gentlemen concerning Part 4 of the summary, "Approval of fee for service principle in pharmaceutical practice allowing lower return for high price prescriptions." I brought this up before in this Committee. The province of Saskatchewan, according to the Canadian Pharmaceutical Association, by the provision of this principle of fee for service, 77 per cent of the prescriptions in the Province of Saskatchewan will be increased in price. Do you approve of this method of bringing down prices by raising them 77 per cent. Point No. 4 would indicate that you do.

Mr. GUNTON: Do I understand you to say, Dr. Brand, that if this were applied, the $2.00 prescription fee for service to be charged by a pharmacy in Saskatchewan, it would raise the price of 70 per cent of the prescriptions filled?

Mr. BRAND: That is it, precisely; seventy per cent of the prescriptions across the counter.

Mr. GUNTON: I think we would still approve this in principle, largely on the basis that the amount by which those prescriptions will be increased, and I obviously cannot say what it is, would be a rather small figure. We feel the saving, on the other hand, to the consumer would be considerable for the very high price prescriptions and so, in a sense, we are aiming our recommendation at the patient who is unfortunate enough to have prescribed for him or who needs very expensive items. Therefore, the saving in dollars we feel would be greater if the principle were applied even though we would have to accept it that each one of the cheaper prescriptions would be more expensive.

Mr. BRAND: Do you feel then that raising the cost by 77 per cent in the Province of Saskatchewan, for example, would be justified by lowering the cost of expensive prescriptions quite considerably.

Mr. GUNTON: We hope that this is the case. Specifically in respect of Saskatchewan, I cannot tell you whether the increase paid, even though a small amount, in 77 per cent of prescriptions, would be greater or lesser than the saving on the expensive ones. We just do not have that data but we expect or hope from our analysis of this situation that it would.

Mr. BRAND: Are you aware that in Saskatchewan for $9 a year for a family you can obtain extended coverage through the medical services insurance and through the group medical services there which will provide for the total cost of expensive prescriptions drugs except for a deductible fee which, I believe, is around $25 over a year. Would you not feel that this would, perhaps, be a better method of saving on the very expensive medicines particularly for those who have to put out a lot of money every month for continuing pharmaceutical care?

Mr. GUNTON: That recommendation is included in our brief as well.

Mr. BRAND: Yes, I know. It is at the end of the list and this is at the top and that is why I wondered.

Mr. GUNTON: I do not think the order of our recommendations, Dr. Brand, indicates our thoughts on priority really. As a matter of fact, in the text of the brief, I think that insurance appears in a much more eminent position.

Mr. FALLIS: Mr. Chairman, I think perhaps it should be stated in another way; that by increasing the cost to 77 per cent of prescriptions, the over-all total cost of drugs may not be increased. This is what we think. This is a different method of distribution of the costs.

Mr. BRAND: Are we not interested in the cost to the person who requires the drug rather than the over-all cost?—

Mr. FALLIS: Yes. In fact the relief is to the person here who is really stung with the 77 per cent of prescriptions that go up. The $2 ones go to $2.25 and the $3 to $3.40. The $17 and $18 ones come down.

Mr. PEART: I do not think, Mr. Chairman, that we have specified any particular fee for service either. We quote the Pharmaceutical Association's $2 but we are not suggesting any amount particularly. We are just agreeing with the principle of a rational fee plus cost, and it could be any amount that was acceptable to the people giving the service.

Mr. BRAND: I do not see how you can agree with a principle that increases the cost of drugs when we are concerned with lowering them.

Mr. FALLIS: That is just what I said. It does not increase the cost of drugs across the spectrum. It is a suggestion to redistribute the cost of drugs.

Mr. BRAND: The lower income person does not care about what it is going to cost and how many million a year for the total drug industry.

Mr. FALLIS: The average person does care about these expensive drugs and this is a suggested method of bringing it down, among other methods suggested.

Mr. BRAND: I think that is my five minutes.

Mr. O'KEEFE: Mr. Chairman, my question is in connection with No. 2 on page 22 of the brief, "Voluntary adjustment of price by manufacturers on expensive products." At the last meeting I asked a question about the manufacturers voluntarily reducing their prices and I was told that this would be against the Combines Investigations Act. Perhaps it was a legal question but I should like you to comment on that.

Mr. GUNTON: We have discussed this fact, that if it were by convention or agreement among the manufacturers, it would indeed be a contravention of the Combines Investigations Act.

Mr. O'KEEFE: I suggest that the combines people would be very happy to see the prices reduced. They also buy drugs, I should think, and I cannot imagine their being against reducing the price of the drugs.

Mr. GUNTON: Perhaps the words "voluntary adjustment" implies a system that we had in mind. We have to tell you frankly that we had no idea of a system, of a committee, for example. This is simply a plea. We must in the medical profession and the manufacturers cut down the price of expensive drugs, but we have no legal teeth to apply this. This is something we say to them "cut them down", but we are not really suggesting a system. I have never, in my mind, had any system in mind. Have any of the other members here?

Mr. O'KEEFE: You say you have nothing concrete to suggest?

Mr. GUNTON: Ask the Pharmaceutical Manufacturers if they have.

Mr. O'KEEFE: But this is your brief.

On Page 21, opposite No. 64, you say,

> The person who suffers from a chronic disease requiring long term continual drug therapy is unfortunate.

We certainly agree with that. You go on to say,

> For him drug costs can assume alarming proportions. We believe that this is an area for provincial government to relieve these costs. In some provinces this has in part been done. In Ontario, for example.

Are there any other provinces, you know of, where this is done?

Mr. GUNTON: Yes, in British Columbia there is a social and medical assisted program for provision of drugs. Ontario, we have mentioned. I will have to defer to the other witnesses at the Committee for any other examples.

Mr. PEART: There are quite a few provinces that supply antibiotics and biologicals such as immunization materials. Quite a few actually supply insulin for indigent people. Saskatchewan supplies penicillin for rheumatic heart disease. There is a variation in what the provinces provide.

Mr. O'KEEFE: May I ask specifically what is being done in Newfoundland or am I being too provincial again?

Mr. PEART: I do not know.

Mr. O'KEEFE: Does anybody know?

Mr. PEART: They have a very comprehensive medical care plan, as you probably know, with their cottage hospital program.

Mr. O'KEEFE: That applies only outside of St. John's.

Mr. PEART: No. The children's health service at St. John's is a very comprehensive one, the Children's health service in hospitals. Drugs can be provided there and, no doubt, they supply them for low income people if they are all on indigent relief.

Mr. O'KEEFE: I am not speaking of those who are on indigent relief, I am speaking of those who are not on relief.

Mr. PEART: I see. I do not know.

Mr. HOWE (*Hamilton South*): Mr. Chairman, I would like to commend the Canadian Medical Association on their brief. I would just like to make one comment on No. 4 on page 22 and that is that there are some drugstores in the Hamilton area who have applied for fee-for-service principle on drugs costing over $5 only, which is very commendable on the part of the drugstores but certainly must be workable if drugstores are able to do it. If you accept that a $5 drug costs 40 per cent less, which is $3, and they add on the $2, which makes it $5, this $5 is the dividing point between drugs being cheaper or more expensive on the fee-for-service principle. I am not trying to interfere with what the drugstores should do but I know that there are several drugstores in Hamilton that are doing it very successfully.

I must take exception, in spite of my opening remarks, to paragraphs seven and eight in the summary because this gets back to the old means test again. The subsidizing of the price of drugs certainly does not do anything toward lowering the price, but rather it takes the money out of another pocket and still pays the large profits to the drug manufacturers. Certainly I, myself, am not in agreement with voluntary insurance programs as government financial assistance because this must involve a means test and, therefore, I cannot concur with that principle of means testing. I think that this must be included in some over-all plan; for people who are not going to have the indignity of a means test before they can get drugs that are necessary for their health.

Mr. PEART: We accept that difference of opinion, Dr. Howe.

Mr. HOWE (*Hamilton South*): I am still entitled to express an opinion.

Mr. HOWE (*Wellington-Huron*): On page 22, in the summary of recommendations, item No. 2 reads, "Voluntary adjustment of price by manufacturers on expensive products". Would you suggest that they reduce the expensive products and raise the price of the cheaper products to ensure that they did make a profit on the operations?

Mr. GUNTON: Yes, we proposed some adjustment of that type but specifically to say that we recommend the increase in price of a less expensive product, I do not think would be correct. Perhaps we could hope that they might operate on a little less profit. I think this is something that we cannot analyse in great detail but we think that that might be possible.

Mr. HOWE (*Wellington-Huron*): It would depend, of course, on the druggist, circumstances in the area in which he operates the volume of the business he does; these would all have to be considered in this type of voluntary program to have any effect, I would imagine.

Mr. GUNTON: We had thought more of directing this recommendation to manufacturers rather than to retail pharmacists.

Mr. HOWE (*Wellington-Huron*): Turn to page five, paragraph 15. I get from that paragraph that you consider that there might be implications in the reduction of the type of drugs in that the standard of the drug and the importance of its components might be downgraded if there was an over-all reduction in drug costs. Is that not what is implied in that paragraph?

Mr. GUNTON: Yes.

Mr. HOWE (*Wellington-Huron*): That you are not all for this cheaper cost of drugs because it might entail a reduction in quality and ability to do the job for which it is prescribed.

Mr. GUNTON: That is right.

Mrs. RIDEOUT: I was interested in Dr. Howe's reference to No. 7 of the summary, "Further government assistance for persons sustaining continuous expense for drug treatment of chronic illness". When you prepared your brief, I was wondering if you had taken note of the proposed legislation under the Canada Assistance Plan which makes particular reference to more assistance toward the cost of drugs for people suffering from chronic illness, or who need more drugs than they can afford to pay for. Do you have something else in mind? I was just wondering if you had any other suggestions that you particularly had in mind in the form of assistance for these people?

Mr. GUNTON: Speaking personally, I regret to say I did not have the Canada Assistance Plan in mind. Dr. Aitken, do you have any further to add to this?

Mr. AITKEN: We had no other particular action in mind.

Mrs. RIDEOUT: I was wondering if you were thinking—I probably should not even suggest it myself—of some form of provision for the cost of drugs under the medicare program?

Mr. AITKEN: This was a possibility which we have mentioned in the brief. We feel that in a comprehensive health program the cost of drugs must be associated; there must be some provision for insuring drug costs as, indeed, everyone wants to insure medical services cost. We feel that it is an important part of the medical treatment and cannot be ignored.

Mrs. RIDEOUT: It always appears to me that when we mention chronic illness, we are inclined to think more of middle aged or elderly people. I am thinking particularly, of our discussions in the Health and Welfare Committee and, of the children who are born with cystic fibrosis. I had the privilege of meeting with the delegations, for the minister, and one of the things that I learned from them was the high price of drugs. In one family particularly they had two children and the cost to provide medication for these children was almost prohibitive. Would you not think, also, that this would include this type of person?

Mr. GUNTON: We should make it clear to the Committee that in many provinces, and for many diseases, there are voluntary agencies which will

provide drugs free. For example, the Ontario Cancer Association will provide anticancer drugs free. In some provinces heart foundations provide penicillin free for prophylactic rheumatic fever. In some instances, the Cystic Fibrosis Foundation will provide medications free for victims of that disease. All these influences, of course, in a free enterprise society tend to reduce the cost to people who are burdened by a long chronic illness. This exists in quite a number of provinces and for quite a number of diseases.

Mrs. RIDEOUT: My concern is this. I live in the province of New Brunswick where we just do not have the advantages that you have in Ontario and across into British Columbia. The people just do not have the advantage of having the opportunity to know about these drugs or to even go to people who can advise them. I am concerned as you are that this must be an over-all advantage to all the people, not just the ones who happen to live at the right place at the right time.

Mr. GUNTON: Especially in some areas the work of voluntary organizations, like the Heart Foundation and the Cancer Foundation, is really not as developed as in others. Admittedly, this is an inequity that you find quite frequently.

Mrs. RIDEOUT: And particularly in children who are affected with diseases that cannot be diagnosed—

Mr. GUNTON: It will be much easier for those children with that sort of problem to get help in a large metropolitan city than it is in a small place.

Mrs. RIDEOUT: Then we get back to the old problem that we were studying in the Health and Welfare Committee, the cost of the drugs is sometimes beyond what the families can afford.

Mr. GUNTON: Here is the point. These children who tend to be on antibiotic drugs often use a new potent antibiotic drug which is excellent. It is with this sort of drug that we are saying our Newfoundland doctors cut down the price of these drugs; but I suppose their response is unless they put millions of dollars into the development of these drugs, how can they cut the cost? This is the sort of request you are making of them. That is the same situation you describe. These are antibiotics and they are very expensive.

Mrs. RIDEOUT: Thank you, Mr. Chairman. I do want to compliment you on your brief too because it is certainly very constructive and very helpful.

Mr. PEART: May I say a word about Mrs. Rideout's question. I think we should make it clear that aside from the Canada assistance beneficiaries who may qualify on a mean's test, we are also recommending that people suffering from chronic conditions get help too. This may please Dr. Howe perhaps because there are people with very disabling diseases such as the type you mention yourself that have a lot of expense and need help to bear these expenses, as far as the cost of drugs are concerned.

The CHAIRMAN: After the debate last night, I am sure that Dr. Peart meant a needs test rather than a means test.

Mrs. RIDEOUT: I just want to make a correction and say I think we should refer to it as a needs test.

Mr. PASCOE: Mr. Chairman, there have been quite a questions asked on voluntary adjustments. I will not repeat them, but on page 21, paragraph 63 refers to the disparity in prices of truly equivalent products. Could any of the

witnesses testify if there is a great disparity in these prices, on the truly equivalent products?

The CHAIRMAN: Between generic products and brand name products?

Mr. GUNTON: We have to answer yes; there is a great disparity.

Mr. PASCOE: The doctors then would know about this disparity in prices. Would they, perhaps, recommend that the cheaper and equivalent products be prescribed?

Mr. GUNTON: The problem is that we do not know, in the case of generic products, which generic products have been produced under conditions of quality control. You asked the question "is it possible that there are some"? There is a disparity between the brand name and the generic product.

Mr. PASCOE: That is your suggestion right here.

Mr. GUNTON: We have to admit that there are truly equivalent products with a great disparity in price but as physicians we are not able, we are not in a position to know, when the generic products really are truly equivalent because the batches vary and importers can import from one company one time and another company another time. This is the information we lack. We must admit that sometimes they are truly equivalent but it is the unknown factor which constantly worries us.

Mr. PASCOE: Going on a little further, you say "obviously it is difficult to reduce them to the level of foreign made imports because our manufacturers must pay Canadian prices for the material and labour used." What countries do you have in mind where the prices and labour are cheaper where they would have equivalent drugs?

Mr. GUNTON: Italy, of course, is one of the countries which is a prime supplier of so-called generic products. Czechoslovakia, I think to some extent, not much in France but I think Italy probably would be the one example. Do other members of the delegation have any comment on that?

Mr. PASCOE: Is there tariff protection against them coming in from Italy?

Mr. GUNTON: They can produce cheaper, because of labour costs and so on, than we can in Canada.

Mr. PASCOE: What about American products coming in? Their prices would be higher. Do their prices compare with Canadian prices?

Mr. PEART: There is a variation up and down. I think as one looks at the relative cost of prices, United States versus Canadian, in some cases our prices are lower and in some cases their prices are lower. I do not think there is a uniformity of differential between the two.

Mr. PASCOE: You ask for no removal of tariff protection for Canadian companies? Do American companies have the same protection against our products? Would you know that?

Mr. GUNTON: You mean, if a drug originated in Canada, could a United States firm produce it? Is there not international recognition in most countries of patents? I think that one of the advantages enjoyed by Italy is that it does not recognize international patent agreements but the United States and Canada do. Therefore, I believe the answer to your question is no; United States firms could not produce, without agreement, drugs which originated in Canada.

The CHAIRMAN: As I say, this is now probably not within the competence of the witnesses to answer.

Mr. PASCOE: They have it down here on their recommendations.

Mr. SCOTT (*Danforth*): Just before leading to my five minutes, Mr. Chairman, on a point of order, how long are we going to be hearing these gentlemen? Are we going to sit again after lunch or this evening?

The CHAIRMAN: It is within the discretion of the Committee. It was our hope that we might finish by 12.30 or 1.00 o'clock. This group have only one scheduled appearance before us.

Mr. SCOTT (*Danforth*): At the risk of treading on sensitive toes, it is hard not to say much on this Committee, with 80 per cent of it being doctors, without treading on toes, but—

The CHAIRMAN: Your figures are a little distorted.

Mr. SCOTT (*Danforth*): I think so, too, but this brief is not just anaemic. I think it is naive for you to come here and try to tell us that a voluntary system of restraints on pharmaceutical companies will reduce drug prices. Are you really seriously advancing that?

Mr. GUNTON: You are making—perhaps it is unfair to make a comment but he is somehow suggesting that item two is our whole brief. It was not—

Mr. SCOTT (*Danforth*): No, but it is the area in which we are primarily interested at the moment, drug prices and this is the area the Committee has been—

Mr. GUNTON: Surely, as a Committee of parliament, this is your province and not ours; really, the enforcing of legislation is not our role.

Mr. SCOTT (*Danforth*): You cannot even give me an answer to what you mean by a voluntary system, how it will be set up, how it will work.

Mr. GUNTON: We did not have in mind a system. I do not know what you mean by a system; do you mean a committee; do you mean a set of rules, that on drugs manufactured above a certain cost price there would automatically be a percentage reduction?

Mr. SCOTT (*Danforth*): I take it your Association would object to government regulation in this field?

Mr. GUNTON: Yes, we would. Dr. Peart, may we have your opinion on that?

Mr. PEART: I do not know whether this line of questioning is in order or not. We came in all good faith, to present what we thought might be done. We are proposing that perhaps the pharmaceutical manufacturers might have a method of reducing the costs and that is as far as we are able to go. We cannot enter into their field. If Mr. Scott does not think this is fair, that is his opinion. We share another opinion, that is all.

Mr. SCOTT (*Danforth*): This is the only opportunity we will have to talk with representatives of the medical field. For example, what would you think of a crown corporation being set up to manufacture and market drugs under their generic name? Would there be any medical problem in that?

Mr. GUNTON: I think we would be opposed on principle, individually and, I suspect, collectively.

Mr. SCOTT (*Danforth*): Why would you be opposed?

Mr. GUNTON: Mr. Howe, and one of the other members of the Committee, touched on this point, that this would almost certainly remove the private enterprise initiative which is now enjoyed by the pharmaceutical companies. We have to admit, as medical practitioners, that we no longer either in practice obviously or in universities originate new drugs. These come from pharmaceutical companies. They have to have this incentive to produce them, and if we are interested in Canada to have a crown corporation to manufacture drugs, we would simply be copiers of everything that is done everywhere else in the world. There would be no initiative in Canada to produce new drugs. We want to preserve the pharmaceutical industry, because it does contribute to our care of patients and really to the welfare of Canadian citizens. I think it would be a dreadfully retrograde step.

Mr. SCOTT (*Danforth*): I am not going to engage in an argument with you, it would not be proper, but I would suggest you look at their statements as to the minimum amount of money they actually put into research for new drugs. It is a very tiny percentage of their total volume in goods. We found out when they were here bamboozling us last week.

Mr. GUNTON: We have seen, however, as members of the medical profession that the pharmaceutical industry in Canada really has, in the last five or ten years, made a lot of advances in research equipment in Canada. We know of them in Toronto and in Montreal. We know from visiting them personally and from discussions with medical directors that these are serious dedicated men interested in drug development and drug research, in terms of what we see and we know.

Mr. SCOTT (*Danforth*): One interesting aspect we found last week is what is called "the detail man", the pusher from the drug company. How does that work? Do you have any comment on how this system operates?

Mr. GUNTON: I have never heard, outside this Committee, that term used for this man. These are representatives of pharmaceutical companies that come to inform us of their new products. I have to say, frankly, that doctors vary in their response to detail men. I personally have always had an open office to them. They come by certain appointments. I talk to them. I am informed by them because they bring useful information about new drugs. I know there are doctors who refuse to see them on the basis that they are indeed attempting to sell and selling is their principle motives. I really feel they do us a service, a considerable service, in informing us. There is no doubt that there is a commercial motive as well but I think that if we abolish the commercial motives we would lose a great deal of information as physicians. Other members here of course, have other views. Perhaps I had better defer to Dr. Fallis on that too, if you would.

Mr. MACKASEY: In paragraph 11 of your brief you outlined it very adequately.

Mr. FALLIS: I do not think I have anything to add except to underline the hope that they would continue to try and improve their training and their approach to the doctor. It has to vary, too, because doctors are so different. Sometimes they have to smash their way in between patients and other physicians and give them appointments and treat them as if a patient were coming in. It does make one pause in the middle of a day to think about this

area of therapeutics that is being presented and often there is a discussion of values, I think.

Mr. SCOTT (*Danforth*): Does most of your information come from the detail man or from journals and periodicals?

Mr. FALLIS: I think that is very hard to assess. I think it is an amalgam that solidifies as you go along. I hope that more of it is from experienced discussions with colleagues and medical reading, journals and articles and so on.

On your question of the crown corporation, you probably noticed some remarks made on page 15 about the differences in marketing and production between the United States and the U.S.S.R. which may be of interest. You may know that in Ontario, the Univeristy of Toronto has a manufacturing division, the Connaught Medical Laboratory, which, in a sense, is a crown corporation and already exists. It has had a valuable effect, I think, on production of new drugs, particularly in the area of injectables, perhaps in vaccines, but they have neither taken the field over nor retreated. They have just been there as a good influence. They seem to be able to get along with the commercial manufacturers all right.

Mr. SCOTT (*Danforth*): Are you prepared to see that extended into other areas?

Mr. FALLIS: No. What I meant was that if there were any need to extend it I think it would have been extended by now.

Mr. MACKASEY: Mr. Chairman, there are many areas I would like to discuss. I will try to limit them to one.

On page 22, item 5, you say, referring to foreign-made generic equivalents that there should be no easing of restrictions without some official assurance of quality. Mr. Chairman, it is not a question I am asking. It is a request of the Chairman, at the moment. I recall that several months ago the Food and Drug Directorate sent two or more people to Italy to investigate the source of generic drugs coming into Canada. Would it be possible, through your good offices, Mr. Chairman, to have their report tabled?

The CHAIRMAN: I will discuss it with Dr. Chapman and find out.

Mr. MACKASEY: I understand from the publicity that was given out that they came back with a very dim view of the source of generic drugs in Italy.

The CHAIRMAN: I will be pleased to look into that matter and see what can be done.

Mr. MACKASEY: Certainly, I would also like, Mr. Chairman, if possible because I have been unable through the library to obtain it—I have tried for two days—to get a copy of the article, "Ironic Contract" published in the Harvard *Business Review* of 1962. I do not know if the library does keep its articles that far back or whether they just do not think highly enough of the Harvard *Business Review,* but I would like to get a copy, if I could.

Mr. AITKEN: Unfortunately it was a misprint. It is "Ironic Contrast", not "Contract".

The CHAIRMAN: I think this was published in a source other than the Harvard *Business Review,* I think it has been reprinted.

Mr. MACKASEY: *Fortune* magazine, I believe.

Mr. GUNTON: I think the C.M.H.A. has it.

The CHAIRMAN: I think it was reprinted in the Medical Association *Journal*. Perhaps they could try to find it for us and we could get it reproduced for all members of the Committee.

Mr. MACKASEY: Section six, Mr. Chairman, surprises me a little although I am glad to see it in there. It shows the doctors are doing their homework. Regarding their comments on patent or tariff protection, I do not quite understand how this could concern the doctors, the tariff policies and patent protection. Why your undue concern for the economic survival of the industry?

Mr. GUNTON: I thought I did answer that in part, perhaps, to Mr. Scott. We believe that there should be an economically healthful pharmaceutical industry in Canada for the reason that most of the drugs that we use now are developed by pharmaceutical companies and it would be blind of us not to acknowledge this fact.

Mr. MACKASEY: Somewhere in the brief—I am going by memory—I think it might be on page six, we get down to cost components. Paragraph 18 begins by saying, "These amounts do not seem to us to be unreasonable". They are talking about drug costs. It continues, "When we consider the level of income and the standard of living of Canadians, the amount of the average prescription and the annual per capita cost appear to be well within the ability of self-sufficient citizens to pay" which is really our reason for existence, Mr. Chairman. In the cost components, further on, down the page, we get back to our federal sales tax of 14 cents out of the dollar. In this particular case the example of the taken drug costs $3.47, and I hope someone will correct me if I am wrong: Total cost $3.47, federal sales tax 14 cents. I finally found out the information I could not get last week, Mr. Chairman. Fourteen cents represents $1.27 if it is applied strictly to the substance going into the $3.47. Then, when you move on to page—

The CHAIRMAN: Would you mind saying that again, Mr. Mackasey?

Mr. MACKASEY: I would just like ot go on record as saying that this total cost of $3.47 must include raw materials of $1.27 for finished product of $1.27 because that is what eleven per cent of 14 cents represents, working backwards. It is $1.27.

Mr. FALLIS: Actually, on the wholesale price of the drugs, I think you will find in the brief that the sales tax is on the wholesale price of the drug; the total cost is the cost to the consumer.

Mr. MACKASEY: The federal sales tax applies to the manufacturing price, not the wholesale price. Therefore, the cost from the manufacturer to the wholesaler is $1.27 and we end up paying almost three times $1.27 which would be $3.81. We end up paying $3.47, Canadian consumer. Whether this is fair or unfair is something we can determine from our Committee meetings. What I am trying to get at, Mr. Chairman, is that last week I did try to find out from the Manufacturers' Association the relationship between the end product price the consumer pays and the cost the manufacturer charges to the wholesaler or distributor, or to directly to the pharmacists. In this particular table we can deduce that something leaving a manufacturing plant at $1.27 ends up in the consumer's pocket at $3.47. I would like to come back to this in another week or two—

The CHAIRMAN: Perhaps you could bring this up again when we are examining the Pharmaceutical Manufacturers Association of Canada. It is not clear to me yet your—

Mr. MACKASEY: I would like it on the record. It is very simple. The federal sales tax can be charged only to the phase of operations involved within the domain of the manufacturer. Fourteen cents represents the tax that would be levied on $1.27. This amount of $1.27 must be the cost of the finished product when it leaves the warehouse of the pharmaceutical company.

Mr. HOWE (*Hamilton South*): May I just interrupt on this point? If we accept the CPMA's figure of 37½ cents being their price of the prescription dollar, if you multiple 37½ by this $3.47 you come out to $1.30. That confirms your point.

Mr. MACKASEY: But, Mr. Chairman, on page 8, item 26, reads, "We would remind the Committee that an important and immediate effect of the withdrawal of this tax would be a five per cent reduction in the retail cost of prescribed drugs". This annoys me, not being an accountant and not having a very orderly mind. The Minister said four. These people say five. The druggists said ten. Our accountant said something like—

The CHAIRMAN: I do not think he said.

Mr. MACKASEY: One ill-advised member of the Committee suggested as high as 19, but it seems to me that it is about time, before we keep going a that we know exactly what effect the federal sales tax does have on the federal dollars. Is it five per cent, is it 10 per cent, is it 12 per cent or is it four per cent?

The CHAIRMAN: I think this is an area that we cannot expect the medical association to cover. As you know, there is a paper being prepared for us by the Department of National Revenue.

Mr. MACKASEY: Could I ask the medical profession how they arrived at the conclusions in paragraph 26?

Mr. AITKEN: We arrived at them by trying to relate the 11 per cent to what we felt were the cost of the production of the drug. I think that at between four and five per cent, at least we are closer than anybody else. We are no expert with figures but we felt this arrives at approximately what it would be as far as the reduction in the retail price is concerned.

Mr. MACKASEY: You are saying, therefore, and again I am relying on my memory and the medium of your table, around $3.47? If under $5.00, 80 per cent of the drugs are purchased. I think under $5.00 was mentioned. Let us take a $5.00 drug. Are you saying that if the sales tax is removed it would only have the effects of reducing that $5.00 drug by 25 cents?

Mr. AITKEN: Five per cent. That is right.

Mr. FALLIS: Mr. Chairman, if it is clear because of the cost components, particularly the large ones the pharmacists service, we have been discussing and showing, how this may vary from district to district, drug to drug and cost to cost. It is pretty hard to give you figures.

Mr. MACKASEY: Could I give you a figure. This gentleman has just told me that it would reduce the cost by 25 cents. If you go back to page six, and you add no federal sales tax, you would reduce that cost component there by 14

cents on a $3.47 item. I do not know if this works out to five per cent. It does work out to five per cent of $3.47. The point that has been bothering me since the beginning is the question of the pyramiding of the sales tax. It seems to me you have not allowed for that. I can understand if the new method of pricing, which the druggists have alluded to and which has been mentioned several times here today, is the actual cost of the product plus a professional fee to be charged to the people the effect of the federal sales tax would be minimal, but where we have the old system which is still prevalent where this is considered part of the cost and pyramided as it goes through so many hands, I still say that the federal sales tax represents closer to 20 per cent of the prescription dollar than it does to five per cent.

The CHAIRMAN: I think this is a point we have discussed many times.

Mr. MACKASEY: But we do not get the answer, Mr. Chairman.

The CHAIRMAN: The answer is supposed to come from the Department of National Revenue and then it will be gone over by our own accountant on the Committee.

Mr. O'KEEFE: My question is about the direct mail. I remember Dr. Howe, in a very dramatic exhibition here a little while ago, brought in a whole bag of matches, rules and gimmicks. I suggested if Dr. Howe is receiving those, all the doctors in Canada or most of them are receiving them. Is that correct?

Mr. GUNTON: That is true.

Mr. SCOTT (*Danforth*): One is saying "no" and one is saying "yes".

Mr. O'KEEFE: Because almost certainly they will be part of the drug costs to the consumers.

Mr. GUNTON: There is no question about that.

Mr. PEART: Mr. Chairman, I am not getting them and I am a doctor.

Mr. O'KEEFE: Do you represent all the doctors in Canada?

Mr. PEART: No. I am just telling you all the doctors do not get them. Some doctors may get them, but I think things have changed a great deal over the last recent years.

Mr. O'KEEFE: Have you any idea of the percentage of the doctors who do?

Mr. PEART: I think much of this has gone by the board at the moment. The amount of direct mailing is being reduced markedly. Pharmaceutical manufacturers themselves have been more selective in the doctors they send things to. They specify by specialty and only send things to those specialists who need that particular type of drug. The Canadian Medical Associations through our Committee on Pharmacy have also asked that this be reduced and I think things are not nearly as bad as they have been reported.

Mr. O'KEEFE: You suggest that this cost is not significant?

Mr. PEART: It is certainly significant. You can see that it is but I do not think it is as great a problem as it used to be as far as the doctors are concerned. I would like Dr. Fallis or Dr. Gunton who are practising men to speak about this. I am not a practising doctor and I get very little of this.

Mr. GUNTON: I do have to disagree, I am afraid, with Dr. Peart. I have found this to be one of the worst features of the pharmaceutical manufacturing companies, and where I am willing to defend them for most of the things they do which is originate new drugs and provide drugs for patients on short notice

of a rare type, I feel that the pressure of direct mail advertising is contributing to the cost of drugs in two ways: One is the actual cost of the material of the copywriters and of the postage. The second, and I think this is important and we would be less than frank not to admit it, is this sort of pressure may influence doctors to prescribe drugs that might perhaps properly not be prescribed. There is no other way to face the issue than it exists. I feel that this sort of pressure that the doctor is exposed to constantly from direct mail advertising, that they prescribe such and such to their patient without any anxiety. He is exposed to this all the time and I think this is not a good influence. This is part of our brief because we feel it could reduce drug costs over all of Canada.

Mr. O'KEEFE: Surely you are not suggesting that there was ever a doctor in Canada who would prescribe drugs that should not properly be prescribed?

Mr. GUNTON: I think doctors are human like anyone, and they are bound to be influenced by this sort of advertising pressure. I think we would be less than frank not to say that we are. I think this is a feature of the operation of pharmaceutical manufacturers that should be discouraged.

Mr. O'KEEFE: You have shaken my faith in doctors. Do you know if there is any place in Canada where a doctor is receiving, I would put it down to, a kickback from druggists on prescriptions.

Mr. GUNTON: I, personally, never heard of it nor have I ever talked to anyone who heard of it. Mr. Mackasey mentioned it to us this morning. We had better poll the others.

Perhaps, in view of the divergence of opinion about direct mail advertising between Dr. Peart and me, we could hear from the others as well, from Dr. Fallis and Dr. Aitken?

Mr. FALLIS: I agree with the brief where it states that this is the least desirable method of pharmaceutical promotion. I would agree that in my own office things seem to be a little better than they were. There is not quite the same volume and the same gimmickery, as you call it, and I seem to sense, whether it is because of my own state of preference to the detail men or whether the releases, as a whole, are making more reasoned references, but it seems to me there is a more reasoned outline of what this new drug is on a sound basis than there used to be. I am afraid that it is true that the doctor, perhaps, gets partly what he desires in this area, and there probably are some who give a warmer reception than others do to the gimmicks when they come in. I think it is fair to say that the profession, as a whole, has been fed up with it and that their objection has met with some response.

Mr. O'KEEFE: When the other doctor suggests that drugs are prescribed that should not properly be prescribed, what exactly is meant by that?

Mr. FALLIS: I do not think he means in the sense that what is being prescribed is a bad practice. He has made up his mind on the basis of lightly considered, briefly stated—

Mr. O'KEEFE: Did you say lightly considered?

Mr. FALLIS: Something comes across his desk and there are only 15 or 20 words on the sheet. There may be some sort of illustration in much the same way that you might see bread advertised and go into the chain store to buy the bread. It is not malpractice that you bought that bread rather than another

bread, but when it comes to selecting drugs, this is not the way you should be selecting them. You should be doing it on the basis of your reading and so forth. I think this was Dr. Gunton's suggestion, that perhaps it makes us lazy and we are taken in by the slickness of it. We think we are showing good judgment but we are really not.

Mr. PEART: Mr. Chairman, I would like to say a word about this. I do not want to give the impression that the doctors are prescribing drugs unnecessarily. This is not the point. They are using an alternative drug. In other words, they may have been used to prescribing a certain type of drug for a certain condition, then a piece of direct mail advertising comes in and so they try another one. It does the same thing, presumably, but—

Mr. O'KEEFE: Would it cost twice as much?

Mr. PEART: Not necessarily. It may cost half as much, but they are just having an alternative drug because of the constant supply of advertising material.

Mr. O'KEEFE: It still might cost twice as much.

Mr. PEART: Not necessarily. It may cost half as much; it may cost twice as much, or it may cost the same price.

Mr. HOWE (*Hamilton South*): My question is right along the same line. I do not agree that this has got any less recently. I do agree that there should be less direct mail advertising. The C.P.M.A. that was here said that of the 37½ cents they got of the prescription dollar, one and one half cent of it was labour, two and one half cents was research and 11 cents was promotion of the drugs. In other words, therein really lies the largest single price of the drugs we prescribe. Would it not seem logical that the cost of advertising one brand against another of the same thing and pushing, such as you suggest, is one of the largest costs that a patient pays when he buys a prescription. It is not necessarily just the gimmicks and just the advertising but the combination of everything added together where they are simply pushing one drug against another that happens to be identical. Is this not really where this competition lies? If a company has a drug and they are the only ones that make it, there is not the same pressure in advertising until it becomes competitive and then the increase in advertising costs will logically go up to try and sell their brand over another brand that is exactly the same thing. Is that not contained in your summary of recommendations, in item No. 3? You use the word "pressure" yourself and this is a pressure type advertising that keeps the cost up to the patients. It is one of the biggest costs.

Mr. SCOTT (*Danforth*): Then you would not agree with some of the drug manufacturers that this type of advertising is very useful and helpful? They were divided last week on their reaction to the bundle of stuff that Dr. Howe brought out. One group admitted right away that this was undesirable. Another group thought they were performing a very useful and informative function with these shoe brushes that were sent out, you know, that sort of thing. You would tend to the view that this is not helpful to you?

Mr. GUNTON: Occasionally they do send out a well-documented, scientifically written brochure on a drug that is useful. A number of them, for example,

sent essences, describing a disease or anatomy. These are useful. They are in the minority. The majority are rather uninformative pieces of cardboard.

Mr. SCOTT (*Danforth*): I wonder if I could ask a practical question. How many detail men a week, for example, would you see in your practice?

Mr. FALLIS: I try to see two or three on a Tuesday morning. I try to give them 15 minutes each. If they are late I do not see them. If I am late I do not see them. To give you some idea of the number that are in our district in Toronto, on this basis, I would see each detail man who is covering his territory conscientiously. When he leaves today and asks for another appointment, he would get in in about five or six months' time.

Mr. SCOTT (*Danforth*): You see each detail man once or twice a year and in that time you spend 15 minutes with him?

Mr. FALLIS: He has that amount of time. Often it is shorter than that, I would think it is around ten minutes usually.

Mr. SCOTT (*Danforth*): During these interviews—I am just trying to find out how it functions—I cannot quite grasp it.

Mr. FALLIS: Usually it is on the basis of some product; perhaps at this time of the year he might leave us something on an antihistamine preparation for hay fever or an anti-diarrheal medication for summer complaint or something like this. In the fall he would probably be describing something in relationship to respiratory disease or, if there is a new advance, he should be talking about that. Or, if there is an important change in a drug, he will describe that and how it affects treatment, or the price if I ask him or whatever—

Mr. SCOTT (*Danforth*): Do you find them generally knowledgeable on the whole drug field?

Mr. FALLIS: I think it varies a great deal. Again, being an optimist, I think it is improving. There is no question that some of them are excellent.

Mr. SCOTT (*Danforth*): How many detail men would there be in the Toronto area? Have you any idea?

Mr. FALLIS: No, I would not.

Mr. MACKASEY: Talking about detail men, do you express the opinion that of all methods of communication with the pharmaceutical industry, you prefer journals? It would require quite a lot of reading on your part, I would imagine. Or am I wrong in what I am saying?

Mr. FALLIS: I think I mentioned the experience and the consultation with colleagues—

Mr. MACKASEY: Beyond that it is a logical statement to make that medical journals are another great source of information, are they not?

Mr. FALLIS: Certainly.

Mr. MACKASEY: How are they suported? Who pays for their existence? Do you buy these medical journals?

Mr. FALLIS: These gentlemen can answer better than I can. There is a brief reference here in our brief. The C.M.A.J., the keystone journal, comes to one as a member of the medical association.

Mr. MACKASEY: I have seen advertisements from the pharmaceutical industries?

Mr. FALLIS: Certainly. The College of General Practice journal goes to every general practitioner in Canada, I believe, whether he is a member of the College or not.

Mr. MACKASEY: In other words, the pharmaceutical industry by reason of their support through advertisements at least are placing at your disposal learned papers written up by particular doctors and professors in the research field?

Mr. FALLIS: That is right.

Mr. PEART: I think, Mr. Chairman, it is fair to say as Dr. Fallis has said, the journals are supported in two ways: by membership fees and by advertising. Certainly, the pharmaceutical industry is a very important group of advertisers in all medical journals and they would have difficulty in carrying on without them, quite frankly.

Mr. MACKASEY: Would you say that their advertisements are of a high level or are they more of an institutional—

Mr. PEART: You have seen this sort of co-operation, I think, between the pharmaceutical industry and the Canadian Medical Association which was handed around. This is the bible on which we base our advertising. We require a very high standard of advertising in the Journal.

Mr. MACKASEY: Getting back to the detail man, the more I check into the detail man the more respect I have for him. Last week, the Pharmaceutical Manufacturers' Association agreed to incorporate into their code of ethics a clause which forbade their members from paying their detail men by commissions. Do you think this is a progressive step?

Mr. PEART: Yes, I do.

Mr. MACKASEY: In other words, you get what you pay for. If you start paying detail men a little more, you may attract better people. On page 11, although you pay, I think, very fair tribute to the detail men, you also say, "we do not agree with those who malign the detail man but we favour his retention in his current capacity with additional training to make him still more useful". This implies to me, sir, that you think the detail man is a very important medium of communication between the doctors and the pharmaceutical industries. The reason I am emphasizing this is that unintentionally Dr. Howe's display of gimmicks, which he did in a very gimmicky fashion, has created the impression that detail men, in general, do nothing more than carry tape measures, matches and the rest of the gimmicks that were displayed, to the pharmaceutical industry. I have found this feeling prevalent among many of the members who were present at the time. I think it has, perhaps, distorted or hidden from view the real role of the detail man. This is why I would like to spend a little time on the detail man. Does he, for instance, carry back from you or the doctors criticisms of a particular drug. Does he bring back details of side effects? Is he a true link in both ways in the field of communications between you and the pharmaceutical industry?

Mr. FALLIS: Yes; I can think of some suggestions that have been made out in the district with regard to packaging, for instance. I can think of an antibiotic liquid for the skin which was appearing only in a large tube. The suggestion was made that a smaller tube should be produced. Shortly after—it was likely in the works, anyway—it appeared on the market. Another time I had a reaction to a preventive measles vaccine. It was the regular detail man for this company. He came in with a very large report that he had to fill in. There were a couple of follow-ups about this which I thought were quite satisfactory.

Mr. SCOTT (*Danforth*): A short supplementary on this specific point: Surely such reports he would take back would be relatively inconsequential. I am thinking, for example, if you found a really serious reaction to a drug, you would not wait six months until he came back again to tell him about it, would you?

Mr. FALLIS: Oh, no. We are asked to report these drug reactions to the Food and Drug Directorate. In fact, we have all been provided with a small pad to do just this and it is very easy to do.

Mr. MACKASEY: Who supplies the pad? It may sound facetious but I would like to know.

Mr. FALLIS: The Government of Canada.

Mr. PEART: Mr. Chairman, could I answer that as I generated the question from Mr. Scott. The detail man is often the intermediary between the doctor and the medical director of the pharmaceutical company, quite a few of whom are here today. Very often, if a doctor has some problem about a drug, he can either call the pharmaceutical medical director himself or he may ask the detail man to be the intermediary. He gets an immediate reply on the telephone probably from the medical director and works out the problem.

Mr. MACKASEY: In other words, a good detail man carries more information than what is available in your pharmacopoeia?

Mr. FALLIS: He should be familiar with most of them. No, I would think the pharmacopoeia would give a better and more complete service.

Mr. MACKASEY: Do you judge a company by the detail man who calls upon you? In other words, I am just trying to convince the pharmaceutical industry to upgrade the calibre of the detail man. If a beatnik comes around in the guise of a detail man representing Ayerst McKenna, what would your reaction be to Ayerst McKenna?

Mr. FALLIS: The same as yours, I suppose.

Mr. MACKASEY: In other words, you feel the detail man should reflect the particular company he represents.

Mr. FALLIS: Yes. I think one is more impressed with his approach and whether he knows his stuff rather than whether he looks like a beatnik. I have seen some that look a little tired.

Mr. MACKASEY: With reference to certain detail men based on experience, based on their conversation, based on their ability.

Mr. FALLIS: One is drawn to stability, too. I can think of one firm where the same detail man has been there ever since I have been in practice. I think that

this is a company that does not seem to be moving their men all over. Each man seems to be pretty stable.

Mr. GUNTON: I do not really think that the character of the detail man influences me. I think it is the product that matters. It is what you know about their products and their therapeutic efficacies; also about the contribution of the companies who do research. I guess I have a little different opinion from Dr. Fallis on that.

Mr. MACKASEY: One of you learned gentlemen put in the words "additional training". Would you like to elaborate on this regarding in what capacity, and what field and what area there should be additional training?

Mr. GUNTON: The pharmaceutical companies tend to specialize their detail men to a certain extent. Some, for example, are assigned to hospitals. Hospitals, as a rule tend to use the newer, more expensive antibiotics, more commonly perhaps than physicians in practice newer hormonal agents. They therefore require for that service men with a greater depth of pharmaceutical or scientific knowledge. Obviously these are the higher class men and if more of them had that accomplishment it would be better.

Mr. MACKASEY: Calling on the doctor rather than the hospital.

Mr. GUNTON: If all of them were of the standard, for example, that the hospital represented, this would be a splendid thing.

Mr. O'KEEFE: I would suggest that if you did pay those detail men a little more it would also cost much more for the drugs. Would the cost not go directly to the consumer? Those are all signs of highly educated gentlemen. All that cost would go directly to the consumer and be reflected in the cost of the drugs. I disagree with Mr. Mackasey in this one instance. You seem to be inclined to the view that direct mailing and the pharmacopoeia have more influence on you than the detail man. I take it that you are a typical doctor, and what is true about you would be true about most other doctors.

Mr. GUNTON: No, I am not really. I am involved in teaching and in teaching therapeutics. I am much more likely to be critical of direct mail advertising.

Mr. O'KEEFE: You would not suggest that other doctors are less intelligent. I suggest that the detail man is completely unnecessary. Would anyone agree with that?

Mr. GUNTON: No. I do not really.

Mr. MACKASEY: Since Mr. O'Keefe has referred to my remarks, I would just like to say I would rather have my life saved by a $3 drug than be poisoned by a 50 cent one.

Mr. HOWE (*Wellington-Huron*): Is this not a detail man, is this not the practice in all types of business where they have a commercial traveller, who sells a certain brand of shirts and a certain product, who calls on the trade to promote the product. Drug companies are no different. They produce a product and they want someone to sell it. Do you not depend on a good reliable detail man to keep you up to date on some of the things that they are producing. You

would certainly object if he called on somebody down the street, a doctor who is a friend of yours, and does not call on you and tell you about this new product.

Mr. GUNTON: We depend on them to keep us informed.

Mr. HOWE (*Wellington-Huron*): They are an important part of the whole operation, I would imagine.

Mr. GUNTON: Certainly, one of their jobs is to sell their products but they also provide this information service and communication service that the doctor requires. He cannot be reading everything in the drug industry and know what is going on as well unless he has the help of the detail man.

Mr. HOWE (*Wellington-Huron*): They certainly do not want to give you poor advice because their livelihood depends on the perpetuation of this business they have started to create with you. I think that they are important adjuncts to the distribution of drugs.

Mr. PEART: Another thing too, Mr. Chairman that we seem to be mixing up. We seem to be mixing up direct mail and detail men. They are two entirely different things. Certainly, some detail men take some of these gimmicks around with them and hand something to the doctor when he comes in—it may be literature or some matches—but, on the other hand, this should not be confused with the direct mail advertising that sends things through the mail which, I think, are diminishing.

Mr. HOWE (*Wellington-Huron*): Of course, we know gimmicks are used in election campaigns to a great extent.

Mr. PEART: You people should know about that better than us.

Mr. AITKEN: We have nothing in our code of ethics about this.

Mr. SCOTT (*Danforth*): I would not object to Mr. Howe's description of them. I think they are essentially salesmen but because the pharmaceutical people place so much emphasis on this other aspect that you have raised, I want to ask you, do the detail men enter into comparative discussions with you on the drug that their company manufactures as against other products. Do they supply details on which you can make some sort of rational judgment?

Mr. PEART: Dr. Fallis could answer that one. This is a question of ethics of the detail man, is it not?

Mr. SCOTT (*Danforth*): I am just asking what they do. I am not judging.

Mr. GUNTON: I think their ethics usually are that they do not mention a competitive product by name. But, often the references are rather obvious, if veiled, so that one knows what they are talking about. Certainly, if the doctor opens a discussion and comes out plump and plain, he will certainly defend himself. He will even, sometimes, present you with statistics about cost, effectiveness, and what not. He does not come in and open up and say, "our product has gone down 50 cents lower than such and such" and mention it by name. That is really rather a brutal attack I suppose and it is not considered ethical. But, if you raise the question he will certainly discuss it. I think they consider that ethical. Another thing is, I do not know whether there is a reference in here to a medical letter or not which is a four page memorandum

that comes around every once in awhile that one subscribes to. There is often great detail in there. That is an American publication that you may have seen. These very often will discuss various drugs in the same area by effectiveness of the drug in general and quality control and comparative costs and so forth.

Mr. SCOTT (*Danforth*): They are essentially there, and I am not quarreling with the idea, to promote the sale of their own product. There is nothing wrong with it. I wonder whether you would admit it.

Mr. FALLIS: Essentially, but to discuss the product in general I always feel.

Mr. SCOTT (*Danforth*): I have two further questions. Have you made known to the pharmaceutical companies your objection to this direct mail advertising to which you take exception? Do you feel their voluntary program of restraint has been effective?

Mr. PEART: I think it says in our brief, Mr. Chairman, that we have done that. We believe the direct mail has been reduced as it says in our brief.

Mr. SCOTT (*Danforth*): Have you given any consideration to the name attached to the drugs? I am thinking, for example, of the Kefauver hearings in the United States where evidence disclosed these fantastically long names that nobody really seemed to understand at all. They were contemplating writing into the legislation authority to reclassify and simplify the names under which drugs are marketed. Have you people given any consideration to such a move, whether it would be desirable or useful?

Mr. GUNTON: From the point of view of buying the drugs produced, we tend to follow the United States pattern. Just to tidy up that matter you raised, in the United States there is now a designation called "USAN", United States adopted name, which by a convention between a committee of the American Medical Association and the Food and Drug Administration of the United States this name should depict a United States name. In general, this USAN name is eventually adopted by the World Health Organization and an attempt is made in the formulation of that name to make it simpler. This is the proper name, the generic name, but the attempt is made to have it short enough that it can be remembered and to avoid the repetition of the chemical formula which no one can really reproduce on an order sheet or in a prescription.

Mr. SCOTT (*Danforth*): Would some such move in Canada be advisable?

Mr. GUNTON: I think it would be accepted for us to try and duplicate this. I think that it is a sensible thing, the relating of these companies to sell us the United States adopted name.

Mr. MACKASEY: Mr. Chairman, I am not sure whether it was the Hall Commission, but one of the commissions recommended the establishment of a national formula. I recall reading it in your brief, somewhere around page three or four, where you oppose it. Would you explain why, because I, being a layman, cannot quite grasp your objections.

Mr. GUNTON: We would not object to the production in Canada of a compendium of drugs, a book which contains a list of every drug, its generic name, its brand name and its firm properties. I think this could be a reasonable thing. We have no objection to that because it would be an excellent source of information. However, there has been a number of committees look into the

possibility of producing such a comprehensive volume and, at the moment, it is under review, I think, by an agency of the government. Obviously, it is going to be a big job for Canada to do this because there are a large number of drugs. What we objected to would be a national formulary in the Hall Commission sense that would imply a restrictive list, that is, that you can prescribe only, say, three or four brands of a certain product. Or you might, indeed, not be allowed to prescribe a very expensive one or a very expensive antibiotic. We think this would infringe on the doctor's freedom to prescribe. We object only to the idea of a restrictive list of drugs. We do not object to an excellent source of information. If it can be produced in Canada, splendid. We hope naturally, that it is made.

Mr. MACKASEY: At the present moment what book do you depend upon?

Mr. GUNTON: Many books. Recently, again the American Medical Association has produced a book called *New Drugs* and this is a review of pharmacology and the actions and preparations of all drugs which have appeared in the last ten years, since 1956. This is the most up to date one but it is not yet in general usage.

Mr. MACKASEY: What concerned me—what frightened me, is a better word, when we were discussing safety last year was a book that you people called the *Pharmacopoeia* put out by private industry.

Mr. GUNTON: No, the *Pharmacopoeia*—there are British *Pharmacopoeia* and United States *Pharmacopoeia* and they are put out by official organizations in both the United Kingdom and the United States. The problem with these books is they are edited by a committee. They do not include drugs which have appeared within the last few years, so that we do not depend on *Pharmacopoeias*. The book that is used most commonly and that you see most commonly in doctors' offices and in wards in hospitals is a commercial book called the *Vademecum*.

Mr. MACKASEY: I would like to get back to my *Pharmacopoeia* which is a red covered book as I recall. Is it not a *Pharmacopoeia*? The point that bothered me was that I took a particular drug that was manufactured by an ethical firm, a brand name, let us put it this way. I think the producing firm was Parke Davis and Company who produced the particular drug under its particular trade name. It pointed out all the normal functions that this drug does, what it applies to and it also went on for a column and a half to list warnings about the drugs and so on. Then I went further on into the book, to the generic section, trying to encourage the promotion of generics as opposed to brand, and I found that the text of the generic section was identical until we came to the section under "warning" which was left out entirely. I then went to the manufacturer of this generic product and asked him why he did not include a column and a half of warnings. He bluntly told me that he paid for this space at so much per inch and why should he pay for the warning. I said, "what protection are you giving to the doctor who prescribed this generic drug, if you do not warn him through the *Pharmacopoeia* of the side effects?" He said, "It is up to him to read the package". I said, "He does not always see the package. He goes directly to the patient". His very callous answer was, "That is the patient's tough luck".

Mr. GUNTON: We agree completely with your point of view. You have made it very explicit and we agree completely. This association supports the project

of the Canadian Pharmaceutical Association to produce a compendium of pharmaceutical specialties which would be a volume, perhaps with a similar purpose, but in which the editorial policy would be decided by an independent group, the Pharmaceutical Association having nothing to do with the individual manufacturers, so that every drug would have the same treatment including pharmacology, side effects, and so on. We support that projected effort of the Pharmaceutical Association.

Mr. MACKASEY: Mr. Chairman, I know Mr. Howe has a question. I just want to leave it, I do not know when we are going to have a chance to discuss this again with you but I think Mr. Turnbull will be back and I can ask it of him. There has been constant reference, in your report and in the manufacturers' report and in the druggists' report, to changing the method of pricing drugs. That is, taking the cost plus professional fee. The emphasis seems to be constantly that this will bring down the costs of the expensive drugs but it seems to me, from the bit of arithmetic I did last night and I do not want to produce it here until I verify my facts, that because the medium of products falls in the range between $3 and $5, if such a method is introduced, it will increase the gross volume in dollars to the druggist by a considerable amount of money. I just do not see how you can reconcile, in your report, the recommendation that this new system be implemented because it is going to reduce the cost of expensive drugs, if it is going to increase by many hundreds of thousands of dollars the cost of the purchase of drugs in general?

Mr. GUNTON: We are concerned, as perhaps you are, about the patient being saddled with extremely high drug bills, antibiotics, for example. We know that is is often a burden, and it is that cost we want to bring down. We do not feel for the lower price prescriptions that the application fee for service could really produce an unconscionable burden on the average person.

Mr. MACKASEY: Have you worked out an over-all result?

Mr. GUNTON: Dr. Brand and I were discussing that. He pointed out the situation in Saskatchewan. We were not able to answer his question. I was not sure that he was clear on your point that the gross cost of drugs to the people of Canada would really be greater or less. We do not know that, now, do we?

Mr. AITKEN: Mr. Chairman, it depends entirely on how high you set a professional fee.

The CHAIRMAN: I think that point was made in the evidence before. Using the $2 fee, the total gross cost of the drug, whether you use that system or the system that has been built up over the years, the total price, is the same, approximately, I mean.

Mr. MACKASEY: Mr. Chairman, in the last three months, I have had occasion to buy drugs that cost me $19 and some cents. I do not mind the cost for two reasons: I could afford it and secondly, it was for a purpose and it accomplished its purpose, but because of chronic illness in my home I have been buying a particular drug in the $3 to $4 range week in and week out for years. Surely, there is a case to be made for the person in Canada not because his individual purchase cost falls in the $3 to $4 class but because his illness has continuity. For example, people who are suffering from diabetes, and this type of thing. Why do you not make a case for these people?

Mr. PEART: We do, under chronic diseases.

Mr. MACKASEY: Yes, chronic disease but you also refer to these as welfare patients.

Mr. PEART: No. I do not think that is our business, Mr. Mackasey. We made that clear that this was not the welfare patients, it was—

Mr. MACKASEY: Would you care, within the next few weeks, to perhaps submit a page and a half brief to the Chairman giving your definition of each chronic case?

Mr. PEART: I wish we could. I do not know who has a good definition of chronic cases. I think the Department of National Health and Welfare have about the best. Mrs. Rideout was here a few minutes ago.

Mr. HOWE (*Wellington-Huron*): Mr. Chairman, you mentioned gimmicks and promotional campaigns. I have in my hand a release from the Lilly Company. I know that all members of the Committee who got it and in which they describe an identacode program of identifying their own products by number. I do not suppose the witness has any information or experience of this type of advertising program that they are using here?

Mr. GUNTON: I only know that it is reported they use it. As far as I am aware this is the first time.

Mr. HOWE (*Wellington-Huron*): Yes, it was released on Sunday.

Mr. GUNTON: In an attempt to identify its products by code number and company seal.

Mr. PEART: Gentlemen, I can answer that if you like. There is a very interesting book being prepared in Toronto now, primarily originating in the Attorney General's Department of Ontario, which is designed to identify all kinds of pills and capsules and so on, the same as the Eli Lilly and Co. Identacode which was announced the other day. Theirs, of course, is primarily to identify their product, but this other book was supposed to identify all kinds of other products they sell. This was a very interesting idea because a doctor going to a house wondering what is in a prescription might be able to identify the fill from its code, you see.

Mr. HOWE (*Wellington-Huron*): I cannot feel that this type of program carried out by a drug firm will be able to reduce the price of the drugs. It takes more operations to mark all these pills so that this will not reduce the price of drugs.

The CHAIRMAN: I would not think so. I would not think it would really add to the cost either.

Mr. MACKASEY: When is the next meeting, Mr. Chairman?

The CHAIRMAN: On behalf of the Committee that is left, I appreciate the brief that has been presented and the questions that have been answered by the Canadian Medical Association led by Dr. Gunton. We give you our thanks and appreciation.

The meeting is adjourned until one week from today when Mr. Turnbull will be back.

APPENDIX "A"

THE CANADIAN MEDICAL ASSOCIATION BRIEF

to the

PARLIAMENTARY COMMITTEE ON FOOD AND DRUGS

1. The Canadian Medical Association welcomes the opportunity to make a second submission to this Parliamentary Committee. We have observed with interest and approval your recommendations tabled December 18/64 and we are pleased that many of them are already being implemented by the Food and Drug Directorate.

2. It is our understanding that the Committee has completed its work under many of its terms of reference and that your present interest relates to drug costs and prices.

3. While the compelling interest of the medical profession is in the availability and therapeutic efficiency of drugs, we are of necessity interested in their cost to the patient. If the price of a required drug is such that it cannot be acquired by the patient, whether over a short or protracted treatment schedule, the drug cannot function as an essential element in the regimen recommended and prescribed by the physician. Such unavailability can result in unnecessary complications and protracted periods of convalescence.

4. We would like to see drugs made available to our patients at a cost which is reasonable. This would ensure that, so far as is possible, our patients could obtain the drugs they require. But if reduction in price in any way impairs the ability of Canadian drug manufacturers to maintain the high quality of their products, and curtails the easy availability of these products, which we as doctors have come to expect, it is our feeling that such a reduction must be resisted, and that in any such consideration, these current high standards be maintained as a first principle. Drugs form the basis of much modern therapy, and we feel that the good health of Canadians must not be sacrificed to the admittedly important but secondary factor of cost.

5. For practical purposes the modern era of specific drug therapy may be said to have commenced with the introduction of sulfanilamide in the mid 30's. Since that time we and our patients have been the beneficiaries of many new and efficacious remedies developed by research much of it done in the laboratories of pharmaceutical manufacturers. In our view undue concentration of price and cost should not be permitted to impede or interfere with this beneficent flow.

6. It is self-evident that the ability to meet the cost of drugs is related to the income of patients. For those patients in the lowest income groups, we commend the programmes in effect in certain provinces, where prescribed drugs are provided free or at reduced cost to recipients of designated provincial assistance programmes. Other provinces provide insulin and other drugs for

chronic conditions to persons with low incomes, and the Welfare Departments of many of our larger municipalities arrange to provide required drugs for these persons. It is worthy of note that in Canada the provision of many biological products, vaccines, sera and immunizing agents have been available to doctors and patients at the public expense without regard for ability to pay. Since most of these products relate directly to the control of communicable diseases, the policy is justified as a preventive measure and its application has involved private medical practitioners to a commendable degree in aiding public health authorities in the virtual elimination of many formerly devasting diseases.

7. It is our view that the area of governmental assistance in the cost of drugs for low income groups deserves more study and attention by provincial authorities. While all seem interested in ensuring that medical services insurance is made available to these persons, we would point out that, in many instances, the ready availability of required drugs is just as important as the availability of the physician who prescribes them.

8. It is our conviction that any concept of medical care insurance should include coverage for the expense of prescribed drugs. This position was established in our Statement of Policy on Medical Services Insurance approved by the General Council of the Canadian Medical Association in June, 1965,[1] which reads:

> This insurance should cover the services of the physician in home, office or hospital, and also, under separate accounting, the services of paramedical personnel working under his direction, and professional services *and therapeutic agents otherwise ordered by him.*

It is also our conviction that self-supporting citizens should purchase their own insurance under voluntary insurance programmes, leaving governments to assist those in need. To quote again from the CMA statement mentioned above[1]:

> We believe that it should be the responsibility of provincial governments... to provide, preferably as fixed-dollar subsidies, enough financial assistance to persons in need to enable them to purchase insurance—using the annual income-tax declaration as the basic criterion.

9. We believe that through co-operation between governments, insuring agencies, the public, and the medical profession, voluntary insurance can be made accessible to every resident of Canada. Insurance plans could be implemented either as an adjunct to medical services insurance contracts, or as a separate insurance package. Whatever the form selected, we feel that such a plan should include all prescribed drugs, and should be offered on a basis of co-insurance, where all expenditures in a one year period exceeding a basic sum paid by the subscriber are refundable.

10. It is considered desirable if not essential that in any system of pharmaceutical benefits the patient should make a small direct contribution to the cost of his drugs. This may either be provided for by the mechanisms of deductible and/or co-insurance.

11. We observe with some alarm the uncontrollable costs of the pharmaceutical benefits under the NHS in Great Britain and even in Australia where drug costs actually exceed the costs of general practitioner services. Associated with such plans the tempting control measure is to establish a

Formulary listing the drugs which will be provided and paid for but limiting the physician's choice, particularly in relation to recently introduced items. While Canadian doctors accept the necessity for formularies applied to hospital practice and to certain well-defined groups of needy patients these are usually arrived at by agreement of the physicians concerned. We do not support the concept of a National Formulary or one which would apply to other large population groups because of the inherent restrictions of any such listings.

12. The Canadian Medical Association has expressed its favourable attitude to the mechanism of Extended Health Benefit policies to provide for prescribed drugs as an insurable benefit and the built-in degree of patient participation is considered to provide a desirable safeguard against the potentially wasteful and very expensive provision of drug benefits to the self-supporting.

13. Group coverage has been, and we feel, will continue to be, the area where drug insurance has its greatest application. Individual coverage, because of its appeal to the high risk segment of any population is a more difficult problem, as recent studies have clearly shown.[2] Such coverage is not generally available at present, but we are hopeful that experience in this field will result in the creation of an acceptable individual contract. We feel strongly that this is an area that must be thoroughly explored in order to provide coverage for those outside of the group reference, since drug costs may be substantial, indeed disabling, to these individuals.

14. Our study and comments on drug costs tend therefore to fall into three separate areas:

1. those factors which affect the over-all cost drugs;
2. those factors which are responsible for the considerable variation in cost between basically equivalent products; and
3. those factors which govern the cost of drugs to patients suffering from chronic diseases.

15. On preliminary examination of the components of drug cost, we felt that possibilities of reduction existed in virtually every area. On further study, this initial impression proved difficult to justify. When we began to consider the implications involved in each proposed change, we found that they were likely to imperil our own basic criterion of assessment, namely, that nothing should be done which might impair the effectiveness of the drugs we use, which might diminish our confidence in the drugs of the ethical manufacturers, or which might retard the benefits of future pharmaceutical research products which we look forward to with confidence.

The Over-all Cost of Drugs

16. The most recent survey of prescription prices by the Canadian Pharmaceutical Association refers to the month of September, 1964.[3] During that month, the average prescription price was $3.47, compared to $3.20 during September 1963.[4] In 1961, the average price was $3.14.[4]

17. The true annual per capita costs are somewhat more difficult to determine, because of the programmes which supply free or subsidized drugs to the low income groups. The cost of drugs as an element of provincial hospitalization insurance under the Hospital Insurance and Diagnostic Services Act

has not recently been reviewed by us but a study conducted in 1960 showed that about 4.7 percent of expenditures under hospital insurance in a province which had at the time, 10 years experience, were for prescribed drugs. By definition this relates to in-patients only, not to out-patients. This percentage gave a per capita annual expenditure for drugs of approximately $1.50 for the provincial population at risk. It is likely that the same proportion currently applies but the per capita amount may have increased. From the data which we have seen, we would estimate that the per capita cost of prescribed drugs provided *out of hospital in 1965 is about $8.00*, yielding a total per capita annual cost of $9.50.

18. These amounts do not seem to us to be unreasonable. When we consider the level of income and the standard of living of Canadians, the amount of the average prescription and the annual per capita cost appear to be well within the ability of self-sufficient citizens to pay. We would again differentiate between the average price, or over-all cost, and the substntial differences between the prices of individual drugs or individual prescriptions. Later in this submission we shall comment on these differences and the consequent mounting expenses which can occur when substantial amounts of expensive drugs are required during a course of treatment.

19. In our consideration of those factors which contribute to the over-all cost of drugs, we have utilized a distribution of costs supplied by the Pharmaceutical Manufacturers' Association of Canada.[5] We have amplified this breakdown so that we can examine the costs of the various components of the average prescription which in September 1964 cost $3.47.[3]

Cost Components	Cost
Pharmacist's Services	$1.74
Distribution Facilities	.29
Federal Sales Tax	.14
Research Costs	.12
Production Costs	.47
Administration	.14
Medical Information and Marketing	.41
Income Tax by Manufacturer	.08
Manufacturers' After-Tax Profit	.08
TOTAL COST	$3.47

We have examined each of these cost components and have certain comments to make.

20. *Pharmacist's Services—$1.74*

We doubt whether any product, which involves the provision of a professional service can be marketed at a lower average cost for the professional service involved. We are very much aware of the value of the service which the pharmacist performs and we doubt whether this average remuneration adequately rewards him for his time and professional judgment Although few prescriptions now call for involved preparation by the pharmacist, he assumes a professional responsibility for the proper interpretation of the physician's order and for the precision of his dispensing and these factors must be considered.

21. When it is remembered that the pharmacist must maintain a substantial investment in inventory, and assume losses on many partly-used preparations, the reason for our feeling that this cost is not excessive becomes even more apparent, since these factors must be included in his cost.

Distribution Facilities—29 cents

22. We understand that this cost component is the expense involved in wholesaling and equivalent facilities.

23. At first glance it appears to be a substantial cost for the service involved. It is apparent however, that the geography of Canada requires extensive wholesale facilities. As well, the existence of adequate distribution centres facilitates the operation of the individual pharmacy and helps to reduce the inventory investment of the pharmacist. If these facilities did not exist the pharmacist would necessarily have to increase his costs by an amount proportionate to the required increase in investment. If we add to this new cost the additional replacement cost to the pharmaceutical manufacturer of a much increased number of out-dated products, we might well find that the total would exceed the present cost of these distribution facilities.

Federal Sales Tax—14 cents

24. We have made repeated representations to succeeding Ministers of Finance and to other bodies such as the Royal Commission on Health Services, the Royal Commission on Taxation and to this Parliamentary Committee about the anomaly created by the imposition of the federal 11 per cent sales tax on prescribed drugs. This is indeed a tax on sickness.

25. We can find no rationale for this tax which is in fact rebated on sales made to hospitals. We are firmly of the opinion that the tax should be removed from all prescribed drugs and we request that this Parliamentary Committee support our representations by recommending its remission.

26. We would remind the Committee that an important and immediate effect of the withdrawl of this tax would be a five per cent reduction in the retail cost of prescribed drugs.

Research Cost—12 cents

27. From our viewpoint this is probably the most justifiable cost component. Continuous research is essential if new efficacious drugs are to be developed. We would comment that the amount devoted to this essential function is too small rather than too large, particularly with reference to research performed in Canada.

28. We are aware of the critical comments of the Royal Commission on Health Services, related particularly to the amount of research performed in Canada and to the allocation of research costs performed in other countries. We too would like to see increased amounts spent on research in Canada. Research is vital to Canada's growth. We are encouraged by the increased interest which pharmaceutical companies are demonstrating in research in Canada and we would hope for the continuation of tax advantages which foster this increased research.

29. We would like to plead the special status of clinical research in Canada. Canada's need for more medical and paramedical personnel is dependent upon an increased supply of teachers as well as funds for physical facilities. Teaching and research go hand in hand and it is essential to meet our future manpower requirements that increased amounts be spent on research related to our medical schools and teaching hospitals.

30. It is our view that 12 cents out of an average prescription cost of $3.47 may be too little to spend on research. We would advance, for your consideration, the suggestion that governmental fiscal policy could be used to encourage more research in Canada, particularly research associated with universities and teaching hospitals.

Production Cost—47 cents

31. This is an important cost component. It contains many factors about a part of this cost component which arises from the sale of basic elements of a which we are uninformed. We have heard and continue to hear criticisms of product from a parent organization to a Canadian subsidiary.

32. We are not in a position to comment in depth on this practice or upon the pricing methods used. We believe however, that if inordinate profits accrued to parent corporations from these sales to Canadian and other subsidiaries this must be reflected in profits substantially higher than those of the subsidiaries.

33. We have compared the 1963 after-tax profits of the larger U.S.A. pharmaceutical firms, expressed as a percentage of invested capital, (which to us is the only fair comparison of profit) and find that they do not differ substantially from the after-tax profit of the 45 Canadian manufacturers surveyed by the Canadian Pharmaceutical Manufacturers Association.[6] For the year 1963, Fortune's study of the pharmaceutical firms among the 500 largest U.S.A. corporations indicates profits at an industry average of 14.7 per cent of invested capital.[7] In 1963 the Canadian survey indicates after-tax profits equal to 14.5 per cent of invested capital.

34. We must conclude from the similarity of these figures that these criticisms have no apparent foundation.

35. To doctors the most important element of production cost is the cost of safety. Every drug is hazardous but safety precautions minimize the dangers. When a doctor prescribes a particular drug, manufactured by a leading Canadian company, he wants the pharmacist to dispense precisely what he has ordered. He assumes that quality control is an essential part of the manufacturing process and he feels secure in this knowledge.

36. We doubt that patients are as knowledgable or as concerned as doctors with quality control. However, if they were aware of the implications of its absence, we are certain that they would consider this cost component as a very reasonable price to pay for the benefits they obtain.

Administration—14 cents

37. We are not aware of the component factors of administrative cost.

Medical Information and Marketing—41 cents

38. The cost of promotion and marketing of drugs has been criticized as being excessively high and arbitrary restrictions have been suggested as a means of controlling this element of the price of drugs. From the viewpoint of the medical profession, which is the target for much of the promotional effort, we discern the following elements in the promotion of pharmaceutical products: (1) field representatives of the pharmaceutical manufacturers, (2) display advertising in publications read by doctors, (3) the medical exhibit, (4) the use of the mail for the distribution of promotional material and (5) the distribution of drug samples. It is proposed to comment on each in turn although we have little factual information to sustain the view that it is too costly.

39. Field representatives or "detail men" call on doctors and pharmacists to provide information on the new and the established products of their firms. Under ideal conditions, this represents the best and most effective means of informing potential users of the merits and shortcomings of pharmaceutical products. To establish the ideal condition, there is required both a corps of very well trained and well informed representatives, preferably with a background of pharmacy and time enough on the part of doctors and druggists to receive and discuss the information on new products and their possible application to the requirements of individual patients. This ideal is rarely attainable, and at the other end of the scale the attention of insufficiently well informed salesmen interested only in promoting the purchase of the wares of their principals can be an unmitigated nuisance to busy doctors. It may be argued that in the current shortage of qualified pharmacists it is wasteful of a scarce talent to use it in this capacity but the questions which arise in the discussion of drugs with responsible detail men make it, from the doctor's viewpoint, useful if the representative has the breadth of knowledge which such background implies. We do not agree with those who malign the detail man but we favour his retention in his current capacity with additional training to make him still more useful.

40. DISPLAY ADVERTISING is a method of promotion and dissemination of information to the medical profession which is commonly adopted by pharmaceutical houses. Such advertising is naturally concentrated on the publications which doctors read and an oversimplified classification applied to Canada would divide them into journals which are the official organs of recognized medical societies and those which have no such sponsorship and which are sent to all doctors without charge or subscription fees. In the latter group, there are four such media identifiable in this country, two of which have close ties with similar publications in the United States and carry a high proportion of identical editorial material.

41. When The Canadian Medical Association made a previous submission to this Committee in May 1964, Honourable Members were provided with copies of a brochure "Advertising in Canadian Medical Association Publications". In this statement the advertising policy of The Canadian Medical Association Journal and The Canadian Journal of Surgery is set forth. In an effort to provide the doctor reader with the necessary information in the products portrayed, advertisers are required to comply with C.M.A. requirements stated under the following headings: Sober Claims, Good Taste, Extravagant or Vague Claims, Artificial Distinctions, Complete References, Resubmission of Copy, Clear

Identification (Proper as well as proprietary names), Total Impressions and Medical Ethics. We were gratified at the commendatory comments of certain Honorable Members and we would now report that this endeavour to promote high standard advertising has met with widespread acceptance among the pharmaceutical houses using our publications to promote their products. We are encouraged to continue our efforts in this direction. It is a truism to state that medical journals could scarcely survive without advertising revenue. We consider receipts from advertising to be entirely justified to sustain the non-revenue producing material of an educational nature and original scientific material which we publish. We also consider journal advertising to be a legitimate method of product promotion, and a real service to medical readers. It is our endeavour to provide advertisers with full value for their expenditures.

42. MEDICAL EXHIBITS are closely related to the educational and promotional activities of field representatives, the essential difference being that displays are mounted where doctors congregate and the contacts of the manufacturers' representatives are multiple rather than single. Exhibit booths of standard size and attractive design are features of medical conventions including the Annual Meetings of the C.M.A. Exhibitors, most of whom are members of The Medical Exhibitors Association of Canada, display their wares and answer the questions of interested doctors who consult them. This is a popular feature of medical meetings and its educational value should not be underestimated. The sponsoring organization rents exhibit space, lighting and other services from the hotel and other buildings in which the meeting is held and in turn rents booths to exhibitors, hopefully making a small profit. As an element of the expense of promotion rental is considered to be small, the travel and maintenance of exhibitors representatives being the major outlay.

43. DIRECT MAIL is a further method of promotion of pharmaceutical products and it is relied on heavily by certain manufacturers in acquainting doctors with the merits of their drugs. The claims made are subject only to the integrity of the manufacturer and the control he exacts over the exuberance of the copy writer. In 1960 when direct mail appeared to be in danger of being carried to extravagent excess, The Canadian Medical Association communicated with the C.Ph M.A. expressing the view that the doctor's mail was being overburdened with apparently expensive examples of the printer's art and asking that curbs be applied. We do not know what action was taken by the member companies but the flood of mail has abated to a considerable degree and examples of really flamboyant gadgetry are becoming rare. It is our view that this constitutes the least desirable method of pharmaceutical promotion.

44. Sampling of pharmaceutical products was, until recently, a widely practised method of promotion and it unquestionably induced many doctors to try new products which they might otherwise not have used so soon. This too was carried to the degree that it appeared to be excessive, wasteful and expensive. Ten years ago The Canadian Medical Association, with the cooperation of the Medical Exhibitors Association, abolished the practice of distributing unsolicited samples at exhibits under C.M.A. auspices. We further supported the F.D.D. in its endeavour to control the practice of sampling and endorsed the current regulation in operation since 1963 which curtails it significantly. In its report to the General Council at our recent 98th Annual Meeting, the Committee

on Pharmacy said "there was widespread agreement in the Committee that the profession prefers the present limitation on sampling over that which previously pertained, that sampling of old preparations not currently covered be controlled and that the regulations should apply to all drug products. Several members expressed the view that certain manufacturers are circumventing the regulations by aggressively promoting request cards among physicians and that they should be curbed. The consensus was clearly that the profession accepts the current regulations which, if changed, should be in the direction of a tighter control of the sampling procedures.[8]

45. In an article "Ironic Contract" published in the Harvard Business Review (September-October 1962)[9] the authors analyzed the differences in promotional and information services between the pharmaceutical industries in the U.S.A. and the U.S.S.R. The methods used are directly opposed and it is interesting that the chief complaint of Russian doctors was the lack of information on drug products. The authors concluded:

1. Vigorous promotion of drugs is not necessarily socially undesirable. In the Soviet Union where drugs are even today only mildly promoted, there are substantial lags in the introduction of new drugs and delays in the dissemination of information about those drugs which have been made available.
2. Brand naming of drugs, in itself, is also not undesirable. By brand naming, the responsibility for quality control is placed with the manufacturer, and the customer is enabled to exert pressure on the manufacturer of inferior products. In the U.S.S.R., where quality control is enmeshed in government bureaus separate from the factory, quality consequently suffers.
3. Customer preference, which branding allows, serves in the United States to stimulate brand manufacturers into carrying reasonable full lines, even if some are sold at a loss. In the Soviet Union, factory managers apparently protect their budget by avoiding highly unprofitable items, much as generic drug manufacturers do in the United States.
4. Finally, if research is separated from production, as in the Soviet system, the process of getting laboratory items into production and out to the consumer is drastically slowed.

Income Tax Paid by Manufacturer—8 cents
Manufacturers After-Tax Profit—8 cents

46. Pharmaceutical manufacturers like other corporations are in business to obtain a profitable return on their investment. Their after-tax profit of 8 cents on the average prescription price of $3.47 is very reasonable, from the point of view of the patient. It is obvious that any action taken which would tend to diminish profits would have a negligible effect on the cost of the average prescription. However, although pharmaceutical profits represent a negligible part of the cost of the average prescription, in total they represent a very attractive rate of return on invested capital. Within recent years drug industry profits in the U.S.A. have compared very favourably with all other industries, and Canadian profits seem to be comparable.[12]

Other Factors

47. Earlier in this submission we noted certain variations in cost about which we wished to comment. They are:

(a) The range of prices of different products for the treatment of different diseases.

(b) The variation in prices of equivalent products for the treatment of the same disease.

(c) The very high cumulative costs associated with the treatment of certain chronic diseases.

The Range of Prices of Different Products

48. The September 1964 survey of the Canadian Pharmaceutical Association sets out the following table representing the range of prices of various prescriptions:[3]

CANADA

All Pricing Methods	222,956 Prescriptions from 723 Pharmacies							
Prince Range	Number of Rx	% of Total Rx	Cumulative %	Average Cost of Ingred.	Average Price	Breakeven Cost*	If Priced by Acquired Cost plus $2.00 Professional Fee	
		%	%	$	$	$	$	
$ 0.01 - $ 0.50	321	0.14		0.19	0.46	1.39*	2.19	
0.51 - 1.00	6,236	2.80	2.94	0.34	0.92	1.54*	2.34	
1.01 - 1.50	19,546	8.77	11.71	0.49	1.36	1.69*	2.49	
1.51 - 2.00	29,287	13.14	24.85	0.73	1.84	1.93*	2.73	
2.01 - 2.50	35,246	15.81	40.66	1.03	2.33	2.23	3.03	
2.51 - 3.00	30,390	13.63	54.29	1.23	2.80	2.43	3.23	55,390
3.01 - 3.50	22,557	10.12	64.41	1.53	3.31	2.73	3.53	or
3.51 - 4.00	19,930	8.94	73.35	1.88	3.80	3.08	3.88	24.85%
4.01 - 4.50	12,898	5.78	79.13	2.21	4.30	3.41	4.21	of all
4.51 - 5.00	11,493	5.16	84.29	2.54	4.80	3.74	4.54	Prescriptions
5.01 - 5.50	6,724	3.02	87.31	2.90	5.31	4.10	4.90	Dispensed
5.51 - 6.00	6,767	3.03	90.34	3.21	5.83	4.41	5.21	at a
6.01 - 6.50	4,866	2.18	92.52	3.56	6.30	4.76	5.56	LOSS
6.51 - 7.00	4,098	1.84	94.36	3.85	6.81	5.05	5.85	
7.01 - 7.50	2,609	1.17	95.53	4.19	7.32	5.39	6.19	
7.51 - 8.00	2,081	0.93	96.46	4.51	7.80	5.71	6.51	
8.01 - 8.50	1,173	0.53	96.99	4.91	8.32	6.11	6.91	
8.51 - 9.00	1,098	0.49	97.48	5.31	8.82	6.51	7.31	
9.01 - 9.50	806	0.36	97.84	5.82	9.34	7.02	7.82	
9.51 - 10.00	986	0.44	98.28	6.03	9.87	7.23	8.03	
10.01 - 15.00	3,152	1.41	99.69	7.28	11.98	8.48	9.28	
15.01 - 20.00	414	0.19	99.88	10.80	17.24	12.00	12.80	
20.01 - 25.00	164	0.07	99.95	14.47	22.70	15.67	16.47	
25.01 - 50.00	114	0.05	100.00	25.01	36.14	26.21	27.01	

* Prescriptions in these price ranges dispensed below breakeven cost, that is ingredient cost plus a Dispensing Cost of $1.20. By "dispensing cost" is meant the total of 1. Compensation for the pharmacists 2. Cost of containers and labels 3. Cost of prescription files 4. Maintenance and replacement of pharmaceutical balances, graduates, other equipment, and typewriter 5. Cost of professional liability insurance 6. Cost of licences, professional memberships, subscriptions, seminars, etc. 7. Cost of open or non-returnable packages of prescription medications which had to be "retired" or destroyed because of spoilage or obsolescence. 8. Delivery expense 9. Office and administrative expense including bad debts 10. Fixed expenses such as rent, light, telephone, etc.

The total annual cost of these ten items divided by the number of prescriptions dispensed in a year gives the average cost of dispensing a prescription and is referred to as "dispensing cost".

Average Gross Margin 50.10 per cent—Average Cost per Prescription $1.73—Average Price per Prescription $3.47.

49. This table shows that 84 per cent of all individual prescriptions cost less than $5.00 and 98 per cent cost less than $10.00. The average prescription price was $3.47 and almost 95 per cent of all prescriptions cost less than $7.00 or twice the average price.

50. We are primarily concerned about the 5.6 per cent which cost more than $7.00. Of the sample, 12,600 prescriptions fell into this category. The total cost of ingredients to the pharmacists was $75,200.00 and the total retail price was $124,800.00. This gross mark-up of 66.0 per cent seems very high. Even if we consider the additional cost ($1.20 per prescription) which the study allocates for overhead, the net mark-up of 38.2 per cent remains substantial.

51. This suggests to us the merits of the cost plus professional fee arrangement which is gaining wider acceptance among pharmacists. The application of this method would have reduced the price charged for this particular group of prescriptions from $124,800.00 to $100,400.00, reducing the gross mark-up from 66 per cent to 33.5 per cent. The net mark-up would be 11.2 per cent.

52. Even with this method, the prices which would have been charged (listed in the last column) are still substantial in many instances. It is obvious from the small number of prescriptions which fall into these higher priced categories that mass production methods cannot be used in the manufacturing process and this fact is prejudicial to lower costs.

53. We believe however, that the pharmaceutical manufacturers might effect some reduction in these prices through voluntary action on their part. Just as the use of costs plus a professional fee method of pricing reduces the retail cost of higher-priced prescriptions, surely the pharmaceutical manufacturers might allocate their costs so as to allow some reduction in prices of the more expensive products.

Variation in Prices of Equivalent Products

54. This is a difficult problem. It relates to patent protection compulsory licensing and importation and "generic prescribing". More time and attention has been devoted to these aspects of the pharmaceutical industry in recent years than to any other.

55. We are concerned about the substantial variations in price for what are held out to be equivalent products. We would like our patients to be able to obtain the drugs they need at the most reasonable cost.

56. Unfortunately this is not as simple as it would at first appear. Superficially one might deduce that all a doctor needs is a price list of all equivalent drugs. This of course presupposes that some person or persons is able to provide such a list and guarantee their equivalency.

57. This of course is the difficulty. No agency in Canada is in a position to guarantee equivalence. The importance of this aspect is underlined in a statement contained in our previous submission to this Committee:[10]

> "A drug must not only be chemically correct, it must be presented in a state which makes it available to the body at an appropriate rate of absorption, noting the changes and alterations which take place in its assimilation and the rate of its metabolism and excretion."

58. Our position on foreign-made generic equivalents is easy to state. Until we can be assured by the Food and Drug Directorate that these imported preparations are reliable and that their manufacturing processes have been properly controlled to yield a product of uniformly high quality, we are unable to consider them as genuine equivalents to Canadian-made products.

59. The Food and Drug Directorate has made it clear that under existing circumstances they are not in a position to give any such assurance as they lack the facilities to engage in any comprehensive testing programme. Thus, at present we must conclude that foreign made generic products do not meet our requirements as stated, and we believe that they must undergo pharmaceutical assay or that the manufacturing process satisfy F.D.D. requirements for quality control before they can be accepted as fully equivalent preparations.

60. In a given drug, not only must the proper amount of active agent in proper chemical form be present, but also the assurance of the absence of noxious by-products or unrelated chemicals. In most circumstances, the physician will choose the product of a manufacturer whom past experience suggests that he can trust implicitly. It is unlikely that even a very substantial price differential will affect his choice.

61. This is the background of our interest and concern. Canadian doctors do not have sufficient reliable information on all available products to make a choice on price alone. We are aware of this situation and at our recent annual meeting our General Council approved in principle further study by representations of interested organizations in the creation of a Drug Information Service probably in the form of a Canadian Compendium of Drugs, which would in part meet the problem.[11] The recent publication by the American Medical Association of the volume "New Drugs" with a Canadian supplement containing the variations of some names between Canada and the U.S.A., may be helpful to Canadian physicians.

62. Beyond this however, the Canadian pharmaceutical industry must assume a responsibility. The leading firms in Canada have a reputation which they have established with doctors who use their products. This reputation should not be used as a licence to obtain unrestricted profits or as an excuse to maintain a high price on a new product longer than necessity dictates.

63. It is our view that disparity in prices of truly equivalent products can be eased by further voluntary action on the part of the pharmaceutical manufacturers. Obviously it is difficult to reduce them to the level of foreign-made imports because our manufacturers must pay Canadian prices for the material and labour used in the manufacturing process. However, in view of the current profit levels some reduction seems possible.

The Cost of Treatment of Chronic Diseases

64. The person who suffers from a chronic disease requiring long term continual drug therapy is unfortunate. For him drug costs can assume alarming proportions.

65. We believe that this is an area for provincial government action to relieve these costs. In some provinces this has in part been done. In Ontario, for example, in addition to supplying immunological preparations for all citizens, insulin is provided without charge on proof of need.

66. Obviously the government cannot supply all drugs free to long term users. We believe, however, that a study should indicate those diseases, particularly those with long-term economic implications, for which governments may assume all or part of the drugs required.

67. Long term requirements for extended psychiatric drug therapy, anti-epileptic drugs, anti-hypertensives, hypoglycemics and anti-cancer agents serve as examples of this type of expense. Increased governmental assistance, in these and other chronic illnesses requiring long-term pharmaceutical treatment, would prevent the financial disaster faced by the individual, and relieve Canadians of the fear of heavy drug expenditures.

68. *Summary of our Recommendations*

1. Removal of the 11% Federal Sales Tax on all prescription drugs.
2. Voluntary adjustment of price by manufacturers on expensive products.
3. Less direct mail advertising pressure from manufacturers.
4. Approval of fee-for-service principle in pharmaceutical practice, allowing lower return on high price prescriptions.
5. No easing of restrictions on importation of foreign-made generic equivalents without some official assurance of quality.
6. No removal of patent or tariff protection for Canadian companies which could prejudice their economic survival, because of the need for a healthy pharmaceutical industry in Canada able to invest in research and development.
7. Further government assistance for persons sustaining continuous expense for drug treatment of chronic illness.
8. Insurance against drug cost should be available to all citizens under voluntary insurance programmes; with government financial assistance to low income groups. Such insurance programmes should include patient participation or co-insurance.

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[1] Canadian Medical Association, The Canadian Medical Association Statement of Policy on Medical Services Insurance, June, 1965, Canadian Medical Association Journal, 93: 47, July 3, 1965.

[2] The *Globe and Mail* (Toronto), July 15, 1965, p. 1.

[3] Canadian Pharmaceutical Association: Prescription pricing patterns in Canadian pharmacies in 1964; a study made by Professor H. J. Fuller and sponsored y The Canadian Pharmaceutical Association, Canadian Pharmaceutical Journal, 98: IV, June, 1965.

[4] Canadian Pharmaceutical Association: 22nd C Ph.A Annual survey of retail pharmacy, Canadian Pharmaceutical Journal, 97: III, September, 1964.

[5] Canadian Pharmaceutical Manufacturer's Association: Personal Communication 1965.

[6] Canadian Pharmaceutical Manufacturer's Association: Personal Communication 1965.

[7] The Fortune Directory: The 500 Largest U.S. Industrial Corporations, Fortune, Vol. 72: p. 149, July, 1965.

[8] Canadian Medical Association: "Report of the Committee on Pharmacy", Transactions of the Ninety-Eighth Annual Meeting: June 1965, unpublished.

[9] Bauer, R. A. and Field, M. G.: Ironic Contrast: U.S. and U.S.S.R. drug industries, Harvard Business Review, 40: p. 89, September-October, 1962.

[10] Canadian Medical Association: Brief submitted to the Committee on Drugs and Food Contamination, Ottawa, 1964, p. 4.

[11] Canadian Medical Association, "Report of the Committee on Pharmacy"; Transactions of the Ninety-Eighth Annual Meeting, June 1965, unpublished.

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 7

TUESDAY, JULY 5, 1966

WITNESS:

Mr. J. C. Turnbull, B.S.P., of Toronto, Executive Director of The Canadian Pharmaceutical Association Inc.

ROGER DUHAMEL, F.R.S.C.
QUEEN'S PRINTER AND CONTROLLER OF STATIONERY
OTTAWA, 1966

24763—1

DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

Vice-Chairman: Mr. Patrick T. Asselin (*Richmond-Wolfe*)
and

Mr. Brand,	Mr. Hymmen,	Mrs. Rideout,
Mr. Chatterton,	Mr. Isabelle,	Mr. Roxburgh,
Mr. Clancy,	Mr. MacDonald (*Prince*),	Mr. Rynard,
Mr. Côté (*Dorchester*),	Mr. Mackasey,	Mr. Tardif,
Mr. Enns,	Mr. O'Keefe,	Wr. Whelan,
Mr. Howe (*Hamilton South*),	Mr. Olson,	Mr. Yanakis—24.
Mr. Howe (*Wellington-Huron*),	Mr. Orlikow,	
	Mr. Pascoe,	
	Mr. Prud'homme,	

(Quorum 10)

Gabrielle Savard,
Clerk of the Committee.

Note: Mr. Orlikow replaced Mr. Scott (*Danforth*) on July 4.

ORDER OF REFERENCE

MONDAY, July 4, 1966.

Ordered,—That the name of Mr. Orlikow be substituted for that of Mr. Scott (*Danforth*) on the Special Committee on Drug Costs and Prices.

Attest.

LÉON-J. RAYMOND,
The Clerk of the House.

24763—1½

MINUTES OF PROCEEDINGS

TUESDAY, July 5, 1966.
(12)

The Special Committee on Drug Costs and Prices met this day at 11.15 a.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Messrs. Brand, Enns, Harley, Howe (*Hamilton South*), Isabelle, MacDonald (*Prince*), O'Keefe, Orlikow, Roxburgh, Tardif, Yanakis (11).

In attendance: Mr. J. C. Turnbull, B.S.P., of Toronto, Executive Director of the Canadian Pharmaceutical Association Inc.

Also in attendance: Mr. A. M. Laidlaw, of Ottawa, Legal Counsel for the Committee.

The Committee resumed consideration of the brief presented on June 14. (*See Issue No. 3 of Minutes of Proceedings and Evidence*)

Mr. Turnbull was further questioned.

At 12.35 p.m., the Committee adjourned to 3.30 p.m. Thursday, July 7, 1966.

Gabrielle Savard,
Clerk of the Committee.

EVIDENCE

(Recorded by Electronic Apparatus)

TUESDAY, July 5, 1966.

● (11.05 a.m.)

The CHAIRMAN: Gentlemen, I think it would be reasonable to start the meeting. We have with us again today, Mr. Turnbull, from the Association of Pharmacists. That is not, of course, the correct title but I think it is the most descriptive one. Mr. Turnbull is the executive director of that organization and they have already presented their brief. Mr. Turnbull kindly came back today to conclude the questioning by members of the committee. You will remember it was the yellow brief which was presented approximately three weeks ago.

As I recall, we were on sections 6 and 7, I think. However, the easiest thing to do is to just let members ask questions in any areas that they wish, seeing that this will probably be Mr. Turnbull's last appearance. The meeting is open.

Mr. HOWE (*Hamilton South*): I have a question which is directly related to this particular section. I see on page 9 a breakdown of the consumer's dollar so perhaps it is appropriate in this section. I would like to ask what percentage of drugs is bought directly from manufacturers?

Mr. J. C. TURNBULL, B.S.P. (*Executive Director, The Canadian Pharmaceutical Association, Inc.*): Is your question, sir, what percentage is bought direct from manufacturers as opposed to those bought direct from a local wholesaler?

Mr. HOWE (*Hamilton South*): Yes.

Mr. TURNBULL: Since I last met with you I have attempted to determine this and there has not been very much time regrettably. With so many other activities going on in the month of June, involving pharmacists across the country, I have not been able to get this figure.

Mr. HOWE (*Hamilton South*): Would it be possible to do so and send a letter to the committee to let us know this? Is it possible to determine this?

Mr. TURNBULL: I would think that it would be possible to give an estimate. On the other hand, I understand the Canadian Wholesale Drug Association is appearing before the committee and undoubtedly they will have quite a lot of that information as it pertains to the wholesale industry. It might be a simple matter of calculation to take the figures submitted by the Pharmaceutical Manufacturers Association brief which, I believe, is around $136 million of packaged human pharmaceuticals and a matter of subtraction would probably do the trick, sir. I will attempt to determine this during the course of the summer months and correspond with you.

Mr. HOWE (*Hamilton South*): I think, coming from you, it would possibly be a more reliable figure because of those whom you represent, than if obtained

from some of the other places which could not determine it. Not that the figure is readily available but still it is one which could be more accurately obtained by you through the druggists than from some of the other places. I think this is a fairly important aspect.

The other question is directly related to that and I do not suppose you would have this figure either. This relates to doctors who do their own dispensing, buying direct from manufacturers.

Mr. TURNBULL: Do you mean the number of doctors or the amount they purchase?

Mr. HOWE (*Hamilton South*): Again, I really meant percentage because I believe that most doctors who dispense—and you can correct me if I am wrong—do buy directly from manufacturers.

Mr. TURNBULL: Presumably so, yes.

Mr. HOWE (*Hamilton South*): Rather than from the wholesaler distributors in the area. This is the rule, is it not?

Mr. TURNBULL: I believe this would be the experience, yes.

Mr. HOWE (*Hamilton South*): The wholesale distributors, as a rule, do not want to sell to doctors because of their status with the drugstore. Is this not true?

Mr. TURNBULL: I would not want to comment on that, sir. I do not believe that is completely true. I think the influence is for them to buy direct from the manufacturers, due to the somewhat advantageous prices when bought on a direct basis. There may be some wholesalers who do not sell to other than retail pharmacists, but not all.

Mr. HOWE (*Hamilton South*): Under normal circumstances, as there is usually a drug store within the area, you would say you are averse to doctors dispensing their own drugs.

Mr. TURNBULL: Yes.

Mr. HOWE (*Hamilton South*): Thank you very much.

Mr. ORLIKOW: Mr. Chairman, I just want to ask one question with regard to one item on page 21 of the brief section 13.4 which deals with patents it says:

> The Canadian Pharmaceutical Association is of the strong opinion that Canada's patent legislation must be such as to provide for the enhancement of an active, self-sustaining and ever-growing pharmaceutical industry—

I gather from that section of which I will not read the whole paragraph, that what you are saying is simply that you are satisfied with the present patent laws and how they are applied in the drug industry.

Mr. TURNBULL: We believe that the innovator of a drug or a process by which a drug is made available in a pharmaceutical form is entitled to patent protection. Possibly the period of time, under present legislation in Canada, could be subject to review and, indeed, this is why we have suggested in this paragraph that such a period of protection need not exceed three years or some other suitable period of time made necessary by the particular nature of the

drug, unless it be produced in Canadian based manufacturing facilities. This is to enhance the usage of Canadian facilities for the production of these drugs.

Mr. ORLIKOW: Is not your association aware of the fact that in many countries, including Canada and the United States, patent and product licensing has been used to keep the price of essential prescription drugs up to a very high rate?

Mr. TURNBULL: I think this is a matter of, shall we say, opinion, which has been expressed in some public circles. I would not say that our association is aware of this.

Mr. ORLIKOW: Well, Mr. Chairman, I have here a photocopy of an article which appeared in *Business Weekly* which is a very respectable business magazine. It is a few years old but I do not think there has been any change. It deals with the United States situation but I am sure the same thing is true here. It says essentially that McKesson and Robbins, which is the largest United States wholesale drug distributor, cut the price—this is August 15, 1964—of tetracycline from $17 a 100 at which it was being sold by Lederle and others to $6 a 100 and, of course, Lederle cut McKesson and Robbins off.

Now it seems to me that if this is the kind of thing which is happening in the United States it can happen in Canada as well. It would be a good thing for the parliament and the government to look at the whole patent situation. I do not understand why the Pharmaceutical Association should be taking this position, which I think it should not as a branch of the pharmaceutical manufacturers. I think they are big enough and strong enough to defend themselves. That is, if they have a defence.

Mr. TURNBULL: I think we are quite aware of the situation which you have brought forward sir. However, I would reiterate that we are not aware that this is directly due to any patent situation. This could be due to other matters.

In respect of your other observation, I do believe that the Canadian Pharmaceutical Association, having to do with the professional pharmacy and the pharmacists of Canada, certainly has an interest in this branch of pharmacy which is represented by industry. We do believe that a strong pharmaceutical industry within our boundaries is a very important thing to our nation.

Mr. ORLIKOW: Well, nobody questions that. But what happened in this particular case—and I know it happens in other cases—is that Lederle not only produces this drug but has licensed four other large companies, Bristol Myers, Squibbs and Upjohn to produce and sell that particular drug at the same price. If you have this kind of situation how can the retail druggist buy an important drug, whether it be this one or aureomycin or one of the tranquilizers, cheaper and in that way give it to the customer? He cannot. You say that the patent laws, as they are, should be maintained. You are really saying that the price will stay at the high level it is. That is what I feel and, if I am wrong, I certainly would be glad to have it explained to me how I am wrong?

Mr. TURNBULL: Well, I would prefer that you do not associate the two things in our statement where we say that the innovators are deserving of patent protection. We are not inferring price protection in that statement.

Mr. BRAND: Mr. Turnbull, without beating the manufacturers over the head when they are not here to defend themselves, most of us have received a lot of

letters, of course, since this has started and we are aware of some of the differences in prices between different retail pharmacists. Now, I get the impression from your brief that most of this is due to the—perhaps I am wrong about this—manufacturers and the way in which they price the hospitals and the pharmacies, with the result that drugs cost much more from pharmacies and so on.

I will give you one example, a letter I received from a jurist in British Columbia. I do not wish to comment on the number of capsules this gentleman is using—far too many from a medical point of view. He points out that he received a prescription for 60 sodium senocal capsules for which he paid $2.45. A few days later—much too short an interval—he then obtained a prescription for 100 and went to another pharmacy closer by—this is in the city of Vancouver —and paid $2.15 for exactly the same product by the Lilly Company. I wonder if you could explain why this parity in prices which occurs at the retail pharmacy level for the same product, that is, sodium seconal, regardless of from where they get it, namely $2.45 for 60 or $2.15 for 100 capsules. Now, surely you cannot blame this on the manufacturers. Can you explain to me how this tremendous difference arises.

Mr. TURNBULL: Dr. Brand, first I should explain that I do not know the list price or the normal cost price at which Lilly would possibly offer this particular product to retail pharmacists so I cannot comment on whether $2.15 for 100 capsules of seconal sodium would be a correct price. Frankly, from what I remember of the price a few years ago, I think it is an exceedingly low price. But then the price could have come down over the years. There have been these claims made and this could be substantiated. No, I could not explain to you why one price is different from another.

I think I mentioned the other day that each individual has an awareness of the value of his own service and is prepared to put a dollar and cents mark on the value of that service and, if he does not value his services particularly high, he is going to have a lower price. On the other hand, we know in pharmacy, that the questioning here this morning would be much greater, Mr. Chairman, if, for example, your same jurist—and I will not comment on the propriety of getting 60 one day and 100 two days later—

Mr. BRAND: I did not say that, I said a few days.

Mr. TURNBULL: Oh, I am sorry, I thought you said two days. But if he had gone to 50 retail pharmacies and got the same price of $2.45 for 60 in every one of them, the questioning would have been more severe here this morning than it is because there is a slight difference in the price.

Mr. BRAND: That is true but it does not answer the question, does it?

Mr. TURNBULL: I do not know the answer. Each man puts a value on his own service.

Mr. BRAND: You would agree, then, that the fault is not entirely that of the manufacturer but that there is something at the retail pharmacy level which seems to contribute to some of the increased costs?

Mr. TURNBULL: Well, certainly, I would expect the community pharmacist will receive remuneration for his services. I do not think we have ever said that

the complete responsibility for the price of drugs rests with the manufacturers. I think it would be an erroneous statement to say so.

Mr. BRAND: What are the retail pharmacies prepared to do to help lower the cost of drugs since they seem to admit that they are too high?

Mr. TURNBULL: I have never heard a retail pharmacist and certainly my office has never made such a statement of admission.

Mr. BRAND: Then you say they are not too high?

Mr. TURNBULL: No, we do not believe that the price of drugs is out of line with the economic situation in Canada. In fact, we have attempted to illustrate this in two or three places in our brief in comparing it with the value of services and goods in other lines in our nation. There have been many proposals. We believe that the more costly, high priced prescription, is the one which is most bothersome to the public. As you are very much aware, the cost plus fee system has been suggested as one of the ways in which the higher priced drugs can be offered at a lower price. This will increase the cost of the lower priced prescription today but not substantially. The fee that is being used in most instances is cost plus $2. There is every evidence that, on the average, this $2 would not equal the present pricing. But it is deemed as a fit and proper fee.

• (11.30 a.m.)

Mr. HOWE (*Hamilton South*): Mr. Chairman, could I interject a question here on the same subject. If you used a dividing line on your prescriptions of say, $5. I know some druggists in Hamilton are doing this and $5 I believe is the dividing line because the cost on $5 is $3 plus the $2 dispensing fee which takes it back up to $5 again. Any drugs over $5 are charged on a cost plus $2 and drugs under $5 are charged at their present rate. Now, if some druggists can do it, is it feasible to adopt this as a policy in order to keep the higher priced drugs down and the lower priced drugs at their same level?

Mr. TURNBULL: We have no policy in this matter. I should explain that we have, over the years, through our economic committee, handled many surveys and come up with this suggestion as worthy of consideration and adoption by the individual pharmacist. I think it is only a matter of arithmetic that once the price goes over that $5 figure the pharmacist is getting a very, very small return on his investment. If he cannot pick it up below $5 he will not be eating three meals a day and keeping a door open for community service.

Mr. HOWE (*Hamilton South*): Well, it takes no more work to dispense a $10 prescription than to dispense a $1 prescription and, based on his time and services rendered in this field only, the $2 profit for the higher level drug would render him as great an income as it would in the lower priced drugs.

Mr. TURNBULL: Well, conversely, sir, there is no less work below $5 than there is above $5. This is a fact.

Mr. HOWE (*Hamilton South*): It would not be feasible then?

Mr. TURNBULL: I know that some are doing this. There is a slightly lower fee below this cut-off point and a bit higher fee above it. And this is true particularly with regard to the smaller quantity prescriptions of phenobarbs and so on.

On the other hand you will readily recognize that some of the items which are prescribed and which are also available over the counter on individual purchase to the individual who sees fit to diagnose his own illness, are going to be more expensive off the shelf, when he selects himself, than they would be through the dispensary where all the records and everything else are maintained.

Mr. HOWE (*Hamilton South*): I was speaking specifically of a dispensing pharmacy; strictly a dispensing store.

Mr. TURNBULL: There is no such animal. A dispensing pharmacy must render a complete pharmaceutical service, that is those over the counter items such as vitamins and analgesics, the more potent cough syrups and so on that are not necessarily restricted to prescription only.

Mr. HOWE (*Hamilton South*): Well, there is one such animal in Hamilton, of which I am speaking. It simply dispenses prescriptions and does nothing else, no across the counter items at all, and it is doing it on the basis of a cost plus over $5 and the normal fee under $5. And I think he eats three meals a day.

Mr. TURNBULL: He does not sell anything whatsoever over the counter.

Mr. HOWE (*Hamilton South*): I am sorry I did not hear you.

Mr. TURNBULL: He does not sell anything whatsoever—

Mr. HOWE (*Hamilton South*): No, nothing over the counter.

Mr. TURNBULL: I am not talking about the individual eating three meals a day, I am talking about 8,000 pharmacists in general, eating three meals a day.

Mr. HOWE (*Hamilton South*): Well, my question was based on the fact that I know some drug stores do it and is it feasible or is this done simply by druggists who have a large turnover and can handle it because of the volume of business. That was really what my question was pertaining to.

Mr. TURNBULL: Possibly, yes.

Mr. BRAND: Do you agree it would be a good idea to put this $2 professional fee into use?

Mr. TURNBULL: Most definitely, we have been advocating it for years but we cannot adopt it as a policy because, of course, the combines people would not agree to our doing so.

Mr. BRAND: I do not quite follow that, quite frankly.

Mr. TURNBULL: Well, the advocating of a pricing method.

Mr. BRAND: If you are adding a professional fee what has that got to do with fixing prices?

Mr. TURNBULL: Well, I think the answer can best come from—

Mr. BRAND: Are you suggesting that doctors who have a schedule of fees are therefore anti-combine?

Mr. TURNBULL: I am not suggesting that, sir.

Mr. BRAND: But you are suggesting that if the druggists did that, it would be?

Mr. TURNBULL: It has been suggested that where a group of pharmacists gets together to set a fee relative to the service to the public generally this would be in contravention of the Combines Act. Now you must recall that this does not pertain to a contract, such as medical fees pertaining to contracts with the medical services insurance company.

Mr. BRAND: We are not talking about medical services companies or anything like that.

Mr. TURNBULL: Does the medical profession enforce its fee schedule?

Mr. BRAND: No. But there should be an interesting test case because Saskatchewan, I understand, is introducing this as of July 1st.

Mr. TURNBULL: What are they introducing?

Mr. BRAND: The idea of a cost plus professional fee.

Mr. TURNBULL: But that is a contract with the Saskatchewan government.

Mr. BRAND: With the Saskatchewan government, not with the pharmacies themselves?

Mr. TURNBULL: No, it is a contract to the pharmacists with the Saskatchewan government on behalf of the medical services division beneficiary. It is at cost plus $1.45, cost being defined as list less a third. The $1.45 is in consideration of the special circumstances of the welfare and indigent individuals who are covered by the Saskatchewan plan.

Mr. BRAND: I brought this up when the manufacturers were before us. You are using the Saskatchewan prices and these were for prescriptions only, by the way, I notice in your brief. By so doing you will increase the cost of 77 per cent of your prescriptions. Do you consider this a good method to reduce the cost of drugs?

Mr. TURNBULL: You increase the cost of 77 per cent? I am not too sure what chart you are looking at sir.

Mr. BRAND: Look at the last page.

Mr. TURNBULL: In Saskatchewan we have to realize that the increase there on those 77 is possibly not as significant as the decrease in terms of dollars of those above the $5 level.

Mr. BRAND: Perhaps so, but you are still increasing 77 per cent of the prescription costs.

Mr. TURNBULL: Numerically, yes. And on a national average you will be increasing possibly 60 some odd per cent, to a not significant level.

Mr. RYNARD: Mr. Chairman, most of the questions I had have been covered but one thing I would like to ask Mr. Turnbull—and I think he has expressed himself quite adequately on this—is whether the professional fee is the proper way to handle this. I was wondering if it is because the man is also running a store that the Combines Act would step in. Surely if he has those articles on the shelf to sell he can sell them as he likes so long as he charges his professional fee? Where would the Combines Act come into this problem?

Mr. TURNBULL: Well, the combines people certainly agree with the suggestion made a moment ago. This is an observation on their part and it would need

a legal opinion, coming from a test case. Regrettably there is a tangible ingredient involved in a pharmaceutical service. Because of this it would not mean tooo much if the pharmaceutical organization were to say to the practising pharmacist: thou shalt charge a professional fee of $2 plus cost of the ingredients, unless cost is defined.

Now the reason you have to define cost is that if a retail pharmacist is in a position that he can buy direct from the manufacturer and possibly in large quantities, his acquisition cost will be much different from the retail pharmacist who is in an out of the way location. He must pay the freight or the express on a purchase made from a wholesaler who is perhaps 500 miles away. So the acquisition cost is very different. This is why, Dr. Rynard, in the Saskatchewan set-up they have had to define cost. But, they only have one purchaser, the Saskatchewan government. The cost has been defined as manufacturer's list less one-third. Even if a pharmacist might buy at less 40 or he might buy at less 25, he will still be paid less one-third plus his $1.45 in consideration of the welfare people. It is that tangible ingredient that borders on whether it is a commercial transaction pertaining to the tangible ingredients plus a professional fee and therefore they are integrated. It would be an interesting test case but I would not want to get involved.

Mr. RYNARD: Thank you very much. It would still leave one fellow in the country, maybe making just as much as the fellow who was not in the country—

Mr. TURNBULL: Yes.

Mr. RYNARD: —under certain circumstances. The other problem that I was concerned with was that under the insurance plans that pay for your drugs today, how is this going to work out in this field? For instance, you will be able—and I think in some places now they are operating—to pay for your drugs in advance on a flat fee. How are they going to work this out under this plan?

Mr. TURNBULL: This is prepaid insurance?

Mr. RYNARD: That is right, this is prepaid insurance.

Mr. TURNBULL: There is only one operating at the moment which we believe is a fit and proper plan, and that is the Green Shield program out in Windsor. Some others have tacked drugs onto their programs or tried to get into this particular field and we, in the association, have come forward in recent months with Pharmacare Incorporated to bring these programs into being across Canada on a deductible basis. Here again, you are operating with one purchaser who will enter into a contract with the pharmacist to provide the services, including the ingredients, at a set contract rate which will be cost plus fee.

Mr. RYNARD: On a risk cost base?

Mr. TURNBULL: Yes.

Mr. O'KEEFE: Mr. Turnbull I am sure you realize that this committee exists to try to reduce the cost of drugs. Would you agree that that is our general purpose?

Mr. TURNBULL: No, I would not wish to agree with it, sir. I was rather disturbed that the terms of reference of the committee inferred that prices are too high so the committee must find a way of reducing them. I would have

thought the terms of reference would have been better to review the price and cost of drugs to determine their correctness of otherwise. And if, otherwise, to find a way to bring them down.

Mr. O'KEEFE: Surely you would not suggest we try to increase the cost of drugs?

Mr. TURNBULL: No, not at all.

Mr. O'KEEFE: Well, do you think that if your association combines to reduce the cost of drugs this would be an infringement of the Combines Act?

Mr. TURNBULL: It most certainly is. Section 34, I think it is. The legal minds could help us on this.

Mr. O'KEEFE: The question came up the other day and that was the impression the legal men had but surely you would not agree with that?

Mr. TURNBULL: I think it—

Mr. O'KEEFE: It is obvious that the Canadian law is basically for the purpose of protecting the consumer and if, by protecting the consumer, it is preventing prices from being lowered, surely that is very little protection, if any.

Mr. TURNBULL: Yes, but the interpretation of the law as it stands today, sir, is that you cannot combine to do good or to do bad. It is as simple as that.

Mr. O'KEEFE: We ought to have that law changed.

Mr. TURNBULL: It would be a fine thing. However, it is correct that a group cannot combine in this manner.

Mr. O'KEEFE: It could never be used as an excuse to keep the prices up. On page 10:

> Two matters directly related to drug ingredient costs and prices must be understood:

Well I agree completely with the first one—"The highly improper tax on illness—" I think the 11 per cent federal sales tax should be removed. I hope it will. But the second one:

> The retail pharmacist pays top dollar for his drug preparations. This causes a disproportionate weighting on the prescription purchased by the private patient and a substantial sudsidization of the sometimes unrealistic prices available to other practitioners, hospitals, governments and similar agencies. This situation is not appreciated by the uninformed. It is certainly not condoned by Pharmacy and we repeat our often stated, firm belief that this gap should not exist.

Could you tell me sir, how large this gap is?

Mr. TURNBULL: It is difficult to know, on the average, just how large this gap is.

Mr. O'KEEFE: Well just approximately.

Mr. TURNBULL: With regard to some drugs and drug preparations there is as much as a 60 per cent difference. In other words, 30 per cent of the price at which the pharmacist is purchasing his products. We know, and I have on file,

copies of invoices where some companies have sold the same product, and not in large quantities, at 10 per cent of the price which the pharmacist must pay.

Mr. O'KEEFE: That is 10 per cent of the cost you pay?

Mr. TURNBULL: Yes. The pharmacist is not in a bargaining position, you must realize this, sir, relative to the items which he purchases, whereas the institution and the government and, possibly, the medical practitioner, I do not know, is in somewhat of a bargaining position.

Mr. O'KEEFE: But surely your large organization would be in a bargaining position as an organization?

Mr. TURNBULL: Not as an organization. We do not get involved in this type of thing and, here again, we could not.

Mr. O'KEEFE: Well that gap would not be the 100 per cent—you say about 60 per cent, but you gave an instance where it would be 90 per cent higher. I understood Mr. Orlikow to give an example a little while ago where it was at least 200 or 300 per cent.

Mr. TURNBULL: Well, no, I do not know of Mr. Orlikow's example. I have some examples where items have been charged through at 37 cents per unit of a hundred whereas the retail price has been $3.77 per unit, in hundreds.

Mr. ORLIKOW: Who gets it for 37 cents?

Mr. TURNBULL: In this particular case it happened to be a government agency.

Mr. ORLIKOW: And the same is sold to the government agency at 37 cents and to the retail druggist at how much?

Mr. TURNBULL: $3.77.

The CHAIRMAN: Is the government purchasing on tender?

Mr. TURNBULL: The government is purchasing on tender, yes.

Mr. ORLIKOW: I suggest it would be of value to everybody, including the retail pharmacists, if they would file with this committee any information of this type so that we could discuss it either with the pharmaceutical manufacturers or with the individual companies. It would be interesting to know.

Mr. CLANCY: That may be, doctor, the reason why the ordinary purchaser buys it at a higher price to make up for the low price at which they sell it to the government.

Mr. ORLIKOW: Well, Mr. Chairman, I think we ought to find out which companies are such good Samaritans that they are selling to the government agencies at a loss, if they are. If they are not selling it at a loss, it makes it even more interesting. Perhaps you would have to get approval from your board of directors, but I suggest that this kind of material should be filed with the committee for perusal by our accountant and the legal counsel.

The CHAIRMAN: I am sure, Mr. Turnbull of course, would not have the authority to release this himself. You are suggesting that he might ask his board if they would give their consent.

Mr. ORLIKOW: I suggest that he take it up with his board with a view to doing this.

Mr. TURNBULL: A lot of this information, you will realize, gentlemen, is contained in the Green Book which was published by the Restrictive Trade Practices Commission when it held its investigation three or four years ago. It is already published, so we are not divulging anything today that has not been well documented over the years. The instance that I used is, of course, a bad instance. Most of them range around 40 to 50 per cent of the price at which pharmacy buys. But this is why we made the statement in our brief that this situation is not appreciated by the uninformed, who believe—and this has been mentioned in the House in past years—that certain prices are so much lower, why would an individual have to pay a higher price at the local drug store? This is the answer to this. Now we believe that either price must be correct. If they are both wrong then let us close the gap.

Mr. O'KEEFE: Then you suggest that the wholesale drug companies could sell to you at the same price of very nearly the same price as they do anybody else, government or any other institution?

Mr. TURNBULL: It would increase substantially the price at which governments, hospitals and other institutions purchase their drugs today. And would decrease the pharmacists price only a slight amount, if you are going to close this gap.

Mr. O'KEEFE: I do not believe for a minute that any association or any manufacturer is selling his goods at a loss to anyone.

Mr. TURNBULL: Nor do I.

Mr. O'KEEFE: Then the only logical conclusion is that the prices could be reduced to if not exactly that level, at least to very near that level.

Mr. TURNBULL: Here again, I think we should be fair to the manufacturer because much of this has grown over the years when it was part of his promotional cost. You have to be fair to the manufacturer also, who is involved with prestigious manufacturing facilities and is countering some of the imported drugs which are coming into Canada and of which there are many. I believe that was contained in the manufacturers brief the other day, a copy of which I have had made available to me.

Mr. O'KEEFE: Just one other question, Mr. Chairman, on page 23 paragraph 13.12, information service. It is very long but you suggest that some of this information is available from many sources and in a great variety of forms. Would one of those forms be the detail man that we discussed the other day?

Mr. TURNBULL: Well, yes, but here of course I am referring to printed pieces.

Mr. O'KEEFE: Yes, I understand that sir, but surely part of the cost is the detail man?

Mr. TURNBULL: Yes.

Mr. O'KEEFE: Would you think his services are necessary?

Mr. TURNBULL: I do not believe I am in a position to say yes or no to that. As a pharmacist who realizes that it is almost impossible for every practitioner, be he medical or pharmaceutical or what have you, to be completely up to date in everything, if he has someone such as the medical detail representative who can bring his up to date yes. I would say he is performing a very valuable service.

Mr. O'KEEFE: Would you say you are dependent on him?

Mr. TURNBULL: I do not think any clear thinking medical practitioner depends on the detail man who comes to him.

Mr. O'KEEFE: I am talking about the pharmacists now.

Mr. TURNBULL: The pharmacist, no, he does not depend solely on the detail man.

Mr. O'KEEFE: Then he is not essential.

Mr. TURNBULL: He is an integral part of it, yes. Just what the loss of him would result in, I do not know.

Mr. O'KEEFE: Well I suggest it would result in the lower cost of drugs.

Mr. TURNBULL: This could better be discussed by the people who pay his salary.

Mr. O'KEEFE: Thank you, sir.

Mr. CLANCY: Could your organization suggest another method of getting the medical profession to know of new products other than by having a detail man?

Mr. TURNBULL: No, we are not prepared to do so. I think one is supplementary to any other method that could possibly be brought into being. I believe that the medical practitioner is a very busy man and finds it very difficult to read all the material that first of all he should read and second, what other people would like him to read.

Mr. CLANCY: Members of the medical profession claim that it takes a considerable amount of time to read the things that they must read.

Mr. TURNBULL: I would think so, yes.

Mr. CLANCY: Well then, what other method would you use to make the medical profession aware of the new products that are manufactured?

Mr. TURNBULL: We have a continuing drug information service which attempted to publish, at frequent intervals, a resume of all the available literature on each or all that was necessary.

Mr. CLANCY: I do not know too much about the medical profession but do not they already have a book in which is published the different drugs which are manufactured and the side effects and so on?

Mr. TURNBULL: Yes, the only one that is halfway comprehensive is the one published by our own association, the Compendium of Pharmaceutical Specialties in Canada, which covers the complete field in Canada. There are others and, regrettably, not too many of the medical profession have the compendium.

Mr. O'KEEFE: But none of them is well prepared.

Mr. TURNBULL: I think it would be impossible to be absolutely prepared.

Mr. ROXBURGH: Just as I was called out there was a statement made on the cost of drugs to the druggist and to a government agency and I did not get the difference in the price. What was that?

The CHAIRMAN: The illustration used was a government agency purchasing a drug for roughly 37½ cents a hundred and the pharmacist paying $3.75 for it.

Mr. TURNBULL: Of course, I think we must appreciate, Mr. Chairman, whether it is still not a fact that for large purchases the government tendering and letting of contracts is based on manufacturers cost plus 10 per cent or something of this nature? It used to be, during the war anyway, for large tendering.

Mr. MACDONALD (*Prince*): That is just a further indictment though, is it not? The 10 per cent of manufacturers cost plus 10, meaning—

Mr. TURNBULL: Of course we do not know whether cost is cost of ingredients only or whether it is the manufacturers complete operation, including keeping his lights on and paying his executives and so on.

Mr. ROXBURGH: Is there no way of finding out? There must definitely be if there are total costs, would you say? If it is 37½ cents, to $3.75 even with the 10 per cent added on, do you not think that is far too much a difference?

Mr. TURNBULL: Oh yes, we have been telling the manufacturers this for years.

Mr. ROXBURGH: In other words, the drug business then, is really run as a straight hardboiled business the same as any other business. It does not take into consideration, under any circumstances, the human element or the human sufferings with which they are dealing. They are nothing but a hardboiled business organization just the same as any other business organization.

Mr. TURNBULL: Maybe—

Mr. ROXBURGH: Yes or no.

Mr. TURNBULL: Maybe the accounting section of the office is but I would not agree with your statement one bit, no.

Mr. ROXBURGH: You would not agree with it? What proof have you to disagree with it?

Mr. TURNBULL: Well I do not think—

Mr. ROXBURGH: No, we have to have proof. You made a statement, Mr. Turnbull, and now we want to have proof.

The CHAIRMAN: You are asking Mr. Turnbull to comment from the drug manufacturers point of view?

Mr. ROXBURGH: On the over-all picture of the drug business.

The CHAIRMAN: I do not think we can ask Mr. Turnbull to comment on what he thinks of the manufacturers. All we can ask him about is what is what concerns the pharmacists.

Mr. ROXBURGH: Well then, as a straight business. It is just a straight hardboiled business, as far as I can see.

Mr. TURNBULL: I do not agree with you, sir, no.

Mr. RYNARD: Mr. Chairman, might I interject a supplementary here and probably it would help answer Mr. Roxburgh's question. On the prescription we issue, if it is for an old age pensioner or something like this, or the people are very hard up, the druggist, on every occasion that I have known of in our town, has reduced that price and cut his profit. On many occasions he has sent samples. I just want to put in a plug here for the druggist and say that he has got a heart, particularly in the smaller cities like Orillia, where I come from. I, for one, appreciate as a doctor that they do do this, if it is necessary.

• (12.00 noon)

Mr. TURNBULL: Thank you, Dr. Rynard. I think the chap who was telling me last week about going down to his pharmacy at 3 o'clock in the morning, had something other than dollars in mind, particularly when the father arrived without his wallet in his pocket.

Mr. ROXBURGH: I agree with that, that happens in all cases; we have individuals. We also have doctors who would not come out under any consideration and we have doctors who go out under all considerations. I am speaking about the business as a whole, not the individual.

Mr. TURNBULL: No, I am sorry I cannot agree with you, no more than any other—

Mr. ROXBURGH: It is run on the same basis as any business.

Mr. TURNBULL: The same economic foundation; I would hope so.

Mr. BRAND: I must support Mr. Turnbull in his argument. I think any druggist who did not run a business as such, would not be in business very long but, most certainly, I can agree that they are coming out at three in the morning. This is not an isolated instance, by any means. We get tremendous co-operation from the retail pharmacist when we need drugs. I do not think there is any question about it.

Mr. TURNBULL: Thank you, Dr. Brand. I have filled some of your prescriptions.

Mr. HOWE (*Hamilton South*): My question, Mr. Chairman, was one more or less of clarification. Mr. Turnbull you said it was contrary to the Combines Act to set a price on drugs. In other words, price fixing is the factor that is illegal, is this correct? In other words, taking a cost and specifically adding $2 to it would be fixing prices generally, that is what is contrary to it?

Mr. TURNBULL: Yes.

Mr. HOWE (*Hamilton South*): Well, what is the difference between that and the schedule put out by the Ontario College of Pharmacy to the pharmacist concerning his dispensing fee and his breakdown fees when he breaks an intact bottle of 100 tablets and dispenses 24 of them? This is done by a schedule of the retail price plus the breakdown fee plus the dispensing fee. Is this not comparable or the same thing as the others?

Mr. TURNBULL: No, actually they have not put out a schedule of this nature for several years now, Dr. Howe, although it still does exist. It now exists, in the main, as a teaching tool. It was discontinued several years ago. Anything along this line from the OCP was discontinued.

Last fall, I believe the Ontario College of Pharmacy did pronounce itself to be in favour of a cost plus professional fee method of pricing and advocated this to its membership but nothing beyond that.

Mr. HOWE (*Hamilton South*): In other words, it is not fixing, it is merely advocating that it would be a good idea to adopt this policy but it is not enforcing it in any way? I ask this in order to understand the law.

Mr. TURNBULL: Yes, basically it is the getting together or the combining to set a method of pricing and then enforcing it, which would be contrary to the—

Mr. HOWE (*Hamilton South*): Previously this OCP schedule—

Mr. TURNBULL: It has never been enforced. It was always merely suggested.

Mr. HOWE (*Hamilton South*): These were just suggested figures such as the medical fees are? Thank you.

Mr. MACDONALD (*Prince*): Mr. Turnbull, one of the assumptions made throughout your brief is that drug costs and pharmacists prices are justifiable. Yet there are certain things which would lead us to believe, from your report, that very few pharmacies can actually maintain their business by dispensing alone and that they must couple this with other things. I am rather surprised that in your brief you did not, in fact, take a stronger line and argue that perhaps drugs prices are not high enough. In light of the statements which are made and supported by certain facts, here, why did you not say perhaps, for instance, that we should be recommending that drug prices should be increased 25 or 30 per cent?

Mr. TURNBULL: I do not believe there is any reason for making such a recommendation, sir. Certainly I am not expressing a personal opinion in this or in the presentation of our brief to this committee but I believe the remuneration is adequate.

Mr. MACDONALD (*Prince*): What you are saying, in effect, is that the price is not too low, it is not too high, it is just right.

Mr. TURNBULL: Well—

Mr. MACDONALD (*Prince*): Is this what you are saying?

Mr. TURNBULL: No, I am saying that we see no reason, in a written brief such as this, for advocating that prices should be higher and we believe that, as they stand, they are completely justifiable and they are a darn good bargain at the community level.

Mr. MACDONALD (*Prince*): The price is high enough, yet it is not too high.

Mr. TURNBULL: Have I stopped beating my wife?

Mr. MACDONALD (*Prince*): The reason I ask this is because we had testimony earlier this morning that the prices can vary quite a bit, on the very same drugs, from pharmacy to pharmacy. I am just wondering how you can make this assumption and, at the same time, agree that you have no control and, to a degree, no knowledge of what is happening in individual pharmacies. To me, it seems like quite a contradiction.

Mr. TURNBULL: As I indicated, I believe to Dr. Howe or Dr. Brand, earlier, when they were talking about the cost of our professional fee, we suggested

that the $2 figure has been used. There is every evidence that that figure should now be somewhere between $2.25 and $2.35. But we are still sticking with the $2 in most areas. Maybe that answers your question of why we do not advocate that the price be higher. Maybe this is the answer to it.

No, I cannot suitably answer, Mr. Chairman, I am sorry. Perhaps I am dense regarding the purpose of the question. We are saying that the prices, as they are presenting charged at the community pharmacy level, are completely justified and are not exorbitant for the services being rendered by the community pharmacist and this is certainly pointed out in the breakdown of the pharmacists' share of the prescription dollar which is somewhere around 45 to 50 cents.

The CHAIRMAN: Could I make a point of clarification, if I may, or ask you for clarification? You mentioned in keeping with pharmacy practice you are not commenting really on the price you are paying for drugs, the manufacturers price. You are commenting on what the pharmacist does with cost after he obtains the drug at whatever cost he gets it.

Mr. TURNBULL: That is correct.

The CHAIRMAN: You are not saying that the manufacturer may not be charging you too much for it, you are just saying that you think the costs are justified from that point on.

Mr. MACDONALD (*Prince*): Well, he has said earlier that he thinks the pharmacist is paying too much for some of the drugs.

Mr. HOWE (*Hamilton South*): If I might interject, at the community level the price of drugs, you feel is fair, in relation to what the druggist pays for them, not necessarily what the consumer is paying in total?

Mr. TURNBULL: This is correct, the consumer is getting very fine value for the service he receives from the pharmacist in consideration for what the pharmacist charges.

Mr. HOWE (*Hamilton South*): That just augments what the Chairman said.

Mr. MACDONALD (*Prince*): Now we are getting to it. We are really talking about two things are we not? We are talking about—

The CHAIRMAN: More than two things.

Mr. MACDONALD: Yes, well my mind can only deal with two at a time. We are talking about the actual cost of services that are being paid for and you say that this is, in your view, a fair price. But you are not really saying too much in terms of what the consumer is paying for the drugs, whether or not he is getting full value in what he is putting out for the drugs themselves, apart from the cost that is included, which would be the pharmacists own cost.

Mr. TURNBULL: No, indeed, we mention this in our brief that it is not the purpose of this particular brief by the CPhA to discuss the disposition by the manufacturer of the amount paid to him by the community pharmacist. I believe this is covered to some extent, at least in the brief presented to you by the pharmaceutical manufacturers association of Canada.

Mr. BRAND: Mr. Turnbull, on pages 9 and 10 you break down the consumer dollars. I have seen so many breakdowns of consumer dollars that my comprehension is broken down. Here you have paid the manufacturer/distributor 62

cents. The manufacturers tell us that 37½ cents of the consumer dollar is their cost. I am afraid I do not quite follow this. Could you perhaps explain it to me and bring me into the picture?

While you are on the subject, you talk about the 11 per cent sales tax and here again we have more figures. This is included in the 62 cents paid by the retail pharmacist and hence its influence constitutes a 9 cent portion of the consumer dollar. Then, of course, you go back to your 50/50 prescription dollar which includes your professional component which you say is 8.3 cents influence and it cost over $14 million consumer in 1964.

Mr. MACDONALD (*Prince*): And the federal government gets 3 cents.

Mr. BRAND: Well, this is it. The Hall Commission says it is 23 cents. Now perhaps I can make this a little easier for you. Obviously, there is a lot of gobbledegook going on here and I am certainly no accountant. One thing seems clear from all the testimony we have had and that is that the 11 per cent is costing money to the consumer. That is the only clear thing that has come out of this whole nonsense. Can you see any reason why we should continue any longer than, say, before the session closes say, in removing the 11 per cent tax on drugs?

Mr. TURNBULL: No, we have not been advocating this for many, many years sir. This is why, by not removing it last year, it has cost the public of Canada over $14 million in relation to prescriptions only.

Mr. BRAND: Regardless of what per cent it is?

Mr. TURNBULL: Regardless of what per cent. However, this $14 million is based on our calculations, which we believe to be correct, regardless of what the others think.

The CHAIRMAN: Mr. Benson admits he collects $19 million, as I remember his figures. Incidentally, that report from Mr. Benson is on the way.

Mr. BRAND: Oh it is. Mr. Chairman, I do not honestly knew whether we need it. Quite obviously it is costing money and it is an iniquitous tax which should be removed, as the Minister of Finance has suggested. Quite frankly, I do not know why we are wasting our time even discussing it. Why do we not send a recommendation through to the—

The CHAIRMAN: I would like to suggest that, as Chairman, of the committee I could ask Mr. Turnbull a very pointed question. The question is very simply this: What assurance does the government have that if it took off the 11 per cent sales tax it would be passed on to the consumer?

Mr. HOWE (*Hamilton South*): In other words, the manufacturer is going to make more money.

The CHAIRMAN: No, no I am suggesting it is put on after the manufacturing level so we are not concerned with that here. In other words, is the pharmacist going to see that this money goes to the consumer?

Mr. BRAND: I think that would be axiomatic, surely.

The CHAIRMAN: Not necessarily. I asked this deliberately because I am sure Mr. Turnbull was expecting the question.

Mr. TURNBULL: Well I and my office cannot give you positive assurance of anything of this nature, gentlemen. Naturally, I would prefer to see it in the pharmacists' pocket than in the government's pocket but this is beside the point.

Mr. ROXBURGH: That is your own pocket.

Mr. TURNBULL: I will tell you this, that prior to last year's budget, not the most recent budget, but in anticipation that this would be removed in 1965, my office did send a mailing to every pharmacist in Canada suggesting that they watch it very carefully and make immediate adjustments. Now, here again, in relation to the combines and so on, we could not make any positive suggestion on how they were going to do this and how much it should be. But we did try to point out the economics of this and that it was not 11 per cent and that if Mrs. Jones had been getting a $3 prescription it was going to be difficult to justify to her the following morning that she could not automatically get it for $2.60 odd. This is going to be a public relations problem, but I would think every pharmacist would probably drop his prices at least 10 per cent; it should be around 8 per cent. As the adjustments are made at the manufacturing level, automatically the price will be in relation to that.

Mr. BRAND: Well now would you explain the difference between the 37½ per cent and the 62 per cents of the consumer dollar.

Mr. TURNBULL: Well, the 62 cents, as we stated on page 9 is the price paid to the manufacturer or distributor. This would include the sales tax would it not?

Mr. BRAND: The 37½ cents includes the sales tax.

Mr. TURNBULL: No, it does not sir. They put it on top of it.

Mr. BRAND: All right.

Mr. TURNBULL: Say, 37½ cents plus 4½ cents plus 8 cents for distribution. Now, I do not know how you will interpret what I am going to say but we do not agree with the manufacturers figure.

Mr. BRAND: Ah, that is what I was coming to.

Mr. TURNBULL: It is as simple as this: we have been conducting a survey for many, many years and these figures are not out of line with some 24 years experience of surveys, therefore we feel our figures are fairly correct. Now the manufacturing fraternity will have the information related directly to its own studies. If they come up with 37½ cents well, we cannot resolve this. It can be resolved if all of the manufacturers products are sold through wholesalers. But we know that they are not, do we not? And if all of their products as listed in their appendices of their brief are sold to retail pharmacists, and we know they are not.

Mr. BRAND: According to page 2.2 here I got the distinct impression that the 11 per cent was included here under manufacturing administration, which would be 4 cents on the 37½ cents as part of the 37½ and 11 per cent on 100 per cent of the manufacturers dollars.

Mr. TURNBULL: No, no, that 4 cents would be the tax on the 37½ cents selling price.

Mr. BRAND: No, this 4 cents is included and the total is 37½ cents. You can look at it if you like.

Mr. TURNBULL: Well, yes, it is not right.

Mr. BRAND: Nevetherles

Mr. BRAND: Nevertheless, that is quite a gap, 37½ to 62.

Mr. TURNBULL: This is not directly related to the prescription dollar only, Dr. Brand. As we state, this is for pharmaceutical services and as close we can come to a pharmacy which is pretty well limited to dispensing and over the counter prescription accessories and this type of thing, without the other merchandising items which might be found in a corner drug store. These figures come up to 62 per cent; this is buying from the manufacturer, direct from the manufacturer and from the wholesaler and related to all of these goods. And, related to all his pricing methods pertaining to them. I believe, there was 43 per cent of the volume of the pharmacies which do the prescriptions, the balance being due to OTC pharmaceuticals and prescription accessories. The 62 per cent is used in our figures; 11 per cent on a 62 cent invoice would be 5.7 cents. Hence, in the selling price, that is for the pharmaceutical dollar, taking it up to a dollar, we are up to 9.2 cents portion, which is represented by the effect of the taxation on every consumer dollar. In relation to the prescription, supposing 50 cents is the cost of the ingredients, 11 per cent in that 50 cent invoice will be approximately 5 cents, a little more than 4.9 cents.

Mr. BRAND: You do not agree with the Hall Commission of 23 cents I take it?

Mr. TURNBULL: No, no.

Mr. BRAND: Then, Dr. Firestone was wrong.

Mr. TURNBULL: I do not know whether Dr. Firestone wrote that particular figure into the brief but whoever wrote it in, we do not agree with it.

Mr. ORLIKOW: Mr. Chairman, if I can interject. The sales tax is included in the price which the pharmacists pay to the manufacturer or wholesaler or from whoever he buys. Then whatever formula he uses, whether it is cost plus a certain amount plus a professional fee, it pyramids so that for an item that cost 50 cents say 5 cents in there goes toward sales tax. When the consumer gets it eventually, he does not pay just 5 cents on that, he pays 5 cents plus, because—

Mr. TURNBULL: Eight point three.

Mr. ORLIKOW: Exactly. I know that your organization is not responsible for the prices which individual pharmacies charge but, using any of the formulas which have been suggested, could you calculate how much would be saved by the consumer on one of the common drugs if the sales tax was taken off?

Mr. TURNBULL: On today's average of $3.47 cents prescription, the reduction would be on or about 8 per cent. In other words some 30 cents, let us say. It would cut this down to $3.10 and on the figures for 1964 it will reduce the consumer's expenditure on retail pharmacy prescriptions by $14 million at least.

Mr. ORLIKOW: Mr. Chairman, I would just like to ask a question which arose out of a question asked by Dr. Brand. He gave an example of somebody who bought the same prescription pills in two different places and got two different prices. I gathered, from the answer which you gave, that it would be

fair to say that just like a consumer who buys groceries or who wants to buy a car, it might be a good idea for the consumer to shop around?

Mr. TURNBULL: No, I do not agree with that, Mr. Orlikow. I would suggest that the consumer select her pharmacist just as carefully as she selects her physician and that she have faith in him or his pharmaceutical services and his pricing combined. Not just price.

Mr. ORLIKOW: Since each druggist—as you have already said—has the right to and does charge what he thinks his services are worth, then there may be differences in price. If the consumer is interested in price, it might be worthwhile for the consumer to check.

Mr. TURNBULL: If she is so inclined, yes.

Mr. ORLIKOW: One more question, Mr. Chairman. Because I think it is important, I would like to get back to the illustration Mr. Turnbull used of the drug for which a retail druggist has been charged $3.75 for 100 tablets when a hospital or a government agency pays 37 cents. I think that is the illustration he gave. I know your organization does not set the price but I want to get clear in my mind the inference we are to draw from this illustration you used. Are you suggesting that when the manufacturer sold that drug to the hospital or the government or institution at 37 cents he was selling it at a loss?

Mr. TURNBULL: No, actually, Mr. Chairman, I am rather sorry I used that for example but I think the question was what is the extent of this and we used the worst example we had lying around. We do not know if the manufacturer is selling at a loss but I think we agree with you gentlemen that they are not going to sell too many items at a loss any more because their sales to institutions and governments constitute a fair size portion of their dollar volume today, as opposed to a few years ago, when it could be written off as promotional cost. What we are suggesting is that there must be a correct price and today, more than ever, governments, hospitals and similar institutions are entering into direct competition with the retail pharmacist. If they are competing with the retail pharmacist, of course a discrepancy in prices is contrary to combines legislation.

More and more as we get into this area where welfare drugs are going to be dispensed by the order of a municipal government out of the outpatient department of a hospital, they are directly in competition with the retailer. If perchance, under Ontario's OMSIP program, more and more medicare is given through outpatient clinics of the hospitals and the prexcriptions are actually dispensed in the outpatient departments, the hospitals are in direct competition with the community pharmacist, who is not only right in that area but in outlying areas of the community in which the hospital complex exists. I repeat, if there is a correct price, it should be somewhere in between. If this very low price is representing some 35 to 40 per cent of the dollar volume of the manufacturer and the very high price is representing some 60 per cent, then we close this gap, it is going to substantially increase the price to the hospital while effecting merely a small lowering of the price to the retail pharmacist.

Mr. ORLIKOW: Of course, if they are overcharging you, they could reduce the price to you and not increase the price to the hospital at all.

Mr. TURNBULL: We are not suggesting that they are overcharging the retail pharmacist. We are just suggesting that it is placing the pharmacist in an unfair economic position in this whole picture. As a result, it is pushing the pharmacist out of many of these programs in which the community should be entitled to his community services. It is being done on price alone.

Mr. ORLIKOW: Well, I would agree with that, but I do not think we have any evidence and you do not have any evidence that they are—

Mr. TURNBULL: That they are competing?

Mr. ORLIKOW: Oh, they are certainly competing. The hospitals certainly are competing and one can hardly blame a government, which has to pay the bill, for arranging to pay as little as possible and one can hardly blame a patient, if he has a choice, for getting a cheaper prescription. But there is no evidence that the manufacturers are selling at a loss to the hospital or a government institution. If they are not, then probably they ought to be reducing the price to the pharmacist.

Mr. TURNBULL: Of course there are many economies to the manufacturer in his selling to the institution as opposed to selling in smaller quantities at the community level.

Mr. ORILKOW: That is the reason.

Mr. TURNBULL: I think there are many things which have been covered in the PMAC brief.

Mr. ORLIKOW: Well they are the ones from which we will find this out.

Mr. Turnbull: There should be one price for equal quantity, of the same dosage form, to all who may be a legal purchaser.

Mr. ORLIKOW: Mr. Chairman, I think Mr. Turnbull will find that nobody on this committee will disagree with that statement. If his organization will restrict itself to that position, I certainly will agree with them. The things I disagree with in his brief are the statements which I do not believe the retail pharmacists have information about. I am not being critical. They cannot know what manufacturing costs are. I think they ought not to be making assumptions which should really be discussed with the pharmaceutical manufacturers or the individual companies.

Mr. O'KEEFE: Mr. Chairman, you remember years ago when you went in to get a prescription and the druggist had all sorts of coloured bottles and it was all very impressive. I am quite sure it is much better now when we have, in most cases, just pills. However, if a customer goes to a drug store and gets a prescription and the cost of the drugs is about $1 at retail level I understand, from other evidence, that the drug manufacturer allows a discount of about 40 per cent. Is that right?

Mr. TURNBULL: In the main, yes.

Mr. O'KEEFE: So that your actual cost, then, is 60 cents of the $1.

Mr. TURNBULL: Yes, right.

Mr. O'KEEFE: Well is your professional fee then added to that $1 of $2.

● (12.30 p.m.)

Mr. TURNBULL: You are referring to a prepared dosage form such as a tablet or capsule.

Mr. O'KEEFE: Well it does not matter which.

Mr. TURNBULL: It is not a compounded prescription?

Mr. O'KEEFE: No matter what, is the $2 professional fee added to the $1 retail cost?

Mr. TURNBULL: No, no it is added to the cost of the ingredients, not to the list price.

Mr. O'KEEFE: But I understood you to say that the professional fee of the pharmacist was about $2 per prescription.

Mr. TURNBULL: Yes.

Mr. O'KEEFE: Well if the ingredients in the prescription cost $1 then would not the total prescription cost $3 to the person who was buying the prescription?

Mr. TURNBULL: Yes but you had said that he bought it at 60 cents not at a $1.

The CHAIRMAN: I think $2.60 is the point you are making.

Mr. TURNBULL: By those who follow this particular system, it would be $2.60.

Mr. O'KEEFE: It would be $2.60 on a 60 cent cost.

Mr. TURNBULL: Yes.

Mr. O'KEEFE: It would be about 400 per cent profit.

Mr. TURNBULL: It is not based on a 400 per cent profit.

Mr. O'KEEFE: I know it is not but is that not in actual fact what it is costing, the difference between cost to you and the cost to the person who buys the drug?

Mr. TURNBULL: True.

Mr. ORLIKOW: The pharmacist who charged a $2 fee on 292s would not get a customer back a second time, would he?

Mr. O'KEEFE: How would the customer know?

Mr. ORLIKOW: Oh, the customer makes it his business to know very often.

Mr. BRAND: But, by the same token, a drug that cost a druggist $10 would sell to a patient for $12 which would only be 20 per cent.

Mr. O'KEEFE: Yes I appreciate that but I was giving the worst possible example.

The CHAIRMAN: Are there any other questions?

Mr. ENNS: Mr. Chairman, there seems to be general agreement on the part of all members of the committee that the reduction or elimination of the sales tax would, in effect result, in whatever decrease but certainly a decrease in the cost of drugs. Would it not be possible to make an interim report to the House before the recess of Parliament, to this effect, with a strong recommendation

that the 11 per cent sales tax be removed from drugs? If there is agreement in the committee, I would so move that we make this interim report this afternoon.

Mr. ORLIKOW: Mr. Chairman, I think there is a good deal of merit in what Mr. Enns says. At the same time, I think there might be a good deal of criticism if we did this at the tag end of a meeting which was not called for this purpose. If this committee is meeting Thursday, I wonder if the Chairman could in some way notify members that a motion of this type would be proposed.

The CHAIRMAN: I am not sure that the Chairman would entertain to receive it. The problem then arises that the terms of reference, as I remember, were to recommend a series of measures and this is the problem, if we do this as a one-step measure. I would really prefer, I think, much more systematically to recommend many measures at the end of the hearings than to do this. This is my personal feeling.

Mr. O'KEEFE: Yes and we would have to be sure that it would be passed on to the consumer.

Mr. TURNBULL: Well, Mr. Chairman, if I may interject, in two briefs that you have received reference has been made to removing the sales tax from prescription drugs and may I suggest to the committee that this definition be very carefully looked at, in that there are prescription only drugs under the schedules of the Food and Drugs Act and Narcotics Control Act and so on. However, these are not necessarily the only prescription drugs.

I would suggest that the sales tax be removed from all drug preparations. If you have any limitation on this that it be all drug preparations other than those which are registered under the present Patent or Proprietary Medicines Act. We do not advocate the latter. We suggest that it be removed from all drug preparations.

Mr. HOWE (*Hamilton South*): Mr. Chairman, I feel as you do, that this should be held until the final hearing because I do not think this is going to bring any immediate dropping of the 11 per cent sales tax. I think it would be superfluous to recommend this as a single item when there are many other factors we have to consider, even from what we have heard now.

The CHAIRMAN: Leaving that point for a moment, the brief which will be presented on Thursday is, I think, in everyone's hands. This is from another group of drug manufactuers. It will be interesting. I hope we have a full meeting for this. This is a different group and they will have a different point of view from the last group we heard. It should prove very interesting.

Mr. HOWE (*Hamilton South*): Will the Canadian Drug manufacturing group go beyond prescription drugs? Does this concern patent medicine?

The CHAIRMAN: No, this is not the patent people. These are prescription drugs also. Are there any other comments? The meeting is adjourned until Thursday at 3.30 p.m. unless the committee wants to have their meeting in the morning?

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 8

THURSDAY, JULY 7, 1966

WITNESSES:

Representing The Canadian Drug Manufacturers: Mr. Leslie L. Dan, B.Sc., Phm., M.B.A., of Scarborough, Ont., Chairman; Dr. George F. Wright, Professor of Chemistry at the University of Toronto, and Research Consultant, Counsel.

ROGER DUHAMEL, F.R.S.C.
QUEEN'S PRINTER AND CONTROLLER OF STATIONERY
OTTAWA, 1966

24765—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

Vice-Chairman: Mr. Patrick T. Asselin (*Richmond-Wolfe*)

and

Mr. Brand,
Mr. Chatterton,
Mr. Clancy,
Mr. Côté (*Dorchester*),
Mr. Enns,
Mr. Howe (*Hamilton South*),
Mr. Howe (*Wellington-Huron*),
Mr. Hymmen,
Mr. Isabelle,
Mr. MacDonald (*Prince*),
Mr. Mackasey,
Mr. O'Keefe,
Mr. Olson,
Mr. Orlikow,
Mr. Pascoe,
Mr. Prud'homme,
Mrs. Rideout,
Mr. Roxburgh,
Mr. Rynard,
Mr. Tardif,
Mr. Whelan,
Mr. Yanakis—(24).

(Quorum 10)

Gabrielle Savard,
Clerk of the Committee.

MINUTES OF PROCEEDINGS

THURSDAY, July 7, 1966.
(13)

The Special Committee on Drug Costs and Prices met this day at 3.50 p.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout and Messrs. Brand, Enns, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), Hymmen, Isabelle, Mackasey, O'Keefe, Olson, Roxburgh, Rynard, Yanakis (14).

Also present: Mr. Herb Gray, M.P.

In attendance: Representing The Canadian Drug Manufacturers: Mr. Leslie L. Dan, B.Sc.Phm., M.B.A., of Scarborough, Ont., Chairman, and Dr. George F. Wright, Professor of Chemistry at the University of Toronto, and Research Consultant, Counsel.

Also in attendance: Mr. A. M. Laidlaw, Legal Counsel for the Committee.

The Chairman referred to a letter dated July 4, 1966, received from the Hon. E. J. Benson, Minister of National Revenue, elaborating on the statement made to the Committee on June 9, concerning the effect of the sales tax on the cost of drugs.

On motion of Mr. Rynard,

Agreed,—That the Minister's letter and the attached schedule be printed as an appendix to this day's proceedings. (*See Appendix "A"*)

The Chairman read into the record a letter received from Dr. R. A. Chapman, Director-General of the Food and Drug Directorate of the Department of National Health and Welfare, with reference to Mr. Mackasey's request to release FDD confidential report to the Committee.

On motion of Mr. Howe (*Hamilton South*), seconded by Mr. Brand,

Resolved,—That an article printed in the Harvard Business Review of September-October 1962 entitled "Ironic Contrast: US and USSR Drug Industries", by Raymond A. Bauer and Mark G. Field, be printed as an appendix to the proceedings if permission to do so is granted by the Harvard Business Review. (1) (*See Appendix "B"*)

On motion of Mr. Mackasey, seconded by Mr. Howe (*Hamilton South*),

Agreed,—That a vote being expected in the House at 5 o'clock, the Committee adjourn at that time and reconvene at 8.00 this evening.

The Chairman introduced Mr. Dan and Dr. Wright.

On motion of Mrs. Rideout,

Agreed,—That the briefs submitted by The Canadian Drug Manufacturers and by Dr. George F. Wright, be printed as appendices to this day's proceedings. (*See Appendices "C" and "D"*)

(1) Such permission granted on August 9, 1966.

24765—1½

Mr. Dan made an oral submission, and during the course of his statement and subsequent questioning, he tabled a book entitled "Drugs, Doctors and Disease—A Survey of the Pharmaceutical Industry", by Brian Inglis, also copies of Annual Reports of several pharmaceutical companies.

At 5.00 p.m., the Committee adjourned to 8.00 p.m. this evening.

EVENING SITTING

(14)

The Special Committee on Drug Costs and Prices reconvened at 8.10 p.m. this day. The Chairman, Mr. Harry C. Harley, presided.

Members present: Messrs. Brand, Enns, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), Hymmen, Isabelle, Mackasey, O'Keefe, Roxburgh, Rynard, Yanakis (12).

In attendance: Same as at afternoon meeting.

The Committee resumed consideration of the submissions of The Canadian Drug Manufacturers and of Dr. Wright.

Mr. Dan was further examined.

Agreed,—That a list of present members of the *Association des fabricants du Québec de produits pharmaceutiques* and of the companies to join in a near future be printed as part of today's proceedings. (*See Appendix "E"*)

Dr. Wright was also questioned.

On behalf of the Committee, the Chairman thanked Mr. Dan and Dr. Wright for their presentation, and at 10 o'clock p.m., the Committee adjourned to the call of the Chair.

Gabrielle Savard,
Clerk of the Committee.

EVIDENCE

(*Recorded by Electronic Apparatus*)

THURSDAY, July 7, 1966.

• (3.45 p.m.)

The CHAIRMAN: Ladies and gentlemen, we now have a quorum. Before we proceed with today's meeting, I have two letters that I would like to have printed as part of today's record. The first one is a letter from the Minister of National Revenue explaining where he obtained his figures in relation to the federal sales tax and its percentage on the cost of drugs. I could read it but it is a four page letter giving examples. I think, rather than file it, we should have it printed as part of today's minutes.

Mr. RYNARD: I move that it be printed, Mr. Chairman.

Agreed.

Mr. BRAND: I would like to ask one question, Mr. Chairman. Does it indicate how methods could be taken to see that any saving, by removal of the tax, would be passed on to the consumer?

The CHAIRMAN: No, this is not a point that is covered in the letter at all.

Mr. MACKASEY: May I ask a supplementary question? Is there any change in his previous opinion?

The CHAIRMAN: No, there is not. He merely backs up his other opinion and gives figures to show how he arrives at that conclusion.

Mr. HOWE (*Hamilton South*): May I ask what figure he arrives at?

The CHAIRMAN: He uses it both sides of the percentage markup figure or the professional fee method and he comes out with 4.13 per cent in one case and 1.8 per cent in another case, and 3.3 per cent in another case. I think those are the figures that he gives me.

Mr. HOWE (*Hamilton South*): This is on the consumer dollar?

The CHAIRMAN: Yes.

Mr. O'KEEFE: Mr. Chairman, how are we going to resolve all those differences and make any recommendations on differences that are as wide and varied as those?

The CHAIRMAN: I think, now, having this from the Minister of National Revenue, we will leave it to our accountant to sort it out and report back to the Committee whether he is satisfied or whether he thinks some other method should be used. I think we should now leave it up to the accountant of the Committee to decide this and explain to the members of the Committee.

The second piece of literature is a letter dealing with the statements made by Mr. Mackasey. The letter is addressed to me as Chairman of the Committee.

Re Mr. Mackasey's request to release FDD confidential report to the special Committee on Drug Costs and Prices.

At the meeting of the Special Committee on Drug Costs and Prices on June 28, 1966, Mr. Mackasey requested the release of a report to the committee which was written by three members of the directorate's staff following their visits to a number of pharmaceutical manufacturing plants, control agencies and representatives of drug manufacturing associations abroad. He mentioned that the report contained uncomplimentary statements about the Italian drug industry.

I presume that the report he had in mind was one which was presented in confidence to the Canadian Drug Advisory Committee at its meeting in March of this year. This was a relatively short report which covered a number of items pertaining to drug control in Europe. It has not been distributed to anyone outside the Canadian Drug Advisory Committee. I do not believe that it would be appropriate to release it to the Special Committee on Drug Costs and Prices since this would in effect make it a public document.

I have reviewed the report and I can assure you that there was no statement in it which was uncomplimentary to the Italian drug industry. Since this was inferred in Mr. Mackasey's inquiry, I believe, in fairness to the Italian drug industry and the authors of the report, that you may wish to draw this matter to the attenion of the Committee.

Yours Sincerely,
R. A. Chapman
Director-General

Mr. MACKASEY: Mr. Chairman, on a point of privilege. I take the letter as an inference that my information came from a confidential committee which name you referred to there as the Canadian Drug Advisory Committee. I take this as a reflection on my integrity, that I would read into the records something of a confidential nature that would, according to Dr. Chapman's definition, be something that should not have been revealed to anyone outside the Committee or outside certain responsible offices of the Department of Health and Welfare.

The CHAIRMAN: I should say that I do not read that inference.

Mr. MACKASEY: I do. I am the person who is implicated. For Dr. Chapman's information, respecting this highly confidential report, one of the sources, and I will reveal other sources as I go along, of information from whence the population of Canada, not people in government circles, can get information about the existence of this particular Committee, its function and where it travelled to, appeared in the January 1, 1966 edition of *Maclean's* magazine. There is an article in that edition about the pharmaceutical industry. This is just one of the sources. Another source, which I do not have in front of me and therefore I do not want to mention until I dig it out, was one of the Montreal newspapers. I am certainly within my rights, Mr. Chairman, in asking that this so called confidential document be placed at the disposal of this Committee even

if we are to meet in camera to discuss it if it has already been published in *Maclean's* magazine and in some of the newspapers in Canada. I think, therefore, that the implication in Dr. Chapman's letter is unwarranted.

The CHAIRMAN: If the document is that public that it has been in *Maclean's* magazine, then I am sure that the implication is not in the letter. All I can say is that we will take the information that you have and look into it.

Mr. MACKASEY: You have read the letter into the record and other members of the Committee and interested people can draw their own conclusions. I have drawn mine.

Mr. BRAND: On a point of privilege, I would have to agree with Mr. Mackasey. The implication is certainly there. I cannot agree that Dr. Chapman would feel that it has already been made public. He already states there that he does not want it to be made public and I take strong exception to this. There is no reason at all why this information—and it must be vital surely to our understanding of the situation here—should not be placed before this Committee if necessary, as it has been pointed out, in camera. I cannot agree that we should not be privy to anything like this; otherwise, there is no point in our meeting here whatsoever if we are not privy to all the information about all the drugs that come into this country and all the manufacturing methods that go on.

The CHAIRMAN: I will be pleased to discuss it with the minister and ask him for this document, either publicly or—

Mr. MACKASEY: Could I have a copy, Mr. Chairman, or could I borrow that copy to peruse it, since I have not seen it, during the Committee meeting and perhaps at the end of the Committee either moderate my statement or elaborate upon it, with the documents in front of me, to form my conclusions a little more accurately because they were formed basically on—

The CHAIRMAN: It will become part of the record but you may have it to look at it now, if you wish.

There are two briefs before us today.

Mr. HOWE (*Hamilton South*): I do not know whether I am in order at the moment or not but I received a copy of a document. Were you going to bring this up?

The CHAIRMAN: I had forgotten about it. It was the document that was sent on to me by the P.M.A.C.

Mr. HOWE (*Hamilton South*): I was wondering if this could not be printed as an appendix to the same one as when the P.M.A.C. were here?

The CHAIRMAN: Yes. I think that can be done. As a matter of fact, in the same mail I had a letter from the Canadian Medical Association sending me a photostatic copy of the same article "Ironic Contrast U.S. and U.S.S.R. drug Industry" which was in the *Harvard Business Review*. Would the Committee members like to have it printed as part of the record? You already have it in your possession.

Mr. MACKASEY: I already received it in the mail today—

Mr. HOWE (*Hamilton South*): I think we should have it printed. Everything helps in this regard and I think it is only fair that this be—

• (4.00 p.m.)

The CHAIRMAN: Would you like to move that, to be seconded by Dr. Brand?

Mr. HOWE (*Hamilton South*): I so move, Mr. Chairman.

The CHAIRMAN: Is there anyone in opposition to that?

Agreed that it be printed as part of today's records if permission is granted to do so by the *Harvard Business Review.*

Motion agreed to.

Mr. HOWE (*Hamilton South*): I would think, Mr. Chairman, that this might be printed, not in today's record, but rather in the record to which the reference is made when the pharmaceutical manufacturers were here. Would this not be more appropriate?

The CHAIRMAN: It is already in the hands of the Printing Bureau, unfortunately. I should also bring to the attention of the members of the Committee and I am sure everyone is aware of it, the situation in the House today. The Committee has been asked if it would adjourn at five o'clock, as I understand there is going to be a vote in the House this afternoon.

Mr. MACKASEY: Adjourned until when?

The CHAIRMAN: That is up to the Committee.

Mr. MACKASEY: Mr. Chairman, on a point of privilege, what is the point of trying to do half a job? This is what is happening. It is not fair to the witnesses, to bring them down here for less than an hour. We should be prepared to meet again tonight, in all fairness to the gentlemen who have travelled a good distance. If we are going to fulfil our mandate, which is a rather important one, we have got to do it at our pace. We cannot just do it superficially, as you mentioned. Press reports that criticize us, in this respect, are accurate and fair. If we are going to do the job with the impartiality and the depth with which we did our study on safety, we need time. If we have to quit at five o'clock, what is the point of even starting?

The CHAIRMAN: We have an hour, Mr. Mackasey. I have no objection to sitting tonight. I am sure we are all going to be here. Does the Committee wish to sit tonight? I do not know if the witnesses are available tonight.

Mr. HOWE (*Hamilton South*): I move we sit at eight o'clock tonight if the witnesses are available.

The CHAIRMAN: According to the witnesses this is fine. Is there any disagreement with that? Shall we adjourn at five o'clock with the understanding that we will reconvene the meeting at eight o'clock this evening?

Mr. HOWE (*Hamilton South*): We can adjourn when we hear the bell, Mr. Chairman.

The CHAIRMAN: There will be no bell because it is a resolution with the Speaker out of the chair. I understand that if we adjourn here at five o'clock it will give every member adequate time to get back?

Would someone like to move that the brief submitted today be incorporated as part of today's records? Is there any disagreement?

This includes, actually, two briefs rather than one: A special submission and another one by Dr. Wright on "A Look at Canadian Pharmaceutical Research". Are you agreed on both of those briefs?

Agreed.

We have with us today, in presentation of their brief, Mr. Leslie Dan who is chairman of the Canadian Drug Manufacturers representing Canadian-owned drug companies and Dr. George Wright, Counsel, who is a Professor of Chemistry, University of Toronto, a consultant on research.

I think Mr. Dan has some remarks he would like to make in the way of an oral submission.

In addition, we have asked that copies of his oral submission be run off at the Xerox but I do not think they are available as yet. As soon as they are we will place them before each member.

Mr. LESLIE DAN (*Chairman, Canadian Drug Manufacturers*): Mr. Chairman, we are representing the views and ideas of the Canadian-owned English speaking pharmaceutical companies. We are glad to add that most of our basic ideas have ben also endorsed by our French speaking counterpart, the AFQPP. l'Association des Fabricants du Quebec de Produits Pharmaceutiques. Mr. Pepin, the secretary of this association, regrets his inability to be here. He is on vacation this week. He thought we would appear a week earlier.

We have forwarded, under separate cover, a formal written submission and we see no point in repeating orally the entire submission. Instead, we shall review briefly some of the highlights and concentrate, in our verbal discussion, on the cost of drugs and prices, the consideration of which is the main function of this Committee.

Our association, which represents about ten per cent of the market, based on sales dollars, and about 20 per cent of the pharmaceuticals sold, based on quantities—because our prices are usually lower—believes that we have a solution to lower the cost of drugs in Canada. The drug costs, at manufacturers' level, are high indeed because a genuine competition among the larger pharmaceutical houses does not exist and because the present protective patents on pharmaceuticals allow the foreign owners to amortize the research cost several times and earn handsome profits. We feel that if our government does not rectify the above two maladies, the cost of drugs will remain high because prices do not come down by themselves.

In the minds of the public and the profession alike, high costs of drugs are usually equated with safety. This belief is fallacious, because our members can manufacture good quality drugs and yet market them at considerably lower prices and thus bring about a considerable saving to the consumer.

We might add when John Consumer purchases a car he can choose the type of car he wishes to buy; whereas, when he buys drugs, he has no choice at all except pay the bill. The physicians who write prescriptions are often not too price conscious and they may not be aware that the same drug can be bought at much lower prices. After all, we have been selling $20 million worth of medications for many years and the public is consuming our medicines with

satisfaction and good results. We feel that our Canadian owned segment of the pharmaceutical industry should be made more viable and more competitive, because this will result in the saving of tens of millions of dollars to the public.

During the course of our discussion we shall draw your attention to a number of important printed matters dealing with the cost aspect of our industry, for we feel that they deserve your attention. We might as well produce for you a very interesting and informative book written by Brian Inglis, published in England last year and entitled "Drugs, Doctors and Disease? Perhaps one paragraph in the foreword of this book might be of interest.

> "One of my objectives, (explains Brian Inglis,) in writing "Drugs, Doctors and Disease" was to press for the setting of a committee of inquiry in Britain."

Then he continues,

> "Perhaps I may be permitted to dedicate this book to them in the hope that it will prove of some assistance to them in their investigation. I do not envy them. Their task is going to be formidable".

In short, the contents of this book should be interesting for the members of this Committee, too. As for our group the Canadian drug manufacturers, let us say briefly that we are a young organization still in a formative stage, doing about $4 million or $5 million worth of business per year. Our French counterpart is larger, doing about $16 million per year. Thus, both of us have only about ten per cent of the $200 million Canadian pharmaceutical market.

The requirements for membership are twofold. First, companies must be Canadian owned. Second, our members must maintain proper pharmaceutical quality controls and standards. In our written submission we expressed our anxiousness to get together with the representatives of the Food and Drug Directorate in order to work out acceptable high quality pharmaceutical standards which our members are eager to maintain. Possibly, compliance with 74-GP-1 standards might be one of the requisites. We would like to prove the opinion expressed by the former director of food and drugs, Dr. Morrell, that the attitude of the manufacturer is the most important consideration, besides his ability and plant facilities. In short, if a particular manufacturer takes the trouble and takes the care to produce high quality pharmaceuticals, yet sells them at moderate prices he certainly can do so. The research department of the Food and Drug Directorate also recorded in its 1964 publication that "there are a number of historic and, indeed, recent instances where large scale manufacturers have failed to fulfil the promise implicit in their national stature. Moreover, evidence from other manufacturers such as electronics implicates that smaller firms are well able to establish solid reputations in quality control", page 47. Therefore, the argument advanced by the larger houses that smaller firms do not have proper products and quality control, in our opinion, is resting on a weak foundation like many of their other arguments. The facts today are to the contrary, if the small manufacturer cares to maintain proper manufacturing control.

The Canadian drug manufacturers, like most Canadians, are greatly concerned over the gradual and systematic disappearance of Canadian ownership in the pharmaceutical industry. In the last three years, companies doing over $20 million volume per year passed into foreign hands and probably for good. Foreign ownership in Canada, in Canadian industries, represents about 60 per cent across the board which, in pharmaceuticals, jumps up to as high as 90 per cent. We feel that this high percentage is not in the interests of our country and our government must take action to maintain a viable Canadian segment in the pharmaceutical industry and thereby assure greater competition. We have outlined in our written submission eleven measures which our government should adopt. The importance of these measures cannot be overemphasized sufficiently. Alternately, the Canadian owned pharmaceutical manufacturers will be relegated to an insignificant group in the industry.

We now intend to comment more directly on the cost of medicines and prices and will be pleased to explain certain aspects of costing, during the question period, to the best of our ability. There are several reasons why we consider prices at manufacturers level to be high and we shall now analyse the various factors which affect the cost of pharmaceutical products and later we will illustrate examples proving our point.

First, raw materials. They usually come from a foreign country. Their price is about the same on the international market, regardless of whether they are bought by Canadian, English or French companies. Usually, it is not too expensive, such as librium, commonly known as diazopoxyde, which costs only about $150 per kilo in Switzerland and about $81 in Canada. Yet, it represents in dosage form about $3500. Therefore, raw material alone is not the major cost.

Second, research to develop raw materials and research on finished products. We are classifying these under the same heading since we do not know the exact relationship between the two. In Canada, companies spend only about three per cent as to sales, which is certainly a modest sum. Abroad, most large houses in the United States, spend only about five per cent to eight per cent and only a very few firms spend over 10 per cent, if any. Research, therefore, cannot be the major factor in the high cost of drugs. Indeed, research is a cost that any large company must bear in order to maintain leadership in the industry. After all, can one imagine an industry doing a business of about $170 million in Canada and about $2 billion in the United States and not doing research ? How will they assure their yearly sales and maintain their market position? To be frank, we are not impressed by the fact that the large houses do research, for they are no different from any other big business. In our opinion, they greatly overplay and overemphasize their research contributions, so that they may charge more for their products and earn greater profits.

The CHAIRMAN: Mr. Dan is on page 20 of his brief.

Mr. MACKASEY: Are you a doctor? I apologize for interrupting. I am intrigued by your brief and have read it three times between six o'clock last night and three o'clock this morning. The point is, everything you are reading to us is in the brief.

Mr. DAN: No, sir. It is different.

Mr. MACKASEY: When you come to something different, would you indicate it for me.

Mr. DAN: I will try to.

Third. Manufacturing into dosage form, such as tableting, encapsulating and so forth. This is a minor cost item, representing about one dollar to two dollars per thousand tablets or capsules and certainly is not a factor of high cost.

Fourth. Quality Control. According to the government surveys conducted by the Food and Drug Directorate in 1960, the firms spent 1.21 per cent of net sales on quality control and no firm spent as much as three per cent of its net sales revenue, so this percentage could not possibly be the reason for the high cost of drugs. While we do not underestimate the importance of maintaining proper quality control by all pharmaceutical companies, nevertheless we respectfully suggest that quality control again has been greatly overplayed by the large houses in order to justify to the pharmaceutical and medical profession and the public, the high prices of pharmaceuticals.

Promotion and marketing. Here the sums spent are extravagant and lavish compared to the money spent on original research, yet the large houses tend to underestimate and overlook the promotional costs. Of course, it is costly to market today any product on a large scale, yet an expenditure of 35 per cent to 40 per cent in Canada, compared to three per cent on research and one and one half per cent on quality control, is out of line. However, the main objective of the large houses is commercial and not scientific. Under such circumstances a landslide difference between promotional and research costs is understandable. This observation is contrary to the public image the large houses wish to build, namely medical and scientific benefactors of mankind.

Depreciation and amortization of capital expenditure. This item leaves a great deal to be desired. The depreciation of fixtures and equipment is a straightforward matter deserving little comment. The amortization of capital expenditure, such as research costs, et cetera, requires deeper probing. Theoretically, it costs X dollars to develop a new product until it becomes successful in the market. Now, one would assume that as soon as the original research expenses were rcovered, the price of the pharmaceutical would drastically drop. This is not the case at all. In practice, prices remain high until competition steps in when invariably prices are brought down gradually. The existence of the protective patents help the manufacturers to charge higher prices for an extended period of time, thereby increasing their profits. The late Senator Kefauver appraised this matter when he said, "patents had to a great extent been transformed in the drug industry from a reward to the individual inventor to an instrument of market control".

We fully appreciate the fact that any industrial leader carrying out original research, is entitled to recover his investment. However, this period of haven should not last longer than three to five years in particular since, during this time, he will also become well established in the market which should bring him sufficiently attractive profits in future years. If the present patent laws were changed in such a manner that after three to five years pharmaceuticals

would be made available to other companies, the prices of pharmaceuticals would come down, on one hand, while the research-conducting company would earn normal, and not excessive profits, on the other hand.

General overhead. This is usually a small item percentage-wise, seldom exceeding four or five per cent based on sales.

Gross profits of pharmaceutical companies. Profits are ecxessive, although by means of window dressing techniques, in the language of the accountants, this may not be immediately apparent.

According to the most recent P.M.A..C submission, the total net profit and taxes for human pharmaceuticals amount to about 15 per cent which is a fairly sizable sum.

The CHAIRMAN: With the last document you have, which was just placed in front of you, you may now follow Mr. Dan who is on page seven.

Mr. DAN: This 15 per cent more correctly should be about 18 per cent or 20 per cent, since the parent companies charge the subsidiary about three or five per cent for research costs conducted abroad. This is a rather unusual procedure since according to the royal commission—page 678—and I quote:

> In the year of 1960 $6,200,000 was charged to the Canadian subsidiaries for research done elsewhere. This is obviously quite an exceptional situation. In most industries foreign companies tend to supply their Canadian subsidiaries with know-how, including their results of research, and with capital and to take the earnings of the Canadian subsidiaries as a return on their investment. In the drug industry it is evident that foreign companies prefer to be separately compensated for supplying Canadian subsidiaries with know-how on one hand, and with capital on the other hand.

In short, it matters little how you classify the extra three per cent or five per cent from the accounting viewpoint, it really belongs in the column of profits.

However, even the 20 per cent may not be the exact figure, since according to the customs laws, the parent companies supplying the subsidiary with raw material must mark up the chemical at least 10 per cent, thus increasing the earnings of the parent company at the expense of the subsidiary. But this is not the only revenue the parent company derives from the subsidiary, consultation fees, executive salaries, trips, et cetera, all contribute towards greater profits for the parent company. In short, in analysing the earning position of Canadian companies, one must also examine the operating statements of the parent company. Here are a few financial statements which arrived only a few days ago. Smith, Kline and French, sales $243 million, net earnings $42 million, add taxes, approximately $80 million; Searle Company, sales $88 million, taxes and net income approximately $44 million.

Mr. MACKASEY: Have you any of your own company's that you are representing today?

Mr. DAN: I have all the statements.

Mr. MACKASEY: You are just tabling the others?

Mr. DAN: Yes, I am handing over the copies.

Mr. MACKASEY: Would you take the time and opportunity to table your own company's at the same time?

Mr. DAN: Yes, I will.

Having examined the various factors influencing the high cost of drugs at manufacturers level, let us turn our attention to a few samples to illustrate our case. We shall examine only the so-called well established medicines which have been on the market for at least 10 years and therefore the manufacturers must have surely amortized the cost of research, probably more than once. We selected phenylbutazone since this was the pharmaceutical discussed earlier during one of the hearings. We could have taken another item, however the ratio would have remained about the same.

I have here this table. I think it is self-explanatory and I am not going to read it.

Mr. HOWE (*Hamilton South*): Mr. Chairman, may I point out at this time that this is the particular drug that Dr. Briant selected from the list I presented at that time to show the need for the extra costs here.

The CHAIRMAN: I think that is what Mr. Dan was referring to.

Mr. HOWE (*Hamilton South*): Precisely.

The CHAIRMAN: It is just because we had already discussed it.

Mr. DAN: In summing up, the cost of drugs at manufacturers level is high today since genuine competition among the larger firms does not exist and the various protective patent laws allow the research cost to be amortized several times. Unless our government urges the pharmaceutical industry to examine its present cost structure, with a view to lowering costs, and unless our government creates an environment of competition, the cost of drugs will not come down by themselves.

Our government should also give special consideration to the Canadian owned drug companies, which seem to have a regulatory and balancing effect in the pharmaceutical market besides preserving some Canadian identity in the 90 per cent foreign-owned pharmaceutical industry.

I thank you, Mr. Chairman.

The CHAIRMAN: The meeting is open for general questioning.

Mr. MACKASEY: I am not really in a belligerent mood today and I would rather bypass my turn. Could we not be quite so restricted to the five minutes. We all have our own way of developing questions. In the last session, I think one of the beauties of our Committee was that we were very non-partisan. We were all members trying to do something.

The CHAIRMAN: I should point out that the five minutes does not restrict you to five minutes. It is five minutes at any one time.

Mr. MACKASEY: It breaks the continuity of what we are after.

The CHAIRMAN: Whatever the Committee wishes.

Mr. MACKASEY: You are the boss—what do you think, Dr. Howe?

The CHAIRMAN: I will go along with ten minutes. Except that I must point out to you that it means that by five o'clock, when we adjourn, only three people are going to get around to asking questions.

Mr. MACKASEY: I am quite willing to forego mine now, if you feel that it will help in any way.

Mr. Dan, I would like to say, I know that it is superfluous, I sincerely regret the death of Mr. Winter who was here last year representing the Empire Company in Toronto, the generic firm. He was a very controversial and interesting witness.

Mr. DAN: Thank you for expressing your views.

Mr. MACKASEY: I say this very sincerely.

I had hoped, in fact I will, start on page one. On every page there is something of interest but in view of the time I am going to have to jump to one or two items and then come back to page one. Just for clarification, you mention English owned and French owned companies. How do you differentiate?

Mr. DAN: We have English speaking companies operating in Ontario—most of them—and French speaking companies. I have a list of French speaking companies. They represent about 12 firms, most of them are in Montreal.

Mr. MACKASEY: What happens to the English speaking firms that operate in the Province of Quebec?

Mr. DAN: They can join us if they so desire. I believe one or two firms expressed their willingness to join us. We are still in a formative stage and we would like to have all the members under one roof, but at the present time it is practical that we operate under our own flag and particularly because we have been—

• (4.30 p.m.)

Mr. MACKASEY: From the point of view of a definition, what you mean is Canadian firms based in Quebec and Canadian firms based in Ontario rather than English speaking—

Mr. DAN: Largely, I would say so. Geographical consideration is the important one at this point. Perhaps in a year it may change but today, yes.

Mr. MACKASEY: I am very sensitive on this point since I am a Quebecer and an Englishman. I would not fit into your category if I ever went into the industry.

Mr. DAN: I think you would because you have representatives of Quebec in our group.

Mr. MACKASEY: English people?

Mr. DAN: Yes.

Mr. MACKASEY: All right, this is incidental. Would you define, as concisely as possible, a generic firm?

Mr. DAN: I do not think it is easy to define concisely a generic firm. Probably a generic firm would be one which sells most of their products by generic name while retaining the identity of the house, on the one hand, and at the present time, is not yet engaged in research altough can and does maintain adequate quality controls.

Mr. MACKASEY: Fine. That is satisfactory.

Mr. DAN: Perhaps I might add that most generic houses market items which have been established on the market; I would say have been on the market for more than five or eight years.

Mr. MACKASEY: You do no research as yet?

Mr. DAN: We do not yet do—in fact it would be more correct if I should pass on the answering of these questions to Dr. Wright. He is more familiar; there are some who started to do research. Perhaps Dr. Wright would care to comment on this.

Mr. GEORGE F. WRIGHT, Ph.D. (*Professor of Chemistry, Research Consultant*): There are certain of us who have started to do research in pharmaceutics. For the most part our capital structure, the capital structure of the companies that are involved, is not at a stature yet where the research is significant.

Mr. MACKASEY: I will get to it later when I go page by page. I think, on page 11, you make an excellent point. You say "how can companies obtain their new products and ensure that the sales are increased and not do research? I would like to ask you the same question. How can you survive without doing research?

Mr. WRIGHT: I happen to be one that does it.

Mr. MACKASEY: According to Mr. Dan a general definition of a generic firm is one that does not do any research.

Mr. DAN: The answer is very simple. At the present time we have a basic volume and our basic volume is large enough to exist. We feel that at this time the market is expanding, and if the market expands our volume will expand with it but the minute we reach a certain field level, we must completely change our orientation, our thinking, and we must do research because research is industrial leadership. You cannot be a leader without original ideas no matter what field you are in.

Mr. MACKASEY: I am interrupting so often because I am trying to get as much out of my ten minutes as possible. I appreciate your brief because it is basic, it is elementary and it raises a lot of provocative questions that apply to the industry. The industry includes yourself, of course. If some of them tend to be embarrassing, they would be the same questions I would ask in the fall coming, out of your brief, to the group that has just departed last week. One of the things that they have been open to charges of, and I think we have not had a chance to explore it, is camouflaging in a sense, by demanding brands, different prices on the same product. What is your opinion of this practice?

Mr. DAN: Bear in mind that today the large houses have virtually the market, say 85 per cent to 90 per cent. These firms have the sales force. Every morning, 2,000 salesmen knock on the doors of 8,000 people pounding one theme. It must have an impact. They go ahead by their marketing impact and obviously if you make so many messages, there has to be some—

Mr. MACKASEY: The point I am trying to get at is I think what we have got to determine on this Committee, in bringing down the price of drugs is this. We have to get rid of all this facade. I will get down to basics. I reread Mr. Winter's testimony today on general safety and he has emphasized that one of the selling points of advancing generics is that you are eliminating brands and getting down to the generic item you can sell it at rock bottom. You have a company price list within your generic firm, I dug it out of the library, which sells, and I am not comparing it with the so-called big name firms, tolbutamide, one half a gram which you sell as a white tablet at a reasonable price at $17 per

thousand. If a druggist asked for tolbutamide from a generic firm, he would pay $17 a thousand. Unfortunately, in my opinion, the same firm produces this white tablet, only this time it is now pink, and the only other variation is that it is no longer round, it is heart shaped and it changes the price from $17 to $24.

Mr. DAN: There might be an answer, namely the production quantities. If you have large batches your cost is lower. If you have small batches—

Mr. MACKASEY: Fundamentally—I am not a doctor maybe the doctors will answer this—how much faster does the patient get well by taking a heart-shaped pink one than a round white one? Is it the same? But you pay $17 to $24. What is the purpose of producing it in two shapes, two colours? Is it to confuse the doctor. Is it to help the druggist? What is the point? In other words, if Dr. "A" prescribes the pink one at $24 a thousand and Dr. "B" prescribes the one at $17 per thousand, who is right?

Mr. DAN: I am not sure that I understand you correctly but our firm does not have two types of—

Mr. MACKASEY: Not your firm, but a firm.

Mr. DAN: It could be that under certain circumstances it might be advisable to have different colours for certain products. This is something which doctors can answer you better. In that case, you have a product with a very high volume and a lower cost and you have a special customs tailored order for a customs tailored—

Mr. MACKASEY: I must insist on the point since we are here to reduce prices. I would imagine, as one trying to protect the public, that it is to the advantage of this Committee to push the $17 per thousand over the $24 per thousand but we would not hesitate to push the $24 if there were a safety factor or if there was something that could be justified. The only justification I get from reading the brief description of the price is that the $17 one is round and therefore it is bound to be produced much easier than the heart-shaped one and it is white, instead of pink, therefore it does not have any colouring in it but it is $7.00 per thousand cheaper. What justifies the same product being sold at two different price levels. That is what I would like to know.

Mr. DAN: I do not think I can answer it because our firm does not price differently. I do not know what motivates other companies.

Mr. MACKASEY: Are you representing a firm or an association?

Mr. DAN: I represent an association. The reason why we have different prices within our own members is that we have different price structures. The point I am making is this: our members usually sell at a lower price.

Mr. MACKASEY: I am not even getting into your price structure as to manufacturing to retail. I want to know why generic firms are as guilty of the same thing as the so-called big firms in producing the identical product at two different prices. It is just like aspirins that sell at 25 cents per hundred and aspirins that sell at 25 cents per thousand. We all understand that. I would like to know why a generic firm, any more than any other firm, can justify production of an identical thing and simply by varying the colour from white to pink change the price from $17 to $24?

Mr. WRIGHT: To the best of my knowledge, the pink triangular tablets you have here are not produced by one of the group that call themselves Canadian pharmaceutical manufacturers, so I think that—

Mr. MACKASEY: I think it is only fair to you that I should identify the firm. The firm is—

Mr. DAN: Mr. Chairman, I would like to point out, as a matter of record that some of our members sell under generic names and some sell under branded names. I would not be doing justice to my group if I would give the impression, incorrectly, that all of our members sell under generic name. We do sell under branded name. The point we are making is that our members, even if they sell under branded name, still sell considerably lower than the large houses.

Mr. MACKASEY: Of course, but not as low as we would like to see it. In other words, we would like to see a situation where you sell at $17 rather than $24. If there is some therapeutic value in the $7, other than the colouring, then we could even justify it on the grounds of safety and the evidence we have had in the past. If it is only for a bit of colouring—the point I am getting at, having read your brief, analysed your brief and having been impressed by your brief, you have two themes. One, that you are Canadian and therefore we should do everything to foster Canadian although we can get into this a little later; and, secondly, the group that was here last week with this very elaborate brief which controlled 90 per cent of the industry are guilty of certain practices which your brief implies all the way through. I just pointed out the same specific practice which we presume they are guilty of, you are guilty of. What I am trying to find out is what is the basic difference? How do you justify this $7?

Mr. DAN: I am not entirely sure that this question is 100 per cent correct because I am unaware of this particular case.

Mr. MACKASEY: I will get off it, and perhaps bring it up again.

Mr. DAN: I am not aware of this particular case and that is why I am only guessing. I will not be sincere if I do not say I am guessing. The only explanation could be that they are different production runs but in my opinion there should not be a difference.

Mr. MACKASEY: All right. Between now and eight o'clock I will acquaint you with my source of reference and you can give me the reason why pink heart-shaped pills are going to make me better faster than white round pills.

Mr. DAN: There should not be any difference.

The CHAIRMAN: Perhaps, Mr. Mackasey, you should either acquaint some of the Committee members with the basis for what you said so that, if necessary, we can ask this company to come before us and explain it themselves.

Mr. MACKASEY: The firm is known as Lukas Products, and it says "tolbutamide tablets, weight five grams, also available from Lukas as tear dropped shaped pink scored tablets at a suggested retail price of $24 a thousand compared to $17 a thousand for plain white tablets containing the same amount of tolbutamide." I think perhaps this may be a significant point, the pink tablet is a look alike of Horner's mobenol. I think it is self-explanatory.

Mr. DAN: I think they should not charge more.

Mr. MACKASEY: In other words, you have a product that will do the job at $17 and by imitating Horner's product they charge $24.

Mr. DAN: In my opinion, it is their own practice.

Mr. MACKASEY: All right. This is why we are here to get rid of wrong practices.

Mr. DAN: I admit that.

The CHAIRMAN: Dr. Brand?

Mr. BRAND: I would like to carry on this point, if I may, Mr. Chairman, in perhaps a slightly different way regarding your profit margins. Since you have tabled the profit margins of the other manufacturers, I want to make sure that you will do the same for your manufacturing group. In other words, how much money does your group make?

Mr. DAN: I shall endeavour to the best of my ability.

Mr. BRAND: I think it is only fair that we have both to compare to see if there really is any difference in the profit margins.

I wish to refer to this look alike that has been brought up by Mr. Mackasey. Surely there must be a reason for it to be a look alike of one which has already been marketed at, as you have pointed out, great expense. I have seen, in my practice, certainly, other pills which have been put out by the Canadian manufacturing group which are look alikes of other pills put out by the other manufacturing groups who control 90 per cent, and they are so close that you cannot really tell them apart. I wonder, perhaps, is there anything here which would suggest that your group is taking advantage of the marketing expense that has already been increased by these other companies in order to sell these, perhaps a little more easily, without going to the expense of doing it yourself?

Mr. DAN: I am under the impression that the look alike tablets are more the exception than the general rule, and you find exceptions everywhere. Personally, and I can speak only on my own behalf in this instance, I am not in favour of having look alikes. My impression is that companies try to have their own type of tablets. The best example is probably Empire where they even imprint the letter "E".

Mr. BRAND: I am glad you mentioned Empire. That is the company I was thinking of. There is a capsule put out by Smith, Kline and French, in fact there are a couple of them, one called dexamyl, the trade name, and the other dexedrine spansule or the dexamyl spansule. Empire puts out two absolute look alikes. If the Committee likes, I can bring them a bottle of each to show them. That would be four bottles. That is the Empire Company.

Mr. DAN: I am under the impression that the first manufacturer imprints the name, shall I say, brands the product. If you take a capsule in your hand and you see the brand name on a product, I do not believe there is any doubt where the product comes from. They must have their name on it.

Mr. BRAND: This is correct but, nevertheless, there is no question that to the uninitiated and to the consumer, and those are the people we are concerned with, there would not be any difference. Is this not correct?

Mr. WRIGHT: Mr. Chairman, could I identify myself with this because I am willing to discuss this at length. I am Mr. Winter's successor and I am supervising and managing Empire Laboratories. I will be glad to discuss any of these matters which you bring up. I do not want to do it now because Mr. Dan is being questioned.

Mr. BRAND: We can return to this.

The CHAIRMAN: I was going to say that separately the Chairman has already invited the Empire Drug Company. I do not think I have ever had an answer to my invitation to appear but we have asked—

Mr. WRIGHT: I will answer it now.

The CHAIRMAN: We would like your company as an individual company in contrast to the association. We are doing this similarly with the pharmaceutical manufacturers individually.

Mr. BRAND: I would point out, Mr. Chairman, that I did not bring up the name "Empire". It was brought up by Mr. Dan himself. I merely used it as an example, since he had brought it up, to find out whether or not these companies are using the already marketed facilities, if you can call it that, of the P.M.A.C. group. This is the thing I would like to have an answer to. It seems to be a clear attempt to do so, in my view. One other question; I would like to know if, when you add research, as you said, in the future as your companies grow bigger, will this add to the cost of your products?

Mr. DAN: This is a question I can probably answer better at a future time. It depends on the cost of research. I think it would add, yes, it would add, but it would add a modest sum.

Mr. BRAND: You have made no estimates as to what the amount would be?

Mr. DAN: It would be a modest sum.

Mr. WRIGHT: There could actually be no increase at all if research is carried out properly.

Mr. BRAND: Is there any reason why research is not being done now then?

Mr. WRIGHT: Yes, for the most of them, because you have to reach a certain capital structure. Empire Laboratories happens to have reached that structure and Empire Laboratories is doing research.

Mr. DAN: I would say that within two or three years you will likely find Canadian companies doing a substantial volume and doing research after a lot of organization. This is a two-way street. We look at the cost of drugs and prices but we also ought to look at our own resources with a hope of assisting you and coming out with the answer.

Mr. BRAND: Pardon me for interrupting for the same reason that Mr. Mackasey did. I am trying to squeeze some in here. I am very pleased to hear that they will be getting into this and that they are already in this field. Do you have any idea how you are going to market them once these new products are brought out?

Mr. DAN: The marketing pattern has not changed in the last 20 or 30 years. You use sales representatives; you use means of publication; you use a certain amount of sampling; probably we would use a little more discretion in the marketing. We feel that we could market at a lower cost than is done at the present time.

Mr. BRAND: By marketing your products, would this add to your price?

Mr. DAN: It would not add. We have marketing costs. We employ sales representatives. But our marketing costs would be lower than the marketing costs at the present time expended by the large firms.

Mr. BRAND: You say you already have this. What action do your members take to keep the medical profession up to date on new information regarding your products?

Mr. DAN: I should point out, at this stage we do not bring out new medicines. That was my qualified first sentence. Therefore, whatever information we bring is not new at this stage.

Mr. BRAND: Let us go on to another one. On page seven it says, "It appears that all our members should comply with the 74-GP-1 standards". I wonder if you could tell me how many actually comply with this at this time and how many have failed to comply?

Mr. DAN: I think I should ask Dr. Showalter to give you the exact information: how many today comply?

Mr. O'KEEFE: What is it?

Mr. DAN: There is a certain standard of firms which comply with this that bid on government contracts and it is considered as the minimum standard.

Mr. BRAND: Let us put it this way. Do all your members now comply?

Mr. DAN: They have to in order to be members. I pointed out that we are in a formative stage. Say of ten companies, three cannot comply, they cannot be members.

Mr. BRAND: Are all those you have mentioned in your brief complying now?

Mr. DAN: At the present time I am not 100 per cent certain because we are in the formative stage. By September, if any one of the firms does not comply, the name will be stricken.

Mr. BRAND: I see. This was not in your brief and that is why I asked it. There was no mention whether they would have to comply or whether they would remain members if they did not comply or what.

Mr. DAN: If they do not comply, they cannot be members.

Mr. BRAND: Is the Lukas Company a member in good standing? Does it comply with the 74-GP-1?

Mr. DAN: My information is that at the present time they are not. My information is that they have applied for reinstatement. By September we will know what will happen.

Mr. MACKASEY: Referring to the word "reinstatement", they have already been in and been expelled for some reason?

Mr. DAN: If you have 74-GP-1 specifications or standards and for one reason or other you lose it, after a period of time you can apply for reinstatement.

Mr. BRAND: You do have a code of ethics, then.

Mr. DAN: It is still in the process of being written.

Mr. BRAND: I wonder if you could tell us how this company lost their right to tender to the government?

Mr. DAN: I think it is public information. My understanding is that one of their products was incorrectly labelled.

Mr. BRAND: Was it not also that was the chloramphenicol tetracycline bit?

Mr. DAN: That is right. I think an error occurred in the plant.

Mr. BRAND: I understand they were also fined for this mislabelling procedure?

Mr. DAN: That is correct. This is probably the normal matter of course.

Mr. BRAND: Do you know if they still sell any products to any provincial governments?

Mr. DAN: I do not know that.

Mr. BRAND: I guess we can find that out from the Lukas Company. Are they coming before us, Mr. Chairman?

The CHAIRMAN: Not to my knowledge.

Mr. BRAND: I wonder if we could ask them to come before us? It would be very useful indeed to add them to the list.

Are there any of the other firms in your group now who have any prosecution pending against them?

Mr. DAN: Not to my knowledge.

Mr. BRAND: There is something on the order paper that I think you put there. Is that not correct?

Mr. DAN: My point is this. If you find some companies which do not fit into the group, they just have to leave. In every professions you may find a few individuals who do not really belong to the profession. I have heard about disbarred lawyers or doctors who lost their licenses or pharmacists who lost their licenses, but that is not typical of the group. In order to belong to this group you must maintain standards and possibly by September or the end of the year. the members that you will have here will be sincere people who like to trade something, who like to do something and work out with the government an answer to the problem of the price of drugs.

Mr. BRAND: I am very pleased to hear this. Perhaps then some of these companies may not be members of your group by September. That is a possibility, is it not?

Mr. DAN: That is exactly correct.

Mr. BRAND: This is my last question. I thought perhaps we should have your brief tabled as an appendix to "A Choice for Canada" by Walter Gordon because it certainly seems to be something along that line, certainly an eulogy of Mr. Gordon's book.

The question is this. You mention the recent takeovers, on page 3: Mowatt Moore, Canada Duphar and Delmar Chemicals. Those two names are in there. You mentioned Frosst, Horner, Fine Chemicals, Elliot-Marion, Bell-Craig. Is your association aware that Canada Duphar and Delmar has been repurchased by a Canadian firm and is now wholly one hundred per cent Canadian?

Mr. DAN: My information is, and this dates back to about a month ago, that they were still part of the Labatt's group. If this happened we are delighted to hear of it.

Mr. BRAND: Yes, this is what I mean.

Mr. DAN: We are delighted to hear it and we would like to see more companies.

Mr. BRAND: I do not know what beer is doing in pharmaceuticals but, nevertheless, in view of what—

Mr. DAN: Now you have just added two more names to our list.

Mr. BRAND: Mowatt and Moore; I believe their foreign ownership is only 20 per cent, is it not?

Mr. DAN: I am not sure of the exact percentage, My understanding is that it was owned by Frosst. You will have to call these people and ask them.

Mr. BRAND: You make quite a point in this brief of the fact that we must have a lot of government help to make this industry go. All these companies, I presume, built up to such a state that they were taken over in this very milieu which you feel is not good enough for the present companies today. Is that not correct? I refer to such companies as Charles E. Frosst, Horner, Bell-Craig Fine Chemicals and all the rest of them.

Mr. DAN: Please repeat the question?

Mr. BRAND: Did these companies not start as Canadian companies, as you pointed out, and did they not build up to such a size that they were finally taken over?

Mr. DAN: Yes.

Mr. BRAND: But they did build up in the very atmosphere in this country which you feel is not conducive to a Canadian-owned industry now. Is that right?

Mr. DAN: I am not sure I fully understand your question.

Mr. BRAND: These companies started in Canada as Canadian companies. They built up to a fairly good size; is this not correct?

Mr. DAN: The atmosphere was different 30 or 40 years ago when the Frosst Company started.

Mr. BRAND: Frosst was not taken over 30 to 40 years ago.

Mr. DAN: They were taken over recently. In a free economy you cannot force individuals to sell out, or not sell out or remain Canadian. We feel that the government should step in and discourage the selling out of companies.

Mr. BRAND: I got that message. I think I should quit. I am taking up too much time.

Mr. HOWE (*Hamilton South*): Mr. Chairman, I would suggest that with one minute to go I could reserve being the first questioner tonight and call it five o'clock. I would only get started and I think, to maintain continuity, and seeing that our last two ten minute question periods lasted 15 minutes—

The CHAIRMAN: The Committee will adjourn until eight o'clock this evening.

THURSDAY, July 7, 1966.

• (8.00 p.m.)

The CHAIRMAN: Gentlemen, I think we should restart the meeting. Dr. Howe, you indicated at five o'clock that you had some questions. The floor is yours.

Mr. HOWE (*Hamilton South*): Mr. Chairman, I would like to carry on with more or less the same type of questioning of Mr. Dan as I believe was taking place at the time of the supper recess.

Mr. Dan, you would say that all the companies which belong to your association are not of necessity of the same standard.

Mr. DAN: That is correct. You see, we start an organization, and in the beginning you accept more or less any one which is Canadian-owned.

Within the next one or two months we are going to establish standards with the assistance of the Food and Drug, and the members must comply with the standards, and possibly by September, to put it bluntly, three or four members may be chopped off the list.

Mr. HOWE (*Hamilton South*): The companies are not necessarily of the same standard.

Mr. DAN: That is correct.

Mr. HOWE (*Hamilton South*): Yet when a doctor writes a prescription for a generic brand of drug he is asking for it by its actual generic name, and the druggist is at liberty to dispense any one of these companies' drugs, although they are not necessarily of the same standard.

Mr. DAN: That is correct. It is up to the druggist, or, shall I say, the pharmacist, to decide from what company he buys. Being in the pharmaceutical business he eventually becomes familiar with the pharmaceutical houses, and from experience he finds out that he can place a greater confidence in some houses than in others.

Mr. HOWE (*Hamilton South*): Yes. But, *per se*, he is not as interested in the patient as is the doctor who writes the prescription?

Mr. DAN: I disagree. The druggist is interested in the patient.

Mr. HOWE (*Hamilton South*): Therefore, actually without changing the shape of the pill, from a heart-shaped pill to a pear-shaped pill, one could give it a name without actually increasing the cost. Is that not correct?

Mr. DAN: Yes; you could give it a name. In fact, I would like to emphasize again, lest I create a wrong impression, that several of the members do sell under brand names, and the bone of contention is that they can sell drugs at a considerably lower price with a brand name.

Mr. HOWE (*Hamilton South*): With or without a name.

Mr. DAN: With a name.

Mr. HOWE (*Hamilton South*): Therefore, it does not make any difference. If you are going to put a label on it anyway and call it meprobamate you could put it on the label and print something different on it. Giving it a name has nothing to do with mass production of the tablets. So that the giving of the drug a trade name will not increase the price of the drug *per se*.

Mr. DAN: I would like to point out that by law all drugs in Canada do carry the generic name; the generic name is under the brand name. However, the issue is not whether you sell a medicine under a brand name or under the generic name. I hope that the members realize that the issue is that we can market and we can sell medicine for considerably lower prices than they are being marketed today.

Mr. HOWE (*Hamilton South*): I realize this from your brief which is sort of representing these companies and presenting their point of view, and you are doing a very good sales job of it. My point is that when the drugs are not named and various companies make these drugs the druggist makes a free selection of probably what is the best buy and dispenses it, although this drug may not be of equal quality to the drug of the same name made by a different company?

Mr. DAN: Dealing with pharmacists, from experience, I can say that price is not the only factor. I have spoken to several of them and they very strongly emphasized that they like to buy good brands; and again, from experience, they feel that somehow they seem to have good brands.

Mr. HOWE (*Hamilton South*): By what criterion can a druggist tell? The doctor is the one who can tell by the effect on his patient. The druggist does not have the things really to go by that a doctor has.

Mr. DAN: The druggist has certain things to go by. If there are complaints, that would be one thing to go by. Secondly, they know the houses. In the drug business you are very widely exposed, particularly if you are established; and pharmacists, by and large, do know from what houses to buy.

Mr. HOWE (*Hamilton South*): I am not denigrating the retail pharmacist, by any means. I know that he is sincere and honest and I am not in any way running him down. My point is that the druggist is naturally going to feel, if he has no other criterion to go by, that if something costs $1.75 instead of $2.50 then in order to please his customer, my patient, he is going to try to get the cheaper drug. A patient will come in to a doctor's office and say, "Well, now, I got that from such and such a drug store for $2.50 and this druggist charges me $3.75," although the name brand, admittedly, may be $10.00.

Surely there is some difference in these drugs? As you say, the companies are not necessarily of the same standard. Two of them may be manufactured under the generic name solely, and therefore the druggist has got nothing by which to choose except possibly the price variation, unless he has had an unfortunate experience with an individual doctor who has said, "This brand does not work."

Mr. DAN: I think it goes a little beyond just the price. From past experience, the house is important. In business you deal with people and if you have satisfactory relationships with certain firms you keep dealing with them. This is the fundamental criterion in any dealings.

Mr. HOWE (*Hamilton South*): Yes; but my point is that this criterion is between the doctor and the patient, not between the druggist and the patient.

Mr. DAN: You have a point there.

Mr. HOWE (*Hamilton South*): That is my point.

Mr. DAN: You have a very valid point.

Mr. HOWE (*Hamilton South*): In writing his prescription the doctor cannot specify unless he writes the name of the company which he happens to know to be more reliable, because he has not got a brand name to go by. He simply has a generic name, and he must specify the company which manufactures it. Therefore, it would not increase the price of the drug to give it a name.

• (8.15 p.m.)

Mr. DAN: That is right; but the doctor can also specify a certain company with whom he has been in touch, or has heard of, or which has called upon him.

I can foresee that within the next few years the Canadian Drug Manufacturers will call upon doctors to present their line, and leave the decision up the doctor to chose a particular brand, made by a Canadian-owned drug manufacturer.

Mr. HOWE (*Hamilton South*): I am now going to ask of you a question which I asked of the druggists the other day: Do you know what is the percentage of direct sales made to drug stores by the drug manufacturing companies which you represent.

Mr. DAN: I called up the Canadian Wholesalers Association and I spoke with their secretary, and he estimated that about 60 per cent of the sales emanating from drug manufacturers go directly to the retailer, and only 40 per cent are handled through the wholesaler.

I also spoke to some of the wholesale houses, and they seem to verify this figure.

Mr. HOWE (*Hamilton South*): You would have no way of knowing whether this particular figure applied in any way to the other larger drug companies.

Mr. DAN: I am talking about the larger houses.

Mr. HOWE (*Hamilton South*): Oh, you are talking about the larger houses.

Mr. DAN: I am talking about the prescription volume in the ethical business. I am talking about $200 million volume ethical business.

Mr. HOWE (*Hamilton South*): Sixty per cent of the sales that are made from the companies you represent are—

Mr. DAN: No, not from our company.

Mr. HOWE (*Hamilton South*): Oh, I am sorry.

Mr. DAN: From the trade.

Mr. HOWE (*Hamilton South*): From the trade, generally.

Mr. DAN: In our own case, I do not know. I would hazard a guess and say that we might have a larger percentage.

Mr. HOWE (*Hamilton South*): You might be larger than the sixty per cent.

Mr. DAN: We might be larger. We might be selling direct a larger percentage. But a pattern is developing. It is not yet crystallized.

Mr. HOWE (*Hamilton South*): This makes their figure of 37½ cents on the prescription dollar rather an interesting figure, if 60 per cent of them are direct sales sold at 60 cents on the dollar rather than the 37½ cents. That is just by way of conjecture.

In your brief you do not attempt, as did the C.P.M.A., to break down your prescription dollar into the amount the manufacturer gets. Could you hazard a guess at how much of the prescription dollar that the consumer pays goes to the manufacturer in the case of the companies which you represent?

Mr. DAN: I would be only guessing, which I avoid.

I might add, in passing, that at the present time the trend on the part of the pharmacist is to sell medicines, or dispense medicines, at cost plus dispensing fee. If they buy our medicines at a lower price, obviouly the public will pay less.

Mr. HOWE (*Hamilton South*): I am premising this on the standard way of dispensing prescriptions, at the retail trade price plus a dispensing fee, and not cost plus. What percentage of the prescription dollar does the manufacturer get back?

Mr. DAN: I cannot give you any definite answer. I would hazard the guess—to put forward an opinion—and say forty to fifty per cent; but this is just a guess.

Mr. MACKASEY: Perhaps I could help Dr. Howe by pointing out that they are specific in their brief on page 19.

Mr. HOWE (*Hamilton South*): Yes, they are specific; I am sorry, I did not realize that. However, it does not break it down like the other one.

I was going to go from the 40 to 50 per cent into some sort of a break down, if it was feasible to give it to me, and the figure in which I am most interested, for obvious reasons, is the percentage that promotion is of the 40 to 50 per cent that you get? In other words, how many cents towards promoting—?

Mr. DAN: All right; again, I would hazard a guess that the promotional percentages are in the neighbourhood of between 20 and the maximum of 25 per cent.

Mr. HOWE (*Hamilton South*): Is that 20 to 25 per cent of the 40 per cent, or of the dollar?

Mr. DAN: Of the sale price; the sale price which you pay to buy. If you sell pharmaceuticals at a price of a dollar per unit, of this probably 20 per cent would be promotional. That includes sales representatives, literature, letters and that kind of thing.

Mr. HOWE (*Hamilton South*): The Canadian Pharmaceutical Manufacturers show 30 per cent of which I particularly was very critical, as being a rather large percentage. You would say that yours is almost the same.

Mr. DAN: About 20 per cent; it is not almost the same; it is about 20 per cent. As I say, this is just a guess, and, again, I do not have figures to substantiate it.

My point is that the percentage for promotion is less. You can, to a degree, streamline promotion, and I personally wonder whether it is 30 per cent or if it is more, because I have briefs which indicate 39 per cent for promotion.

Mr. HOWE (*Hamilton South*): You do not do actually as much direct mail advertising, nor do you have detail men on the road in the same numbers as the larger companies?

Mr. DAN: That is correct.

Mr. HOWE (*Hamilton South*): This actually reduces prices, and this is one of the factors, small though it may be, which keeps this lower?

Mr. DAN: That is what we strive for, a more efficient way of marketing.

Mr. HOWE (*Hamilton South*): And more ethical, shall we say?

Mr. DAN: And also more ethical. Very shortly, during the summer months, we shall also work out our code of ethics.

Mr. MACKASEY: Could I ask a question there? Are you inferring that detail men are unethical?

Mr. DAN: I beg your pardon?

Mr. HOWE (*Hamilton South*): I did not mean that. Detail men are not unethical. I have had experience with many of them and it is quite the reverse.

By "ethical" advertising I meant the promotion of a drug with regard to its qualities, its contra indications, and so on, rather than by the gimmicks which I produced here one evening a couple of weeks ago. This is what I meant. I am not reflecting on the detail men. I want that on the record. These men are sincere, hardworking men, and I am not criticizing them. They are there to do a job.

Mr. MACKASEY: That is why I asked the question. I knew you would want to—

Mr. HOWE (*Hamilton South*): I am glad you did, to clarify it, because I would not want any misinterpretation of what I said.

I have now lost my train of thought—

Mr. CHAIRMAN: Perhaps that is a good place to leave it!

Mr. HOWE (*Hamilton South*): Yes, I guess.

The CHAIRMAN: I think Mr. Dan has a list of the present members of your Quebec Association which is related to your association.

Mr. DAN: Yes; in deference to Mr. Mackasey I would like to hand them over to you.

The CHAIRMAN: We could actually put that on the record.

Mr. ISABELLE: Mr. Dan, apparently, from what I have heard since we have been here this afternoon, you represent a group of companies who seem to be imitators. They buy the substance and they manufacture it and sell it to the public. Am I right? This is the impression that I had.

Mr. DAN: Not entirely; I do not think that today in the industry you will find five original people.

It is true that the medicines they sell may have been on the market for some time, and the medicines are available for purchase. In fact, interestingly enough, we ourselves buy these medicines from the same raw material dealer as do the large companies. Therefore, I consider a large percentage of these medicines as being in the public domain.

Tomorrow, you yourself can start up a business, buy the raw materials and put them into tablet form and market them. I wonder if you would consider yourself a imitator or as someone who is in the pharmaceutical manufacturing business?

I think we have to draw a very clear line between companies which are engaged in doing business and, shall I say, industrial leaders who have the ideas.

We have to face facts. Not everybody has the resources, be they financial, be they organizational, or be they mental, to come out with new ideas, but that does not mean that the rest of the people—and, to be frank, most of us belong in that category—cannot, or should not, have the right to exist, because invariably yesterday's imitators are today's leaders.

Mr. ISABELLE: Where do you obtain the required clinical information about your products in order to properly inform the medical profession?

Mr. DAN: Again, I should point out—

Mr. ISABELLE: Are you using the literature which has been published by the ones who first discovered such a drug? Where do you get your information?

Mr. DAN: Let me explain. The products which we handle are usually the so-called established products. It is true that one firm, or perhaps several firms, may develop products, but eventually these products get into medical text books, become, shall I say, the property of the public, are discussed in universities and various institutions, and plenty of literature is available.

I doubt very much that any one of such would launch upon a product today, because today we do not feel we are capable of coming up with new products; but our aim is that as we shall go inside, and I foresee that we shall. We shall carry out precisely the same function which is being carried out today by the large houses, yet streamline our entire marketing operation, and when the time comes we hope we shall prove that.

Mr. ISABELLE: I thought you were reprinting in different colours the original information.

Mr. DAN: I do not think that knowledge today belongs to one specific company. If my impression is correct, knowledge is the contribution of many thinkers, and the minute an idea has been passed on to various scientific groups, printed in journals and scientific publications, I do not feel that it is the property any more of any group. It belongs to the public, because of the nature of the product involved.

Mr. ISABELLE: Now, on page 6, paragraph 10 you state "our government should remove the new drug status from all preparations as soon as they appear in the official pharmaceutical standards such as the British Pharmacopœia and the United States Pharmacopœia." This would force the department of National Health and Welfare to rely on foreign publications to set their policy. Do you not feel that the Food and Drug Directorate is in a better position than foreign organizations to analyze the standards of drugs in Canada?

Mr. DAN: At the present time, I think—and I may be mistaken—that in Canada we do follow B.P. and U.S.P. standards. Therefore, obviously, their standards do have a weight in Canada. If it is good enough in Britain, or good

enough in France—because the drug did get into publication, having been screened to us—this is probably a criterion. This does not mean that automatically, because an item gets into publication and becomes open in Canada, this is a sign and the bell rings and Food and Drug will take a look at it. Under certain circumstances there could be delay. Judgment is very important in pharmaceuticals, and they have the final say in Canada or when a new drug should come off the so-called new drug list.

Mr. ISABELLE: At the bottom of the same page, page 6, you state: "Our group firmly believes that for the interest of our country a health balance of at least twenty-five Canadian ownership versus seventy-five per cent foreign ownership should be maintained."

On what do you base these figures, and what, in your opinion, is the present balance?

Mr. DAN: I would like to make clear that we do welcome foreign investment in Canada. I would not want anyone to interpret this, or any other, paragraph as meaning that we do not welcome it. However, in matters of health—and the pharmaceutical industry is a very important industry—we feel that we should have some say.

On the question of why there should be this balance, the large companies, which are very strongly entrenched, have about 80 per cent of the market and we cannot dislodge them. I do not think that they should be dislodged, because they are right here. We have to find a *modus vivendi*, a co-existence, and, interestingly enough, if you have two groups—a large group and a small group—not only do the two function better but the public benefits, too. To consider another industry, for example, in the car industry perhaps 100 per cent foreign ownership is the answer because of the nature of the industry. In banking it is probably the other way round and you should have a ratio of perhaps 100 per cent Canadian, or 95 per cent Canadian. Every industry is peculiar, and it is our judgment and our judgment may be wrong—that there should be a certain balance, and if it goes beyond it then action must take place to maintain this balance.

• (8.30 p.m.)

Mr. ISABELLE: Just one last question, Mr. Chairman, and it is a comment at the same time. Are you aware that some of your companies which are listed on page 17 are going to appear in court for something that they have done which was contrary to pharmaceutical ethics? I put a question on the Order Paper the other day, and the question I asked was if there was any legal proceeding being instituted against Barlow-Côté Laboratory from Quebec, because apparently they distributed SDM tablets which contained Sulfamethoxy pirydazine when they should have contained something else, as per the label.

Mr. DAN: If any one of the members does not maintain the standard, as I have pointed out before, they will be chopped off.

Mr. ISABELLE: Yes; but he does not need a standard to put—

Mr. DAN: But automatically this disqualifies him. It is self-understood.

Mr. ISABELLE: Because I am afraid some of the names who are—

Mr. DAN: Yes. I want to stress this point that we are in a formative stage, and invariably the chap has to be thrown out.

The point is that out of this something will emerge, which ought to benefit the country, and I think it will, if properly handled.

Mr. ISABELLE: But you are favouring more pharmaceutical companies in Canada? Do I understand correctly?

Mr. DAN: Yes; and strong ones so that their voice should be heard.

Mr. ISABELLE: And you think that the price would come down if we increased the number of companies?

Mr. DAN: Absolutely; you see no one is going to lower a price just because one day he walks into the office and it is a beautiful, sunny day. The market is too matter-of-fact. Where there is competition the price goes down; but not only that, competition stimulates new ideas. The best example of that is in wartime. I do not think that any nation came up with so many new ideas and inventions as it did during the war. Why? Because they had to.

Mr. ISABELLE: I think your principle is wrong. It is not because there will be more companies that the price will come down. If—

Mr. DAN: Not because there will be more companies. What we emphasize is that this is a viable segment. I think that there will be fewer companies. That is likely what will happen.

Mr. ISABELLE: There are many companies which are interested only in profit. If they are competitious they will compete and they are interested in only profit, and to hell with the research. You will find out, when you get your group organized, that many of your group are not spending too much money on research.

Mr. DAN: They will.

Mr. ISABELLE: I was surprised at the promotion percentage which you gave to Dr. Howe. Was it 20 per cent, you said, that your companies spent on promotion?

Mr. DAN: Marketing expenses.

Mr. ISABELLE: Marketing expenses; yes.

Mr. HOWE (*Hamilton South*): A supplementary at this point, if I may: That being the case, why do your companies not cause lowering of the prices of the larger companies?

Mr. DAN: I would like to refer you to a finding of the royal commission which pointed out very clearly that not until competition stepped in about 1960 that prices began to drop; and prices are dropping. I could quote from records to prove my point, that not until 1960 did prices begin to fall. Take for example, butazolidine which used to market, if I remember correctly, at $13.00; it dropped down to $10.00, right now it is $8.90. There is a trend downward, and it will go further down up to a point of balance.

Again, we cannot push them down to an unreasonable level, but the point is that they will come down, and if that happens the taxpayer—the public—will save millions of dollars.

Mr. HOWE (*Hamilton South*): It has always been a point of interest that if one of the larger companies drops their price on a standard product other companies which manufacture the same drug automatically lower theirs.

Mr. DAN: This is my point. In other words, just like you have a dam, the water is around. Eventually at a certain point there is so much pressure of the water that the dam breaks and the whole dam breaks. In short, if tomorrow we offer certain pharmaceuticals at a lower price, and if this is known to the profession and if someone from our company calls in your office and offers identical medicine at a lower price, then obviously if another company asks how they can do it and the other cannot. These people have been in business a long time and they are successful, why cannot you do it? Now this information goes to their head office and they take another look at it and eventually the prices will come down, but that is not the important point. The important point is the creation of a certain atmosphere. When the atmosphere is buoyant people buy, when the atmosphere is tight, people do not buy. The same thing applies to drug companies as in any other business.

Mr. O'KEEFE: Surely that is the same.

Mr. DAN: It should not, but I am talking about the larger companies, and they feel that there is a complete reshuffling and reorganization in prices, they have to take a close look at them. They just cannot maintain their old prices. It is the law of economics, and anybody who has a business understands it because you feel it in your blood, that now is the time to drop the prices because you are either losing ground or the market trends are changing, or for whatever reason.

This is what we aim at, and we believe that we are not only going to drop the price, but that in the long run we all will benefit, the public getting more medicines at lower cost on the one hand, and the larger companies thinking up new ideas on the other.

Mr. ROXBURGH: Mr. Dan, the price at the present time is actually too high.

Mr. DAN: I would like to qualify this, the price at manufacturer's level. We cannot talk about the price at the retailer's level or wholesaler's level, although we are under the impression that at the wholesalers' and retailers' levels they are fairly reasonable. I understand that drugs have to be distributed across the country in a certain fashion, and the pharmacist has to subsidize his operation in order to get to the most distant corner of the country. I do not think I am qualified to answer that. But at the manufacturer's level it is our opinion that it is high; it is our opinion that it could be made lower and it is our belief that it shall be made lower in the next year or two.

Mr. O'KEEFE: Mr. Chairman, Mr. Dan and Dr. Wright, you agree that this Committee is sitting and you are here to help reduce the price of drugs.

Mr. DAN: Did you say to help produce?

Mr. O'KEEFE: Yes; to reduce the price of drugs.

Mr. DAN: To reduce—I misunderstood the word. I think that this Committee is sincerely searching an answer that is extremely complex, and I myself and Dr. Wright, who are in the business and are in a little closer touch, are sincerely searching, and I am also convinced that the members of the PMAC are. We are all sincerely concerned in finding an answer. There is an answer because the market is shifting.

Mr. O'KEEFE: Basically you would agree with me that the purpose of this Committee is to try to reduce the price of drugs to the consumer.

Mr. DAN: I believe it should be. I believe that is what it is.

Mr. O'KEEFE: Do you think that your firms could get together and, by mutual consent, reduce some of the costs which you incur in your—

Mr. DAN: I would qualify my answer to get together without infringing upon the combines law. I am not too familiar with the details, but something of a streamlining amongst our firms must take place. Possibly out of the 15 firms of which by September only 10 will be left, after a year or two there might only be two or three around who will do a volume, I envisage, between $2 to $5 million. These firms will grow I hope in the not too distant future to large enough force to be noticed, and they are going to reduce the price. It is an effort which is a combined effort and this is the only way I can conceive it to be successful.

Mr. O'KEEFE: By combining.

Mr. DAN: By combined efforts on the part of the government and on the part of the manufacturers.

Mr. O'KEEFE: Then you or your counsel do not think, as others did, that a high-priced and I presume high-powered counsel, when I asked the same question in each case suggested that it would be against the Combines Act.

Mr. DAN: If they would get together?

Mr. O'KEEFE: Yes.

Mr. DAN: Again, I am not an authority on answering this question. If I get together with a manufacturer, my understanding is, and we agree, that neither of us will sell merchandise at a lower price that may violate the Combines Act. But if we reorganize our operations, in the sense that we say, merge three or four companies or we put under the same roof three or four companies, or we try to bring about more efficiency as one does, only the export market and that is it. We have highly trained and many lingual detail men calling in the country, another one, shall I say, does only the government and hospital area, the third does only the retail business, whereby we also reorganize the manufacturing facilities, and we get rid of the unnecessary expenses and the fragmentation which exists in the industry, we think that we can come up with an overall lowering within our own ranks.

Mr. O'KEEFE: Would Dr. Wright agree with that?

Mr. GEORGE WRIGHT (*Professor of Chemistry, University of Toronto*): Yes. I would actually go further and say that there are many other things that could be accomplished by organization of Canadian manufacturers. There are such things as mutual interest in patent litigation; such things as mutual interest in clinical investigation, things that are—

Mr. O'KEEFE: What about the 39 per cent of the consumer's dollar that is used for promotion purposes? Someone used that figure a little while ago. I think it was you.

Mr. WRIGHT: Yes. I do not know exactly what you wanted to know about it.

Mr. O'KEEFE: What I am trying to find out is that you agree that you could combine to cut the price of drugs to the consumer and in each case, when I asked the same question at other meetings, I was told no, it was against the Combines Act. I have a copy of the Combines Act here and on page 16, part V it is headed "Offences in relation to trade"... I just want to put this on the record,

Mr. Chairman, if I may. "The court shall not convict the accused if the agreement or arrangement relates only to restriction of advertising or some other matter not enumerated in subsection 3." I just want to put this on the record because you remember the answers we got a little while ago.

The CHAIRMAN: And I should point out that I think Dr. Wright, nor Mr. Dan are legally trained nor legal counsel, nor do they have legal counsel with them.

Mr. DAN: If you are asking whether or not we could market more economically in a more streamlined fashion, absolutely.

Mr. O'KEEFE: I am glad to hear that.

Mr. DAN: It can be done. And this is what we are striving for.

Mr. O'KEEFE: I hope other persons will agree with me.

Mr. DAN: I do; and I want to give an example. Look at the supermarkets. Remember the supermarkets thirty years ago and as they are today.

Mr. O'KEEFE: There is a big difference in supermarkets. When the consumer goes into a supermarket she knows the difference between Duz and Pride and all these sorts of things. When she gets a prescription she is completely at the mercy of the pharmacist and the doctor. The prescription could be $12.00, or it could be $6.00; it could be any amount. She has no control at all. There is quite a difference. I do not agree with you there.

At the end of page 19 your comment (3): "Manufacturers follow multiple pricing policy. Governments, hospitals, doctors, large customers, likely buy under better terms than the average retailer." I think that is a masterpiece of understatement.

Would you, or could you, give me some idea of how much better those terms are?

Mr. DAN: This particular paragraph refers to an understanding of the gross ratio—the gross markup—of the pharmaceutical industry, especially with regard to larger houses. In short, when they quote a certain percentage, that is the percentage across the board and not necessarily the two per cent, in the sense that 40 per cent of the market is institutional. There you have to submit quotations on a puchase base on tender.

I have no idea what figures they submit. There have been studies made. It is conceivable that there is a substantial difference, and again—

Mr. O'KEEFE: What would you consider substantial?

Mr. DAN: For instance, the wholesale house may buy at $10 per thousand and the government may buy at anywhere between $3 and $5. If a particular product is under patent and there is only one supplier then the government has no choice. They must pay exactly the price that is demanded by the manufacturer, because they have no other supplier to turn to. On the other hand, if there are three suppliers there is very keen competition among the three suppliers to offer the products for sale at a lower price.

Mr. O'KEEFE: You cannot give me any specific figures.

Mr. DAN: Not unless I quote from—

Mr. O'KEEFE: Surely some of your companies supply government institutions?

Mr. DAN: I beg your pardon?

Mr. O'KEEFE: Surely some of your companies sell to government institutions?

Mr. DAN: Not until I have a figure in my hand, an actual written quotation, can I give an exact answer, because I would—

Mr. O'KEEFE: I am not asking you to give an exact answer.

Mr. DAN: But there is a difference, and it depends entirely on the type of product. If the product is such that there is only one supplier, then the price is usually high. If the product is such that the government can go to ten suppliers then the price is usually low and the difference is noticeable.

Mr. O'KEEFE: Would it be four or five or six times as much?

Mr. DAN: I would not say four or five. It might be two or three times less, or four times less. I say less. If the base price at wholesalers' level is $10, the identical product could be conceivably offered to the government at a price of $5.00 or $4.00 per thousand units.

Mr. O'KEEFE: That is very modest.

I think I have very few other questions, Mr. Chairman.

Mr. DAN: Excuse me, for a moment. I am talking about the trade in general. In our instance, where we have lower prices, the difference is quite a bit less. I should make that very clear.

Mr. O'KEEFE: I did not quite understand that, Mr. Dan.

Mr. DAN: When I made the differentiation, I did not refer to our makers. On page 19 I was discussing the pharmaceutical patterns in general and not in specific reference to our own group.

Mr. O'KEEFE: What really applies to everybody applies to your group, and it is obvious that the hospitals and the government institutions in Canada buy drugs at a very small fraction of the price that the consumers in Canada pay.

Mr. DAN: That is correct; and this merely substantiates our point that it is possible to market drugs at a lower price.

Mr. O'KEEFE: But do you do that?

Mr. DAN: We do. Pardon me, I misunderstood you. When we tender our prices is not too much lower; the percentage is very little.

Mr. O'KEEFE: I will not pursue this point, because it is pretty obvious.

On page 8, in the second paragraph, you say: "We believe, as expressed by a former food and drug director, the respected Dr. Morrell, that the attitude of the manufacturer is the most important consideration besides his ability and plant facilities." Would you define attitude in this connotation?

Mr. DAN: Attitude I would define as the co-operation, the willingness, the frame of mind; and when I say willingness, I mean willingness to work out a problem, willingness to understand your particular problems, and a general behaviour pattern.

In this instance I was quoting Dr. Morrel because I felt that he was quite familiar with the drug business and he may have—

Mr. O'KEEFE: You are talking, then, about proper pharmaceutical standards.

Mr. DAN: That would be one of them. If the Food and Drug would get together with us—and they do get together with us—because of problems of a professional nature, with a view of, shall I say, improving our operations, as they constantly do—and which suggestions we greatly appreciate—then we should, shall I say, cheerfully comply with their suggestions and implement them right away.

Mr. O'KEEFE: Are you suggesting that that is not done by everyone?

Mr. DAN: I am not so sure. I think Food and Drug can answer that better.

Mr. O'KEEFE: This is your brief, sir.

Mr. DAN: It should be done. If the house goes out of the way to show the proper attitude to comply with their request, to introduce certain standards, to follow the regulations, to follow the measures, then they do comply and they do carry on the business on the proper level; and our members, the ones who will remain members after September, must be the ones who comply.

Mr. O'KEEFE: They must have the proper attitude.

Mr. DAN: They must have. With regard to who are the ones in Food and Drug who do not have the proper attitude, I think that if you get in touch with Food and Drugs they might name one or two firms which, in their opinion, do not have the proper attitude but it is not for me to name.

Mr. O'KEEFE: I agree. On page 7, in the last paragraph you say: "It appears to us that our plants—and there are not too many—should be visited by a drug inspector more frequently, in order to assure all parties, the government, the trade and ourselves, that we are conducting our pharmaceutical manufacturing in the proper manner." Could you tell me, Mr. Dan, how often those inspectors call now? I do not expect exact figures.

Mr. DAN: Again, it depends on the plant. I would say two or three times a year. Perhaps once a year.

Mr. O'KEEFE: Once a year.

Mr. DAN: I would say probably a minimum of once a year; someone says it might be two or three times a year.

Mr. O'KEEFE: What you are saying now is that a drug inspector goes to those plants only once a year.

Mr. DAN: Again, I cannot answer how often they go, because I am not with the Food and Drug Directorate. All I can say is that in my place the drug inspector has come three times in the last twelve months.

Mr. O'KEEFE: How often do you think they should visit.

Mr. DAN: That depends on the particular firm. Here my suggestion was that if the Food and Drug inspector visited us more frequently to make sure that we were running our affairs correctly—and they do have helpful suggestions, and their suggestions seem to be in the direction of improving the operation over a period of time—this would help us on the one hand to run our operation in the proper fashion and also, on the other hand, assure the public that it is possible to manufacture good quality merchandise.

There are some people who think that there is a fundamental difference between two medicines, and we contend that there is and that there should not be.

Mr. O'KEEFE: One more question, Mr. Chairman, on the detail men. You have those gentlemen in your employ, have you?

Mr. DAN: Yes.

Mr. O'KEEFE: Do you think they are essential to your operation?

Mr. DAN: I think they are. A detail man is essential.

Mr. O'KEEFE: Why?

Mr. DAN: No company today, regardless of what it sells, can have the proper relationship without having contact with the consumer, or the customer, or, in this case, the doctor. You cannot do away with that. There is always personal discussion between the parties and sometimes a two-minute discussion over a cup of coffee can accomplish more than lots of letters. The question is can you make your operation more efficient. They do have need for field representation.

Mr. O'KEEFE: I understand.

The CHAIRMAN: Dr. Rynard, I have your name from this afternoon.

Mr. RYNARD: Mr. Chairman, some of the questions I was going to ask have been answered, but I was rather intrigued by Mr. Dan's reference to the government helping, and I did not get the point he was trying to make there. In what way should we as a government help the pharmaceutical business?

Mr. DAN: This can be answered in this fashion: Firstly, by creating a climate and environment which favour our growth. I have listed 11 points which, in our judgment, should help in favouring our growth. Secondly, by—

Mr. RYNARD: Just give us this very briefly, in our own language. I do not want to take up the time of the Committee.

Mr. DAN: By helping to become reorganized.

Mr. RYNARD: By putting money into organizing your firm.

Mr. DAN: Not necessarily in that fashion. How you reorganize a sector of an industry is a complex problem which I do not feel that at this moment I am qualified to discuss, but it did happen in the past that various segments of the industry at large have been reorganized through co-operation.

What the answer will be today, I do not know. In six months we will probably all know it. Probably the Department of Industry would be the proper arm of the government to look into this matter, but something has to be done.

Mr. RYNARD: You mean by incentives, or in some form like that, or by tax-free concessions, or what?

Mr. DAN: Perhaps that is the answer. What we will have to do is to put our heads together and come up with ideas and look at the various projects which we consider sound, and the project which we feel is the soundest is probably the one which should be implemented. Something has to be done.

Mr. RYNARD: You feel that the Canadian pharmaceutical industry should go to the Department of Industry?

Mr. DAN: I think so; and I think so because at this point we are at that level of our existence that if we do not then we are going to disappear completely.

I believe and our organization believes, and probably many of us believe, that it is not in the interest of the country that in the field of health we should be completely out of the picture. We have got to have some say, although we realize that we will never be the major force in the pharmaceutical industry.

Mr. RYNARD: It was intriguing to me, if I did not misunderstand you, to hear you say that lowering your prices would increase the amount of drugs that you sold.

Mr. DAN: Yes, it would.

Mr. RYNARD: I would like to know how you arrive at that; because surely at any given time there is a certain saturation point in drugs. How are you going to increase the market by lowering the price? Are you not going just to increase your difficulties in that you are getting a lower sales dollar and you are increasing the difficulties of your business?

Mr. DAN: I can show you, if I am permitted, a very interesting chart.

Mr. RYNARD: You might do it with candy, but you are going to have an awful job convincing me that you could do it with drugs.

Mr. DAN: I have been glancing over the public statements of various companies, and what has impressed me most is the tremendous growth in the pharmaceutical volume during the last ten years. This curve shows that in the last ten years the entire output did not increase by 5 per cent per year but increased by 300 per cent. It is our judgment, right or wrong,—

Mr. RYNARD: Is that the total industry?

Mr. DAN: The total industry, yes. This is the picture, the volume—With the coming of pharmacare, or, shall I say, the prepaid prescription, it is our judgment, rightly or wrongly, that there will be an upsurge in the medications consumed. Our population is increasing and the rate will be quite noticeable.

Mr. RYNARD: Is this in over-the-counter sales?

Mr. DAN: At this moment, I understand we are discussing the pharmaceuticals—

Mr. RYNARD: You are speaking about increasing drug sales.

Mr. DAN: The entire market will—

Mr. RYNARD: Is this great increase you have talked about in over-the-counter sales, or is it by prescription?

Mr. DAN: I would say both, but primarily prescriptions. They will increase, and, God willing, if we are here in five or ten years—

Mr. RYNARD: I do not know how you could get the doctors to do that.

Mr. DAN: Well, more people.

Mr. RYNARD: Oh, you have just got your population increase; and that is not the figure you quote there, because you have quoted a 150 per cent increase.

Mr. DAN: Three hundred; more people, more medicine.

Mr. RYNARD: Yes, but you have not got that increase. You have only got about a half a million or less than half a million, a year.

Mr. DAN: Rightly or wrongly, it is our judgment that the pharmaceutical market is in a very strongly expanding phase, looking five or ten years ahead.

Mr. RYNARD: You may be right, but you are going to have a hard time convincing doctors that by doing that you will increase your sales very much. It does not seem possible to me.

Mr. DAN: Probably from your viewpoint. I do not envision that you can double our patients, because there are only so many patients that you can handle. But the number of patients will increase, the number of doctors will increase; doctors may write prescription medicines more readily. It is our judgment, rightly or wrongly, that the market is in a very strong expanding phase, and, shall I say, as businessmen we feel it. It is in the air. We may be incorrect, but we feel we are right.

Mr. RYNARD: This might be possible. There is another thing that you said about the Food and Drug people calling on you more often. This would be just to see whether you have a clean house or not, that they inspect you would it not?

• (9.00 p.m.)

Mr. DAN: How often they call or what makes them to call on a certain house, I cannot answer because I am not with Food and Drug.

In our brief we proposed that they should call on us more frequently, so that we do have a clean house, so that we do have proper standards and that any one of us who is not running our affairs properly should be told so. With the co-operation of the various departments your Committee, on the one hand, the food and drug on the other, and the various departments of government I can envision that we are going to go into a sizeable industry in Canadian content, yet the other side will also exist. But we do not want to be suppressed, and if we do something we shall be suppressed.

Mr. RYNARD: I would not suggest that we want suppression at all, we want you to grow but how often do you have an independent assay.

Mr. DAN: Every time.

Mr. RYNARD: By an independent—

Mr. DAN: Yes; Every single time.

Mr. RYNARD: By an independent canvass?

Mr. DAN: Yes.

Mr. RYNARD: Outside your own?

Mr. DAN: That is right.

Mr. RYNARD: For every batch of drugs?

Mr. DAN: For every batch of drugs, and we even go a step further, but again I should not speak on my behalf because I speak for the association. Let me rephrase that the members of our association never release any medicine to my knowledge without having assayed a particular batch, and this is part of the over-all quality control. Because if they do, they do not do proper standards.

Mr. RYNARD: That is not done in your own dispensary then, or your own plant?

Mr. DAN: I beg your pardon?

Mr. RYNARD: That is not done in your own factory, that is by an independent man?

Mr. DAN: By an independent.

Mr. RYNARD: I see.

Mr. DAN: Mind you, I should point out that some companies may have their own quality control laboratory in the premises and they are perfectly entitled to use their own quality control, and double check it by others, if they so desire.

Mr. RYNARD: Do you use the same firm all the time?

Mr. DAN: No. We use two or three. Usually we use two or three firms, and you feel that they are capable.

Mr. RYNARD: Do you use any more than one assay on any batch of drugs?

Mr. DAN: I would say about two to three per batch.

Mr. RYNARD: Per batch.

Mr. DAN: Yes. It is essential.

Mr. RYNARD: When a pharmaceutical house loses its licence, can it still go on and sell to provincial governments?

Mr. DAN: I should point out that in Canada we do not have licence to be a pharmaceutical manufacturer, therefore, what I think you are likely referring to is a licence to sell to governments. It is not something that a manufacturer must have because my understanding is there are a number of large companies who, for one reason or another do not have the licence, because they just do not care to have any, but they still may operate.

Mr. RYNARD: But they could be expelled from your association and go on and sell to government.

Mr. DAN: Oh, absolutely. It is not up to me to decide. If he loses the licence then the government does not buy. It does not mean that he has to get out of business. Today the law is such that anybody can become a manufacturer if he so desires. Of course, the food and drug does step in, if a person does not run his operation properly and I just was told a few minutes ago that some firms at the present time are being prosecuted. These firms will be off the list.

Mr. RYNARD: Do you suppose that firm could sell to the government?

Mr. DAN: I do not believe he can. I am not the government to answer.

Mr. ENNS: Towards the end of your oral submission, Mr. Dan, you spoke of one of the reasons for the high cost of the manufacture of drugs was the seeming lack of competition amongst the major houses, and that in fact the present patent laws were protecting a high price level. Do I take it that you are not in favour of patents per se, or am I assuming wrongly?

Mr. DAN: If I may go over again one of the important points I made that we are in favour of patent laws because we feel that an inventor should be rewarded for his invention, but the fundamental impression is how many times should he amortize his research expenditures because we are of the opinion that he amortizes it more than once. We are in favour of giving him a haven for a period of three or four years during which time he recovers his investment and what is equally important, he gets a foot hold in the market. It is very

important. Beyond that point of three or five years his licence should expire or alternatively cost licensing or compulsory licensing should be made available.

Mr. ENNS: You spoke of the possibility that some of your companies would eventually go into independent research themselves. Am I correct in that?

Mr. DAN: We envisioned it.

Mr. ENNS: You envisioned it. And this is conditional on a certain sales volume before you can accommodate—

Mr. DAN: You have to have a certain volume before you can open up a research department.

Mr. ENNS: It ties in with my question on patents, and I am wondering whether you think it possible to isolate the cost of the development of the cost of a drug and charge it to the promotion of that drug when you are going to have to carry a research staff continuously. You cannot just pay them once they get off the drug—

Mr. DAN: Theoretically, and accountingwise it should be that if it costs say X million dollars to develop a product after the research cost has been recovered almost fully the price of the product would drop, but it does not happen. Not only until competition sets in or the market is open, not until that point, does the price come down. I feel that by offering a shorter period of shall I use the word perfection, shall I use the word haven, the large manufacturer can carry out the operation; they can develop new products; they are still going to remain the industrial leaders; yet the public will benefit on the one hand and the products will be more reasonably priced.

Mr. ENNS: I agree with the logic of your argument, and it appeals to me that there should be a quicker way of reducing the cost of a new drug, and yet, as I think back, probably in the last five or may be ten years, there has been a fantastic development of the wonder drugs, so to speak, the antibiotics and so forth, that have been produced and maybe the system of patent protection has been part of the stimulation for this kind of research.

Mr. DAN: No.

Mr. ENNS: There is a reward, as you call it, for innovation, for invention, for development, for research. Perhaps it has retained the high cost of this wonder drug or this marvellous product, but at the same time it seems to be producing more and more of these products. Now, I am in a quarrel within my own mind, whether or not we should say this would be cheaper. On the other hand, if it produces more things that minister to human ills, then maybe this price is not too high to pay. I am just asking your opinion as to how you think—

Mr. DAN: At this point now we have enough evidence, based on reports of the royal commission, based on independent observations by many learned people in different countries, that the patents seem to be more on the unfavourable side, from the public viewpoint, than on the favourable side. Patents should be retained only for a certain period of time. Patents should expire either very quickly, or the medication should be made available to the public, and they will not have to decrease research at all because studies have shown, and this book deals with it, that in countries where there have been no patents pharmaceutical research did take place. You see research has to be done in order to be an industrial leader. If you do research, if you have original ideas, if

you have original products, you must be a leader. By their size, by their marketing impact they will always maintain their position. They will always be ten miles ahead of us. And we can catch up only if we have the same type of research. We firmly believe that the patent laws should be changed and I might add in passing, that this has happened in almost every country. In the Philippines, for example, a protection is offered for a period of three years for any new product and beyond that time protection is offered only if the particular substance is manufactured in that country, but if it is not manufactured, it is open.

Perhaps Dr. Wright may have some of his own observations, I think he knows a little more about research than I do. I am only looking as it from the administrative viewpoint.

Mr. ENNS: No; I am satisfied with the answer.

Mr. HOWE (*Hamilton South*): May I interject a question here? Do you then start to manufacture after the patent rights run out or do you buy the patent rights from the originator of the product.

Mr. DAN: Possibly we would manufacture.

Mr. WRIGHT: I would like to answer that question. We would like to buy the patent rights from the companies if they would let us do so.

Mr. HOWE (*Hamilton South*): In other words, you start to manufacture after their patent rights run out.

Mr. WRIGHT: We would not. Well, it depends on the patent, whether it is a good patent or not. But in other businesses, in other industries in which patents operate, licensing, cross-licensing, is quite a common practice. It so happens that there is very little of that, at least freely disposed, in this business. So the answer to your question is certainly we would be much more amenable to patents if we found that these patents were reasonably manipulated.

Mr. HOWE (*Hamilton South*): When these patents run out, or whenever you do start to manufacture, from where do you buy your raw key chemicals?

Mr. DAN: We could buy from a number of sources. We could buy from the original inventor; we could buy from a suitable house who offers the material—

Mr. HOWE (*Hamilton South*): You are not committed to buying from one place? You do not have to pay a balloon price to a parent company? You are free to buy these chemicals?

Mr. DAN: We would be committed only—

Mr. HOWE (*Hamilton South*): To buy these chemicals anywhere you can get them.

Mr. WRIGHT: There is another aspect to this, that should be mentioned. Too many people do not realize the nature of our Canadian law in respect of drug patents. I have no doubt that the legislators wrote that law out of consideration for the Canadian public. This law with respect to a chemical that is used for a drug says that "this material is patentable as a food or medicine only according to the process that is specified by the patent company," and so if another process can be found—

Mr. HOWE (*Hamilton South*): Excuse me, to manufacture it or to make a manufactured product out of it.

Mr. WRIGHT:—to manufacture; it has to do with material, which is the only thing that one can patent. So that according to our Canadian law, a patent may exist. We may be manufacturing the dosage form because it is made by a process that is not covered by the patent.

Mr. HOWE (*Hamilton South*): In other words, manufactured in a different manner.

Mr. WRIGHT: That is correct.

Mr. HOWE (*Hamilton South*): Which circumvents patent rights.

Mr. WRIGHT: And all too often when patent litigation is occurring the public does not realize that this is in issue rather than a mere pirating of process.

Mr. HOWE (*Hamilton South*): There are some instances where this raw key chemical is specifically bought and manufactured with the permission of the originator or discoverer of this particular drug, and manufactured under a different name by buying this patent right.

Mr. MACKASEY: On a point of order. We agreed that at the beginning of the Committee, and I do not mean this for Dr. Howe, I mean this in all fairness to the witness, to discuss patents in the fall. Now, I have got 85 questions I would like to discuss on patents. We are just wasting the witness' time. This is the point. The witness has not been made aware of this. If we are going to discuss patents tonight I would like to feel free to discuss patents. I point out, that we made this decision, now I would just like you to rule on it one way or the other.

The CHAIRMAN: Well—

Mr. HOWE (*Hamilton South*): Well, before you rule on it, is this not a key point in the generic manufacturers' acquisition of the drugs at this point. That is the only reason I brought it up. I was not going to go any further than this. Is this not an issue in this particular point that maybe in part explains the reduced prices at which they can manufacture the same drug.

The CHAIRMAN: Well, you are really both right. When the P.M.A.C., if that is the proper initials, were before us we decided, because of the limited time we had, that we would discuss the patents in the fall. Now, this was not really decided on today. I just say that the brief that Dr. Wright submitted is not going to be discussed today. That was on research, and again this is all tied up with patents. I was hoping, Mr. Mackasey, that this would not come up to any extent in the examination tonight, with the understanding that this will again come up in the fall and if necessary we will have this group back before us again.

Mr. MACKASEY: I was only trying to be fair to Dr. Wright who did not know. My reference was not to Dr. Howe.

Mr. HOWE (*Hamilton South*): It would be unfair—

Mr. MACKASEY: It was Dr. Wright who was making the statements.

Mr. HOWE (*Hamilton South*): I am all through, Mr. Chairman.

Mr. HYMMEN: Mr. Dan, you have mentioned several times that your organization is in the formative stage. Have any of the firms in your group belonged to the P.M.A.C.; I think that is the title? Pharmaceutical Manufacturers Association.

Mr. DAN: Not to my knowledge. No. They do not belong to the P.M.A.C.

Mr. HYMMEN: They have not at any time.

Mr. DAN: Not to my knowledge, unless we had a member in Montreal, Nordic Biochemicals. They belong to the P.M.A.C. I am not sure; I do not believe they were recent members of P.M.A.C.

Mr. HYMMEN: In your brief, you seem to ridicule or minimize the importance of the cost angle of research which the other group mentioned. I believe, they quoted a figure of 7 per cent at the manufacturer level. That would be considerably less at the prescription level. When you compare this with other types of industrial firms do you have any information as to the research and development costs which other manufacturing firms allow in their cost analysis?

Mr. DAN: Perhaps Dr. Wright would like to answer.

Mr. WRIGHT: If you are referring to other chemical industries, it is roughly the same.

Mr. HYMMEN: That is what I say, you mention the television industry, but we are not analysing the television industry or any other industry except the drug industry. They put a figure in, or they explain in part their breakdown of their costs, and it is 7 per cent. In the brief you discount that, although it is still a cost. Now, another thing, following Mr. O'Keefe's question, in your group or the industry as a whole, what is the percentage of gross sales to hospitals and governments?

Mr. DAN: I do not have any statistics on hand today. I would hazard a guess, and this is merely a guess, it could be as high as 20 to 25 per cent.

Mr. HYMMEN: Twenty-five per cent.

Mr. DAN: It could be as high as—it could be less, I would have to get statistics.

Mr. HYMMEN: You would suggest then that the large reduction in cost which you mentioned would have to be counterbalanced somewhere, would it not? Am I putting words in your mouth? Mr. O'Keefe was trying to get some information from you as far as your own firm was concerned.

Mr. DAN: I do not know in our group what percentage goes to hospitals because we have no statistics available. I know what is happening to the industry at large because we have figures available. That is why I am guessing, and if I guess, I may be right, I may be wrong, so I had better not guess, I had better get the information.

Mr. HYMMEN: Mr. O'Keefe failed to get the information.

Mr. DAN: Because I do not know the figure.

Mr. HYMMEN: Fine.

Mr. DAN: I would take an educated guess that it could be from ten to twenty per cent.

Mr. HYMMEN: Now another question. I hate to suggest this one in the presence of so many learned colleagues in the medical profession. Assuming that the doctors are busy people and they get to use a certain brand of drugs, and they certainly have not the time to investigate other generic named drugs, or non-branded drugs, in your opinion, and this was mentioned in the P.M.A.C.

brief that some central agency could correlate and supply information, do you think that if this type of arrangement were made that the doctor could readily ascertain the information? In other words, is the doctor in his busy life, using branded drugs which he knows gives results, maintaining the high cost of prescriptions?

Mr. DAN: I would say so. At the present time they know the items. They are people of habit. Just because they are very busy does not mean one more reason. If they are educated right from university, and this is precisely what the royal commission of health recommends, that they should be made more price conscious, they would look for this type of medication; besides they find they would have these medications in the compendium. They would be made aware that they exist. Now what they prescribe is up to them, but they should be made aware, and I think that there is an awareness growing among them, that it is possible to write medicines which have a lower cost factor, yet they are equally effective.

Mr. HYMMEN: Another question. And with all respect to Mr. Mackasey, I am not going to involve you in the patent law or anything else; but in your brief you mention the reduction from 17 years to 3 or 5 years on patents. Now, one of the suggestions that has been made repeatedly is that the high cost of drugs is due to the low volume. If you reduce your patents, and allow free competition, in other words you have many, many more people making the same type of drugs, are you not defeating your purpose?

Mr. DAN: I question the comment "low volume". I would say that most firms derive as much as 60 to 80 per cent of their sales based on five or ten best sellers. Therefore, low volume is not a factor.

Mr. HYMMEN: What would be your estimation, in your own manufacturing of your break even point on a run of a particular drug?

Mr. DAN: Approximately a minimum of 50,000 to 100,000 tablets per batch. What does a low run mean. It means that you run that batch once a year or twice a year and during that period of time, that batch is sitting on the shelf. A batch run might be millions or a million every month, or every week. I feel that the run itself is not the—

Mr. HYMMEN: You would say that if that run were increased to ten of fifty thousand, you would not reduce the cost by that much.

Mr. DAN: Possibly a reduction in the cost for medicine but the volume of fifty thousand per year would not be significant but I do not think it is a significant item dollarwise. We are interested in the items where you sell millions a day or millions a week.

Mr. HYMMEN: I have one final question and this has to do with the raw material chemicals which, in this table you supplied, you suggest are mostly foreign.

Mr. DAN: That is correct.

Mr. HYMMEN: Now, in your estimation, would a reduction in the cost of drugs be affected to any great extent by some change in the tariff structure.

Mr. DAN: Possibly it could. What puzzles us to a great extent is this anomaly that one of our members may purchase from a well established pharmaceutical dealer, a particular raw material and the identical raw material

would also be purchased by, shall I say, one of the larger companies; the raw material comes from identical source. We know exactly where it is coming from because this medicine has been on the market for some time. They pay the same price, or with very little difference, allowing for quantity purchases, and yet you find a great deal of difference in the price of our product compared to theirs, and yet for one reason or other our product is not good and theirs is. That is an anomaly and I am afraid we cannot accept this, because we maintain that both are equally good products. There is a price difference for obvious reasons.

Mr. MACKASEY: Turn to page 19, please. Mr. Chairman, on the discount structure achieved by the manufacturer $4.50 plus 50 cents sales tax, he received $5.00 and he gives 50 cents to the government sales tax, and he has $4.50. I think that is straightforward and I appreciate it more in this brief than I did in the other brief we had. The relationship, $4.50 plus 50 cents sales tax to the retail price is half. Am I right, sir?

Mr. DAN: Yes.

Mr. MACKASEY: Fine, Then, is this indicative of the structure of the pharmaceutical distribution pattern in Canada of your association. I mean, you use this as an example, because I presume this is the problem in your industry.

Mr. DAN: I would say yes.

Mr. MACKASEY: Like Mr. O'Keefe I have a particular question I would like to ask both witnesses. I think that you make it very clear that the sales tax is precisely ten per cent of the retail price.

Mr. DAN: To be more correct, it may work out at a little lower price than ten per cent.

Mr. MACKASEY: Would it be over nine?

Mr. DAN: Perhaps based on the sales volume, nine. Of course, there are exemptions they give to hospitals.

Mr. MACKASEY: But the guy that goes to the corner pays ten per cent of the retail dollar according to your figures.

Mr. DAN: Pretty close, between nine and ten.

Mr. MACKASEY: Presuming the structure is maintained, of course, and the structure I am taking about is the druggist buys for $6.00 after going from the manufacturer, paying sales tax the wholesaler, he gets it $10.00 less 40 per cent, $6.00, right.

Mr. DAN: Yes.

Mr. MACKASEY: All right, and the relationship between retail price and manufacturers price plus tax is just double.

Mr. DAN: The tax remains at the earlier level because—

Mr. MACKASEY: Well, the tax is incidental now. It costs him $5. I have a price list here from one of your firms again, where the wholesaler's cost, if you look on your No. 16, is $3.00. You stay on 19. This one I have is confidential. The suggested price to the public is $8.00.

Mr. DAN: I am sorry, I do not have that.

Mr. MACKASEY: Well, this would go from one of your member companies to the druggist. You send him a catalogue and you say the suggested price to the public $8.00.

Mr. DAN: Right.

Mr. MACKASEY: You go back to table 19. The manufacturer's cost incuding sales tax would therefore, be $4.

Mr. DAN: Not necessarily that. The suggested price may not have a great deal to do with it.

Mr. MACKASEY: Well, why have you got it in your table?

Mr. DAN: It is a guideline. I think the trend today is away from suggested prices.

Mr. MACKASEY: Let us use your guideline; retail price $10.00, cost to the manufacturer $5.00.

Mr. DAN: Yes.

Mr. MACKASEY: Here is a price, $8.00 suggested retail. Cost to the manufacturer $2.70. Suggested price to the public $13.00, manufacturers cost $5.10.

Mr. DAN: I have to look at the particular table.

Mr. MACKASEY: Well, I am looking at one, and I am looking at your structure. The point I am getting at, these are the prices that a druggist tomorrow can buy from one of your member firms. He can buy chloramphenicol, retail to the public at the suggested price of $8.00 for 100 capsules. He pays $3.00.

Mr. DAN: In this instance, the retail price—

Mr. MACKASEY: Well, I can give you 25 items.

Mr. DAN: This does not necessarily have a bearing. What is important at this point is the cost, what the pharmacist pays for it and the pharmacist invariably has his own dispensing fee.

Mr. MACKASEY: That is his own man and he should.

Mr. DAN: I doubt very much that a pharmacist would charge $8.00. That is my point.

Mr. MACKASEY: You use it yourself because you go to the pharmacist and say this suggested retail level of $10.00 plus 40 percent. You pay $6.00.

Mr. DAN: In that instance—

Mr. MACKASEY: Well, in the instance in your brief on page 19, which I presume is a composite of the pricing practices of your company's because otherwise you would not insult us by putting it in.

Mr. DAN: For instance, the pharmaceutical distribution pattern in Canada is not necessarily ours.

Mr. MACKASEY: Why are you interested in somebody else's? What is your practice? You are the people that are here, what is yours?

Mr. DAN: If we sell to the wholesaler we probably would sell list price less 40 per cent, exactly what you have got here.

Mr. MACKASEY: So let us stick with this and consider you. Retail price of $10 less 40 percent, $6. If you followed that pattern here, the suggested price to the public would be a lot less than $8.

● (9.30 p.m.)

Mr. DAN: As you pointed out, the suggested price to the public does not have any practical significance.

Mr. MACKASEY: But it is still the basis for your pricing set-up.

Mr. DAN: I would say the basis is more the cost than the suggested price.

Mr. MACKASEY: Very well. I made my point. The point I am getting at is the spread in the generic prices I received, percentage-wise, is as great as it is in the group that appeared last week. I keep using the word group because I forget precisely what they call themselves.

Mr. DAN: I beg to differ here because the price today, if you watch the trend, is more dictated on cost rather than the suggested list price. The suggested list price is not the actual price at which the pharmacists are selling—

Mr. MACKASEY: Well, let us put it another way. Between the manufactured cost and the cost to the druggist, from your table and I compared it with their table, it is about the same. Now, because we are short of time, I would like to address a few questions to Dr. Wright.

Dr. Wright, one of the areas of contention in the old brief, you will recall that last week, is this mysterious 30 per cent for promotion costs. You have established today, pretty well, or at least one of your points, that you under sell these people because promotion costs are lower than the direct mail prices, et cetera. Last year Mr. Winters was here and I am only continuing, not a feud, but a discussion that ran out by the clock. Would you say that advertising in the *Vademecum* falls under promotional costs?

Mr. WRIGHT: It enters into our promotional costs.

Mr. MACKASEY: This is the point we discussed, Mr. Winter and I, whom I respect to have the courage of his convictions. He mentioned he was in business not to make profit—it is on record—but because of humanitarian purposes, which I did not quite grasp. However, I would like to refer, for instance, to what we had discussed the last time. In this book, Empire Laboratories produce,—you can help me, perhaps, on the generic name, I am going to try it, it is chloramphenicol, that is a generic term. Therefore, normally the druggist or the doctor who trusts your product, your production of this, could ask for it in generic terms and the patients would receive the benefit. This is the way it should be. Further in the book Parke, Davis produce the same thing is under their fancy name of chloromycetin.

Mr. WRIGHT: All the doctors know it.

Mr. MACKASEY: So, a young doctor who depends on this book for information about the drug, turns to the generics. The amount of space you have allocated to the description of this drug is 3½ inches. The amount of space that Parke, Davis has allocated for the description of the same product is 21½ inches. Now, allowing for a better re-writer and cutting out the fancy phrases, try to reconcile why you would devote 3½ inches and Parke, Davis 21½ inches.

Mr. WRIGHT: I agree with that; 3 inches costs us $21.

Mr. MACKASEY: Never mind. Do not force me to put Mr. Winter's answer on the record. There are two significant chapters or paragraphs left out of yours which are not left out out of Parke, Davis, one is marked "warning" and the oher is marked "side effects". Right? Now, why and how can you justify this? I checked with the people who put out—

Mr. WRIGHT: You do not want an answer yet?

Mr. MACKASEY: No, because it is going to take a detailed answer—I sense it. I checked the cost of the book. A column 8 inches, $275; this is obviously private industry. A page, 16 inches, $550. You have saved 18 inches by eliminating the warnings and the side effects to which, I presume, a doctor is supposed to have access, which works out, as far as I am concerned, to a saving of about $600. How do you justify leaving out the paragraph entitled "warning" and the paragraph entitled "side effects"?

Mr. WRIGHT: I leave it out for this reason, and this applies especially to this contraversial drug, that if I would put in the customary warnings, then I would have something of questionable reliability. I do not think it is a good policy to do this with a drug unless you are sure, and we are not that sure about chloramphenicol.

Mr. MACKASEY: Could I interrupt you for a moment. I know you doctors want to get into this but I have been waiting for a year. Some of these warnings may be inaccurate, in other words. They may, if a doctor reads them and takes them at face value, prevent him from administering that particular drug to a particular patient whose description fits the warning. But you are saying that if you leave it out entirely, he can give it indiscriminately to anybody who he thinks needs this drug. In the first case, he may be preventing somebody who should have it from getting it, but I suggest that your solution could lead to a fatality.

Mr. WRIGHT: My response to that is that I have much more respect for the medical profession than you seem to have. I do not consider this man to be a clod. In fact, I am sure he ought, according to his profession, know more about it than I do.

Mr. MACKASEY: In other words, you stick to the point that the warning and the side effects should not be included in this very massive document; but it lists a fairly new drug and a very new doctor who depends on this book for all the recommendations and for all the information, should know who should or should not have it? Is this what you are saying?

Mr. WRIGHT: I think he should look first. I have put some contra-indications into the latest *Vademecum* on this drug but with very much soul searching, because I cannot say enough and not spend more money than I should with respect to the price of the drug.

Mr. MACKASEY: I am not questioning your financing; I am just pointing out that Parke, Davis spend on its drug, at least, to include warnings and side effects, $550 more than does Empire. This comes under promotion. These are one of the vagaries that we are trying to establish. What is promotion? Is it all gimmicks, or is some of it spent sensibly? As a layman I would have a lot more confidence in a doctor who could read or who has access to the warnings and the side effects as outlined in this book, than one who referred to a book that does not have these.

When Mr. Winter was here, and he was a very honest and forthright man, he said just what you said that a doctor should know it or let him look up Parke, Davis' warning and Parke, Davis' side effects.

Mr. WRIGHT: Of course, there are other places to look it up and the people whom I call salesmen and other people call detail men, can go around and if the doctor asks this, we will send him literature, references about this which cover the subject in all respects rather than two or three words.

Mr. MACKASEY: You have introduced my next point. The detail man, if he is responsible, and if a doctors asks him, will go back and get the literature and arrange for the settlement. In other words, do you agree that literature or other sources of information are needed?

Mr. WRIGHT: Most of us should.

Mr. MACKASEY: From the source of the drug supplier; whether it is by generic or brand name, somebody has to supply him with literature.

Mr. WRIGHT: That is quite so.

Mr. MACKASEY: Supposing it is an emergency and he has to make a snap decision. Let us say, a pædiatrician who has a youngster there and goes to this particular book; he has confidence in the generic firm; he looks up the generic page, as I might call it, excuse the expression; he reads what it is recommended for, et cetera, but because there is no warning and no side effects listed he presumes that this thing is safe to all children of three years of age, indiscriminately, and something happens.

Mr. WRIGHT: A baby dies and my faith in the medical profession. . . .

Mr. DAN: If I may interrupt you for a moment, Mr. Mackasey. I do not share Dr. Wright's view and I do not think it is fair to question him on something he did not do because it was done by the late Mr. Winter who is not here. I would say that if we would put in our products, we would put in the side effects, we would put in the contra-indications—

Mr. MACKASEY: Excuse me, when you say "we" who are "we"?

Mr. DAN: I would say the members of our association.

Mr. MACKASEY: Is Empire a member of your association?

Mr. DAN: When the book was printed, they were not.

Mr. MACKASEY: This is the 1966 edition.

Mr. DAN: That book was printed considerably before our association was formed. This is one of the very reasons—

Mr. MACKASEY: What is the deadline for the production of this book?

Mr. DAN: It has been on the market for several months. By September we shall have a code of ethics and I would like to make it very clear and dispel all misunderstanding. In September this very point will be brought out and I personally believe as a pharmacist, and I consider myself a pharmacist—

Mr. MACKASEY: In this code of ethics will you insist that they include it?

Mr. DAN: It must be included whenever we have a reason and firm enough ground to include other side effects or warnings.

Mr. MACKASEY: The point is, you will include it?

Mr. DAN: Absolutely.

Mr. MACKASEY: Therefore, up to now your own private conclusion, and I appreciate your honest answer, is to leave it out is unethical?

Mr. DAN: What happened in the past—

Mr. MACKASEY: No, no. Do not evade the question.

Mr. DAN: I would say yes.

Mr. MACKASEY: That is fine. I appreciate your saying so.

Mr. DAN: I would definitely say so and this is the very thing which we are going to eliminate.

Mr. MACKASEY: How big is Empire? According to your brief you are the one firm that sells over $1 million, and yet you cut corners in a book, doing, according to your own spokesman, an unethical practice to save so much lineage at so much an inch?

Mr. WRIGHT: Mr. Dan prefaced this by saying that he and I had a slight difference of opinion on this.

Mr. MACKASEY: I see. In other words, you have a difference of opinion and say: "I am sorry, I do not know who is right or wrong. It is up to the doctors?"

Mr. WRIGHT: Right. I have to mention to you that although it is not here, it is on the reference card, where it has the contra-indications, that the doctor has in his hand.

Mr. MACKASEY: From where did you get your reference cards, from Empire?

Mr. WRIGHT: Yes.

Mr. MACKASEY: Is it just sent out as a piece of direct mail?

Mr. WRIGHT: Oftentimes or as delivered by the salesman.

Mr. MACKASEY: In other words, you do have direct mail? Sometimes you mail it and sometimes you deliver it by—I think you slipped—you called it salesman but you meant the detail man?

Mr. WRIGHT: I called it salesman.

Mr. MACKASEY: Fine. You are quite honest about it, then. In other words, you do have direct mail? You have detail men or salesmen? You do have literature for which the doctor can ask?

Mr. WRIGHT: That is true.

Mr. MACKASEY: You do advertise or describe your product in these books or similar reference books? Where do your promotional activities differ from Smith, Kline and French, Horner or Ayerst or any of the other ones? What is your gimmick?

Mr. WRIGHT: Only in the matter of degree.

Mr. MACKASEY: I see.

Mr. DAN: I should go on record as saying that when we draw up our forms this is one of the very important aspects that I, as pharmacist, would very definitely demand to have included. The members of our association will have to adopt it once a compendium of some stature will be formed. At the present time we have several books; we have a compendium by Dean Hughes; we have the P.G. Book which is a guide yet into which book are you putting it. Maybe you will put it in another book but once it is an official book, it has to be included.

Mr. MACKASEY: I would just like to conclude with a statement, Mr. Chairman, because I know there must be other questions. I do not want you to get the impression that I am against generic firms; I think there is room in Canada for generic firms. I think that if you meet the standards you are going to set you are going to force the other, so-called, big people, to be a little more competitive and a little sharper in the pricing, et cetera. I think there is room for generics; do not get me wrong.

Mr. DAN: I think you have the gist of my entire presentation.

Mr. MACKASEY: Yes, that is all right, although I did not quite appreciate your appeal to Canadianism because I am an internationalist in thinking.

Mr. DAN: So am I.

Mr. MACKASEY: Yes. You have a lot of good references in there to Walter Gordon's book which does not cut a lot of ice with committees. I mean I would have hoped that your presentation would have been on sounder ground.

Mr. DAN: With all due respect the issue is a point of balance, and that depends entirely on the industry—

Mr. WRIGHT: Mr. Chairman, may I point out to Mr. Mackasey one aspect of the *Vademecum* about which he was talking. If he will look at most firms that list or advertise here, he will see that they have additional products, including Empire. If you will look at those additional products I think you will find that contra-indications are not included. Do you think it is safe, then, to have additional products in the *Vademecum*?

Mr. MACKASEY: I will ask the doctors to answer you because I am not going to evade it but the doctors' opinions—

Mr. DAN: In support of the point you tried to make. *Vademecum* is not considered today as the bible of the doctors, unless I am mistaken. If and when a compendium is prepared which, I understand, is in the process, it has to be done properly.

Mr. MACKASEY: May I ask one supplementary question. Do you approve of the licensing of all the drug companies?

Mr. DAN: This has been discussed, if I remember correctly, since I read practically all the hearings before, and the views expressed by the food and drug directorate and also accepted by some of your members—perhaps the word registration might be better than licensing.

Mr. MACKASEY: You are very consistent in the industry. That is what the big boys suggested; there is a subtle difference between licensing and registering.

Mr. DAN: When you say licensing I refer to licensing, to be in business, referring not to patents on which we all agreed.

Mr. MACKASEY: No. I am referring to licensing and registering. We went all through that exercise.

The CHAIRMAN: The government is doing to do neither; they are doing nullification.

Mr. MACKASEY: They had better start doing something.

Mr. BRAND: Mr. Chairman, I had a lot of questions but I must confess I am somewhat speechless at some of the things I have heard in the last few minutes. I speak as one who has a name that is not only a brand name but a generic name as well. I would like to ask Dr. Wright, if I may, if he thinks money is more important that safety?

Mr. WRIGHT: No.

Mr. BRAND: Do you agree with the recommendations of the Hilliard report?

Mr. WRIGHT: No.

Mr. BRAND: With what specific recommendations do you not agree?

Mr. WRIGHT: I do not agree that because a drug happens to come from some place besides the United States, it should be considered as a questionable product.

Mr. BRAND: Is this in the Hilliard report?

Mr. WRIGHT: This is my interpretation of one of the recommendations.

Mr. BRAND: You are reading between the lines, are you? May I read a statement from the report into the record here and see if you agree with it, sir? They are talking about safeguards in drugs and so forth and what the responsibilities of the manufacturers should be. It is on page 2 of the brief.

You must also know—

Referring to the manufacturer.

—what is to be done when side effects occur or when an overdose has been taken. Therefore, any company manufacturing such a drug should always be able to provide complete informational material about the product to the medical and paramedical profession, maintain a complete up to date file on the properties of and clinical experience obtained with this drug and be able to supply the necessary information very rapidly—

I will underline that, myself.

—to any physician who needs it. This should be available in a matter of hours.

This goes on to the recommendations under (b) of the same page:

The responsibility of the marketing company to be completely familiar—

These are one of the main responsibilities.

—with all the uses, effects and side effects of such a drug and to make the information immediately available at all times to the prescribing physician who may require it.

Do you agree with these statements?

Mr. WRIGHT: I endorse that statement completely.

Mr. BRAND: And yet, what you said before is not strictly the same thing. You talk about the *Vademecum* in terms which seem to me to be somewhat, not to praise it, shall we say.

Mr. WRIGHT: I take it for what it is.

Mr. BRAND: What is it?

Mr. WRIGHT: It is a trade name reference.

Mr. BRAND: And yet you buy space in it.

Mr. WRIGHT: That is correct.

Mr. BRAND: Are you aware—

Mr. WRIGHT: Of course, we have some products that are sold under trade names.

Mr. BRAND: All right, let us go on, as far as the *Vademecum* is concerned. Reference has been made by Mr. Dan to the fact that this reference in the *Vademecum* is not the responsibility of the present management of the company. Is that correct?

Mr. WRIGHT: Yes, but I take responsibility for whatever happens in this company.

Mr. BRAND: Are you aware, sir, that it is the custom of other companies under the P.M.A.C. group—if that is the right term—when they come out with additional side effects, and such, to send them for insertion into the *Vademecum*, so that there will not be this type of missing link, shall we say?

Mr. WRIGHT: I know there are supplements and that we submit information for supplements when we have it and consider it to be reliable.

Mr. BRAND: You said once again a statement you made before. You do not consider the references to chloramphenicol to be reliable; is that correct?

Mr. WRIGHT: No.

Mr. BRAND: Then why did you make that statement?

Mr. WRIGHT: They are much too narrow. There are new things appearing about chloramphenicol as you undoubtedly know, doctor.

Mr. BRAND: Yes I do. That is why I am asking you the question. Not only new things but there are old things that are very well known about the drug and the potential dangers of this drug as a killing drug.

Mr. WRIGHT: That is correct.

Mr. BRAND: For the life of me I cannot understand your attitude that you do not think it is necessary to put it in there.

Mr. WRIGHT: I certainly would believe in putting it on the bottle.

Mr. BRAND: On the bottle?

Mr. WRIGHT: Yes.

Mr. BRAND: You are trying to tell me that your bottles are so large you can put all the information on there; 21½ inches worth of information on this drug?

Mr. WRIGHT: I am not teaching a medical course on this bottle; I am warning the doctor that he might refer back to his—

Mr. HOWE (*Hamilton South*): May I interject here. How many doctors see a bottle as they write a prescription for it?

Mr. BRAND: Perhaps the druggist hands them over; I do not know.

Mr. DAN: I do not know, Dr. Brand, if I can, at this moment, make our point clear that if we put our products in the *Vademecum* as of now, as of September, as it is planned to function, it should be done properly and the very reason we are here is that our ideas may differ. It is all right if we differ as long as we disscuss it because invariably after a while we do come to the right answer and will do things in the right fashion. I heard your views and I respect them; I

heard the views of Dr. Wright and I may not agree with them; you heard my views, too. This will develop to the point that I, the pharmacist, feel very strongly that it should be there.

Mr. WRIGHT: I might say that when we get our new Canadian compendium, I think that we shall have much more information than we do here.

Mr. BRAND: I quite agree with you but what do we do in the meantime? Are you going to suspend selling your drugs until such time as this comes out, as you are taking no other measures? What are you going to do in the meantime? You are talking about a 300 per cent increase in the sale of drugs. I am afraid I would quit my profession completely if I thought it was going to be the case that they were flooding the market with nothing attached to them about the dangers of these drugs. I am simply appalled.

Mr. WRIGHT: Doctor, I have never written a prescription in my life. I only supply drugs to those who write prescriptions.

Mr. BRAND: It is quite obvious.

Mr. HOWE (*Hamilton South*): Mr. Chairman, if I were to say that I have, for many years, used the *Vademecum* as a method of getting an intelligent outline of the properties and uses of a drug plus, plus its contra-indications and possible side effects, would you not say that this is considered to be, maybe, one of the more reliable forms to get this rather than the direct mail type of advertising that we do get that is pure advertising to push a drug? That is this not, maybe, considered among the medical profession, as one of the more reliable sources of information?

Mr. WRIGHT: We are not talking about the same thing. When I talk about the direct mailing, I am talking about the reference cards which we usually issue as a file card, which contains the information on contra-indications.

Mr. HOWE (*Hamilton South*): I am not condemning the mail cards or the literature or any of the advertising except that this is something that has it all combined into one book that is handy to keep because, as you know, doctors' offices get cluttered up with all manner of advertising and one has to segregate out what is the best source of information on a drug if one is prescribing it. You certainly cannot see the bottle.

Mr. WRIGHT: I would point out to you, again, that if you look at the number of supplementary or additional products you will find that contra-indications are not shown in most cases here.

Mr. HOWE (*Hamilton South*): I have been lucky because any I have looked up, I would not prescribe the drug without seeing the contra-indications and any I have looked up have had these. It could very easily be that I have not used any of the additional products until they came out in the next year when it would possibly have the contra-indications in it at that time.

Mr. WRIGHT: Well, of course, frequently some of these contra-indications are on old drugs. For example, with the long acting sulphas, these drugs have long been on the market and they have long since been in the additional drugs lists of drug manufacturers when their effects were known.

Mr. HOWE (*Hamilton South*): But these still were not on the index cards nor were they in the direct mail advertising that we received, either.

Mr. WRIGHT: Some of us, at least, took the long acting sulphas off our lists.

Mr. ROXBURGH: You made a statement a little while ago when you were talking to Dr. Brand about the cards you sent out. You said you usually sent them out. Do you always send them out?

Mr. WRIGHT: We send them out as soon as we can get a reasonable card on it. I think, for example, that there are eight of them in process right now in my own establishment. I know others do this, too.

Mr. BRAND: May I ask who makes up these cards for you?

Mr. WRIGHT: Yes, I can tell you that. At the moment, I have a student who took his masters in philosphy, and he is searching the literature, including the competitor's information, on it.

Mr. BRAND: I did understand you to say, masters in philosophy? Is that correct?

Mr. WRIGHT: That is correct, sir, but this teaches him, I think, to go around at various places and literature.

Mr. BRAND: Do you have anyone who has a direct contact with the medical profesion, or any schol of pharmacy, or anything of that nature, who is trained to look up this type of thing in medical literature?

Mr. WRIGHT: Well, of course, if this individual goes up to the department of pharmacy, or if he goes up to the food and drug administration, which always welcomes this sort of thing, or if he goes to the department of pharmacology in the university of my home town, he can get this information from experts.

Mr. BRAND: Does he?

Mr. WRIGHT: Yes.

Mr. BRAND: But you do not have anyone of that calibre. That answers my question.

Could I go to something else because at the moment I am too upset to continue further with that? You talked about the independent assay, Mr. Dan, I believe, and you felt this was done two or three times on the finished product. Do you think it is sufficient any more to perform a simple test on the finished product?

Mr. DAN: Yes, it is necessary.

Mr. BRAND: Do you think it is sufficient?

Mr. DAN: You have to do tests monthly or yearly, sir, after you have done the initial two or three tests. It again depends on the product. On some products which are known to be fairly stable, perhaps the frequency should be less.

Mr. BRAND: Are these tests done?

Mr. DAN: I beg your pardon?

Mr. BRAND: Are these subsequent tests done?

Mr. DAN: Yes, they are, by food and drug regulations.

Mr. BRAND: Yes, I am aware of this. How about intermediate supervision of the actual steps or processes of manufacture?

Mr. DAN: You are probably referring to the raw material which—

Mr. BRAND: I am referring to the steps of the process of manufacture.

Mr. DAN: Do you mean why does a thing get put in tablet form? Is that what you are referring to?

Mr. BRAND: I was referring to the process of being compounded and put into—

Mr. WRIGHT: I think it is the custom—I think we follow the custom of other firms—that the bulk material is analysed as it enters the plant and before it can be used.

Mr. BRAND: Do you do any actual manufacturing?

Mr. WRIGHT: Yes.

Mr. BRAND: In the manufacturing process—

Mr. WRIGHT: I was going to continue. The material then, once it has been released from quarantine as manufactured, as purchased, then goes to mixing and tableting. Samples are taken every half hour—this is the custom in the trade—and transferred to the control laboratory. This, then, forms a bulk material which goes into another quarantine. If this material, then having been analysed, is used within three months, it does not suffer another analysis at that point; if it is there longer than three months, then by routine, it again goes back to analysis. It is then packaged; sample bottles are taken out of the packaging operation and these go to the laboratories for analysis.

Mr. HOWE (*Hamilton South*): May I just interject a question here? Is this tested as to the potency of the active drug or is this tested as to the vehicle in which the drug is being carried, such as a tablet or liquid?

Mr. WRIGHT: It would certainly be tested with respect to disintegration time.

Mr. HOWE (*Hamilton South*): In the proper medium.

Mr. WRIGHT: That is right.

Mr. BRAND: Your test would then disclose the presence of potentially dangerous by-products or isomers or chemicalized emergents that may have to be removed and things like that?

Mr. WRIGHT: These things are developing all the time. I do not say that in the past they were being done. Each time a new report comes in the literature —you know the latest one on penicillin—this then come to a soul searching in the plant and also a searching for a new method of analysis, usually.

Mr. BRAND: You are in favour of this very careful control regarding isomers and chemical contaminants and everything else. Is that right?

• (10.00 p.m.)

Mr. WRIGHT: Most assuredly.

Mr. BRAND: So there are parts of the Hilliard report with which you agree?

Mr. WRIGHT: That is right.

Mr. BRAND: Fine. Thank you very much.

The CHAIRMAN: Mr. Laidlaw, do you have any questions that you would like to ask.

Mr. LAIDLAW: Mr. Chairman, I understand that further questions on patents and research will be reserved until the fall and it is also my understanding that these gentlemen will, perhaps, be invited back to discuss this aspect?

The CHAIRMAN: Yes, as individual companies rather than as an organization or if this group wants to have the organization back, we can certainly do that in the fall. I think it is obvious to the Committee that this Committee is going to have to meet early in the fall and work out a new format of meetings. Our meetings are too disjointed; I think we have to decide that when we have a drug company here, we are going to have to sit morning, noon and night and sit steadily. It appears to me, as the Chairman, that the members are feeling frustrated, as is the Chairman; that you are not being able to follow your questions through their normal sequence, and I think we would all like to see some change in format. If you would think this over during the summer months, I would be most pleased.

Did you have any questions, Dr. Laidlaw?

Mr. LAIDLAW: No. I had no questions other than on those subjects.

The CHAIRMAN: If there are not other questions, I would like to thank Mr. Dan and Dr. Wright for coming before us and suffering the questioning and presenting their brief.

The meeting is adjourned to the call of the Chair which will probably be in the fall.

APPENDIX "A"

MINISTER OF NATIONAL REVENUE — MINISTRE DU REVENU NATIONAL

Ottawa 2, July 4, 1966.

Personal & Confidential
Dr. Harry C. Harley, M.P.,
House of Commons,
Ottawa, Ontario.
Dear Dr. Harley:

In view of the difference expressed concerning the sales tax content in the consumer list of drugs as presented by me to the Committee on Drug Cost Prices and that presented by the Canadian Pharmaceutical Association, I feel that I should re-emphasize and elaborate on the statement I made to your Committee.

In the first place, the Canadian Pharmaceutical Association that is the pharmacists, did not give a breakdown of their calculation with the result that we cannot comment on the validity of the result of such conclusion. We can, perhaps, make certain assumptions which, of course, must be treated only as assumptions on our part. As I pointed out in my original statement, our figures were based on the sales tax as an amount turned over to the Crown and identified as the amount of sales tax applicable to the sale by manufacturers of their pharmaceutical products.

It should be remembered that the Canadian Pharmaceutical Association represents pharmacists who, with few exceptions, are not manufacturers, hence, do not pay tax directly to the Department and, consequently, do not ordinarily know the amount of sales tax paid by manufacturers on purchases of drugs made from them.

The Canadian Pharmaceutical Association is careful to point out that the 9¢ portion of the consumer dollar is not the amount of tax in that dollar, but that it is the "influence" of the tax that brings our figure of 1.8¢ and 4.96¢ to their 9¢ figure.

By "influence" we assume that the pharmacists mean that their subsequent addition of other costs to their tax included purchase price paid to the manufacturer brings the 4.96¢ amount to 9¢. This would be true if they added definite percentages to their cost. However, this is not a universal practice. Where the pharmacist takes as a base for tax his consumer price of the drugs (i.e., the price suggested by manufacturers) and adds a straight professional fee, e.g., $2.00, there is no "influence" in the final price.

Where the pharmacist adds a percentage mark-up plus a fee, the "influence" will result only from the percentage mark-up. Obviously, the percentage of mark-up and the amount of fee can be shifted according to the pharmacist's own wish.

As I mentioned before the Committee, the Department conducted an investigation of the pharmaceutical industry for sales tax purposes in 1959 and, at that time, it was found that the determined wholesale value, on which

sales tax may be accounted for by manufacturers who cannot themselves establish their wholesale price, was the suggested sales tax included list selling price to users, less discounts of 40% and 15½%. The investigation also revealed that the tax on approximately 55% of the manufacturers' sales (dollar value) would be accounted for on this determined value.

I mentioned that the sales tax paid to the Receiver General on pharmaceuticals sold directly to users, not including prescriptions, was 4.96¢ on each one dollar of sales to users. This computation is shown as I on Schedule "A" attached.

As far as pharmaceuticals sold on prescription are concerned, I mentioned the tax on prescription drugs could vary between 1.8¢ and 3¢ on each consumer dollar, depending upon the method of determining the selling price. These two figures are outlined in II (*a*) (*b*) also shown on the attached Schedule "A".

By use of the professional fee method, the tax varies between 1.32¢ and 4.13¢ and this is outlined in III (*a*) (*b*) of Schedule "A".

No matter which method the pharmacist uses to arrive at his sale price to the consumer, which price includes costs such as his overhead, advertising, bad debts and his profit, the fact remains that the amount of tax paid to the Receiver General by the manufacturer bears a relation to the price at time of consumer purchase from the retail pharmacist in the amount I have previously given.

Yours sincerely,

E. J. Benson,
Minister of National Revenue.

Appendix "A"

I. Suggested sales tax included list selling price to users, say 1.00
Less discounts of 40% and 15½% ..... .493

Taxable value ..... .507
Sales tax 11/111ths — 4.96¢

II. PRESCRIPTIONS

Percentage Mark-up Method

(a) Suggested sales etax included list selling price to users, say 1.00
Mark-up — 175% 1.75

2.75

Sales tax paid to Receiver General — 4.96¢
Tax expressed as a percentage of
selling price to user — 1.8%

(b) Same as above with 50% mark-up ..... List 1.00
Mark-up 50% .50

1.50

Sales tax paid to Receiver General — 4.96¢
Tax expressed as a percentage of
selling price to user — 3.3%

III. PROFESSIONAL FEE METHOD

(a) Suggested sales tax included list selling price to users, say		1.00
Professional fee, say		2.00
		3.00
Sales tax paid to Receiver General — 4.96¢		
Tax expressed as a percentage of selling price to user — 1.32%		
		Comparative
(b) Same as above, but an expensive pharmaceutical, say	10.00	1.00
Professional fee	2.00	.20
	12.00	1.20
Sales tax paid to Receiver General — 49.6¢		
Tax expressed as a percentage of selling price to user — 4.13%		

APPENDIX "B"

(From *Harvard Business Review*, September/October 1962, Vol. 40, No. 5)

Ironic Contrast: US and USSR Drug Industries

By Raymond A. Bauer and Mark G. Field

The ironic contrast (or lack of contrast!) represented by the following quotations points up lessons for all American businessmen, whether concerned with the pharmaceutical business or the working of the economy as a whole:

An official of Czechoslovakia's state health establishment, concerned with the manufacture and sale of drugs recently asked a European representative of an American drug firm for some material from the hearings held as a result of the Senatorial (Kefauver) investigation of the American pharmaceutical industry. Curious about the interest shown, the American asked if he wanted the entire transcript. "Not so," replied the official. "I don't want the full text, just the rebuttal material used by your American manufacturers. *They say our drug prices in Czechoslovakia are too high!*"[1]

According to Senator Estes Kefauver, who headed an investigation of the U.S. pharmaceutical industry, "Ethical drug prices are generally unreasonable and excessive. They are unreasonable whether compared to costs, to profits or to prices in foreign countries...Under the big drug companies' brand names, [certain] products are sold to druggists for around 18 cents a tablet and the suggested price to consumers is 30 cents a tablet. Yet the cost of production for these tablets, including tableting, bottling and packaging is no more than 1.5 cents per tablet. [A] patient will frequently remain for long periods on a dosage of about 100 of these tablets a month. Thus he pays $30 a month for his medicine, for which his druggist paid $18 and which cost around $1.50 to produce."[2]

Speaking before the Supreme Soviet of the U.S.S.R. in February of 1957, Maria D. Kovrigina, then Health Minister of the Soviet Union, complained bitterly about the retail prices of drugs in the U.S.S.R., particularly antibiotics. Pointing out that over the previous five years the unit cost of production in the medical industry had been more than halved, she wondered why this did not entail a corresponding decrease in the retail prices of Soviet pharmaceuticals. On the contrary, concluded Madam Kovrigina, "The prices of some highly effective preparations are four, five and even six times the wholesale prices. Reducing retail prices of medicines...is a very important step. We have made such a proposal to the U.S.S.R. Council of Ministers and we expect our request to be met."[3]

In support of "The Drug Industry Antitrust Act," Senator Kefauver went on to say, "Prices [must] be brought down, not by governmental fiat, but by the rivalry of competing producers in the market. To make this competition fair as well as effective, certain safeguards and limitations are provided for [in the proposed bill]. These safeguards will also have the corollary effect of improving the quality and reducing the quantity of information distributed to the

[1] Walter A. Munns, president of Smith Kline & French Laboratories, in a speech before the New York Security Analysts, Inc., January 9, 1962, New York.

[2] Statement of Senator Estes Kefauver, Hearings before the Senate Subcommittee on Antitrust and Monopoly, *The Drug Industry Antitrust Act*, S. 1552, Washington, July 5, 1961, p. 2.

[3] *Izvestia*, February 8, 1957, p. 5.

physician. . . Unless this measure or something closely resembling it is adopted, the American people, whose patience with price gouging in drugs is wearing thin, will demand that their Government adopt the tougher approach of direct governmental controls."[4]

The Major Complaints

The irony is not just that, as these quotations reveal, the Soviet and the American systems of drug production and distribution have both come under attack from critics at approximately the same time. The major areas of criticism are identical in the two countries—the role of research laboratories, the social costs of promotion, problems of brand differentiation and quality control, and the relationship of the producer to the consumer. But, since the economic systems of the two nations are so different, it is not surprising that the specific charges within this general area of discontent are reversed, like mirror images.

Vice Versa

The major complaint made against the American ethical pharmaceutical industry is that there is too great a disparity between the costs of production and the retail prices of drugs required to maintain the health and life of the nation. The "high price of drugs" is usually attributed to two distinctive causes: (1) allegedly unnecessary duplication of research facilities for competitive commercial reasons, and (2) purportedly excessive promotional costs.

In the Soviet Union and other Eastern Communist countries, a reverse situation is receiving equally bitter criticism. There, the system for promotion of drugs is minimal, and pharmaceutical research is conducted, not by individual drug firms but by government-sponsored "institutes," supposedly without wasteful duplication.

Indeed, in one sense, the Soviet system seems to embody the ideal alternative to the U.S. commercial drug system that some critics cry out for. Why then do the Soviets not find it ideal. Are there lessons that we Americans—whether critics or friends of the pharmaceutical industry—might learn from a comparison of the assets and liabilities of each system? Why doesn't the Soviet experience with "non-profit" drug production and distribution lead to lowered costs and greater efficiency? Are the arguments for changing the institutional arrangements and practices found in our system economic or political? Let us take a closer look and see.

Underpromoted Drugs?

One major criticism of the American ethical drug industry centers around the high costs of promoting drugs, along with the practice of maintaining brand names and brand lines. Critics of the American pharmaceutical industry see no justification for price differentials to exist between these branded drugs and the unbranded "generic" drugs that are chemically identical in their main ingredients and which, since they usually are not promoted in any substantial way, generally sell for less at the manufacturer's level.

Regarding the expense of promoting branded drugs as especially unwarranted, the more extreme of these critics argue for reducing promotional activity to some minimum system of announcements of new drugs, with the

[4] Statement of Kefauver, op. cit., p. 15.

major job of communicating the drug's characteristics and usefulness to be performed by the medical profession or the government, or by both. Brand names, presumably, would be done away with, or become for all practical purposes irrelevant. The assumptions behind these criticisms are more complex than generally recognized, and seem to be based on the following beliefs:

1. A satisfactory noncommercial source of information about drugs can be established without too much difficulty.

2. If information is reasonably available, physicians will take the initiative to see that they keep up to date.

3. The well-informed physician will not be concerned with the reputation of the firm producing the drug, but only with the drug's properties as described in an official pharmacopoeia.

4. Adequate quality can be ensured at reasonable cost by a government inspection system.

5. An ample supply of pharmaceuticals will be produced if reasonable profits are allowed on individual drugs.

The Difference

One way of finding out whether these beliefs have much validity is to see whether they hold true in the "non-profit" Soviet system, where drugs are underpromoted. Note that although we use the term "non-profit", it is true that in one sense Soviet manufacturers must operate at a profit; that is, the value of the production must exceed the input in terms of materials, personnel salaries, and so on. Indeed, the high prices Madam Kovrigina complained about may have been due to unreasonable profits in this sense. Profits, on the other hand, do not play the critical role they do in the West, where they determine the life and death of a firm.

Perhaps more relevant here is the fact that the Soviet pharmaceutical system is "noncommercial." As such, it is operated by the government and is characterized by rather extreme centralization and bureaucratization, and also by the existence of rigidities and slowness in action that are so often associated with an advanced bureaucracy.

Having over-all responsibility for the pharmaceutical system of the Soviet Union are two specialized organizations within the U.S.S.R. Health Ministry:

(1) The Pharmacological Committee (itself a part of the Department of Specialized Medical Assistance of the Ministry), primarily an advisory and "expert" organization, has the primary duties of recommending new pharmaceutical preparations and of removing from the market pharmaceuticals that have become obsolete. Within that committee there is a commission "on instructions and informational materials," which presumably prepares literature giving knowledge about the existence and the application of new pharmaceuticals.

(2) The second organization concerned with pharmaceuticals is also lodged in the Health Ministry and is entitled the Department of Pharmaceuticals and Medical Technology with a Quality Inspectorate. The main functions of this department are (a) to ensure the standardization of drugs produced in the Soviet Union, (b) to edit the Governmental Pharmacopœia of the U.S.S.R. and to make periodic additions to it, and (c) to examine complaints of nonstandard production.

Neither of these two organizations seems to incorporate a formal, specialized, active, and dynamic system for disseminating information about new drug products to the physicians practicing in the U.S.S.R. that in any way parallels the work done by the American drug industry's detail men (the name given to drug company salesmen who regularly visit physicians for the purpose of familiarizing them with their company's new drug offerings in the hope that the physician will prescribe them when suitable). Rather, the picture appears to be one of general announcements in the medical and sometimes the lay press or other media of mass communications when a new compound or agent is cleared for production. Special information supplied to physicians often amounts to nothing more than simple one-page "flyers." These steps, it is clear, make information minimally available, and, presumably physicians with initiative and interest could keep informed thereby.

No Time

Unfortunately, this assumption about the initiative of the physician and his ability to keep up with new medical products seems to be as unfounded in Soviet society as it is in the United States. Indeed, the belief that people automatically will make use of information or products if these are available is not borne out by the evidence. In the particular case of physicians, it would be closer to the truth to assume that in many instances they are much too busy to give a careful reading to the little flyers that flutter across their desk or even to peruse the medical literature systematically in search of new drugs. Or, alternately, such minimal sources of information may not make an adequate impact on the physician's mind.

Thus, the expectation that doctors will dutifully note such drug innovations and promptly prescribe them for the next patient to whom they apply seems to be expecting too much under contemporary conditions of medical practice. Rather, it would seem that more active methods are necessary to force-feed this information to physicians. And, to some degree, the Soviet medical literature reveals that Soviet health authorities are well aware of the communication problem and are attempting to take certain steps that will remedy it. Complaints of inadequate information about new products are endemic. Eight such complaints were registered during the first seven months of 1961 in one source, *Medical Worker,* a semi-weekly house organ of the Ministry of Health. The flavor of these complaints can be gathered from the following fairly typical extracts:

"Information about new drugs is given irregularly so that practicing physicians do not know about them and are deprived of the possibility of using them. The process of replacing old-fashioned drugs by new and more efficient ones, is too slow."[5]

"It is necessary to point out that as yet physicians and pharmacists are poorly informed about new drugs. Any information is purely accidental...The pharmacological council has advised the State Publishing House of Medical Literature to publish as soon as possible four publications on new pharmaceutical products."[6]

[5] *Medical Worker,* April 4, 1961
[6] Ibid., June 6, 1961.

"Too much time is wasted in pharmacies on compounding prescriptions, and this is only because the physicians do not know about the pre-compounded drugs. . . .Obviously, only very few general practitioners follow the literature in which the new drugs are described. . . .On the other hand, pharmacy employees do not inform physicians about existing drugs. *They do not come to the polyclinic and do not promote the new pharmaceuticals.*"[7]

This picture is an ironic inversion of the situation in the United States. Missing are the complaints about "junk mail" and "pill peddlers." While there may be difficulties associated with an "overpromoted" drug system, the Soviet experience indicates that "underpromotion" produces its own characteristic problems.

℞ for Soviet Drugs

Efforts have been made in the U.S.S.R. to give greater publicity to new pharmaceuticals. For example, polyclinics have been requested to set up special displays of new pharmaceuticals. According to the Soviet press, however, these displays often are nonexistent. Nor are there listings of currently available drugs, presumably because of the intervals between the appearance of new editions of the official pharmacopœia.

As we have seen, some of the remedies proposed by the Soviets (and to some degree implemented by them) appear to be quite orthodox by our standards: publication of pamphlets, displays or exhibits, listings by the Health Ministry, and so forth. Even more interesting and significant, however, is the fact that representatives from the pharmacies or from pharmaceutical warehouses or subdepots are now being sent to the clinics to inform physicians about what new pharmaceuticals are available and, in turn, to find out their needs and requirements.

A Rose by Any Other Name

These representatives are, doubtless, the functional equivalents of the U.S. drug industry's detail men. And, significantly, Soviet criticism is leveled at those pharmacies that do not use detail men, or do not engage intensively in promotional activity, while praise is heaped on those that do. For instance, a 1960 article in the *Medical Worker* approvingly describes how a representative from a pharmacy periodically visited physicians and appeared before assemblies of doctors, providing information on new drugs. Such assemblies make it possible, of course, for the representative to reach a wide range of physicians, since they take place periodically at the district polyclinics where physicians in the community, all working under one roof, see their patients. One might well wonder, however, whether such mass presentations adequately can meet the need which is served by the person-to-physician presentations provided by the U.S. detail men.

There is a definite but subtle overtone of "unsocialism" to complaints that representatives of pharmacies are not sufficiently diligent in promoting new drugs. But even more unorthodox is the proposal of vigorous advertising. Historically, advertising has been regarded by Soviet authorities as a socially wasteful device for foisting off on people goods they do not need. Since this

[7] Ibid., May 19, 1961.

attitude has, of late, undergone some modification, the advertising of pharmaceuticals has come to be advocated as a means of keeping doctors informed. For example, articles in both *Medical Worker* and *Pharmaceutical Affairs* in 1960 and 1961 complained that new pharmaceuticals do not become immediately available to practicing physicians. Why? Because of "a lack of well-established information about medical novelties." Both articles advocated an information service via press, radio, TV, leaflets, and so forth.

Import for the U.S.

Soviet experience with a functionally inadequate informational service for pharmaceuticals, and the recent Soviet awareness of the role that can be played by various forms of promotion (either detail men or increased advertising activities in the mass media—or both) should not be taken as justification, per se, of any level of expenditure or any one promotional practice. It should alert us, however, to a closer examination of the by-product of promotional activities in the selling of pharmaceuticals.

A distinction between what have been called *manifest* and *latent functions* may be useful in this context. The manifest function of promotion, advertising, and detail men—at least in our society—is to sell drugs by persuading doctors to prescribe a certain product by its brand name. But this, as we have seen, is often looked upon with suspicion as a kind of maneuver that eventually increases the prices of pharmaceuticals. Furthermore, such activity has been criticized as being of no social value and should, therefore, be eliminated.

Overlooked is the latent consequence of such promotional activities; i.e., they serve as professional transmission belts for new information from the manufacturer to the consumer (the physician and his patient). That such a latent function is *not* superfluous is indicated by the inadequacies (in this respect) of the Soviet system in informing the medical profession about pharmaceutical innovations, and by the efforts of Soviet health authorities to create an institutional system to remedy these inadequacies.

In the light of this examination, then, a question arises about the wisdom of a frontal and wholesale assault on current American practices in the pharmaceutical field. One might ask whether the promotional practices of the ethical drug firms are as antisocial in their consequences as some would have us believe. One might even raise the question as to what might be the social "costs" involved in eliminating these practices. While it is true that, in some instances, abuses have taken place, the question is whether the baby should be thrown out with the bath water.

Noncommercial Research

Both in the Soviet Union and in the United States, the second large area of complaint centers around pharmaceutical research. Since Czarist times, scientific research in the Soviet Union has been carried out primarily in research "institutes" separate from universities and industry. (The closest approximation in the United States might be a government organization such as the National Institutes of Health.) Research in pharmacology takes place in these institutes mainly under the aegis of the Academy of Medical Sciences and Ministry of Health of the U.S.S.R. Production, on the other hand, occurs in organizations

that now are under the control of regional economic councils called *sovnarkhozy*. An approximate parallel in the United States would result if research were performed in university and government laboratories, and production handled by private firms.

Bogged Down

We have already seen the charges leveled against the American industry. But what is the Soviet complaint? Essentially, it concerns unnecessary delays in getting valuable results of pharmaceutical research into effective use by doctors and patients owing, first, to problems in communication between institutes of research and production establishments, and, secondly, to bureaucratic delays, sometimes severe, between governmental testing and evaluation of new drugs and ultimate approval for production.

To anyone familiar with a reasonably technical industry, the steps between laboratory research and production are far from trivial. Under the best of circumstances, this requires the close day-to-day collaboration of laboratory, engineering, and production personnel, and involves adjustments, redesigning, and rethinking that may go on for months, and perhaps in extreme cases for years, before the laboratory product has been debugged in production.

As a result of the Soviet arrangement, there are difficulties of communication and coordination between institute and factory which constitute a major bottleneck in getting pharmaceuticals into production. To quote a recurrent theme in the Soviet medical press: "It is essential. . .that research and production be brought closer together so that research accomplishments may be put into practice more rapidly." A measure of the seriousness of this problem is the fact that in the first nine months of 1961 this topic was brought up five times in the Soviet monthly journal, *Medical Industry*.

Inadequate Setup

The picture that emerges is one of an institutional arrangement definitely inadequate to the complexities of converting a laboratory product into something that can be produced economically in volume. Note the tone of the following complaints:

"The chemico-pharmacological establishments are slow in bringing a number of the new pharmaceuticals into production. Many pharmaceuticals which have been approved for use in general practice are not yet on the market.... The planning bodies do not perceive clearly enough the conditions that exist in the factories when pharmaceuticals are produced... Representatives of the factories noted that the technical instructions received from the institutes frequently do not meet present day requirements. Quite often when they are followed they cause great difficulties and large financial losses."[8]

"We have too few scientific research institutes concerned with the search for new pharmaceuticals.... It is a secret from no one that in our country the period from the birth of a new preparation in the laboratory to its introduction into practice is on the average from three to four years. In some cases it is seven years."[9]

[8] *Medical Industry*, May 1961, p. 63.
[9] *Medical Worker*, July 5, 1960, p. 3.

It may be, of course, that Soviet critics of their own system are overreacting to its difficulties. But, to some Soviet authorities, at least, the liabilities of the present institutional arrangement are obvious. If it were matched against the American system, it is conceivable, but certainly not proved, that the Soviet arrangement could produce—on a ruble-for-ruble or man-for-man basis—as many or more laboratory products as could the U.S. industry. But *the testimony of the well-informed Soviet sources is that the separation of research from production tends to produce substantial delays in the availability of drugs to physician and patient.*

The speed with which the American ethical drug industry can move a drug from research into production offers a sharp contrast to Soviet slowness. Under ordinary circumstances, an American pharmaceutical manufacturer will begin to work on production problems as soon as laboratory and clinical tests suggest the clinical and commercial worth of the drug. The development of production methods and, in fact, the stockpiling of the drug are usually done in *anticipation* of approval by the Food and Drug Administration. Thus, in most cases, lag between government approval and the availability of the drug is nonexistent. *One must again weigh the social costs of the two arrangements.*

Bureaucratic Impasse

The separation of drug research from production in the Soviet Union is not the only cause of delay. An additional cause is the elaborate bureaucratic procedure for the screening of new drugs. Here, once more, we find repeated complaints in the medical press. The reasons for delay seem to be several: the complexity of the procedure, the conservatism of the criteria employed, and some overloading of personnel and facilities. Here is a typical complaint in *Medical Worker*:

"Already four years have elapsed since *biliarin* was proposed. This interval is sufficient to study the drug from all sides, to test it clinically and, having established its useful action, to legalize it and place it into the practice of medicine. But this has not yet been done. The Pharmacological Committee until now has not delivered the drug its 'right to life' and this is why it is not being produced anywhere."[10]

An example such as this is probably extreme. We have seen no estimates of the *average* time required for the screening of a drug. Yet the lesson involved is clear and straightforward; there is no point in further elaboration or documentation. No responsible person, either in this country or in the Soviet Union, has denied the need for some form of official screening of drugs. But in both countries there are complaints that introduction of drugs is unduly delayed.

Obviously, there are a series of factors to be balanced off against each other: the cost of a more adequately staffed and equipped screening system, the dangers of passing unsafe drugs, the problems raised by delaying the introduction of new drugs, and so on. Any such screening system will always consume *some* time therefore, proposals to extend the responsibilities of government screening authorities must be made with realistic consideration of the delays involved and the need for increased facilities and personnel. There are indications that, in the Soviet Union, steps are being taken to decentralize and speed up the screening process.

[10] August 16, 1960, p. 3.

Poor Quality

Of more interest, in the light of what is known about problems of quality throughout the Soviet economy, is the question of the quality of drugs produced by Soviet production establishments. Unfortunately, our direct knowledge is quite incomplete. However, what we do know fits in so well with the rest of the Soviet scene that we can venture to fill in some gaps from our generalized knowledge.

There are also frequent complaints in the press about the poor quality of Soviet pharmaceuticals. For instance:

"Our industry does not always produce medicaments of good quality. And so it happened, for instance, that from the overall number of pharmaceuticals which were sent this year for evaluation to the Central Pharmacological Research Institute, more than half were rejected, mainly ampules.... The rejects were found especially often in the products of the Khabarovsk and Novosibirsk factories, in the Kharkov factory called 'zdorovie Trudiaschchikhsia,' and in the Moscow factory named 'Semashko'....The above examples show that the workers of the chemico-pharmacological industry do not always work conscientiously."[11]

"Every year, there is an increase in the production of various drugs in our country. Many of them are sent for evaluational testing to the Central Pharmacological Research Institute. In the last year, for example, 112 various drugs were sent to us—ampules, tablets and others. And, it is deplorable that 75% of them did not meet the requirements of the official governmental pharmacopoeia and the technical standards. In the first three months of the current year, the Institute received some dozens more of pharmaceuticals and this time again, from the 74 tested, 58 did not meet the requirements."[12]

The fact that there is an endemic problem of quality facing the Soviet drug producers cannot be doubted by anyone familiar with the medical press of that country. The reasons for this problem seem also to be clear. As is generally true in Soviet industry, quality control is not well built into the manufacturing process. The Soviets rely on testing done by an independent inspection system, in this case, the Controlling Analytical Laboratories of the Pharmacological Administration.

Efforts to maintain quality control by policing via an external inspection system have been one of the conspicuous failures of the generally successful Soviet economy. In various ways this failure is being acknowledged throughout the economy.

The first signs of corrective steps which might be taken in the pharmaceutical industry have occurred recently. Last year a writer in the *Medical Worker* stated:

"At the present time, the testing of the quality of medicaments is carried out, as a rule, in the Controlling Analytical Laboratories of the Pharmacological Administration. This work ought to be done first of all in the factories themselves by their technical control branches. It is really there that the necessary conditions should be created for the continuous control of the quality of the entire output. . .The time has come when we are justified in demanding

[11] *Medical Worker*, February 24, 1961.
[12] Ibid. July 14, 1961.

that the medical industry deliver production only of the first quality. For this purpose it is indispensable to organize closer contact between the industry and the network of pharmaceutical specialists. The managers of factories should give detailed accounts at the meetings of pharmaceutical societies. In the immediate future there will take place an all-union scientific convention in which representatives of the chemico-pharmaceutical industry, of research institutes, and pharmaceutical workers will take part. The convention is devoted to the problem of the improvement of the production and control of quality of the medicaments in ampules."[13]

This attempt to get the producing organization to take responsibility for quality has become relatively familiar in recent years in the Soviet Union. Four decades of running a socialist economy have cured Soviet economists and administrators of the tendency to take quality for granted.

Until relatively recently the task of inspection was left in its virtual entirety to the government bureaucracy. There were a number of difficulties with this system:

1. Quality remained substandard.

2. Minimum standards also became maximum standards. Manufacturers had no economic incentives (and Soviet manufacturers do operate according to economic incentives) to produce any quality beyond the minimum required by the established standards.

3. In addition to the fact that quality continued to be unsatisfactory, the system of inspection turned out to be cumbersome, expensive, and, to a large extent, ineffective.

Marketing Innovations

Recently, the Soviet decision has been to pass on this inspection function, at least in part, to the manufacturer and the consumer. Each factory has been required for some time to affix to its products some identifying mark. At present, manufacturers in many areas are being urged to adopt a trademark which really is a somewhat more overt version of the production mark, thus making it still easier for the consumer to identify the factory.

At the present time, we have no evidence that the Soviet Union is pushing trademarks or brand names *in its pharmaceutical industry*. To the best of our knowledge, all Soviet factories producing the same type of drug use the same name for it, and often the same type of packaging. While no factories have made a deliberate attempt to publicize their names, it is nonetheless true that the consumer can identify, from a careful reading of the package, which factory or which economic regional council is responsible for its manufacture.

Capitalism Copied

Some recent developments on the Soviet economic scene would lead us to believe that the situation in the pharmaceutical industry may not be essentially different from that in the consumer goods industry where trademarks have been, or are in the process of being, developed. If responsibility for quality control is to be placed prominently on the factory, the logic of the situation would be that the factory would then try to give itself a distinctive identity in order to capitalize on the superior quality of its products.

[13] Ibid., November 28, 1961.

There are also problems related to selective shortages of particular drugs. Since the mid-1930's Soviet pharmaceutical manufacturers, like other Soviet enterprises, have been put on an accounting basis. This means that, in contrast to earlier practices in which costs and prices bore little relationship to one another and no detailed accounting of either was kept, enterprises were assigned quotas of goods to produce, realistic prices were assigned to them, a planned "profit" became a criterion of the soundness of management, and bonuses (as well as other incentives) were made available to managers who exceed the planned production.

With this partial return to capitalistic practices, some products naturally turn out to be more profitable than others. From this arises the perennial Soviet problem of the "product mix". Sanctions are employed (or attempted) to get the required mix of products out of the enterprise. But, in one way or another, factory administrators manage to evade controls on the product mix so as to maximize their profits.

The Soviet press regularly reports complaints of shortages of drugs and medical supplies. Among these shortages are frequently the most prosaic of items such as glucose, talcum powder, tincture of iodine, bicarbonate of soda and even saccharin. In fact, in good commercial fashion, Soviet pharmacies often seem to prefer to stock costly medicines which will produce a high profit for a small turnover, as is obviously the case for the antibiotics whose high retail prices so scandalized the former Health Minister.

U.S. Situation

Now that we have seen how the Soviet Pharmaceutial system works, let us turn back to the United States and consider the parallel situation.

Perhaps the best starting point is the contention of the brand-name manufacturer that we must not look at the profitability of his individual products. If an investigating committee accuses him of making unduly high profits on a particular item, he counters by answering that these profits make it possible for him to carry some items which are essential to the medical profession but which give him little or no profit, perhaps even a loss.

In terms of over-all strategy it makes sense for the manufacturer to carry such low-profit items because he attempts to promote himself and his line of products across the board. An inverted way of describing this situation is to say that "customer (i.e. doctor) control" compels him to produce a fairly wide range of items, as well as to maintain quality.

The brand-name manufacturer's picture of his situation is certainly validated, at least in part, by the franker settlements of the generic drug manufacturers who admit that they limit their efforts to producing generic versions of only those drugs which can be sold profitably. Such manufacturers are quite specific in stating that there are certain drugs which they will not manufacture. Furthermore, they are equally direct in acknowledging the effort and cost that must be undertaken to educate (or, to use the more commercial term, "promote") doctors in the use of a *new* drug.

It would appear, then, that the economic motivations of American generic drug manufacturers and their role in promotion are surprisingly similar to those we have attributed to the Soviet manufacturers.

This raises a further interesting question relative to deciding to manufacture a costly drug whose demand is quite limited. We have seen that in the American situation, according to the statement of brand-name manufacturers, it "makes sense" to carry a reasonably full line even though certain items of that line will be marketed at a loss. This loss will be recouped with other items that are in wider demand. The logic of competition here appears to force the manufacturers to turn out some items that individually are unprofitable. As long as the situation remains as described, the public benefits in the long run.

Soviet Circumstances

In the U.S.S.R., on the other hand, the issues are drawn in a different kind of array. The logic of the situation in the Soviet economy would impel the medical authorities to act like generic drug manufacturers. Insofar as decisions to produce this or that item are highly centralized, the likelihood is that in many instances drugs that are in restricted demand and which require high capital investments for their production may not be put into production at all. The absence of competition makes it also unlikely that another manufacturer would undertake such a production, so that in the end the drug will not be manufactured at all, and the general assortment of pharmaceuticals from which the physician can choose will be quite limited. For example, there is specific evidence of delay in the introduction of cortico-steroids, the "wonder drugs" used in the treatment of arthritis.

It is, therefore, a moot point whether a decision made by a central governmental body with respect to the production of a full line of drugs would be more favorable to the public welfare than a decision made by a pharmaceutical firm competing on a market and desirous of impressing its brand name on the medical profession. Here, again, it seems that the manifest function of promoting a brand name has the latent effect of encouraging the production of certain unprofitable items. An analysis of the Soviet pharmaceutical situation shows that we cannot take for granted that "wise and rational" decisions are to be "naturally" expected from a central governmental or quasi-governmental body, or even that such decisions per se will lead to the provision of certain items for the population.

Conclusion

Certainly a parable of this length ought to have a moral. In this case, the moral is a simple one—that is, we must be careful about quavering before criticism of our established way of doing things, and about assuming blindly that if our way has some drawbacks, then it is bad, and that a completely opposite method is all good.

We have taken the U.S. pharmaceutical industry as our example, since it has come under such piercing criticism, and compared it with the Soviet system of drug production and distribution. Here are our conclusions:

1. *Vigorous promotion of drugs is not necessarily socially undesirable.* In the Soviet Union where drugs are even today only mildly promoted, there are substantial lags in the introduction of new drugs and delays in the dissemination of information about those drugs which have been made available.

2. *Brand naming of drugs, in itself, is also not undesirable.* By brand naming, the responsibility for quality control is placed with the manufacturer,

and the customer is enabled to exert pressure on the manufacturer of inferior products. In the U.S.S.R., where quality control is enmeshed in government bureaus separate from the factory, quality consequently suffers.

3. *Customer preference, which branding allows, serves in the United States to stimulate brand manufacturers into carrying reasonably full lines, even if some are sold at a loss.* In the Soviet Union, factory managers apparently protect their budget by avoiding highly unprofitable items, much as generic drug manufacturers do in the United States.

4. *Finally, if research is separated from production, as in the Soviet system, the process of getting laboratory items into production and out to the consumer is dractically slowed.*

It is our hope that this exaggerated parable will drive home the point that while our system has faults, the way to correct these faults is to examine carefully the possible drawbacks of those alternatives that seem so easy and obvious, and only to adopt what survives that test.

I find the medicine worse than the malady.

—*Beaumont and Fletcher* (sixteenth century)

APPENDIX "C"

SUBMISSION

TO THE SPECIAL COMMITTEE

OF THE HOUSE OF COMMONS

on the

COST OF DRUGS

by the

CANADIAN DRUG MANUFACTURERS

(*Representing the Views of the CANADIAN-OWNED Companies*)

Submitted July 7, 1966

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I. DESCRIPTION OF THE CANADIAN DRUG MANUFACTURERS

The following presentation to the Committee represents the key ideas and observations of the Canadian Drug Manufacturers, a group of Canadian-owned pharmaceutical companies. Our views, in all likelihood, will markedly differ from those of P.M.A.C. We do have, nevertheless, a number of comments to make on the present state of our pharmaceutical industry, which should interest our Government in formulating its policies on the Medicare Program.

The Association of Canadian Drug Manufacturers is a very young, perhaps only a few months old group, consisting of about 15 members, and still in its formative stage. Invariably more members will join us and others may even drop out, if they fail to comply to the pharmaceutical standards we shall adopt and practise. A list of our membership is attached to this presentation, under Appendix I. To our knowledge, only one of our members, Empire Laboratories, is doing a business over one million dollars, whereas most of us, likely has a volume of about $250,000-$500,000. per year, with an estimated total group volume of about 3½-4 million dollars. We do not know the exact financial position of our French-Canadian counterpart, the A.F.Q.P.P. (L'Association Des Fabricants du Quebec de Produits Pharmaceutiques), but we are under the impression that their volume is about 16 million, and therefore our combined volume is likely to be about 20 million dollars per year. This would represent only about 10% of the entire Canadian Pharmaceutical Industry, which has an estimated sales volume of about 200 million dollars per year.

As it is apparent, we are a comparatively small, young, but determined group of Canadians, who are Collectively experienced in the pharmaceutical business and have viewpoints of our own.

II. OUR OBSERVATIONS AND IDEAS FROM THE VIEWPOINTS AS

1. Canadians
2. Professionals
3. Businessmen

We shall present our observations and ideas from three viewpoints, as Canadians, as professionals, and as businessmen, because all combined should give a good understanding of the pharmaceutical industry in Canada. We have been informed that our French-speaking colleagues, whom we greatly respect, also agree with most of our basic ideas although they will make a presentation on their own.

1. *Our views as Canadians*

As thoughtful Canadians, we are deeply concerned over the gradual disappearance of the Canadian ownership in the pharmaceutical manufacturing industry.

We are fully aware that our country open-mindedly welcomes the participation of foreign capital in the development of our economy, since this assures a more rapid expansion of our economy on one hand, while it raises our standard

of living on the other hand. This is all very good, however, the fundamental question is—"Just how far should foreign ownership extend in any phase of our industry, without having undesirable effects in our country?"

Foreign participation in Canadian industry today is at a level of about 60% across-the-board as to ownership, whereas in the pharmaceutical industry, it approaches the level of about 90%.

We wonder if it is desirable from the Canadian viewpoint that our pharmaceutical companies be taken over one by one, once they have achieved a certain size and stature? Just to refresh our memories of recent take-overs, we would like to draw one's attention to the following take-overs:

Ch. E. Frosst Co., F. Horner, Fine Chemicals,
Mowatt & Moore, Elliott-Marion, Bell-Craig.
Canada-Duphar and Delmar Chemicals.

All these companies have been taken over in the last three years, and approximately 20 million dollars worth of pharmaceutical business, produced by Canadian-owned companies, has disappeared, probably for good. After all, once a company has been taken over, it is extremely difficult, if not impossible, to repossess it.

Perhaps Walter Gordon, our former Minister of Finance, like most of us thoughtful Canadians, is not entirely unjustified in expressing his great concern over the disappearance of our birthright, when he writes:

> In the next few years Canada is almost certain to lose economic and, to a certain extent, political control over large areas of our national being. If we do not admit this, we will not define the extent of the loss, and we will not be in a position to determine what Must not be lost.
>
> ...Page XI—"A Choice for Canada" by Walter Gordon.

We are therefore raising our first important question, "Does our Canadian Government want to see the complete disappearance of the Canadian Ownership in our pharmaceutical industry and relegate us to an insignificant group of people or does our Canadian Government want to see the emergence of a small but viable and imaginative group of Canadian-owned pharmaceutical companies, which make a contribution and impact in our industry, create an atmosphere of competition and fully utilize their creative talents?"

This is the fundamental question, for if our Canadian Government does not see fit to justify our existence, then we should perhaps completely submerge and sell out on a large scale to foreign owners.

If our Government, in its wisdom, does see the importance of maintaining a viable Canadian Content in the pharmaceutical industry, then it should do its utmost to discourage companies from selling out and create an atmosphere and an environment which is healthy for the growth of the Canadian-owned pharmaceutical companies.

We feel that certain definite measures should be adopted very rapidly, and they are as follows:

1. Our Government should recognize the existence of our Canadian-owned pharmaceutical companies, and the particular contribution they are making in the pharmaceutical industry;

2. Our Government should assist our growth and expansion by giving us financial assistance, when merited, through the IDB, and perhaps even declare the Canadian-owned segment a "depressed one" in the generally prosperous pharmaceutical industry; or perhaps even make available subsidies under certain circumstances.

3. Our Government should critically examine all new legislation affecting the pharmaceutical industry, in order to see that the new laws do not affect adversely the growth of the Canadian-owned pharmaceutical companies;

4. Our Government should urge all Governmental Agencies, Federal, Provincial and Municipal ones alike, hospitals and all other institutions, to "Buy Canadian" pharmaceuticals, as long as our prices and the quality of our products are right and competitive;

5. Our Government should assist us in our research activities by providing research funds on worthwhile projects, fully or partially, since invariably a few of us sooner or later will engage in pharmaceutical research, which is an absolute must, once a company develops into a certain size;

6. Our Government should help us with export financing, since a few of us are anxious to build our volume more rapidly by entering into the export area, in particular since we do not have parent companies which would restrain us from exporting;

7. Our Government should give us representation or establish proper liaison with the various officials of the Department of National Health and Welfare, so that our group may offer our consultations in matters of mutual interest.

8. Our Government should instruct the Department of Industry—which Department already has taken an interest in our affairs—to carry on with continued effort and assist us in becoming a significant group in the pharmaceutical industry.

9. Our Government should establish an institute for drug evaluations and clinical investigations in order to assist all manufacturers to carry out the necessary clinical tests in hospitals or any other suitable places, being similar in operational concept to the Ontario Research Foundation;

10. Our Government should remove the new drug status from all preparations as soon as they appear in the official pharmaceutical standards, such as B.P., U.S.P., N.F., B.P.C.

11. Our Government should give preference to marketing of new pharmaceuticals developed by Government Institutions, Universities or hospital research teams, through Canadian-owned companies.

We might add finally, that we are aware that the pharmaceutical industry is international in concept and operation. Therefore, the establishment of an international network of houses throughout the world, is the order of the day, and peculiar to our industry. Nevertheless, our group firmly believes that for

the interest of our country, a healthy balance of at least 25% Canadian ownership versus 75% foreign ownership should be maintained— as it is today in England—or at least a large enough Canadian ownership to have a regulatory and balancing effect in the pharmaceutical industry.

2. *Our viewpoint as Professionals*

The members of the Canadian Drug Manufacturers consider themselves a highly-trained, professional people and as such, they wish to maintain high professional standards and comply with our Drug Regulations.

The maker of pharmaceuticals has an old history, dating back thousands of years, and has always been a respected individual as long as he maintained the standards of his time. Today, the basic makeup of the modern manufacturer is not different, merely the ramification of his work has become very complex, due to the advances in the pharmaceutical industry during the last 30 years.

Therefore, if we wish to become recognized by our Government, the profession and the public alike, we must maintain high pharmaceutical standards, self-imposed or otherwise. We therefore ask the assistance of our Government and its proper agent, the Food and Drug Directorate, to help us to become "properly rated."

It appears to us that all our members should comply to the 74-GP-1 standard, or any other satisfactory standard established by the law. The compliance with this standard should be one of the requisites to become a member in our group.

It appears to us that our plants—and there are not too many—should be visited by a Drug Inspector more frequently, in order to assure all parties, the Government, the trade and ourselves, that we are conducting our pharmaceutical manufacturing in the proper manner. Probably one specially trained Drug Inspector could look after our affairs regularly, and his upkeep—from the economical viewpoint—would be very little, considering the overall benefits the public would enjoy in the maintenance of a viable Canadian segment in the pharmaceutical industry.

We challenge the view of the P.M.A.C. that only "their" members can maintain the proper pharmaceutical standards and that our products are of inferior quality. Instead, we believe, as expressed by our former Food & Drug Director, the respected Dr. Morrell, that the "attitude" of the manufacturer is the most important consideration, besides his ability and plant facilities.

Whether it be self-enlightment, or the establishment of stricter Drug Regulations that will impose upon us the proper professional standards, is immaterial. The fact is that our members can conduct themselves on the proper professional level and we would like to be recognized as such.

3. *Our views as businessmen*

As businessmen, we shall attempt to examine to a limited degree, the operating structure and some business aspects of the pharmaceutical industry, and shall pass on some of our observations on the costs of drugs.

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In dealing with the costs of drugs, one should define at what level costs are examined, such as retail, wholesale or manufacturing. We are not qualified to examine critically the drug prices at retail and wholesale levels, since we are not engaged in those activities. If we may add in passing as observers—after all we do deal with retailers and wholesalers—we are under the impression that drug prices at those levels are "reasonable," since drug stores and wholesale houses have operating statements readily available. Besides, competition among retail stores—in particular as of most recent—exists in a very lively manner.

We feel that we can comment on the drug prices at manufacturers level from a more direct knowledge of our own affairs, although little or no information is available on the operation of the Canadian pharmaceutical subsidiaries.

It appears to us that our Government has an access—in fact they already possess this information—on the profitability of the pharmaceutical companies in Canada and the comparative position of the industry with respect to other industries.

However, there are available financial statements of the publicly-owned pharmaceutical companies abroad. These, our Government likely possesses, and here the figures speak for themselves, and very loudly so.

There are several operational aspects in our industry which puzzle us a great deal and we would like to submit them to you for your consideration.

We are mindful of the fact that large pharmaceutical companies periodically do come out with important new pharmaceutical specialties, but we wonder why the prices of medicines are kept up uniformly high for a long period of time among the few companies "licensed" to market the particular pharmaceutical? We wonder whether research costs are amortized only once or several times, and when drug prices drop, is it primarily because of competition or external pressures? We wonder why medicines such as sulfa drugs, penicillin and polio vaccines—which were available to all the manufacturers without licence, were sold at low prices to the public, whereas others were kept up at a high price?

We wonder what really determines the price of drugs. Is it a cross-licensing arrangement with the tacit understanding to sell drugs at the "prices the market bears" or is it "competition" or some other "factor"?

We wonder why our members can sell drug "a"—already on the market for over 10 years—at prices of about $6. per thousand, and make a reasonable profit, whereas another manufacturer still sells the same drug in Canada for about $41. today, and sells the identical medicine in England for about $17. per thousand tablets? The sample is not unique.

The perennial answer of course, given by all large pharmaceutical companies in their attempt to explain drug prices, is the "high cost" of pharmaceutical research. Just how "high" are these "high costs"? According to the Hall Commission Report, it is estimated to be about 3% in Canada based on sales. According to other reports in the U.S.A., it is about 5-7% for most companies and only a few companies spend as much as 10% on research, whereas they readily spend 35-40% of their sales volume on all kinds of promotional activities.

We wonder therefore, is not research *greatly overplayed* by the various pharmaceutical companies, in order to uphold their "image" before the public, and assure their profitability to the shareholders?

We may "marvel" at the pharmaceutical discoveries we have been blessed with by the various pharmaceutical manufacturers but objectively we are not impressed by the fact that they "do research". Can one imagine an industry with a volume of 170 million dollars and not doing research at all? How will they obtain their new products and assure that their sales will increase? Of course, a television company will do research in developing colour sets, and a pharmaceutical company will do research in developing new and better medicines. In both cases "brains" and "creative thinking" are involved by human beings. Therefore John Public justly wonders why drug costs are high, by contrast to other products where a greater competition exists.

Drug Patents also deserve some comments. We believe that the original inventor of any product, including drugs, should be rewarded for his ingenuity for a certain period of time. We feel, on the other hand, that the present PATENT LAWS on drug inventions should BE REDUCED FROM 17 years to about 3-5 years. The inventor will recover his investment on research during this period of time without fail, in particular since he also has the opportunity to become firmly established in the market being the first one there.

Alternately, we would urge the Government to implement a quicker and more efficient way of issuing compulsory licenses in a very short period of time, rather than becoming entangled in long and costly legal proceedings as is the case today. Perhaps the compulsory licensing approach could become a more practical and quicker way of solving the problem than changing our existing Patent Laws.

We might add in passing that several economists wonder why patent systems should be allowed at all within those areas of industry where "widespread distribution of the new product would be of immediate benefit to the community". (Page 30, Drugs, Doctors and Diseases—by Brian Inglis.)

Others, such as the Kefauver Committee, decided that "patents had to a great extent been transformed in the drug industry from a reward to the individual inventor into an instrument of market control". If so, then should our Government not take another closer look at our present patent system of drugs and critically examine it?

The members of our group feel that the most effective way to lower the prices of any product, including drugs, is by means of competition. If our Government encourages an atmosphere of competition in our industry, drug prices gradually must come down. The recent interest on the part of physicians, pharmacists, some manufacturers and the public in Generic medicines, serves to this end.

III. GENERIC VERSUS BRAND-NAME MEDICINES

Generic-name medicines are those which are marketed by various manufacturers under their officially-assigned names, rather than by trade names. For example, Butazolidine is a trade name, and a registered trade mark, whereas

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Phenylbutazone is the generic—or also proper name—since it has an official status and it is in the public domain.

We should point out immediately that some of our members market their pharmaceuticals under brand names, others under generic names, while some of us under both names, or with a distinctive feature, such as Phenylbutazone, but specifying a special company.

In most cases our pharmaceuticals, whether marketed under brand names or generic names, are usually sold at much lower prices than those of the large companies.

Perhaps a brief background on generics might be appropriate at this point.

Generic medicines had different meanings and associations at different periods. Before about 1950, almost all companies, large and small alike, marketed generic medicines. No special importance or stigma was attached to them in those days. Examples of generic medicines are glycerin, ascorbic acid, acetylsalysilic acid, and so forth.

During the period of about 1955-1963, generic medicines were almost synonymous, or at least associated with, so-called "generic houses," which fell into disrepute because they were accused of:

1. selling substandard medications;
2. having no research at all but existing as parasites;
3. violating drug patents;
4. operating fly-by-night companies;
5. rocking the boat of the profitable large pharmaceutical companies.

Perhaps in those days the above accusations were not entirely unjustified.

Since about 1963-66, due to self-enlightment and stricter drug regulations, the generic industry corrected itself since now:

1. their pharmaceuticals have proper quality controls, in particular if company maintains 74-GO-1 standards;
2. no longer are they violating some patents which did not hold up in the courts;
3. they are now firmly entrenched in the pharmaceutical market.

Our understanding is that some of the companies are already doing research and as the other ones increase in volume and size, they are bound to become engaged in research sooner or later.

We firmly believe that today good houses do have high-quality pharmaceuticals which do not differ from the products of the large maker, except in price. Invariably generics cost much less and represent a considerable saving to the individuals or the taxpayers. Today, many welfare patients receive generic medicines and are satisfied with them.

Some of our members—as pointed out before—market their pharmaceuticals under their own brand name, which sell at a lower price than the drugs from the larger houses. They feel that it is possible to market pharmaceuticals with less promotional fanfare, and lower operating costs. Besides, they are also satisfied with lower profits.

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It is a matter of more than passing interest that in England—according to Sir Hugh Linstead (June 8, 1966 speech in Hamilton at the O.P.A. Convention), about 25% of the medicines today are generically written, as opposed to branded specialties—and yet they represent only about 15% of the total drug expenditure.

It appears that if our Government wishes to save the taxpayers money during the prepaid prescription programs—as part of the overall Medicare program—it is well advised to encourage physicians to write medicines by generic names, whenever possible, or alternately issue a formulary listing all products, branded ones and generics alike, but with a price ceiling.

It is also a point of interest that most—if not all—Government agencies already purchase medicines by their generic names.

It is most improbable that generic medicines will ever have a greater market share in the near future than 15-25%. Yet they will bring about a substantial saving in the overall costs of medicines on one hand, while they will also exert a "regulating" activity by means of competition, on the other hand.

In the opinion of Sir Hugh Linstead, they did not affect adversely at all pharmaceutical research in England, and it is unlikely that they will in Canada, should there by any significant research done in Canada in the future.

IV. WHITHER CANADIAN-OWNED PHARMACEUTICAL INDUSTRY?

Having appraised the position of the few Canadian-owned pharmaceutical manufacturers, the question arises, "What is our future?" This depends on two factors, the attitude of our government, and the attitude of our manufacturers.

If our Government considers it desirable to create an ENVIRONMENT which is FAVOURABLE TO THE GROWTH of Canadian-owned drug companies, SOME of our most imaginative and enterprising INDUSTRIAL LEADERS WILL inevitably EMERGE. Under such circumstances we predict that:

1. A few large companies will emerge;
2. They will market drugs at lower prices yet engage in research;
3. Under the influence of competition, all drug prices will come down and the taxpayer will pay less for prepaid medical programs;
4. The large companies will have to co-exist with the smaller companies, each making a contribution to our economy in a regulatory and balancing fashion;
5. The Canadian ownership in pharmaceutical manufacturing shall be preserved.

If our Canadian Government makes the existence and the operation of the Canadian-owned company very difficult, by creating an unfavourable environment for growth, then the companies will quickly sell out almost completely, and their owners will likely enter into other businesses where conditions are better.

We have a great confidence that our government and our law makers will correctly appraise our industry and understand our viewpoint and will then act accordingly.

V. SUMMARY

The Canadian ownership in the pharmaceutical drug industry is sadly disappearing. Unless our government steps in quickly by creating an environment favourable to the growth of Canadian-owned pharmaceutical companies, they will quickly disappear. The complete "take-over" of the pharmaceutical industry will likely have serious economic and political consequences for our nation, besides the loss of our identity as Canadians.

APPENDIX I

MEMBERS OF CANADIAN DRUG MANUFACTURERS

Mailing Address: Canadian Drug Manufacturers,
P. O. Box 433,
Scarborough "A", Ontario.

(Protem) Chairman—Leslie L. Dan, B.Sc. Phm., M.B.A.
Counsel—Dr. George F. Wright,
Professor of Chemistry, Research Consultant

Aerosol Custom Pharmaceuticals Ltd.
24 Sable Street,
Toronto 15, Ontario

Barlow Drugs
Cap Rouge, P. Quebec

Canada Pharmacal Ltd.
50 Picadilly St.
London, Ontario.

Canadian Nutritional Products Ltd.
283 Danforth Road
Scarborough, Ontario

Dymond Drugs Limited
46 Spalding Drive
Brantford, Ontario

Empire Laboratories Ltd.
301 Lansdowne Avenue
Toronto, Ontario

Jules R. Gilbert Ltd.
3701 Dundas Street West
Toronto, Ontario

K-Vet Laboratories Ltd.,
P. O. Box 273,
Galt, Ontario

Lukas Pharmaceuticals
2 Thorncliffe Park Drive
Toronto, Ontario

Medipharm Pharmaceuticals Ltd.
49 Millwick Drive,
Weston, Ontario

Noco Drugs Limited
24 Sable Street,
Toronto 15, Ontario

Novopharm Ltd.
1290 Ellesmere Road
Scarborough (Toronto), Ontario

Nordic Biochemicals Ltd.
4324 St. Lawrence Blvd.
Montreal 18, P. Quebec

W. E. Saunders Ltd.
P. O. Box 2784
London, Ontario.

Templetons Limited,
56 Colborne Street,
Toronto 1, Ontario

APPENDIX II.

APPROXIMATE PROFIT STRUCTURE OF THE VARIOUS LEVELS IN THE PHARMACEUTICAL INDUSTRY

	Percentage (before taxes)
Manufacturing (Large Companies)	
— Canadian Subsidiary (human pharmaceuticals)	15%
— Foreign Parent Company	20-35%
WHOLESALER	0.9%
RETAIL PHARMACY	4-5%

Comments:

1. In assessing the True Earning position of any subsidiary company, the Parent Company must also be examined;
2. If the Parent Company is a Complex, engaged in many activities, such as producers of raw materials etc., only the pharmaceutical division should be considered.
3. Return on Investment is also a very effective way to measure the earning position of any industry. It is interesting to note that most industries in Canada have a Return on Investment of about 10%, whereas pharmaceuticals have 19.5%. We wonder what is the return on NET capital employed?

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APPENDIX III

PHARMACEUTICAL DISTRIBUTION PATTERN IN CANADA
(through retail drugstores)

Conventional	*Direct*
Manufacturer	Manufacturer
↓	↓
Wholesaler	
↓	
Retailer	Retailer
About *40% of volume* sold via Wholesalers	About *60% of volume* sold Direct to Retailers

DISCOUNT STRUCTURE

Conventional		*Direct*	
Retail Price	$10.00	Retail Price	$10.00
less 40% retailers markup	4.00	less 40%	4.00
	6.00		6.00
less 16⅔% wholesalers markup	1.00	less Sales Tax—about	.50
	5.00		
less Sales Tax 11%	.50		
Received by Manufacturer	$ 4.50	Received by Manufacturer	$ 5.50

Comments:

1. About 60% of pharmaceutical sales (according to C.W.A.—Canadian Wholesalers Association) is made direct to retailers, at list price less 40%, thus manufacturers are also performing the wholesalers function.
2. Many pharmaceutical houses give only 25% or 33⅓% discount to retailers—when goods are bought via wholesale house.
3. Manufacturers follow MULTIPLE PRICING POLICY, e.g. Government Hospitals, Doctors, Large Customers, likely buy under better terms than the average retailer.

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APPENDIX IV

FACTORS AFFECTING THE COST OF A PHARMACEUTICAL PRODUCT

ITEM	COUNTRY OF ORIGIN	% SHARE
RAW MATERIAL	Foreign (mostly)	
RESEARCH TO DEVELOP RAW MATERIAL	Foreign (mostly)	
MANUFACTURING INTO DOSAGE FORM (e.g. tableting, capsulating etc.)	Canadian	
QUALITY CONTROL	Canadian	
RESEARCH ON FINISHED PRODUCT —Product development —Clinical etc.	Foreign and Canadian	
PROMOTION & MARKETING —sales force —journal advertising —samples —product information to trade —miscellaneous etc.	Canadian	
DEPRECIATION AND AMORTIZATION OF CAPITAL EXPENDITURE	Canadian and Foreign	
GENERAL OVERHEAD	Canadian	
GROSS PROFIT	Usually Foreign	
TAXES	Canadian	
NET PROFIT	Usually Foreign	

APPENDIX V

WHAT ACTUALLY DETERMINES THE

PRICE OF A PHARMACEUTICAL

1. OBJECTIVE	—	Cost Factors
2. SUBJECTIVE	—	What the Market Bears
	—	Competition

APPENDIX "D"

A Look at Canadian

Pharmaceutical Research

A brief submitted by

George F. Wright

to

The House of Commons Special Committee

on Drug Costs and Prices

Government of Canada

Ottawa, Ontario

A LOOK AT CANADIAN PHARMACEUTICAL RESEARCH

By George F. Wright

The word "research" derives from the French "recherche" meaning "diligent search." It is implied that the search is for knowledge, but knowledge may be of different kinds. Consequently "research" is commonly divided into fundamental or basic research versus applied or developmental research. It is my opinion that the pharmaceutical industry does practically no fundamental research. On the other hand they do a large amount of developmental research.

There is nothing unusual about this developmental activity. Modern industry in our present day economy is expected to carry on extensive research programs as adjuncts to marketing programmes. A division is usually made on the one hand between those investigations aimed at existing products and the customer's use of them and on the other hand to the development of new products. Industrial research is as much a part of modern business as is advertising and for the same reason: It is of benefit to the stockholders. The large pharmaceutical houses are no different from other big businesses in this respect. The indirect benefit to the Canadian public is valuable but it is no more than nowadays we expect.

What is unusual about research by pharmaceutical houses is that they sanctify it. They nurture this sanctity by association of their new drugs with the betterment of health and the lower death rate among humans. But the fact is that improved nutrition has contributed much more to human health than have drugs. It is significant that drugs have been least successful for cancer and diseases of the heart which do not seem to be dependent on nutrition. Some have even said that modern drugs obstruct advancement in public health because they are not designed for avoidance of sickness. With the exception of old drugs like quinine and a few new drugs used for contraception and other gonadropic applications the modern drugs are not designed for preventive medicine. Instead of this ideal of the future, our drug manufacturers concentrate on the more profitable curative drugs of yesterday and today. This is good and proper business but it does slightly tarnish the golden calf of pharmaceutical research as it is advertised.

It would be foolish to deny that improvement in drugs has made life more livable. So has modern fire fighting equipment. Sickness and fire are matters of emergency and the best is none too good in the time of need. At such times one is loathe to shop for bargains. But in this noncompetitive circumstance it becomes a matter of morality that the costs of such services are not onerous. For this reason, when high drug costs are blamed on research the anatomy of this research ought to be examined closely.

Drug Research By Molecular Engineering

There are several paths that may be followed in the genesis of a new drug. The first of these might be called the "sharpshooter" methodology. Both the weapon and the target are known. The game is to center on the target by repetitive correction of error. The assumption is made that pharmacological action is directly related to chemical structure. An old drug of known structure but with low potency and/or undesirable side effects is chemically disassembled

and its parts are examined to discover the key group of atoms responsible for pharmacological action. Then various new attachments to this key group are made chemically until an optimum of physiological activity is attained.

Perhaps the oldest example of this procedure is the creation of synthetic local anaesthetics by alteration of the chemical structure of cocaine. One of the newest examples seems to be the synthesis of new antitubercular drugs along the pattern of the relatively ineffective substance called Spermine. Economizing shortcuts are possible by application of *pro-tem* theories during the programme but the procedure is essentially like an assembly line. A laboratory is built in which a number of alternatives are synthesized on a routine basis using standard organic chemical procedures and then are tested on animals by a similar routine. In contrast to fundamental research the method is admirably adaptable to group effort; indeed it is characteristic of a laboratory of this type that the staff is frequently "in conference," receiving instructions for tomorrow's work.

To be sure there is no guarantee of success. The company may fail to find a better drug just as the dye chemist may fail to synthesize a better colour. However the history of developmental research shows that it pays. Over the period of time that the investment may be amortized the risk has been found to be low.

Another use of the same type of laboratory is the practice that John T. Connor of Merck calls "coattail riding." The term applies to the alteration in chemical composition of a competitor's product to the degree necessary to avoid patent infringement. Although Connor does not consider the practice to be admirable he would, as an economist, no doubt admit that it keeps the industry on its toes. Besides that the molecular engineering research which I described above is of itself coattail riding. Molecular engineering research depends upon careful and continuous scavenging of the scientific literature for new fundamental ideas from Universities and other non-profit institutions. Also it depends upon the methods of synthesis and analysis devised by fundamental academic research that proceeded it. When I indulge in coattail riding I consider myself to be in exalted company such as that of Mr. Connor.

One of the valid objections to coattail riding is the creation of unnecessary drugs. But this is only an exaggeration of the original danger arising from the molecular engineering practice. It is only natural that a large capital investment will be defended whether or not its product is sufficiently valuable to justify introduction into the Pharmacopoeia of Drugs. However this danger can be minimized by a supervisory body to define a need of novel therapy and to advise in the initial stages whether a socalled novel drug meets the definition. Such supervision has been lacking. I do not believe that such supervision will decrease incentive among the pharmaceutical research laboratories. It will only change the mode of operation so as to make them more efficient. The judgment when to discontinue a research programme in other chemical industries is dictated by competition. In an industry which caters to public health the competition factor is weak. Other regulation is necessary to prevent over-expenditure of wealth on horse-drawn buggies.

Drug Discovery by Screening

There is another method of developmental research for new drugs which depends more on physiology and less on chemistry than does molecular engineering. It has been called the "shotgun" method of drug discovery. More formally it is known as the multiple screening procedure. It is based on the converse assumption that much is yet unknown about the association between chemical structure and pharmacological action. It is significant that much of its present application involves cardiac and cancer therapy. By this method a programme of physiological tests with animals is set up for as many different physiological aspects as the investment will permit. Substances are chosen largely at random to be classified according to pharmacological action. It was this type of screening procedure which brought the sulpha drugs into existence.

The multiple screening procedure can be productive not only of new drugs but also of new ideas about drugs in the sense that theories arise out of the accumulation of unprejudiced facts. Understandably it is not a method which is favoured (at least publicly) by commercial drug research laboratories because new uses for well-known compounds are not patentable in Canada. Some significance must attach to the observation that new drugs emanating from commercial drug research laboratories are almost always new and therefore patentable compounds, despite a reservoir of about two million known chemicals the majority of which have not been examined pharmacologically. The "sharpshooter" argument that patented drugs have been molecularly engineered to minimize undesirable side effects has not been borne out in practice. In retrospect it would appear that some of the "sharpshooter" products would have benefitted by a subsequent "shotgun" screening! It would be refreshing to see a new drug appear on the market which had done service before as, say, a stabilizer for gasoline. Such an occurrence is unlikely at the present time, except from a non-profit institution.

A Canadian Drug Institute

There are ramifications, modifications and combinations of the two principal procedures for discovery of new drugs, influenced, among others, by medical research. It is evident that both the sharpshooter and shotgun methodology can exist together. Nevertheless the profit motive is greater in one than the other and a non-commercial counterbalance to industrial drug research would seem to be desirable.

I have indicated earlier that some regulation concerning the therapeutic value of new drugs is needed. Offhand one might expect that the utility of a new drug would be a function of patentability but such is not the case. A chemical substance must have hitherto been unknown to be patentable, but its degree of utility is accepted by the examiner as an unproven assertion by the applicant for the patent. In part this is due to the fact that patent examiners are not medical men. Much of benefit to the public would accrue if the patent law not were strengthened in respect of the utility of drugs. I do not believe that developmental research would diminish as a consequence. I do believe that the quality of developmental research would be improved.

However I believe that there is a better way of retaining the advantages of research without suffering the economic and social problems that it has created

in the drug field. I propose the establishment of a Canadian Drug Institute, to be subsidized initially by the Federal Government and maintained by taxation and by charges to industry for services rendered. However neither government nor industry should be involved in administration. This function should be supervised by a Council drawn from the professions of medicine, pharmacy, pharmacology and chemistry.

The Institute as I envision it would not duplicate, but rather would supplement the duties of the Food and Drug Directorate. It should have six main functions which I have listed in the order of implementation.

1. To assess the therapeutic requirement for a new drug in Canada.
2. To regulate some preclinical and all clinical trials of a new drug.
3. To assess the therapeutic value of a drug proposed anew for use in Canada.
4. To participate in multiple screening tests for discovery of new drugs.
5. To be involved in fundamental research in pharmacology and medicine.
6. To promote the development of preventive medicine in Canada.

I would not expect all of these functions to be implemented simultaneously.

I have already indicated the reasons, economic and therapeutic, for the first and third of these functions. I recommend the second function (involvement in preclinical and clinical test) because it interconnects the first and the third and also for the following reasons:

A. Animal life, and finally human life, is unavoidably involved in the fruits of the developmental research on drugs. Experimentation with human life is too serious a matter to be left entirely in the hands of the experimenter, no matter how proficient he may be. Enough evidence of questionable practice is already at hand to indicate that drug research may suffer severe and unjustified restriction if any more instances such as Thalidomide arouse the public. It is time that the professions police themselves. The joint professional involvement in the Institute that I have suggested will provide this self-discipline in which Canada may well pioneer.

B. The costs of clinical investigations are exorbitant, largely because of the haphazard way in which they are organized and conducted. The result of these high costs brings some drugs into use because it becomes too expensive to examine more than a few of the candidate substances which may have utility. One may question whether the chlorine in the 5-position is really significant, but there it is, protected by a patent which is protected by the clinical investigation that was made on it. It would seem to be in the public interest that a committee in a drug institute of the involved professions were to supplement the good work of the Food and Drug Directorate with respect to clinical investigations.

C. There is considerable of latitude in which clinical investigations are carried out depending on whether the investigators are safety or efficacy-conscious. In consequence there are drugs on the market which are as

safe as sawdust, and about as effective. But they are more expensive than placebos and they are not prescribed in the same way. Committee review from an Institute of clinical trials in progress would decrease the number of unnecessary drugs, with benefit to the prescribing doctor.

D. The small drug companies today are unable to support animal colonies in which preclinical studies may be made, nor is there sufficient of commercial service testing with animals in Canada to which such companies may turn. In the interest of Canadian drug research a service laboratory in the Institute should be maintained.

It is evident that the establishment of a preclinical testing laboratory in the Institute will provide an establishment for the fourth function when it can be implemented. The fifth and sixth functions will depend upon Canadian's enthusiasm for their Institute as it develops.

Summary

I do not believe that drug research in Canada is an unmixed blessing, especially since it is not very Canadian. Analysis of developmental research methodology indicates that it is unbalanced in Canada and it needs to be regulated. I propose the establishment of a Drug Institute to effect this regulation.

APPENDIX "E"

List of the present members of L'Association des Fabricants du Québec de Produits Pharmaceutiques:

Nova Drug Limitée	3660 St. Joseph Boulevard West Montreal.
Unik Medical Labs Inc.	286 St. Paul Street West Montreal.
J. M. Marsan Co. Ltd.	2795 Bates Road Montreal.
Laboratoire Bio Chimique	2323 St. Aubin Road Chomedey, P.Q.
Anglo French Drug Ltée.	2795 Bates Road Montreal.
Neo Drug Limited	5476 Upper Lachine Road Montreal.
Millet & Roux Co. Ltd.	2323 St. Aubin Road Chomedey, P.Q.
Casgrain & Charbonneau Ltd.	445 St. Lawrence Boulevard Montreal.
Ethica & Co. Ltd.	3398 Metropolitan Boulevard Montreal.
Laboratoire Pentagone Ltée.	3800 Metropolitan Boulevard Montreal.
Laboratoire Franca Ltée.	3555 Metropolitan Boulevard Montreal.
Laboratoire Demers Ltée.	2721 Tremblay Street Quebec City, P.Q.
Laboratoire Octo Ltée.	920 Port Royal Street East Montreal.

Companies to join in a near future

Laboratoire Nadeau
Laboratoire Desbergers

OFFICIAL REPORT OF MINUTES

OF

PROCEEDINGS AND EVIDENCE

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LÉON-J. RAYMOND,

The Clerk of the House.

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament
1966

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 9

THURSDAY, OCTOBER 13, 1966

WITNESS:

Mr. Laurence Wilson of Montreal, Quebec, Member of a Firm of Consulting Biologists.

ROGER DUHAMEL, F.R.S.C.
QUEEN'S PRINTER AND CONTROLLER OF STATIONERY
OTTAWA, 1966

24767—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

Vice-Chairman: Mr. Patrick T. Asselin (*Richmond-Wolfe*)

and

Mr. Brand,	Mr. Hymmen,	Mrs. Rideout,
Mr. Chatterton,	Mr. Isabelle,	Mr. Roxburgh,
Mr. Clancy,	Mr. MacDonald (*Prince*),	Mr. Rynard,
Mr. Côté (*Dorchester*),	Mr. Mackasey,	Mr. Tardif,
Mr. Enns,	Mr. O'Keefe,	Mr. Whelan,
Mr. Howe (*Hamilton South*),	Mr. Olson,	Mr. Yanakis—24.
	Mr. Orlikow,	
Mr. Howe (*Wellington-Huron*),	Mr. Pascoe,	
	Mr. Prud'homme,	

(Quorum 10)

Gabrielle Savard,
Clerk of the Committee.

MINUTES OF PROCEEDINGS

TUESDAY, October 11, 1966.

The Special Committee on Drug Costs and Prices having been duly called to meet at 9.30 o'clock a.m. this day, the following Members were present: Messrs. Chatterton, Enns, Harley, Howe (*Hamilton South*), Isabelle, MacDonald (*Prince*), O'Keefe, Orlikow (8).

There being no quorum and the witness not having appeared, the Chairman adjourned the meeting until 9.30 a.m. Thursday, October 13, 1966.

THURSDAY, October 13, 1966.
(15)

The Special Committee on Drug Costs and Prices met this day at 9.45 a.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Messrs. Chatterton, Enns, Harley, Howe (*Hamilton South*), Hymmen, Isabelle, MacDonald (Prince), Mackasey, O'Keefe, Whelan, Yanakis (11).

In attendance: Mr. Laurence Wilson of Montreal, Quebec, member of a firm of Consulting Biologists.

After outlining his background, Mr. Wilson summarized his brief and gave further information on the advertising of drugs.

Before proceeding to the questioning of the witness, the Chairman conveyed to the Committee the invitation of the Chairman of the Pharmaceutical Manufacturers Association of Canada to visit the premises of its member companies.

He also brought to the attention of the Committee a resolution passed by The Catholic Women's League of Canada in August 1966, with respect to the high cost of drugs.

On motion of Mr. MacDonald (*Prince*),

Agreed,—That two letters, dated October 5 and October 7, from Mr. W. J. Blakely, Accountant of the Committee, re: Submission of PMAC, and re: Sales Taxes, be printed as appendices to this day's proceedings. (*See Appendices "A" and "B"*)

Mr. Wilson was examined on his presentation. It was agreed to print the brief as an appendix to this day's proceedings. (*See Appendix "C"*)

At 11.40 a.m. the Committee adjourned to 9.30 a.m. Tuesday, October 18, 1966.

Gabrielle Savard,
Clerk of the Committee.

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MINUTES OF PROCEEDINGS

EVIDENCE

(Recorded by Electronic Apparatus)

THURSDAY, October 13, 1966.

• (9.45 a.m.)

The CHAIRMAN: Gentlemen, I think we could commence this morning's meeting.

These are some letters and other material I would like to read into the record at a later time but we will let them go for the present. We will now open the meeting.

This morning we have with us Mr. Laurence Wilson from Montreal. His brief has been before the committee; in fact, it has been in our possession for a longer period of time than the committee members have had it. I am sure that everyone has read it. I will now ask Mr. Wilson to introduce himself to the committee.

Mr. LAURENCE WILSON (*Member of a firm of biological consultants, Montreal*): I have been asked to identify myself as to my occupation and why I should write such a brief. I would say that it is more as an outsider looking in than an insider telling a story. When I wrote the brief I had just come out of hospital and was writing from the patient's point of view.

For five years before my illness I had been editor of *MD of Canada,* one of an American chain of medical publications. Before that I had been a member of the scientific staff of the Office de biologie at the University of Montreal. At various times I have engaged in advertising, research and journalism and once I had a spell as an advertising man. That, I believe, is enough background on why I should do this. The reason I wrote this brief was that I was in hospital and I had time to think about it. Once in a while every one of us should spend some time in isolation and look at life from a broader point of view than actually earning our dollars.

Now, to summarize what I have written here—and I am not going to read it to you as I have been told that you do not want me to read it to you and I do not want to do it, either—is that the Hall Commission wanted to cut down the amount deductible, for income tax purposes, from advertising expenditures to 15 per cent of total sales.

In the United States the amount is said to be—I am no accountant and I do not know the figures but I have asked other people and I have been a member of the Pharmaceutical Advertising Club, ex officio—24 per cent of sales. In Canada it is about 29 or 30 per cent. Pharmaceutical companies in the United States spend on doctors from $3,000 to $4,000 a year per doctor. They spend $60 per year on postage costs alone. I give you these figures for what they are worth; I do not question them; I do not know too much about them.

However, what I want to say is that in Canada we follow very much the same system as in the United States; we have the same pharmaceutical firms, we have the same everything, but we have not yet caught up with the United States where the average doctor takes his post graduate education—and I am using this term a little frivolously as it is not post graduate education but provides what some people call their post graduate education—by reading advertising and reading matter that is not written by doctors but is written by people who did not know the subject 20 minutes before they started writting it; it is written by advertising men for two major publications in the United States which are greater, richer and considered more important than the *Journal* of *the American Medical Association* itself. The same does not apply to Canada so far although the press, in which non-doctors write for the purpose of pushing advertising, gets more revenue than the medical press itself.

Now, the contention of this brief is that the patient who is paying all this—you are lying in bed and you are paying—is being served by an exact industry, a precise, marvellous industry, the pharmaceutical industry, and by a doctor who has had many years of training and you do not like a lot of this money to be spent on frivolous things that are only done for the sake of putting money into somebody's pocket. The proper place, according to our Canadian system—in other words, the capitalist system—for advertising to appear is in the doctors' own professional magazine where the editor or the contributing doctors, who are not going to be influenced by advertising, can in safety contradict that advertising and they can draw attention to its weaknesses. I can tell you as a medical editor, not as a doctor, that if you hear it said, which is a fact, that salicylates are better for rheumatism than some of the much advertised drugs, if you want to hold your job you will be careful not to say that because salicylates are only aspirin. They do not cost much and the other drugs cost a lot of money and they bring in the revenue and they pay you a salary.

If we are going to be treated by a doctor, the doctor is himself a human being; he is influenced; he works a ten-hour day. He is influenced by things that come to him. He does not know the ins and outs of advertising, journalism and the rest of it. He is influenced. He gets these samples, and so forth. At this time of the year he receives sometimes ten and as much as twelve pounds of matter in the mail a month. He cannot possibly read it all. He never does. He puts it straight into the waste paper basket. Advertising paper is the most expensive paper in the world, I believe, because it has short runs. Twenty thousand doctors in Canada is a short run for a printer with a four-colour press. It is a big run if you are sending out five cent post-cards, it is a thousand dollars, but if you are printing for them it is a very short run and you will find the average printer—I will give you an example, the Montreal *Gazette*—does not like that kind of printing and yet it is one of our leading printers. It is too short a run, too expensive, and it does not really justify the effort, but it does justify the effort because, as I say, in the States they are spending $3,000 to $4,000 a year per doctor and that is the target that is being aimed at in Canada.

There is no reason why this $4,000 should not be spent on the doctor if it is well spent, if it is not frittered away, if it is not taken away by people whose only aim is to make money. How much of this goes down the drain? I cannot give you the figures on that but it is a great deal and more than is actually

spent on serious advertising in Canada. I do not know the percentage; it is possibly about 20 per cent more, albeit non-sponsored advertising in Canada is greater than the United States doctor-sponsored advertising. What to do with that situation is very simple. It is very simple indeed because we have a Canadian precedent. In Canada we used to have the same situation in sampling. Everybody received samples. I do not know about newspapermen present here but I have been a newspaperman and I have received samples, sometimes of most alarming drugs. Somebody would give a sample on this list and they would send it out to everybody. I have had most alarming drugs sent to me. I did not have thalidomide sent to me, that was after my time, but I have had queer drugs about sex, about the restoration of sex, and old men's remedies, and so forth. These drugs went to newspapermen, they went to nurses, doctors' secretaries, doctors' wives. You bought them in drug stores. The doctors did not want to throw them in the waste paper baskets and they gave them to the druggists and you bought them in drug stores marked "Physicians' sample".

If you were a pharmaceutical firm you could not stop because your rival down the street was sending out these things too. But the government acted. Why did the government act in that? According to keynesian economics the government could step in, not to hinder anybody but to help somebody, like a traffic cop. Once in a while when things go wrong and people cannot do it themselves the government can come in as a kindly figure and stop it. So the government came in and passed a bill that this sampling must stop unless asked for. There was no opposition that I know of. Nothing happened. Every doctor in Canada receives all the drugs he wants. He signs a post-card every six months. He gets all the drugs he wants but the doctors and the nurses and the other people do not get them. There was a bad situation which was righted by a very simple thing.

In this other type of advertising Canada has not yet reached the same stage as in the United States where great industries are shovelling out this material and many people are employed. If you were to stop it in the United States now you would put a lot of people out of jobs. That makes a very difficult situation. You cannot very well pass legislation in a case like that. Policy is the art of the possible and there it becomes impossible. You will have strikes and people hitting back at you. In Canada I estimate that about 20 people altogether, including stenographers, would lose their jobs if legislation were passed curbing this great outpouring of advertising.

As for advertising agencies, I do not know of one that depends entirely upon pharmaceutical advertising. Some would lose an account; some would not. I do not believe, and this is important, that the amount of savings per patient would be very great because I believe the pharmaceutical companies are not advertising now to sell drugs, they are advertising for prestige. I found an ad in *Time* magazine today by a well known drug firm; it is not expecting to sell drugs to anybody, it is advertising for prestige. They have been pushed into expensive advertising. There are 25 very good medical publications in Canada and they are all starved for advertising because they are most faculty publications, provincial publications, local government publications, and so forth, and they are specialty publications. They are starved for advertising. They do not get much. Nobody is interested in putting four colour advertising into their papers, and yet they are read a great deal. People go for the social, the showy,

and they go into the four-colour jobs, which includes the Journal of the Canadian Medical Association, of course, but some others are not published by doctors at all and are published for profit, they are the pace setters and those are the ones that make the money.

The Hall Commission talked about various things but did not say advertising; it said advertising, sales promotion, detail men and other similar items. This is a term quite impossible for you as legislators to handle because it is too vast. What is promotion? The big promoter of LSD is a doctor in the United States who is in hiding some place. But we all know about LSD and it has never had a line of advertising. The big promoter of LSD also was Aldous Huxley, Aspirin was promoted after the war when it was taken over from the Germans, not in publications but by Noel Coward in his plays. I do not know whether advertising actually sells drugs. For example, contraceptive pills; if you take any general medical publication nowadays you might think it should be called the Contraceptive Gazette because it advertises almost nothing but contraceptive pills, except two publications, *L'Union Médicale du Canada* and *Laval Médical,* two French Canadian publications which do not on conscientious grounds use this advertising. Yet the fact remains that we have figures and you have figures here in Ottawa which show that the present Canadian population, and therefore French Canadian doctors, use these products just as much and maybe a little more than anybody else. So what is the purpose of this advertising? *Time* magazine occasionally has a very, very expensive insert from a Canadian firm saying, for example, that it is doing research. There are four firms doing research in Canada. I have communicated with the four and only one has been willing to tell me what it is doing. They are doing research.

• (10.00 a.m.)

It is paid for, of course, fifty-fifty by the Canadian Government. I do not think research enters into the picture at all to remind many drug firms. In winding up I say that what succeeded with sampling only two years ago could very well succeed while the time is ripe, while no big Canadian organization has entered into this business and built up staff that would have to be acquired and while no big Canadian concern is in it to say that tax exemption privileges shall be accorded up to 15 per cent, exactly as the Hall Commission said, on printed matter that goes to the doctor.

I have mentioned detail men, here I have eliminated it in my text, it is on page seven. I think detail men are too hard to handle.

This is no cure-all but it would make the doctor's "slush pile"—I do not apologize for the word "slush pile", it is a term used in publications—of papers disappear. I have a paper here, I am not going to tell you the name of it but it is a fairly good paper on a drug used to reduce tension in the eyeballs or of the kidneys or someplace where it has been building up dangerously. It is only used about six times a year by the average doctor and an interne would use it about twelve times a year. It is hardly worth the advertising. They send this out. It is printed in the United States. It is very simple. It is printing imitating typewriting but it is very simple and it consists of a large number of pages and I do hope that any time a doctor injects a drug into me for the purpose of taking the pressure out of the eyeballs, for example, that he knows what he is

doing. I do hope he knows all the counter-indications because every drug in the world, including common table salt, has counter-indications. It was given to me by a doctor as a sign of the incompetence of drug firms, and I do not agree with him because I am using my head and nobody else's. It was sent out with a slide rule dosage calculator so that you can put the weight and the dosage, and so forth, together and give the patient exactly what he needs to prevent him from becoming blind or having his kidneys fail him. I do not believe that any one of Canada's 20 thousand doctors read that because it came with the "slush pile" of coloured stories, funny stories, gramophone records and things that open up like accordions. It came with all that and it is a very dull-looking manuscript. Doctors and scientists have to read dull things and they read them for a very serious purpose. I cannot see a man taking time out of a ten-hour day to read this, and yet he should. I think we should give the doctor more time and give the pharmaceutical company more time by cutting out all this deadwood and all this wicked material devised to make money out of the sick man for people's pockets—some Americans—by a very simple piece of legislation that can be applied and it was applied and it succeeded in the sampling situation. That is all I can say.

The CHAIRMAN: Gentlemen, before we go on to questioning, there are a few things I would like to bring to your attention. First of all, would anyone like to have read into the record the list of meetings in the future at this time or would you prefer I just send this around for your information? Incidentally, before I forget, I had a telephone call from the gentleman who was to appear before us Tuesday, Mr. van Ular. He apologized. He had written telling us that he had had an accident and that he would be unable to come. He apologized that he had not arrived here in time for the Committee meeting, so I rescheduled him at a much later date.

There is a letter of invitation here from the Smith Kline & French company to any members who have never seen a drug firm in its operation to visit a drug firm just to see how it operates and how drugs are made. They have offered the use of their facilities for anyone who might want to go through a drug company. If anybody wants to do so they can speak to me about it. The company is in Montreal.

There is also a resolution here from the Catholic Women's League of Canada. I think the best thing to do with this would be to put it in the minutes: "Be it resolved that we, the Catholic Women's League of Canada assembled, strongly urge the Commons Special Committee on drugs whose Chairman is Dr. O. H. Harley, M.P., to take immediate and firm action in the preparation of a realistic report to the House of Commons".

There are two communications from Mr. Blakely, the Committee's accountant.

Mr. MACKASEY: Was a bill instituted, Mr. Chairman?

The CHAIRMAN: No, neither one of which is a bill.

Mr. MACKASEY: I suggest that you read them.

The CHAIRMAN: I think they are too lengthy. I would like to have the Committee's approval to print them today. One is regarding submission of P.M.A.C. to the Special Committee on Drug Costs and Prices. As you remember,

there was some discrepancy between Dr. Briant and Mr. Blakely. This is a letter explaining the discrepancies. The other is the report that the Committee has been waiting on regarding federal sales tax and its influence on drug prices, which we asked our accountant to prepare in an effort to try to explain the discrepancies between the various figures that have been quoted in committee on the influence of the federal sales tax. May we have a motion that these be printed as part of today's record. All agreed?

Agreed. As you know, we are beginning an examination next Tuesday of six to eight drug companies, hearing one a day at which time Cyanamid of Canada, whose brief is now in your possession, will be in front of the Committee. I have spoken to both the accountant and the legal counsel for the Committee. It is their intention, at my request, that they will be here at nine o'clock. They will then have a few minutes' chat together about the brief. They will meet in the room where the Committee members are to examine the witnesses. If any Committee member wants to go and talk to our accountant or to counsel about anything in that brief and to discuss it with them, they will be available there from 9:15 o'clock until 9:30 o'clock. I thought this would be a reasonable way to do it so the members of the Committee can have the benefit of their opinion before the witnesses appear. They will be in the same room the Committee is meeting in. The door will be closed until 9:30 o'clock until the meeting itself starts.

Mr. MACDONALD (*Prince*): It is too bad it cannot be a little longer than 15 minutes. Some of these briefs—

The CHAIRMAN: I am sure they will have no objection to meeting you at nine o'clock. This will give you half an hour. They will both have studied the brief beforehand and will have made their notes on the side.

If there are no other matters, we will return to the questioning of the witness.

Mr. HOWE (*Hamilton South*): I would like to commend you first on the brief. I think it is excellent. It is the type of material we need from somebody who is on our side and in agreement with us.

There are just two or three things, rather briefly. You said that the stopping of sampling was done by a government order to help the drug companies. I thought it would be worthy of note that this did not reduce the price of drugs, however.

Mr. WILSON: I do not believe it will and I do not believe that this measure that I am talking about now will substantially reduce the price of drugs. What I am saying here might reduce it by about ten per cent, which is a negligible amount, 90 cents instead of one dollar. I believe it will put order into the drug business and that is a part of economics.

• (10.10 a.m.)

Mr. HOWE (*Hamilton South*): Of course, what we are interested in is lowering the price of drugs.

Mr. WILSON: Good economics will lead to better housekeeping and to lower prices. I believe that it could lower the price of drugs.

Mr. HOWE (*Hamilton South*): It will be a saving as far as the garbage man is concerned, no doubt, as far as doctors' garbage pails are concerned.

You made a statement in your brief that 80 per cent of the currently used drugs of this kind were not known ten years ago. Do you believe that to be accurate? As a practicing doctor, I believe that certainly the bulk of drugs that are being used today were being used ten years ago. I think this is the point, that drug detail men and much of our advertising are purely competitive; in other words, it is a matter of identical products being advertised forcibly through the various means that you have stated in straight competition with another drug company who is making the same thing. If 80 per cent of our currently used drugs were new within the last ten years, one could then justify a lot of the advertising that is done because this would be a form of promotional advertising of new drugs which would justify more of it. I feel that it is unjustified myself as a practitioner because most of it is simply competitive. In other words: "use our drug instead of drug X because ours is better." Likewise, the other man comes in and convinces you the other way; yet, they are identical drugs which are simply being competed.

Mr. WILSON: I must agree with you because I understand what you are saying is true. I have been influenced by the Pharmaceutical Advertising Club and by things said by the College of General Practice.

Mr. HOWE (*Hamilton South*): I believe that a lot of the drugs now used are combinations of old drugs which come out under a new name, but I do not think that 80 per cent of the actual generic drug is new in the last ten years.

Mr. WILSON: That is quite possible.

Mr. HOWE (*Hamilton South*): I agree with you in another thing, and this has come up before in this committee, that the *Vademecum* is certainly the most reliable source of information for doctors. It is usually unprejudiced and unbiased, and so on, yet it was brought up by Mr. Mackasey in one of our meetings early in the summer that all drug companies do not admit the contra-indications, such as you have set out on page 2 about the middle of the page. This, I think, is something that should be enforced even if it cost them a few hundred dollars more to extend their description of a drug to include these contra-indications. I think this would be money much better spent than on some of the foolish gimmicks in advertising that are received and thrown in the waste basket or, in some instances, put in paper bags and brought to this committee to show how ridiculous they are.

Mr. WILSON: A point there is that *Vademecum* is a private publication and the government can go too far in forcing a private publication to do things, especially when that publication itself is not covering the field and is not getting all the advertising it would like to get.

Mr. HOWE (*Hamilton South*): I do not think that the enforcement should be to the publishers but rather to the drug company doing the advertising. It should extend to all the contra-indications because I believe that this is the most reliable source of information about a product—its uses, its dangers, its complications, its packaging and its dosage, and so on. This gives you, without pictures, without gimmicks, without four-colour advertising, a pure and simple scientific explanation of a drug in a very brief form, which is really all the average doctor needs.

Do you not agree that this is almost sufficient as far as paper type of advertising is concerned?

Mr. WILSON: Yes, I think it is.

Mr. HOWE *(Hamilton South)*: If you could call it advertising. It is more descriptive than advertising.

Mr. WILSON: Well, it is advertising in the sense that it is paid for by the companies and the doctor buys it, does he not?

Mr. HOWE *(Hamilton South)*: No, it is given to him.

Mr. WILSON: I see. I have to buy it.

Mr. HOWE *(Hamilton South)*: It is promotional but it is informative. I think you could put it that way instead of straight advertising.

I think that covers my point. I would just like to reiterate that I am thoroughly in agreement with what you said in this document here.

Mr. O'KEEFE: Mr. Wilson, I would like to commend and congratulate you, too, on this brief. On page 4, under the heading "The Remedy", you say "After all this, the remedy is surprisingly simple. It is twofold, as already explained. The first part consists in giving government backing to the drug houses to get them out of what is commonly called a 'rat race'."

What kind of government backing do you envisage?

Mr. WILSON: The backing I had in mind would be some type of legislation that would curb the privileges of people who distribute so much mail and they would then stop this practice. The industry would then feel that the government was on their side and was helping them. As I say, in our changing system of economics the government should step in to help somebody when he is overwhelmed with his problems and not before and not after.

Mr. O'KEEFE: There is one other phrase in your brief which intrigues me, Mr. Wilson, and that is in connection with "sponsored golf games". Can you tell me how sponsored golf games add to the cost of drugs to the patient?

Mr. WILSON: I have sailed on board ship and have been at conventions, and so forth, with doctors at which there were fashion shows and many things like that. This money comes out of the funds of the drug company; the drug company derives its money from the patient—the sick man—or, in the case of medicare, from the policy holder; in the case of national medicare, from the taxpayer, and some of this money is being spent to entertain doctors. The brief does not object too much to that; the brief allows that promotion is done in a very large number of ways and it attacks none of them except one, and that is printed advertising. The Hall Commission attempted to take it all in but it, of course, could not do it. It makes an impossible piece of legislation. This is a simple piece of legislation. It will reduce that "slush pile". It will not do much else.

Mr. O'KEEFE: But you do talk about golf games and other things.

Mr. WILSON: Yes. The golf game is given as an example of the many ways in which a pharmaceutical company and any other company which has a promotion department takes out people for fishing expeditions and many other things. Some of these are good and some are bad.

Mr. O'KEEFE: You are suggesting that all these things add to the cost of the drug to the patient?

Mr. WILSON: Well, the only income of the pharmaceutical industry is from the patient. There is just no other income.

Mr. HOWE *(Hamilton South):* Mr. Chairman, I think what Mr. Wilson means is that the drug companies do, in fact, sponsor various things such as doctors' golf games with very valuable prizes, and this spread all across the country to all these various local golf games contributes a fair amount of money as far as what they represent is concerned. They do not give drugs, they give very valuable prizes.

Mr. MACKASEY: Mr. Chairman, I would like clarification from Mr. Wilson on one point: On the bottom of page 3 of your brief, Mr. Wilson, you say: "To contrast the two top publications in respect of page rates: *Journal of the Canadian Medical Association,* $330 a page and $100 for each additional colour; *MD of Canada* (a commercial give-away promotion magazine, edited in the U.S.), $470 a page and $130 for each added colour." What is the circulation of the *Journal of the Canadian Medical Association* and the circulation of *MD*?

Mr. WILSON: About 17,000; the other one is about 22,000.

Mr. MACKASEY: In other words, the one that is charging a little more has a little bigger circulation?

Mr. WILSON: It has a little bigger circulation.

Mr. MACKASEY: Your brief is more accurately broken down in that way, page per thousand? This is usually done.

Mr. WILSON: It might have been. This is a pharmaceutical situation. These are known figures; the amount of money taken in by non-medical publications, if I may say it that way, is considered to be greater than the amount of money taken in by medical publications.

Mr. MACKASEY: But that is not the point I am discussing. You made that quite clear in your brief.

The CHAIRMAN: Gentlemen, could I make one point? I am not sure whether *MD of Canada* is a free publication to the medical profession in that it is not paid for, whereas the...

Mr. MACKASEY: This is inaccurate.

• (10.20 a.m.)

Mr. WILSON: Yes, I agree.

Mr. MACKASEY: You are getting on the record what is not in the record. If you advertise in *MD of Canada* at $470 a page you are getting greater circulation than if you advertised in the *Journal of Canadian Medical Association* at $330. In other words, if you take into consideration circulation the rates are very similar.

Mr. WILSON: Somewhat, yes.

Mr. HOWE *(Hamilton South)*: There is a far greater volume over a paid circulation than there is over a free circulation.

Mr. WILSON: Yes, of course. In advertising you usually take it that way, that paid circulation, according to the APC is a much better bargain than unpaid.

Mr. MACKASEY: It is a matter of opinion, with the ad agencies which is preferred, I would imagine.

Mr. WILSON: Yes. But the advertising precept is that—.

Mr. MACKASEY: Mr. Wilson, I have read your brief and listened to Dr. Howe's comments, and I agree with Dr. Howe's sentiments on the question of this gimmicks matter. We have been through it at just about every meeting and we have had representatives of the pharmaceutical industry here who have agreed with Dr. Howe and agree with you. They contend that gimmicks are a much smaller part of their advertising dollar today than it was a year or two ago, or even five years ago, when enlightened people like yourself start exposing it for what it is. Nevertheless, the thing that concerns me about your brief and about your presentation this morning is that everything you have said is equally applicable to the food industry, the automobile industry, the television industry, and to all industries and businesses that are run under the free enterprise system. It is competitive business.

Mr. WILSON: Yes and no.

Mr. MACKASEY: Would you consider that the drug industry is competitive?

Mr. WILSON: The architects, the biologists, and every profession that I know of, except the doctors, is not inundated by the same mass of material. As the Hall report said, drugs are something different. But drugs are also a small, highly profitable business; portable, exportable, and there is a lot of money in them and there are a lot of people getting money out of this.

If you are an architect you do not get this kind of mail. If you are an engineer you do not get it. If you are a veterinary surgeon or a dentist you do not get it.

Mr. MACKASEY: Mr. Wilson, in other words, your main purpose here this morning is to come to the assistance of the doctors who are receiving mail indiscriminately.

Mr. WILSON: To protect the patient who is lying in bed sick and is paying out of his dwindling bank account for the attention he is getting, and is being bled by this system.

Mr. MACKASEY: Would you explain, because I am really vague on this, how you are relating it now to the patient. Are you telling me that the doctor does not have enough knowledge of his profession that he is prescribing for the patient strictly on the strength of advertising in trade publications?

Mr. WILSON: I do not like using names but Dr. "X", who was formerly the president of the Canadian Medical Association, Canada's supreme body, later became the president of a pharmaceutical association which in its way was Canada's supreme body, and while he was president of the Canadian Medical Association he deplored the misuse of wonder drugs by doctors. He and other physicians deplored the fact that there are doctors going around who do not diagnose, they omit the stage of diagnosis. They see an infection and they give an antibiotic and they bump it off, or maybe they do not.

Mr. MACKASEY: Could I stop you there, Mr. Wilson? The point I am trying to get at without badgering you or fighting with you is that I can understand, knowing doctors here, that doctors would know of new drugs, never mind the brands. They would know a sulpha drug when it came along; they would know of the latest antibiotics; they would know the latest methods, etc. As far as I can see, these advertisements try to persuade the doctor to buy Smith Kline & French's product over Robin's product or over Horne's product, or vice versa.

Mr. WILSON: Yes.

Mr. MACKASEY: But unless I am under a misapprehension I was always under the impression that the advertising was designed to stress the virtues of one brand over another, rather than introduce something completely new to the doctor. What I am getting at is that the doctor should know from other sources that sulpha drugs have arrived, when they did arrive many years ago and the proprieties they have. All the advertising does is try to convince the doctor that Robin's product is better than somebody else's, in the same way as ads try to convince us that one television set is better than brand "X" on the next page.

Mr. WILSON: There is a great deal of that.

Mr. MACKASEY: A great deal of what, sir?

Mr. WILSON: There is a great deal of boosting one particular product as against a competitor, and that is the source of a great deal of this extra advertising. Let me cite a case, Salk vaccine. When Salk vaccine was discovered, vaccines having similar effects were discovered simultaneously by three separate parties: there was Cox, there was Sabin and there was Salk. If the government had not eased that competitive situation it could have become a competitive situation—if it had licensed all three drugs. Then the anti-conception pill would not have had a chance compared with the tremendous bonanza to advertisers of three competitive brands. The government did ease that situation and it was a good thing for all the children.

Mr. MACKASEY: What you are saying, Mr. Wilson, is that by eliminating competition between three brands it lowered the cost of drugs.

Mr. WILSON: I do not know whether it did.

Mr. MACKASEY: It did lower the cost of drugs. It prevented the doctors from being bothered with a lot of literature.

Mr. WILSON: Three to four thousand dollars is spent on a doctor by advertising firms a year in the United States, according to the gross figures, which are only an estimate, and it cut into that considerably.

Mr. MACKASEY: I am a little confused. You have said on several occasions this morning that its effect on the eventual cost to the patient is incidental. Therefore, the only other logical reason that you have for your brief is that it annoys the doctors.

Mr. WILSON: No, no. It is always a good thing to create order out of chaos especially in such an exact profession as medicine. The Greek word for "order" is "oíkónómus". I am talking strictly on an economic subject, which is the subject of this committee. I believe that before things get too chaotic and cost too much money that they can be put into order with a friendly hand from the government.

Mr. MACKASEY: May I ask a straight question here? What effect does it have on the eventual cost to the patient, this excessive advertising that you are talking about? What effect does it have in your opinion, and I do not expect you to get down to dollars and cents?

Mr. WILSON: It is very difficult to do an accountant-like job on this because the amount spent is a fairly large thing, the $4,000 per doctor in the States, and I would say that it is about $3,000 or $2,500 in Canada, is borne and paid for by the patient. Eventually that would be saved to the patient.

Mr. MACKASEY: You see, sir, earlier we had accountants' figures here in a brief that we challenged, and at which our accountant was present, where the cost of the prescription worked out to about a copper. Is it the copper we are trying to save on the prescription or is it the abuse of the mails in making a nuisance of themselves through the medium of gimmicks to doctors, and if so, would you not extend this proposed legislation to myself, who may be on the sucker list of some mining corporation or some book club? Would you not give all the people of Canada the benefit of this type of legislation?

Mr. WILSON: When it becomes necessary. The brief—

Mr. MACKASEY: Excuse me. That last statement is important and I do not want to get back to the brief. You say "when it becomes necessary", but is that not a matter of opinion when it becomes necessary?

Mr. WILSON: The Hall Commission in Volume 1, page 42, in its recommendations said: "That in the application of the provisions of the Corporation Income Tax to manufacturers, importers, and distributors of drugs, consideration would be given to establishing a maximum of 15 per cent"—they give a reason for it—"This recommendation differs from that of the Restrictive Trade Practices Commission for two reasons." Now this is what we are talking about. "The drug industry is different from other industries in that its products are essential for health and, indeed, life. 2. The great bulk of production of drugs for Canadian consumption is produced by non-Canadian companies."

It is different because its products are essential for life. This might save a man from going blind some day. It is not just a bottle of beer.

Mr. MACKASEY: All right. But you are jumping back again to a very pertinent and good point, and I am not necessarily disagreeing with you, you are saying that this very good piece of literature gets lost in all the other literature.

Mr. WILSON: Yes.

Mr. MACKASEY: Who produced that good piece of literature?

Mr. WILSON: A drug firm.

Mr. MACKASEY: A drug firm. Now it is good in your opinion, if you set yourself up as a judge as to what is good and what is not good.

Mr. WILSON: No. If I had to give an opinion on that from an advertising point of view I would find fault with it. The main fault I find is that it did not effect your first purpose.

● (10.30 a.m.)

Mr. MACKASEY: From the information concerned.

Mr. WILSON: From the point of view of the doctor who produced it it is exactly the kind of thing I would like to see if there were such a publication as the *Vademecum* and there were enough volume to include it. I would like to see this put in there because the doctor could turn it up and when he wanted to treat my eyes or my kidneys he could see what he must know and what he must not do and how much to give.

Mr. MACKASEY: The point I am trying to make, Mr. Wilson, is that I view with suspicion any effort to tamper with advertising in free enterprise whether it is drugs, food, television, shoes or anything else unless someone points out to me clearly, and without referring to degrees, that it is creating a hardship. No one has convinced me, including the Hall Commission, that it has a strong effect on cost of drugs. We have these figures in front of us; one cent per prescription. Secondly, no one has convinced me that it has been detrimental to the health of the patient because a good doctor does not buy a pig in a poke no matter how heavily it is advertised. He might buy one brand as opposed to another brand of the same basic product.

Mr. HOWE (*Hamilton South*): Mr. Chairman, with Mr. Mackasey's permission may I interject a couple of things here. There is one thing which you said that I think is wrong; you said something about one cent, and I presume you mean advertising costs on a prescription. By the P. M. A. C.'s own admission there was 11½ cents on promotion of their 37½ cents on the prescription dollar.

Mr. MACKASEY: Of the 11½ cents I think one per cent was direct mail, the other was detail men.

Mr. HOWE (*Hamilton South*): I think he admitted to two cents on gimmicks alone. Here is the point I think we are losing; we are comparing advertising of drugs with advertising of television sets, and so on. The direct consumer receives the benefit, if it is a benefit, of advertising when it comes to television or refrigerators. But the consumer does not receive any of the benefit of the gimmicks; the doctor gets them and he is actually acting as a promotional sales person for the drug company to sell to a patient, who receives none of the benefit of this advertising in other forms of advertising. Therefore, this advertising really is in a different category and if we can save the patient money by reducing this kind of advertising to the doctor it would be beneficial.

Mr. MACKASEY: If we could eliminate the gimmicks tomorrow I would not feel too badly.

I think you have proved more powerfully than anybody the absurdity of gimmicks when you came in here with a bag of them and put them on the table. We all agree. I agree one hundred per cent. I am basically talking about advertising in magazines, because according to the question you asked Mr. Wilson he was associated for some years with a magazine called *M.D.* and early in the brief—I believe at the bottom of page three and the beginning of page four—Mr. Wilson was quite specific about advertising in magazines. Frankly, I should apologize, Mr. Wilson, because I am talking about magazine advertising rather than the gimmicks.

Mr. WILSON: Both the gimmicks and the "slush pile", the 12 pounds of material to the doctors.

Mr. MACKASEY: How do you know it is 12 pounds and not 8.7? This annoys me because five witnesses have come here and everybody has a different evaluation of the weight of the mail that a doctor receives per month.

Mr. HOWE (*Hamilton South):* Would you like me to weigh mine for a month?

Mr. MACKASEY: How much does it weigh?

Mr. HOWE (*Hamilton South):* I said would you like me to? I have never weighed it. I do not know.

The CHAIRMAN: It weighs the same amount every month.

Mr. HOWE (*Hamilton South):* It is very heavy to carry down to the garbage pail or the waste basket.

Mr. MACKASEY: This is just for the sake of accuracy. We get a lot of mail, too much mail, the doctors are getting this mail and they accept all these things. All the witnesses say that a doctor gets 6.8 pounds one month, or he gets eight or ten or twelve pounds, and I want to know what is the source?

Mr. WILSON: This was weighed on my doctors' scale.

This "slush pile" is a very interesting thing. It is in demand. It has a market value. I have spoken to doctors about this "slush pile" and it is very awkward for them to gather it all up and put it in a box and give it to somebody. They give the job to their secretary and the secretary finds it has a market value. They sell it to pharmaceutical companies who want to analyze what the doctors are receiving and to make their own release accordingly. It is a very interesting thing, this "slush pile". It should be studied more, and it is studied in detail.

Talking about this small amount, this one cent. I have read balance sheets—I am no accountant, I am not very good at accountancy at all—but I have read statements by good firms saying their advertising is .0001 per cent of the total cost. In that case, if that is true—which I doubt—they should not object. I think it is about 25 per cent and I am told by the Parmaceutical Advertising Club in Montreal and in Toronto, where they have to deal in such things, that it is about 29 per cent. If it is so small they could have no objection to this piece of legislation going through. They will lose one half of their exemption.

Mr. MACKASEY: I am now referring to page two of the manufacturers portion of prescription dollar in the submission to the House of Commons Special Committee on Drug Costs and Prices by the Pharmaceutical Manufacturers Association of Canada in June of this year. If you could give us some information proving this is wrong we would appreciate it, because we fully intend to delve into this with them this fall. I would appreciate any concrete evidence you can give us that this is inaccurate. It sets out under manufacturers portion of prescription dollar the following: field sales expense, 5½ cents administration of marketing, selling and advertising functions, 1½ cents; advertising and promotion, 4 cents; medical and pharmaceutical advertising, 1 cent: direct

mail advertising, 1 cent; samples, 1 cent; medical exhibits, space and other, 1 cent. This is the basis of my earlier opinion that one cent per prescription is spent on direct mail advertising.

The CHAIRMAN: You are quoting 1 cent out of the manufacturers' cost of 37½ cents. If you would use the figures on the opposite side of the page it gives the percentage, I think.

Mr. HOWE (*Hamilton South*): That is on the dollar, not on the prescription.

Mr. MACKASEY: It is on the dollar prescription.

Mr. HOWE (*Hamilton South*): It is not on the prescription, it is on the prescription dollar, which is—

Mr. MACKASEY: It is on the 99 cents, and it is such a minimal amount that you can see that if the prescription is $5 they are saying it is 5 cents.

Mr. HOWE (*Hamilton South*): The total is 55 cents.

Mr. MACKASEY: I think this is an important point, Mr. Chairman, and it sets out here. The manufacturers portion of the prescription dollar, which is 37½ cents, and that is one third of the prescription. In other words, we can then multiply all these components by three. Direct mail advertising is then 3 cents on 37½. All I am saying, Mr. Wilson, is that from the point of view of economics these arguments do not stand up.

Mr. WILSON: Direct mail refers only to certain letters which are sent. Direct mail does not include magazines, for example, and it does not include many things.

Mr. MACKASEY: How do you categorize magazines?

Mr. WILSON: As I said at the beginning, I am no accountant.

Mr. MACKASEY: This has nothing to do with accounting. When you were with *M.D.* and a drug company was advertising in that magazine, would it be fair to assume they would classify that as medical or pharmaceutical advertising?

Mr. WILSON: I do not know how they classify advertising in a magazine, whether they call it direct mail or whether they call it by some other name.

Mr. MACKASEY: If it is under direct mail it means it is even less, because it has to be included with all the gimmicks and everything.

Mr. WILSON: It is not direct mail, it is something else.

Mr. MACKASEY: We have it here, I can help you out. It is broken down into four categories. There is medical exhibits, space and other. I assume that refers to conventions and it obviously is not there. Samples. It would not be under samples. The other two categories are direct mail advertising and medical and pharmaceutical advertising.

Mr. WILSON: For example, *Time* magazine has a—

Mr. MACKASEY: Excuse me for a moment, Mr. Wilson, I am asking the questions. There are only two categories left, direct mail advertising and medical and pharmaceutical advertising.

Mr. WILSON: I am producing a fifth category.

• (10.40 a.m.)

Mr. MACKASEY: But you see, for their dollar they do not have a fifth category.

Mr. WILSON: But they have spent the money.

Mr. MACKASEY: The money they have spent on magazine advertising has to fit into one of these four categories.

Mr. WILSON: It cannot. You cannot fit *Time* magazine advertising into one of them. It just is not safe.

The CHAIRMAN: You are asking Mr. Wilson to comment on a brief which you have in front of you but which he does not have in front of him.

Mr. MACKASEY: Well, I will be glad to put it in front of him.

The CHAIRMAN: No, but the point is—

Mr. MACKASEY: Mr. Wilson is evading my question.

Mr. WILSON: No, I am not. You have asked me to pick sides. You have asked me to fit five pints of beer into four glasses and I cannot do it.

Mr. MACKASEY: I am sorry, Mr. Wilson. If we are going to talk about beer, you are down to my level and I can make it quite clear. I have the four glasses of beer right here and there is the big pot. Here is the beer which is your general advertising dollar.

Mr. WILSON: Yes, yes.

Mr. MACKASEY: Now, for the sake of accounting, instead of calling it class A, B, C and D so that the balance sheet is a little more knowledgeable, they say they spent so much on direct mail, so much on advertising and conventions, so much on samples and so much on magazine and newspaper advertising and institutional advertising, such as appears in *Time*. So it is in one of the four categories. Now, I just want you and I to agree on which of the four categories because there were specific amounts indicated for each of the categories. You now have the brief and I am just quoting from memory. Samples, I think, are down there as one cent on the manufacturer's portion of the dollar. Conventions, I think, are another cent and advertising in magazines is a cent. Am I right on that, Mr. Chairman?

The CHAIRMAN: I wish you would get away from this cent. I think you are just confusing everybody. I do not know about the other members, but I wish you would use the percentage figures which are quoted. They add up to 11 per cent.

Mr. MACKASEY: We will use that because four times three is twelve. It works out to 11 per cent of the retail dollar.

Mr. WILSON: Yes, 11 per cent.

Mr. MACKASEY: Of the retail dollar.

Mr. WILSON: The figure I have is 29 per cent and here they give 11 per cent. This is for a particular item.

Mr. HOWE (*Hamilton South*): What are we leaving out of that 11½ cents of the 37½ cents?

Mr. MACKASEY: There is research.

Mr. HOWE (*Hamilton South*): No, no, I see it being promotion. I do not have the brief in front of me and that is why I am asking the question.

The CHAIRMAN: I should say the 30 per cent that we have been talking about in the past is an addition made up of what is called "field sales expense", 15 per cent.

Mr. HOWE (*Hamilton South*): That is the one we are leading up to.

The CHAIRMAN: Administration of marketing, selling and advertising functions, 4 per cent; advertising and promotion,—which is what we have been talking about here—11 per cent, which totals 30 per cent, and this is the 30 per cent.

Mr. HOWE (*Hamilton South*): But that 15 per cent must be included in the over-all promotion of a drug. The field representative—

Mr. MACKASEY: Mr. Wilson is not advocating elimination of the detail man but the brief, and I have read it several times, is pin-pointed to advertising. He is making an excellent point. Advertising expense on direct mail through the medium of gimmicks, which we all agree is—

Mr. HOWE (*Hamilton South*): No, the detail man brings the gimmicks and I would presume that this would come under field representation.

Mr. MACKASEY: You and I do not want to get at cross purposes.

Mr. HOWE (*Hamilton South*): No.

Mr. MACKASEY: I would like to ask you a question which may eliminate it. Do you think the field man will be eliminated or will he still come with something else?

Mr. HOWE (*Hamilton South*): No, but I think that the field man's—the detail man's—over-all expenses can be cut down by the elimination of some of the things he carries with him to give to you. The majority of the gimmicks come directly across your desk from the detail man. They do not come in the mail.

Mr. MACKASEY: Possibly someone else can take over, Mr. Chairman. I feel embarrassed that I have talked at length, Mr. Wilson. The point I would just like to summarize, sir, and I could perhaps come back to it, is that whether we like it or not the drug industry in Canada operates under a free enterprise system and advertising is part of that system. Whether it is drugs or not, the company supporting brand A has a perfect right to advertise its product as opposed to brand B under our system, and as opposed to the pharmaceutical industry in Poland or Russia.

Mr. WILSON: Or Denmark or any one of the democratic countries like that?

Mr. MACKASEY: Well, Denmark has a little different system. There is not too much competition in many areas, but that is something else.

The point I am getting at is that you have not made your point and you have admitted on two or three occasions that the effect on the cost of the drug to the patient is minimal. Yet you are more concerned, and this seems to be the theme of your brief, that the doctors are being annoyed by too much mail—what you call the "slush pile".

Mr. WILSON: I do not represent the doctors; I represent the patient.

Mr. MACKASEY: All right, but you have been making a case for the doctors and not for the patient. Now, if you make a case for the patient I would gladly listen to it.

Mr. WILSON: I am writing as a patient; I am not writing as a doctor.

Mr. MACKASEY: But your whole brief is talking about the literature that the doctor receives.

Mr. WILSON: It refers to the fact that the doctor is too busy to read these and because he is getting these things he cannot read good briefs like you have in front of you.

There has been a book written on the general practitioner in Canada by a child specialist in Toronto—I forget his name for the moment—but it states in that book that the doctor is an over-worked man who has many problems and he should be in a position to read continually because medicine changes continually, and he is being annoyed by a lot of material which prevents him from reading such things as this, and as a patient I feel very much alarmed about this.

Mr. MACKASEY: I see.

Mr. WILSON: I am paying for it.

Mr. MACKASEY: In other words, what you are saying is that the patient is not getting adequate treatment from the doctor because he is so tied up with the reading of this other material that he does not have time for medical briefs and the patient is suffering because of it. That is a summary of what you have just said?

Mr. WILSON: No. The effecting of order out of chaos is always to be found, eventually, in economics but here is a case where the pharmaceutical industry has got its house out of order through competition—useless, wasted competition—and each one is trying to give the doctor something that will show up and stand out more than the other one. There are people who are very much employed in that business. There is a man who has a brief waiting to see what Cardinal Leger is going to say next about contraception and they are going to play that up in their advertising, and so forth. All this costs a lot of money, and it is usually money about nothing. Dr. Wylie of the Canadian Medical Association also felt the effect of this when he was a doctor: doctors who see a new drug and write a prescription on it to see how it will work without actually diagnosing the patient.

Mr. MACKASEY: Do you mean that there are doctors who would actually do that?

Mr. WILSON: There is a whole book on the subject written and published three years ago by a doctor who made a survey on behalf of the College of General Practice. Doctors are human beings.

Mr. MACKASEY: What you have just said is that the patient has to be protected against the unscrupulousness of certain doctors who would do just what you have described.

Mr. WILSON: Every patient and everybody in the world has to protect himself as best he can through legislation, if possible, against incompetence which exists in all fields and which is promoted by some people in the medical field.

Mr. HOWE (*Hamilton South*): Mr. Chairman, I think the doctor really has only one source of information on his drugs and this is from the person who discovered the drug or who is manufacturing the drug, and this is the drug manufacturer. I do not think this could be termed as being unscrupulous on the part of the doctor because he has no other source of information. I think the

doctor is the last one in the world who wants to eliminate a source of information; what he does want to eliminate is the unnecessary junky advertising that is received day after day that is purely competitive against another drug and which, according to the figures in that brief, is also hidden in that 15 per cent.

For example, your field representative or detail man has a certain quota of samples per month or per quarter that he is allowed to give out to doctors and I think that also hidden within that 15 per cent is a lot of the advertising under the over-all cost of your field representations. I do not think it is all within that one cent or within that 3 per cent, I think it is in some of the other things, too, and I think the over-all elimination of this could conceivably considerably lower the cost of drugs to the patient. I think this is what Mr. Wilson means and it is certainly, as a practitioner, how I feel. I do not think the doctor, prescribing according to his advertising, is being unscrupulous.

Mr. MACKASEY: Mr. Chairman, I took this inference from Mr. Wilson's remarks. I would just like to make my position clear, Mr.Wilson. I agree with you that a lot of advertising is in bad taste, not only in the drug industry but in all industries. I agree with Dr. Howe that gimmicks are insulting but we have to define when it is a gimmick and when it is some unusual piece of promotion. Some of the so-called gimmicks have proven to be of use.

At the same time I am very reluctant and very loathe to interfere with the advertising industry in general because when people set themselves up as censors as to what is good advertising or bad advertising, they are not so far away from people who set themselves up as censors in the field of literature and books. This is a fundamental part of our free enterprise system.

• (10.50 a.m.)

If we ever reached the point where we had one drug company operating in Canada, and only one drug company, then you would eliminate the necessity for advertising brand A versus brand B. But this is not our system; we have many drug companies, as you know, and we have much legislation to protect or to keep competition legitimate. They circumvent this legislation the same as the automobile industry does when they can get around it; the same as cartels in paving, and all the rest of it. We all know about this. These things are protected by legislation. I just do not know why the drug industry should be different because they are selling pills on a competitive basis. You and I or anyone else can go down to the stock market and buy shares in that company. Until we change the system, why put them under a handicap that you are not putting other private enterprise under, particularly when you have not proved to anybody's satisfaction that this advertising is detrimental to the health of the patient. Dr. Howe (*Hamilton South*) did mention, and I am glad about it, that there is added protection between advertising and the patient, and that is the integrity of the doctor and the medical profession to recognize the need for this, but the quickest way to eliminate poor advertising is for the doctors not to prescribe to that particular company's brand if the advertising promotion effort of their item is in bad taste. Certainly a doctor can distinguish between a good piece of literature and a bad one, or a good piece of advertising and a bad one.

Mr. HOWE (*Hamilton South*): How can he do it if they all advertise that way?

The CHAIRMAN: And he does not have time to assess it all. Mr. MacDonald has a question.

Mr. MACDONALD (*Prince*): One of the things that I am concerned about that Mr. Wilson does not seem to answer specifically enough for me, at least, is the fact that if there is to be some limit set on the amount that can be spent on advertising, and you suggest 15 per cent, as the Hall Commission said,—

Mr. WILSON: The Hall Commission recommended.

Mr. MACDONALD (*Prince*): What guarantee is there that in setting that figure that we would in any way change the kind of "slush pile", as you call it, that is coming to the doctor? It might not be as large but is there any guarantee that they would improve the quality of the information the doctor is going to receive? I think this is just cutting down on the amount rather than making any effective change in the style of advertising.

Mr. WILSON: The brief says that there are some thirty medical publications in Canada, many of which are starved for advertising. We live under a capitalistic system, and when a doctor receives a publication he does not pay for that publication, he depends upon advertising to defray part of the cost. Many of them are starved. Publications of faculties, publications of specialties, publications of provinces, accident prevention associations and publications like that are starved.

Competition among advertisers has caused them to bring up, largely from the United States, plates in four colours which can only be placed in certain wealthy publications. Competition, as I said earlier, has become social rather than practical and everybody wants to get on top. So, you read these many four-colour advertisements. If they could not spend all this money they might have to revise their practice and spread their advertising over to, as you might say in parliamentary language, the four provinces.

Mr. MACKASEY: How would that improve the situation? You would share the wealth.

Mr. WILSON: No, advertising is not wealth. Advertising is not a means of making money. It should not be.

Mr. MACKASEY: What you are saying, Mr. Wilson, is take it out of the hands of three or four of the big printers who are equipped to do four-colour runs and you have put it in the hands of forty or fifty or one hundred printers who can do two-colour runs.

Mr. WILSON: No. No. The point of view is still the patient. He is in bed and people are squabbling over his body and they are putting nails in his coffin. He does not like it.

Mr. MACKASEY: I do not think I would like it either.

Mr. WILSON: And you would like it less if you were being treated for intra ocular pressure to know what he is doing, and the poor doctor—this is a fairly rare subject, it does not come up very much but he has got it, every doctor has it—everything that is rare comes up in every doctors practice because there is no geographical exception.

Mr. HOWE (*Hamilton South*): Surely if we can control quantity we can control quality too, can we not?

I mean if the quantity of advertising is being reduced, surely we can also control the quality of that advertising.

Mr. WILSON: We could order it. Now another thing. There has been an argument but a question has not been asked, and it would be a good question to ask, I think, and it is given about penicillin. Penicillin when it was first produced cost many thousands of dollars per ounce or milligram and now it costs almost nothing. This has been achieved by sales. That is the argument that is used quite a lot. It would be a shame if they used people as guinea pigs to bring down prices. Since then we have had vaccine which has done exactly the same thing, and there is Banting's discovery which has also done exactly the same thing without excessive advertising and without using people as guinea pigs.

Mr. MACDONALD (*Prince*): But these are remarkable discoveries. You cannot class these in the general line of drugs that are developed from year to year. These are things that have stood out as landmarks in terms of new drug discoveries. I do not think they should be regarded as being a typical situation, I would not think. Not being a medical man I cannot state this with great authority. But is would seem that way to me in the drugs you have indicated. Discoveries like penicillin, Salk vaccine and insulin, these are that almost anyone would know about shortly after the discovery because of their importance in one particular area.

Mr. WILSON: Yes.

Mr. MACDONALD (*Prince*): But there are hundreds of other drugs being produced that in some way the doctors have to receive sufficient information about them so that they may be aware of their use in minor ways.

Mr. WILSON: This brief says that there should be advertising. It says it may be exaggerating the situation a bit but there is such a renewal of drugs these days that advertising is a necessity. This brief says this on page 3, I think it is.

Mr. MACDONALD (*Prince*): In connection with the question I asked you about the kind of advertising we are going to get even with 15 per cent. Apart from the fact that the Hall Commission chose a figure of 15 per cent for you, in your own experience in the years that you spent working for one of these particular magazines was there any reason why you decided to choose the Hall figure as an acceptable one, or was there some other figure that seemed more desirable?

Mr. WILSON: I hitched my brief on to somebody else's reasoning. I think that anyone who does any work in any sphere whatsoever goes by what other people decide to do to try to get a basis.

Mr. MACDONALD (*Prince*): But how did you come to this conclusion as a person who has worked in this sphere for many years? You say you hitched to somebody else's reasoning. Why did you do this. Is it fair to ask this question?

Mr. WILSON: In biology we talk about recapitulation. When you are born you go through the stages of being an insect or a fish, and you become various things, and eventually you become a human being. I cannot afford to do that. I read what is going on in the advertising field, the pharmaceutical field, the medical field and the patient field, and out of this I fin something reasonable, and I say "why do not we do this?" There is nothing original about this brief.

Mr. MACDONALD (*Prince*): Yes, but there must have been some motivation because obviously you are now hitting at the very industry in which you yourself were employed for five years. You must have had some motivation for making this move.

Mr. WILSON: Yes, I was a patient in hospital. A good motivation.

Mr. MACDONALD (*Prince*): But surely you did not find out things in the hospital you had not known before.

Mr. WILSON: No. I talked with hundreds of doctors. I have worked as a biologist in a research station in Long Island, New York. This is a picture that has been annoying to me for a long time.

Mr. MACDONALD (*Prince*): And we have provided a forum for you.

Mr. WILSON: You have provided a forum. As a matter of fact, I spilled my argument to a Member of Parliament who introduced me to this forum. I did not deliberately put my name down to talk on this subject, I came to it by gradual degrees.

(Translation)

• (11.00 a.m.)

Dr. ISABELLE: I am under the impression, as I have been at previous committee meetings that we are wasting our time, because we are not discussing this subject, which is a study of the price of medication. In any organization which affects the economy we always have a manufacturer and a consumer. The spread between the pharmaceutical company and the consumer is a very broad one. In the literature we receive from the companies, and I must admit that I never read it because when I want information, I consult the Vademecum, look up the names of companies well established in the field and with a reputation for research. The problem of the pharmaceutical industry is that half the firms involved are racketeers. The well established firms have to compete with the firms that make no budgetary provision for research of any kind, with firms that are out after the profit, and profit alone. I call these firms that just have offices and nothing more the "jobbers" in the trade. I am wondering whether the pharmaceutical industry,—because it is an industry,—spends as much on sales promotion as soap companies do. I am also wondering whether the pharmaceutical companies should not be obliged to direct their promotion literature towards certain specific goals such as preventive medicine. This would eliminate the articles written by doctors with the sole purpose of making reputations for themselves and would put the major companies in a better position so that in five to ten years' time, the major companies should be able to cut their promotion expenditures by half.

I spoke of penicillin a moment ago. There has not been much of a rise in its price since its discovery so something has certainly happened and I believe that we should look into the matter to find out what that something was. We are simply wasting our time in talking about percentages. What we shall also have to examine is how best to protect the pharmaceutical industry because our legislation permits irresponsible companies to do exactly the same work as the responsible pharmaceutical companies.

• (11.05 a.m.)

Mr. WILSON: Yes, you are quite right but this is not a topic covered in my paper. This is a matter coming under regulation of companies and, of course, competition has played its role in the promotion of certain products, or better said, the legislation governing promotion.

Dr. ISABELLE: The legislation?

(*English*)

Mr. WILSON: That is right, the legislation. The laws are not made right. They should be amended. In brief I agree that it would be a good thing if we could curb some of the interloping pharmaceutical companies but it is not the subject of my brief.

Mr. HOWE (*Hamilton South*): Mr. Chairman, just one aside, shall we say, to Mr. Mackasey. I would just like to bring out a point. I realize you are not the witness, but you are sort of acting this way this morning, in a little cross fire. Within the last month I have received from one drug company three egg cups. When you multiply this by 20,000 doctors, that is 60,000 egg cups. Do you not object to paying for my egg cups when you buy a prescription, on a matter of principle?

Mr. MACKASEY: I thought of that three days ago when, as I say, you dumped everything but egg cups on the table.

Mr. HOWE (*Hamilton South*): I did not have the egg cups then.

Mr. MACKASEY: I agree with you. I am against gimmicks. Certainly that is a gimmick.

Mr. HOWE (*Hamilton South*): On purely principle alone, even if this is only one cent on your prescription of ten dollars, of your paying for any kind of gimmick advertising of somebody else to any doctor in your prescription, no matter how small it may be.

Mr. MACKASEY: I often wonder, when I listen to the doctors, Dr. Howe talking about these things realizing, they are members of a strong medical association, the strength of which is sometimes exaggerated and sometimes underestimated, why, as an association, you do not meet with the Pharmaceutical Association and straighten these things out as other industries would do with the people concerned. It seems the most effective method in the world of eliminating gimmicks is not by others stepping in but by the doctors of your association going to the pharmaceutical industry and saying, "as of January 1, 1968, we have agreed, as an association, to reject all gimmicks and you pay the return mail on them." Do you not think this is much more logical than bringing legislation into the House of Commons preventing gimmicks and then we will have to turn around and define them?

Mr. HOWE (*Hamilton South*): Possibly, although I do not see any direct interrelationship between the drug companies and the medical profession in this respect. I can see your point, and it is well taken but there is no direct relation, any more than you, as a consumer of a refrigerator, can step in and say, "I am not going to receive your advertising and I am going to send it back to you".

Mr. MACKASEY: Except, sir, that since the medical association represents all the doctors, and as one or two or three associations represent all the pharmaceutical houses, it does not seem to me that you could not have a little summit conference and say, "please do not send me those gimmicks" for instance, your Canadian Medical Association could take a survey, an objective survey, among the doctors as to how they feel about it. Obviously, if they keep sending gimmicks, some doctors must be appreciating it, ill-advised or otherwise. Your medical association might meet with the pharmaceutical association and set up a code of ethics between the two associations as to what is good advertising and what is bad advertising. It will probably come back to Mr. Wilson's point of view. It would settle the problem faster than anything I can think of and, what is more important to me, it would reduce government interference into some phase of private enterprise. This is what I ask.

Mr. HOWE (*Hamilton South*): Of course, our interest here as a Committee is to reduce the cost of drugs and I think we are hitting at one angle of it only. I think there are many others, and I am sure you have some ideas as well as I have. This is simply one phase of this over-all investigation. Maybe it is one phase we should or should not look into. Perhaps we should make recommendations to the Canadian Medical Association that they take steps. But how, by this, can we be assured that the drug manufacturers will pass this saving on to the consumer, small though it may be. Every small bit is going to add up to enough to make the saving worth while.

Mr. MACKASEY: We do not know.

Mr. HOWE (*Hamilton South*): Whether it is done by the government or otherwise.

Mr. WILSON: Whereas an envelope percentage will take care of that. If they cannot deduct for tax, you do not have to define the gimmick. They can send out all the gimmicks they wish. If a leading company wants to specialize in sending out gimmicks, egg cups and that sort of thing, from now on, it can do so but it is squandering its advertising money.

• (11.10 a.m.)

Mr. MACKASEY: You would not mind that?

Mr. ENNS: No, as long as it is not more than 15 per cent.

Mr. MACKASEY: You would not mind that? In other words, you are not standing to the principles with which you started. You are just saying that all you are interested in is the drug company getting its advertising down to 15 per cent and you do not care on what it is spent; whether it is egg cups or what.

Mr. WILSON: No; but if I were the competitor I would be glad if he were doing it.

Mr. MACKASEY: No, you are not a competitor. You are a man who has presented a brief.

Mr. WILSON: As a person, I think it is horrible.

Mr. MACKASEY: You have a very responsible brief here, for a purpose. One of which is, I presume, to drop the cost to the patient and two, to protect the doctor from what you call the "slush pot" or whatever it is. Now you are telling

us that you do not particularly care what form the advertising takes provided it does not add up to more than 15 per cent.

Mr. WILSON: This is shown by MER 29 which is a drug put out to absorb cholesterol which coats our arteries and eventually develops into arteriosclerosis. It was put on the market with a lot of advertising, expensive advertising; it was found to give people kidney trouble and it was found to give them opacity of the eyes, or cataracts.

Now, their advertising was done very well; it was remembered by doctors who did not see anything about when it was taken off the market. They did not advertise in the same way that they had taken back what they had said. The doctor, when he looked over his nine pounds or six and a half pounds, if you like it, of his slush pile, did not go through it minutely to find out what happened. There were some communications from the Canadian government; there were also some communications from the Department of National Health and Welfare but he did not read all of them and maybe MER 29 was far from his mind; possibly he had no arteriosclerotic patient at the time and so he never knew about it. Three months later he still had some on his shelves and was handing it out to people. This is the hit or miss system which I say is chaos.

Mr. HOWE (*Hamilton South*): That company, Merck Sharp and Dohme, was honest enough to withdraw this drug on their own without any pressure, were they not?

Mr. WILSON: I agree with that. I also agree that it prevented the fanfare which would otherwise have happened and the adverse publicity which I would deplore but which sometimes becomes necessary for people to see, when you have to shout above the cloud.

Mr. HOWE (*Hamilton South*): If I remember correctly, they even wrote letters to doctors explaining this, so that they would not use samples.

Mr. WILSON: That is right. They did a very honest job on it.

Mr. MACKASEY: Then we have no argument on this.

Mr. WILSON: Pharmaceutical companies are very honest. Let me give you one case history; if you want to break up I will just give you one. The word pharmaceutical company is a big word. It is like talking about a doctor; you are an M.D. and you are treating patients; so you are an M.D. and you are a medical director of a drug company. You are doing two different jobs in two different aspects with two different sets of ideals or loyalties.

There was a leading Canadian drug company which does research that was working on a drug to prevent cancer—one of those drugs that cheat the cancer by feeding it a food that it cannot assimilate. As an editor I had a memo passed to me that I should do something about this so I agreed. I was not a free journalist,—I was a man doing a job—and I telephoned to the research department and talked to the doctor in charge. He said that it was not anywhere near ready for any kind of writing on it and would I please wait. So I did wait.

Within a month, when the edition had passed, I received a call from the sales manager who wanted to know what kind of a man I was; that this had appeared on the C.B.C., in the Canadian press; it had appeared in feature

articles in some newspapers; it had been used in a popular scientific magazine in the United States and was it not about time that I caught up with it.

I then telephoned again to the research department and received the same answer. Pharmaceutical companies are, as I said, honest people. They have various people in their employ. It is not one single unit.

After six months I telephoned again because I wanted to know what was happening, and the doctor said they had had various clinical tests and they had all failed, and would I please not talk about it but since I had asked the question he was willing to answer me. Their animal experiments had not been what they thought they should be. I respected the honesty of the man; I respected the honesty of the firm; I was sorry that his experiment had not succeeded.

A year later I was simply writing a list of firms who were doing research on cancer and they were A, B, C and D. D was the firm in question. So I asked if they would let me mention it in the list to the simple extent of saying that they had done research on cancer—no more. I received a letter saying provided I put it in exactly those words and said no more than that, they would allow me to do it but I gathered that the experiment had been a failure. It does happen; we all fail at something. Endeavour means failure sometimes.

During that time that company's shares on the stock exchange went up considerably. Advertising has many purposes; publicity has many purposes. I am not able to say all the ramifications of this. I do not say the company itself pushed up the shares; I just say that they did go up and that it was, no doubt, a feather in the cap for somebody who did make their shares go up.

Mr. MACKASEY: Mr. Wilson, you are saying that they were advertising that they had found—

Mr. WILSON: No, they did not advertize. They did it the other way. They talked to the Canadian Press; they talked to the C.B.C. and they let it be known they were doing some research—and God knows we all want that research—and that they were getting some results. Unfortunately they were not getting the results they wanted. There were disputes, obviously, between the research man who is a very conservative man—he is a typical pharmaceutical man who counts in milligrams and does not want to go one inch farther than the truth—and the advertising manager whose business is to sell and make money for the firm. These two are necessary. In medicine there are muscles that prevent others muscles—

Mr. MACKASEY: What had they to sell in this case.

Mr. WILSON: They had to sell the idea.

Mr. MACKASEY: No, but to put their product on the market for the other man to sell.

Mr. WILSON: No. It was not on the market. It would have been developed into a product for them to sell.

Mr. MACKASEY: If it had been successful.

Mr. WILSON: Yes, if it had been successful.

Mr. MACKASEY: But what I do not understand is what were they trying to promote? Obviously they were promoting something that did not exist.

Mr. WILSON: They were doing what my good friend who spoke just now and whose name I do not know—

The CHAIRMAN: Dr. Isabelle.

Mr. WILSON: Dr. Isabelle was saying that companies have to look after their prestige, and the sales manager has to look after the prestige in a different way, and rightly so, because we hope that companies will look after their prestige by doing good work. It is part of their publicity. It does not come into this plant here. It is work done by the front office and is not called advertising: it costs just the salary of the man plus the time of the man and other things but it does not come into this. Many other things do not come into this.

Mr. ISABELLE: Do you think that the nationalization of the pharmaceutical industry would help to solve the problem?

Mr. WILSON: I do not believe that nationalization is a matter that I should talk about here.

I have come with something that I believe is practical, applicable, simple and would get results but would not cure the whole problem. Nationalization is not something that I would advocate here. I do not think it would be well received and I do not think it would be practical.

The CHAIRMAN: Gentlemen, earlier I should have received a motion that we print today's brief as part of today's proceedings. Do you all agree?

Agreed.

Are there any further questions? If there are no further questions, on behalf of the Committee I would like to thank Mr. Wilson for coming and making his presentation.

The Committee will meet again on Tuesday at 9.30; as I mentioned the legal counsel will be available to the Committee at 9 o'clock on that morning.

APPENDIX "A"

ENGLAND, LEONARD, MACPHERSON & CO.

Chartered Accountants

October 5, 1966.

Dr. H. C. Harley, M.P.,
Room 241, West Block,
Parliament Buildings,
Ottawa, Ontario.

Dear Dr. Harley:

Re: Submission of P. M. A. C. to the Special Committee on Drug Costs and Prices.

On July 26th, 1966 I forwarded to you a copy of my letter to Dr. Briant in which I requested clarification of certain matters in the P. M. A. C. brief.

I discussed these matters within him by telephone in August and I present below my report on them.

Breakdown of Manufacturer's Dollar (Page 2.3.)

The variances between the percentages as calculated from the amounts shown in column 2 of schedule E.2 and those shown on page 2.3 (refer to schedule enclosed with letter of July 26th) have now been explained. As expected, there had been some reallocation of amounts. The main adjustment was the deduction of other income from manufacturing costs.

Rate of Return on Resources Employed

Dr. Briant advises that the rates of 15.6 per cent (before taxes) and 7.6 per cent (after taxes) as quoted on page 3.5 of the brief, are the rates for the *total* operations of the industry. These rates were calculated from the amounts appearing in appendices E.1 and E.2 (as was assumed in my letter) but after adjusting net profit by adding back interest expense of $0.4 million, an adjustment with which I agree. It should be noted, however, that for *human pharmaceuticals only,* the similar rates of return are 21.1 per cent (before taxes) and 10.6 per cent (after taxes).

With respect to the calculation of the rate of return for the industry (before management fees, royalties and dividends) quoted on page 3.6 of the brief as amounting to 9.7 per cent, I understand that, as a result of my enquiry, Dr. Briant now considers this rate to be in error. I believe he now estimates it at 10.5 per cent. The difference is minor and the reasons for it are even less significant. The important thing to note is that in these calculations Dr. Briant has assumed that management fees were excluded from the expenses appearing in schedule E.2. Whether or not this assumption is correct I cannot say, although I understand his reasons for making it. If we assume he is correct

then, in my opinion, the details of his calculation are slightly in error. I believe the rate of return (after taxes) should be 11.5 per cent. Alternatively, if his assumption is in error, then I believe the rate should be 12.7 per cent.

I might point out that, in the calculation of the rates discussed in the preceding paragraph, the operating results for packaged human pharmaceuticals, rather than total operations, have been related to total resources of the industry. While I believe this to be incorrect in principle, it is also my belief that rates would be changed only slightly if the operating results for total operations had been used.

It should also be noted that these calculations apparently exclude the net earnings, management fees and royalties pertaining to bulk human pharmaceuticals. How significant this may be, it is not possible to say.

Appendices E.3 and E.2

Dr. Briant advises that I am correct in my assumption that column 2 of appendix E.2 and column 3 of appendix E.3 are supposed to be different presentations of the same amounts for expenses, taxes, and net earnings. He also states that other income has been deducted from either materials or other expenses, which would explain most of the difference between the totals of the two columns as outlined in my earlier letter.

Other Variances

With respect to the other variances noted in my letter, Dr. Briant is unable to offer proper explanation. Theoretically, there should not be any such variances. For the most part, however, the differences are minor and it would appear that, with the possible exception of the calculation of the rate of return on resources employed, as discussed above, these have not led to any incorrect or misleading conclusions.

Other Matters

As requested, Dr. Briant forwarded to me a copy of the consolidated balance sheet of the 41 companies reporting in the survey. From this information and from the information appearing in appendices E.2 and E.3 I have made the following calculations of rate of return on capital employed:

	Total Operations	*Human Pharmaceuticals*
A. Profit (before taxes, royalties, management fees and interest expense)	24.2%	32.4%
B. Profit (before taxes and interest expense)	17.8%	23.8%

(Note: In these calculations I have made the same assumption with respect to management fees as was made by Dr. Briant.)

I should think that this latter calculation is on a basis similar to that used in determining the rates quoted on page 376 of the report of the Restrictive Trade Practices Commission. It will be noted there that the rate for 1960 was 20.55% and the average for 1953-1960 was 19.82%.

Yours sincerely,

W. J. Blakely.

APPENDIX "B"

ENGLAND, LEONARD, MACPHERSON & CO.

Chartered Accountants

October 7, 1966.

Dr. H. C. Harley, M. P.,
Room 241, West Block,
Parliament Buildings,
Ottawa, Ontario.

Dear Dr. Harley:

Re: Sales Taxes

As requested, I have reviewed the various calculations relating to the effect of sales taxes upon the prices of drugs to the consumer. As you know, these calculations have covered a wide range of conclusions. It seems to me there are two basic reasons for these variances: (1) interpretation, and (2) variable factors.

In the first place, what is meant by "effect of sales taxes" or, as the Canadian Pharmaceutical Association put it, "influence of sales taxes"? I suggest that those who have estimated this "effect" at 5% (or less) of the consumer's dollar are dealing with the *amount of tax paid only.* On the other hand, those, who have suggested that the "effect" is approximately 10% are dealing not only with the amount of sales taxes but also with the result of the application of *pricing policies* at the wholesale and retail levels. Accordingly, this 10% includes not only the actual sales taxes paid but also the mark-up added by the wholesaler and retailer on the tax. Ignoring, for the moment, alternative pricing methods and applying the "list price" basis, the effect of these two approaches may be demonstrated by the following calculation:

	Excluding Tax	*Sales Tax*	*Including Tax*
Manufacturer's price	$ 1.00	$ .110	$ 1.110
Wholesaler's margin (20%)	.20	.022	.222
Retailer's cost	1.20	.132	1.332
Retailer's margin (66⅔%)	.80	.087	.887
Consumer's price	$ 2.00	$ .219	$ 2.219

In this example it may be seen that sales taxes plus the margins added thereon, represent 9.87% of the consumer's price. However, the actual sales taxes paid represent only 4.96%—the balance is margin added at the wholesale level (0.99%) and the retail level (3.92%). Therefore, in this instance, depending on

which interpretation is taken, the "effect" may be said to be either 4.96% or 9.87% of the price paid by the consumer.

The second apparent cause for differences in the figures reported is the variation in the pricing methods being used. I understand there are three basic methods—list price, list price plus a fee, cost price plus a professional fee. Where either of the latter two methods is used, there may be a further variation in the amount of the fee that is added. Obviously, under such circumstances, a wide range of calculations may be produced for the effect of sales taxes on the price of drugs to the consumer. The "list price" method was demonstrated by the calculation in the preceding paragraph. For the other two methods it would seem that the most reasonable approach is to consider averages. Using the averages as developed from Professor Fuller's survey in 1964 for the Canadian Pharmaceutical Association, I obtain the following:

	Per Cent of Retail Price	
	List Plus Fee	*Cost Plus Professional Fee*
Sales tax	4.1%	4.4%
Wholesaler's margin added to sales tax	0.9%	0.8%
Retailer's margin added to sales tax	3.4%	....
	8.4%	5.2%

It should be noted that in these calculations, I have applied discounts of 40% and 16 2/3% at the retail and wholesale levels respectively. I understand these to be the normal margins (reference: page 307 of the Report of the Restrictive Trade Practices Commission).

Perhaps at this time I should also consider the suggestion made by one of the committee members that the "federal sales tax represents closer to 20 per cent of the prescription than it does to 5 per cent" (page 398 of the minutes; a similar suggestion is included on page 83 of the minutes). I believe this rate is related to the retailer's *cost* rather than his *selling price* of the drug. On page 83 of the minutes, the rate of 17.6% is mentioned. In the example discussed on that page, this rate of 17.6% represents the relationship of the salestax (including margins added) of 17.6 cents, to the retailer's cost of the drug of $1.00. This same amount (17.6 cents) represents 11% of the price to the consumer of $1.60, which it should be noted, excludes the fee normally added by the pharmacist. If we take the retail price of $2.00, which was suggested by Mr. Turnbull as being appropriate under the circumstances and which includes the normal fee, the 17.6 cents then represents 8.8% of the price to the consumer. This latter rate is very close to the rates quoted by others.

I hope these comments will serve to clear up the confusion resulting from the various figures which have been quoted from time to time. If further clarification should be desired or if you should wish to discuss these comments in person, I shall be pleased to do so.

Yours sincerely,
W. J. Blakely.

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APPENDIX "C"

A presentation to the

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

By

Mr. LAURENCE WILSON
5161 Macdonald St.
Montreal, Québec

on the

ABUSES IN THE ADVERTISING OF PRESCRIPTION DRUGS

The Hall Commission found the price of drugs excessive and expressed a warning in these words (Vol. 1, page 40): "Either the industry itself will make these drugs available at the lowest possible cost, or it will be necessary for agencies and devices of government to do so. We must not confuse the distribution of essential drugs with the distribution of cosmetics and sundries."

Two pages later (Vol. 1, page 42), the Commission offered a recommendation, No. 64, which reads: "That in the application of the provisions of the Corporation Income Tax Act to manufacturers, importers and the distributors of drugs, consideration should be given to establishing a maximum of 15 per cent of total sales as the allowable deductible expense for advertising, sales promotion, detailmen and other similar items."

In a footnote Recommendation No. 64 is commented as follows: "This recommendations differs from that of the Restrictive Trade Practices Commission for two reasons: (1) The drug industry is different from other industries in that its products are essential for health and, indeed, life; (2) The great bulk of production of drugs for Canadian consumption is produced by non-Canadian companies."

THE PRESENT OBJECT

The present representation suggests that this Committee make a firm recommendation along similar lines to those of Recommendation No. 64, while somewhat modifying it in detail and as to target.

The recommendation tells the industry, in substance: "Police yourself or be policed by the Government."

The industry was later represented as opposing what appeared to be a threat to its power to promote its products. But it is fair to state its actual substance as something quite different: it was the reaction of companies caught up in a competitive machine not within their control, and then admonished to behave themselves.

The present representation suggests that the problem has two stages. The first stage would consist recommending the application of the 15 per cent rule,

not for the immediate purpose of reducing prices, but for the purpose of restoring to the industry, through its individual companies, control of its own advertising. The second stage would come later. Once the companies had regained control of their own wasteful advertising practices they could then work out a pattern, on their own or with government help, to reduce prices.

THE PROBLEM

The effectiveness of advertising prescription drugs must not be impaired. Eighty per cent of currently used drugs of this kind were not known ten years ago, and they must be made known by advertising and other methods. There have already been some workable suggestions for making advertising, which is now in a chaotic state, more compact and more immediately available to the busy doctor. One is for the government and the drug houses (manufacturers, importers and distributors) to get together on a monthly publication (compare the U.S. Drug Letter) listing new drugs and their characteristics, with a running commentary on current clinical findings, good and bad. The other is for an extension of the *Vademecum International* principle. This is a commercial publication, an annual compendium with quarterly supplements, which classifies currently marketed drugs by characteristics, manufacturers' claims and contra-indications.

None of this begins to tell the doctor all he must know in handling anything so potentially healing or potentially hazardous as the modern drug, but that is a matter for his own basic and current reading. The best practical combination at this time in Canada is for the advertising to appear in the official organs of the doctor's own association where it can have no influence on editorial policy and where authorities can go deeper into the matter between the same covers. At all events, the working doctor should be able to count upon an orderly and dignified presentation of advertising matter by the members of so orderly and minutely accurate an industry.

But what does the doctor actually get? Every month he gets 6 to 10 pounds, by actual weighing on a doctor's scale, of a miscellany of papers. These papers, pamphlets, brochures, magazines and occasional novelty formats such as accordion-pleated booklets and phonograph recordings are products of the ingenious devices perfected on Madison Avenue. They form no orderly pattern but are deliberately discordant, each designed to stand out above its fellows. And for good reason. It is necessary to picture this pile of paper, which in an actual test filled a washing hamper to overflowing. In sheer reading bulk it is from three to five times as weighty as the British compendium, *The Medical Annual,* which it is generally considered takes a busy doctor a year to read properly. A doctor who read his pile through would read an amount equivalent to about fifty copies of that weighty British compendium every year.

And what would he read? For one thing, he would read some of the most expensive paperwork in the business world. It consists largely of expensive paper and four-colour advertising, and is embellished in the reading matter by the psychological tricks at which the advertising profession is adept. Produced for Canada's 20,000 doctors it is considered an uneconomical short run and unit costs are higher than in the U.S. However, the cost is handed down to the patient or, in medicare, the policyholder or even the public taxpayer. Much of the basic material is carried over from the United States to make the advertising promotor a second profit in Canada.

The doctor's nurse, secretary or wife might get more out of the reading than he. One trick used in this mass of advertising, one among many, is that of sugar-coating the advertising with matters of non-medical, cultural interest, such as fiction stories. The aim here is to have the nurse rescue the item from the waste basket, where, as every doctor must agree, most of it goes almost as soon as received. One advertising medium which appears in the pile offers this feminine angle in its prospectus as a sales argument to advertisers.

Although many doctors have taken the trouble to intervene with addressograph centres and have used other means in an attempt to get off the various mailing lists (names of these doctors are available), the fact remains that the tricks are often successful. So much so that commercial publications, run by promoters for profit, now eclipse the doctors' own association organs in the amount of money they can get for advertising. To contrast the two top publications in respect of page rates: Journal of the Canadian Medical Association, $330 a page and $100 for each additional colour; MD of Canada (a commercial give-away promotion magazine, edited in the U.S.), $470 a page and $130 for each added colour. Actually the difference is greater. The commercial magazines use a greater ratio of advertising matter (in one: 55 per cent) and allow such tricks as gatefolds as well as cardboard pages that deform the publication and cause it to fall automatically open at this place or these places. Medical texts used in these publications can hardly fail to be subject to the advertising manager's inspiration and veto; the trend is to use other subjects than medicine, aiming at a "class" bias on the principle of making it necessary for the advertising managers of particular firms to "keep up with the Joneses" because they "can't afford to stay out." This is in line with the influence of the cosmetics industry noted by the Hall Commission; it is also in line with over-elaborate packaging and other devices covered nowadays by the once meaningful term "pharmaceutical elegance."

All this is to show that the problem has gotten beyond the control of the drug houses. Part of the hypertrophy of advertising has been a weed growth, unchecked until it became too big to check. But another reason is that promoters have entered who are independent of either drug houses or doctors; they are in it for money. It is too late now to ask the industry to discipline itself.

The Remedy

After all this, the remedy is surprisingly simple. It is twofold, as already explained. The first part consists in giving government backing to the drug houses to get them out of what is commonly called a "rat race." The principle here is clear enough. When a man going to a new city wants to advertise for, say, an apartment, he does not feel favoured when he finds there are some half a dozen newspapers he must advertise in. He would rather use one. Advertising managers of companies feel the same way. They are not at all happy to have to fight for recognition in the doctor's monthly (to use the common publisher's term) "slush pile." But they have no alternative.

There is a simple and recent precedent here. The drug houses once had a similar problem in the distribution of samples. Not only every one of Canada's 20,000 practicing and non-practicing doctors, but also their nurses, secretaries, wives, and people on the compagnies' mailing lists such as journalists, had a free source of drugs. The government ended it by passing legislation and then, after

discussions, enforcing regulations that now prevent much of the waste without preventing doctors from receiving the samples they can use.

The same principle can be applied here. It consists of deflating the inflated advertising budget by the means suggested in the Hall Commission's recommendation. Uniformly applied, it would cause every company to revise its advertising expenditures for maximum effectiveness and minimum waste.

Exceptions are often made in applying government measures. It is important to get the 15 per cent rule on the books before making exceptions. But the subject can be briefly discussed here. There might be an exception for all medical periodicals that are the organ of recognized medical association, certified as such by such a body as the Royal College of Physicians and Surgeons or one of the provincial Colleges. A more lenient criterion might cover all medical publications to which the doctor subscribes, and this would automatically cover all the forementioned since the subscription is part of the membership dues. A still broader criterion would follow the rule of the sampling regulation: any doctor might receive any publication (as a deductible item for the advertiser) on condition of asking for it at stated intervals. In this latter case, the promoter would send him a postal card every six months, to be signed and returned. It would be very effective. Some free periodicals in the group have used this method more than once in order to demonstrate the extent to which they are read. Response has been from 2 to 3 percent.

Some likely objections to the basic recommendation, the 15 per cent rule, may also be briefly discussed here. Some may fear that invincible vested interests are threatened. Not so. It is to the advantage of the drug houses and the medical profession; both resent the influences that have led to a hypertrophy of advertising. Those who live by stimulating this hypertrophy consist largely of a few promoters, established in another country, and interested only to the extent of making a second profit.

Then it may be said there will be unemployment. But the people concerned in Canada are about 20 in all, including stenographers. As for the printers, their thoughts are well known. Even by charging high prices they are not happy with the elaborate makeready they have to use for such short runs; 20,000 is a big figure when it comes to sending out samples but it hardly justifies tying up a rotary press. Printers are not going to complain.

It will certainly be said that the legitimate medical press would lose under the 15 per cent rule. If this argument appears to offer too big a barrier, then the present representation has already suggested methods of making an exception in this case. But this representation does not suggest any exception at this stage. The target here, as in the Hall Commission recommendation, is that of helping the patient, not the doctor or drug house.

Actually, with the 15 per cent rule, advertisers would still be able to keep up their advertising in the two big official medical journals, the CMA *Journal* and the Union *Médicale*. They need this official recognition and would not want to forego it. Taking the larger picture, there can be little doubt that the legitimate medical press has suffered considerable loss from competition by non-medical and high-priced promoters (and this could include even medical doctors in promotional activities not officially recognized as already defined).

The long view is that having to make less money go as far (or farther) the advertiser will do well to get out of the deluxe field and make greater use of the

entire medical press, not just a few of its main publications. There are some 30 good medical periodicals in Canada. They are not usually set up for expensive advertising but they are all read by doctors who use drugs. Common experience in any field shows that the smaller publications, produced because there is a need for them, are the ones most likely to be read from cover to cover, and by readers who know what they want. Practical medicine stands to benefit, not lose.

How about the drug houses? Would their sales drop? It is fair to expect that they would get a better balance in the sales picture and be freed of a certain kind of flashy competition. This means sounder and better business.

There is a point here that is more readily illustrated from the over-the-counter field than from that of prescription drugs, the principle being the same. Tablet X is currently so popular in Canada just now that it is swamping out competition. It is an American tablet, the most effective as to ingredients permitted under U.S. regulations, and the advertising build-up, carried over to Canada, emphasizes this point in the psychologically powerful but non-committal way advertisers have. It goes to doctors too, and some are persuaded. But the fact is that its formula is that of tablet C, a tablet of the third order of effectiveness produced by a Canadian company that also produces the more effective A and B tablets for less mild conditions.

Here is a case where advertising is playing up inferior merchandise and harming good medicine. It is a kind of Gresham's Law and the doctor's "slush pile" is full of examples of good currency (quiet scientific reports) being pushed out by hard sell material. This is not an exception; it is the rule. It is the reason why in pharmaceutical manufacture you may often find the doctor in charge of the laboratory and the sales manager in conflict. The author of this representation could illustrate this point copiously with current examples.

Recommendation Considered

The Hall Commission recommendation cited above does not recommend firm application of the 15 per cent rule but only its consideration. It also speaks of "advertising, sales promotion, detailmen and other similar items," which is a group not easy to define.

It is suggested that this could be strengthened by defining a firm target. It is suggested that the first step in enabling companies to regain control of their own "promotion" would be firm help in getting rid of what has been called the doctor's "slush pile". This could be done by restricting the tax privileges of printed advertising. As detailmen also visit the doctor, they too should be included. But what is known as sales promotion, and might be extended to include scholarships research, education, sponsored meetings, sponsored golf games, and so on through a long list might well be left for another time, as too complex for the moment.

Thus there would be three steps or more. The first, already accomplished, was concerned with samples. The second would be concerned with printed advertising and detailmen. It is not impossible that the drug houses, their self-sufficiency restored by the first two steps, might handle the rest themselves.

SUGGESTED RECOMMENDATION

That fifteen per cent of total sales be the allowable deductible expense for advertising to medical doctors in circulars, journals or magazines.

That exception be considered for material paid for or asked for.
"Paid for" could mean cost included in membership fee.
"Asked for" could mean by postal card, as for drug samples.

Thus any physician would receive all the pharmaceutical advertising he wished. And firms wishing to circularize physicians would still have a deductible margin to pay for it. Their circulars, having the dignity of a personal communication, being no longer just matter in a "slush pile", would do them more good.

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 10

TUESDAY, OCTOBER 18, 1966

WITNESSES:

Representing Cyanamid of Canada Limited: Mr. S. R. Stovel, President; Mr. F. W. Pape, Executive Vice-President; Dr. Claude Gendron, Medical Director; and Mr. J. A. Bertrand, Manager Medical Products Department, all of Montreal.

ROGER DUHAMEL, F.R.S.C.
QUEEN'S PRINTER AND CONTROLLER OF STATIONERY
OTTAWA, 1966

24876—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

Vice-Chairman: Mr. Patrick T. Asselin (*Richmond-Wolfe*)

and

Mr. Brand,	Mr. Hymmen,	Mr. Pascoe,
Mr. Clancy,	Mr. Isabelle,	Mr. Prud'homme,
Mr. Côté (*Dorchester*),	Mr. Johnston,	Mrs. Rideout,
Mr. Enns,	Mr. MacDonald (*Prince*),	Mr. Roxburgh,
Mr. Howe (*Hamilton South*),	Mr. Mackasey,	Mr. Rynard,
	Mr. MacLean (*Queens*),	Mr. Tardif,
Mr. Howe (*Wellington-Huron*),	Mr. O'Keefe,	Mr. Whelan,
	Mr. Orlikow,	Mr. Yanakis—(24).

(Quorum 10)

Gabrielle Savard,
Clerk of the Committee.

Note: Mr. MacLean (*Queens*) replaced Mr. Chatterton on October 13; Mr. Johnston replaced Mr. Olson on October 17.

ORDERS OF REFERENCE

THURSDAY, October 13, 1966.

Ordered,—That the name of Mr. MacLean (*Queens*) be substituted for that of Mr. Chatterton on the Special Committee on Drug Costs and Prices.

MONDAY, October 17, 1966.

Ordered,—That the name of Mr. Johnston be substituted for that of Mr. Olson on the Special Committee on Drug Costs and Prices.

Attest.

LÉON-J. RAYMOND,
The Clerk of the House of Commons.

24876—1½

MINUTES OF PROCEEDINGS

TUESDAY, October 18, 1966.
(16)

The Special Committee on Drug Costs and Prices met this day at 9.40 a.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout and Messrs. Brand, Enns, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), Hymmen, Isabelle, Johnston, Mackasey, MacLean (*Queens*), O'Keefe, Orlikow, Tardif (14).

In attendance: *Representing Cyanamid of Canada Limited*: Mr. S. R. Stovel, President; Mr. F. W. Pape, Executive Vice-President; Dr. Claude Gendron, Medical Director; and Mr. J. A. Bertrand, Manager Medical Products Department, all of Montreal.

Also in attendance: Mr. A. M. Laidlaw of Ottawa, Legal Counsel for the Committee, and Mr. Blakely of Kingston, Accountant for the Committee.

The Chairman introduced Mr. Stovel who, in turn, introduced the other representatives of the Company.

On motion of Mr. Howe (*Hamilton South*), seconded by Mr. O'Keefe, *Resolved*,—That the submission of Cyanamid of Canada Limited be printed as part of today's proceedings.

Mr. Stovel made a short statement and answered questions in relation to the brief. He was assisted by Messrs. Bertrand and Pape, and by Dr. Gendron.

In order to assist the Members in the consideration of that part of the submission dealing with patents, Mr. Laidlaw reviewed the patent situation; he was questioned thereon.

At 12.10 p.m. the Committee adjourned until 3.30 p.m. or after the Orders of the Day.

AFTERNOON SITTING

(17)

The Special Committee on Drug Costs and Prices reconvened at 4 o'clock p.m., the Chairman, Mr. Harry C. Harley, presiding.

Members present: Messrs. Enns, Harley, Hymmen, Isabelle, Mackasey, MacLean (*Queens*), O'Keefe, Orlikow, Pascoe.

In attendance: Same as at morning sitting.

The Committee resumed consideration of the submission of Cyanamid of Canada Limited.

Mr. Stovel commented further on the operations of the Company and referred to "Some Guiding Principles of Good Corporate Behaviour in Canada" given by the Minister of Trade and Commerce on March 31st, 1966.

Mr. Blakely asked questions of the witnesses.

Agreed,—That a publication called "Key Business Ratios in Canada" (1965) by Dun & Bradstreet of Canada, Ltd., be printed as an appendix to this day's proceedings, provided permission to reprint is granted by the Publisher.* (*See Appendix "A"*)

The Chairman referred to another document entitled "A Study of Canadian Physicians' Attitudes to Medical Mail Advertising and Pharmaceutical Literature, September 1966", published by Canadian Facts Co. Limited of Toronto and Montreal.

It was agreed that copies be obtained for the Members of the Committee.

Mr. Laidlaw gave further information on Patents and Compulsory Licensing.

Messrs. Stovel, Bertrand, Pape and Dr. Gendron were further questioned, most particularly on patents and research.

The Chairman thanked Cyanamid of Canada Limited for their submission, and the representatives of the Company for the information supplied to the Committee.

At 5.50 p.m. the Committee adjourned to 9.30 a.m., Thursday, October 20, at which time Hoffmann-LaRoche Limited will present their brief.

Gabrielle Savard,
Clerk of the Committee.

*(Permission granted on October 20, 1966.)

EVIDENCE

(Recorded by Electronic Apparatus)

TUESDAY, October 18, 1966.

● (9.40 a.m.)

The CHAIRMAN: Lady and gentlemen, we now have a quorum.

First of all, I would like to apologize, and assure you that it was out of the Chairman's control that we have this small room today. We had this meeting booked a long time ago, but we were pre-empted out of our room by another committee which thought it was going to need more space. I am sorry that it is rather crowded for the witnesses and for the committee, but we have asked for a larger room for future meetings, and I am sure that we will get one.

I would like to introduce, this morning, Mr. Stovel, President of Cyanamid of Canada Limited, and I would ask him to introduce the gentlemen he has brought with him.

We are here this morning, and for whatever part of today is necessary, to discuss the brief of Cyanamid of Canada Limited, which you have all had in your possession for approximately one week.

Mr. S. R. STOVEL (*President of Cyanamid of Canada Limited*): Thank you, Dr. Harley.

Accompanying me today, to assist in answering your questions, are Mr. John Bertrand, to my immediate right, manager of our medical products department and whom your committee has met before; Dr. Claude Gendron who is sitting two to the right, who is our medical director; and Mr. Fred Pape, the gentleman on Mr. Bertrand's right, the executive vice-president of our company.

I am confident that this group will attempt to answer your questions.

If I might be permitted I would like to make a few general comments.

I will assume the responsibility of fielding your questions of a general nature on Cyanamid of Canada's operations and its policies.

Mr. Bertrand will deal with questions of a specific nature related to our drug business, or more general questions related to the drug industry.

Dr. Gendron will discuss subjects of a technical nature, and particularly those related to his function within our organization.

Mr. Pape will attempt to clarify queries on the international aspects of the medical operations of Cyanamid. We have assigned this area to him because of his extensive knowledge gained through a number of years at the medical research laboratories of our parent company which is at Pearl River, New York.

This is my third appearance before your committee with other representatives of Cyanamid. We were present on November 21st, 1963, to discuss our brief on the subject of the safe use of insecticides and pesticides. On July 10th, we appeared and discussed our brief on safety, effectiveness and quality in the pharmaceutical research and drug manufacturing industry.

Furthermore, a few days prior to our last visit, we accompanied your members on a full-day tour of our central medical research laboratories and arranged for the members to seek out and obtain any information they required first hand.

I would also like to point out that the foregoing activities were completely of a voluntary nature. We respect the heavy responsibility placed on the members of this committee, and have attempted to be of assistance. We are here again today to try to assist you.

Many hours were spent putting our brief together and assembling the type of information which we hope will prove helpful. We have attempted to be factual and to state our position in a clear, concise manner. We are aware of the appearance of the Pharmaceutical Manufacturers Association of Canada before this committee. We are active members of this Association, and, as such, contributed to its brief when surveys were made to compile statistical information.

Today we are prepared to speak for Cyanamid of Canada Limited alone, and, in particular, to answer questions on the operation of its medical products department.

The CHAIRMAN: Thank you, Mr. Stovel.

As you are all aware, this is a very extensive brief and I think, in fairness to the Cyanamid Company, and to make sense of the questioning which will follow, we should have a motion to include this brief as part of today's proceedings.

Mr. HOWE (*Hamilton South*): I so move.

Mr. O'KEEFE: I will second that.

Motion agreed to.

(The brief of Cyanamid Company follows):

CYANAMID OF CANADA LIMITED

Submission to

HOUSE OF COMMONS SPECIAL COMMITTEE

ON DRUG COSTS AND PRICES

October 18, 1966

TABLE OF CONTENTS

— 1 —

INTRODUCTION

Cyanamid of Canada Limited is a subsidiary of American Cyanamid Company, Wayne, New Jersey, which operates an international organization engaged primarily in the development, manufacture and marketing, in most countries of the Free World, of a wide range of chemical and pharmaceutical products. It is worth noting that the worldwide Cyanamid organization stems from its first plant, built in 1907 at Niagara Falls, Ontario.

American Cyanamid occupies a prominent position in the pharmaceutical industry as a result of its manufacturing operations in 19 countries of the world, and through the operations of its Lederle Laboratories Division at Pearl River, New York, which is one of the world's major research centers for the discovery and development of pharmaceutical products.

Cyanamid of Canada has eight manufacturing plants in Canada at the present time, producing a wide range of chemical and other products for health, home, agricultural and industrial purposes. In total, Cyanamid of Canada, at the present time, employs approximately 3,000 people, with gross assets having a value in excess of $100 million.

In addition in Eastern Canada, Cyanamid of Canada, in partnership with local businessmen, operates thirty fertilizer bulk blending plants, and also operates two blasting agent plants.

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Cyanamid of Canada and its subsidiaries are diversified producers of chemical products for the Canadian and export markets. It is the largest single exporter of chemicals from Canada, and accounts for more than 10 per cent of the total exports of chemicals from this country.

The manufacturing and marketing of medical products in Canada is carried out by the Medical Products Department of the Company. This comprises two product groups, ethical pharmaceuticals and surgical sutures. In this country, Cyanamid of Canada, through its Medical Products Department, manufactures pharmaceuticals by the most advanced methods with very strict systems of quality control. These pharmaceuticals are ethical drug products in the true sense of the term; that is, they are sold by pharmacists primarily on the prescription or recommendation of a physician. They are identified by the Lederle label.

This submission to your Committee deals almost exclusively with the ethical pharmaceutical segment of our medical products business. These products include the broad spectrum antibiotics such as Declomycin (demethylchlortetracycline), Achromycin (tetracycline) and Aureomycin (chlortetracycline), steroids such as Aristocort (triamcinolone), biologicals, hematinics, vitamin preparations, diuretics, and many other pharmaceutical products. The Lederle product line in Canada includes about 90 individual products in over 200 individual package forms.

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About 60 per cent of the Lederle sales volume in Canada is represented by products entirely manufactured in Canada using Canadian raw materials; 22 per cent is manufactured in our Montreal plant, using imported pharmaceutical chemicals; 15 per cent is packaged from imported finished products. This leaves approximately three per cent of our volume, which is imported in finished dosage form, primarily made up of low volume specialty products, such as antitoxins, allergenics, etc., including such rare biologicals as Botulism Antitoxin and Anti-Rabies Serum. All finished products come to us from Lederle Laboratories, Pearl River, N.Y., where the high quality of manufacturing and quality control is consistent with that found in our Canadian plant.

Two of Cyanamid's eight plants are engaged in the manufacture of pharmaceutical products. We have invested several million dollars in our pharmaceutical business, of which $3,000,000 represents the original cost of fixed assets. We have over 200 people directly employed in pharmaceutical manufacturing and marketing operations. Together with those employed in related service functions, the total employment arising out of our ethical pharmaceutical business approaches 300.

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In line with our traditional policy of manufacturing products in Canada whenever the market volume in this country economically justifies local manufacture, we have, since our last appearance before your Committee, opened a surgical sutures manufacturing operation in Montreal. This facility, involving an additional investment in excess of one-half million dollars, is now on stream and is designed to produce approximately 98 per cent of our Canadian sales of surgical sutures.

Although tetracycline is offered in Canada in some finished dosage forms by several firms, Cyanamid is the only basic producer of this antibiotic in Canada. We have established and now maintain the only complete manufacturing cycle in this country and offer the widest range of product forms. Since the tetracycline group of products represents the largest single item in our ethical pharmaceutical sales volume, much of our submission is directed to the field of antibiotics.

Long before the discovery of tetracycline, Lederle products consistently played a prominent role in the field of public health in Canada and the United States. As the name implies, the original Lederle Antitoxin Laboratories Inc. (incorporated in 1906 and now the Lederle Laboratories Division of American Cyanamid Company) had, as its main business, the manufacture of biological and bacterial products. It had the reputation in North America of being the foremost in its line of antitoxins, vaccines, toxoids and sera. In 1917 and 1918, when an influenza epidemic was raging in Canada, Lederle influenza-combined vaccine and pneumonococcus-combined vaccine were supplied to emergency hospitals. In 1927, during the severe typhoid epidemic in Montreal, Lederle supplied large amounts of typhoid-combined vaccine to the Montreal City Board of Health.

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Until 1939 Lederle was a conservative producer of biologicals involving a minimum risk in its total operation. At that time, Cyanamid management introduced a new operating philosophy that would henceforth direct the efforts of the Lederle organization to study the causes and search out the cures for the principal aliments that afflict mankind and, at the same time, continue as a producer of biologicals.

This decision radically transformed the character of Lederle's business. Henceforth, it would be highly research-oriented. The decision was made with full appreciation of the large risk involved. It would require an investment of millions of dollars to expand the company's facilities and increase its staff, with no assurance whatsoever of success. Cyanamid's management took the position, however, that if only a single drug were discovered that would conquer even one major disease, the public would be well served and Cyanamid would prosper.

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From that day, Cyanamid's worldwide pharmaceutical business has been dependent upon the continued discovery of new and better drugs. From the beginning, because of this research program, it was recognized that the level of earnings generated to meet these objectives must be higher than Lederle had previously known. Unless earnings which were reasonable in terms of these new demands could be achieved with some regularity, Cyanamid recognized that there would not be sufficient funds to finance the ambitious programs of research and development upon which it had embarked.

During the early years of this expanded research effort, earnings remained at a low level while Cyanamid continued to pour substantial funds into the program. Fortunately, with the discovery of Aureomycin chlortetracycline and its introduction to the market in December 1948, earnings improved to the level necessary to sustain and broaden the research program. Here in Canada we have contributed over the years to the research fund necessary to underwrite the program, and the Canadian people have, of course, shared accordingly in the fruits of Cyanamid's successful research projects at Pearl River. A brief outline of our breakthrough in antibiotics is detailed in Appendix A.

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The introduction of Aureomycin in Canada in 1948 let to the decision to erect a pharmaceutical plant in Montreal, designed to refine crude chlortetracycline, to produce pharmaceutical grade Aureomycin, and to produce and package finished dosage forms (capsules, tablets, liquids, ointments, injectable forms, etc.) of Aureomycin and many other Lederle products. This facility went on-stream in 1952, employing about 40 people initially in direct manufacturing operations.

As the demand grew for Aureomycin and its related successor Achromycin (not only for the treatment of human disease, but also for the prevention and treatment of disease in the animal health field), it became economical to establish antibiotic fermentation facilities in Canada. This was accomplished at

our Welland Plant in Niagara Falls, Ontario in two stages, between 1958 and 1962. From the same research laboratories that discovered Aureomycin and Achromycin, came Declomycin in 1959, and this unique and superior member of the tetracycline family is also produced by fermentation in our Canadian facilities.

A fundamental commercial policy of Lederle Laboratories since its earliest years has been its adherence to the most rigorous standards of quality control in the manufacture of its pharmaceutical products. No considerations of expense or labor saving are ever permitted to interfere with the quality or purity of a product. Lederle drugs are subjected to far more stringent tests than the standards set by our regulatory bodies such as the Food and Drug Directorate.

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These stringent quality control principles, observed in every Lederle plant throughout the world, require an annual outlay of many thousands of dollars in Canada alone. Our insistence on such a policy is a major reason for the wide acceptance of the Lederle name in doctors' offices and hospitals throughout the world.

The pages which follow contain much information about our methods of operation in Canada, particularly as they relate to drug costs and prices. As a preamble to this discussion, it might be well to set forth our guiding objective for the conduct of our pharmaceutical business:

> To conduct an ethical pharmaceutical and biological business so that contributions to medical knowledge may be made and products for the conquest of human disease can be marketed at a rate of return consistent with the resources committed and the risks involved, while maintaining the highest standards of business and community conduct.

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THE NATURE OF THE PHARMACEUTICAL BUSINESS

The knowledge of the fundamental fact that there are two kinds of pharmaceutical businesses in existence today is basic to the understanding of drug costs and prices. These two kinds of businesses differ greatly in most of their operations. There are indeed variations and "gray areas" between the various companies within each of the two main categories which at times tend to confuse the prime issue, but the basic differences exist. On one side of the scale are the "*Innovators*", on the other the "*Copiers*". While it is difficult to be both at the same time, a company may start as one and later change to the other.

How do these two businesses differ? Basically, in objectives, operations and costs.

The *Innovator,* year after year, invests substantial sums of money for research to search out new contributions or improvements to medical care. The *Copier* spends no money for research. He rides the coat-tails of the *Innovator* and either duplicates his products or formulates known drugs without significant costs. He has no research investment to recover.

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The *Innovator* discovers potent new drugs, usually with many side-effects, and must conduct extensive and expensive clinical research to learn all the indications, contraindications, side-effects, dosages and schedules, while the *Copier* reads the *Innovator's* scientific and medical publications, brochures, package circulars, and labelling, and copies them without cost at a later date.

The *Innovator* invests a substantial sum of money in developing the data necessary to file, first, a preclinical submission, and later a new drug application with the Food and Drug Directorate (FDD). This requires detailed information concerning the chemistry and pharmacology of the active ingredients, animal test results, methods of manufacture, methods of laboratory assay, stability data, human clinical trial results, proposed label and circular copy, etc.

The *Innovator* must have the facilities and personnel available, for example, to determine the proper expiration date of each dosage form which he plans to market. The FDD cannot and does not give him the effective shelf life of his particular product. The *Innovator* conducts in his own development laboratory the necessary, stability data to determine this variable and submits this data with his new drug application. After reviewing this data, which often runs to several volumes, the FDD may authorize the *Innovator* to market his product.

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Manufacturing also presents costly problems. The *Innovator* may produce several product forms of the same product. For example, with tetracycline there are 50, 100, and 250 mgm. capsule forms, a pediatric drop, a syrup, a topical and an ophthalmic ointment, several intramuscular and intravenous injectable forms, as well as combinations of the new drug with other existing drugs. *The Copier* supplies only those few forms for which there is a large market.

The *Innovator* must then disseminate complete information to the physicians about his new potent pharmaceutical product. Doctors must know the indicated uses for the new drug, the dosage schedules, and also the contraindications, precautions, warning statements, and all the known and observed side-effects—in short, all that is known about the drug at that point of time.

The *Innovator* must maintain highly trained personnel and facilities to conduct "on-going surveillance" of his new product. Regardless of the regulations and requirements of the Food and Drug Act, unforeseen adverse side-effects may develop months or years after a product is introduced. Each report received from the field, no matter how trivial, must be scrutinized in great detail, and often the *Innovator* has to fall back on the very research facilities which developed the drug in the first place, to fully analyze, evaluate and take action on the information received from practicing physicians.

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For the *Innovator*, the commitment to quality imposes specific economic responsibilities. The cost of establishing and maintaining strict manufacturing standards and procedures, the quality control necessary to check each step in these procedures, as well as the cost of marketing such precise technical products must be reflected in the price of the finished product. Further, the

reputable pharmaceutical house places above cost considerations not only scientific objectivity but also a sense of responsibility to patients and physicians. This philosophy, plus the mechanism for implementing it, means that the drugs sold by that firm must bear these costs. There is no shortcut to quality.

One of the best illustrations of the *Innovator's* "on-going surveillance" is the fact that as an *Innovator* we maintain, in every one of our several pharmaceutical shipping offices, a permanent written record as to the distribution of each lot number of each of our pharmaceutical products. Should it ever become necessary to recall a particular lot of a particular product, we are able, within a matter of a few hours, to contact the specific customers who received this particular lot. This procedure is not specifically required by the Food and Drug Act. It is an illustration of what we mean by a philosophy of quality control. It also illustrates the difficulty that we and other similar companies have in attaching a precise dollar and cents cost to quality control.

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There are countless other procedures built into our manufacturing and distribution processes that illustrate this concept. The simple identification test performed on each packaging lot before final release of the product for distribution, to minimize the possibility of mis-labelling, could prove as vital as the very complicated series of laboratory assays performed on the capsule or tablet during manufacture. These tests are not required in the Food and Drug Act, and these are the type of tests that the *Copier* will often ignore.

Meanwhile, the *Innovator* not only must recover the cost of his original research in this theoretically successful drug; the *Innovator* also must recover the cost of his unsuccessful research projects, for it is obvious that only a very small percentage of research programs result in commercially profitable products. He is also reinvesting money in continuing research programs to develop new and better drugs, and to reduce the cost or improve the manufacturing and/or the quality control procedures for drugs which he already has on the market.

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While this extremely complex process is going on year after year, what about the *Copier*? What has he been up to, and where in the process does he really enter the picture? His pattern is essentially part opportunistic, part parasitic. The *Copier* doesn't become very interested in a particular product until a wide demand has developed as a result of the *Innovator's* efforts. It takes several years for these ideal conditions to develop. Given a widespread demand for a particular drug, where virtually every physician has been informed about the basic characteristics of the drug, and uses it more or less routinely in his practice, where the government is likely to be a quantity purchaser, where hospitals purchase the product routinely, the *Copier* sees and pursues a golden opportunity. Through the artful use of publicity, a sympathetic press may be obtained that will assist in developing an emotionally aroused public attitude towards drug prices.

The *Copier* is secure in the knowledge that he need not invest money in research costs or in the cost of informing the physician and the pharmacist about the benefits and risks of the drug. He need not invest in a pre-clinical

submission or a new drug application to the Food and Drug authorities, for by the time he becomes interested, the drug may be no longer subject to the requirements of the "new drug" section of the Food and Drug Act. He knows he can market his product without even submitting his method of manufacture, his method of assay, etc., to the F.D.D. In fact, it was not until October 1, 1966, that the Food and Drug Act required the *Copier* to even notify the F.D.D. that he was in or intended to enter the pharmaceutical business in Canada, much less submit details of his product claims, labelling, copy, etc.

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The *Copier* restricts his activities to a limited number of products and only markets the most popular forms of these products. For example, with tetracycline he markets a 250 mg. capsule and a syrup form, ignoring the necessary but less profitable lower volume forms such as ointments, and those forms such as intramuscular and intravenous injectables where the government regulations are more stringent and where more highly specialized personnel and facilities are required.

The *Copier* obtains his bulk active ingredient on the world market at the lowest possible price—often from Italy where there is no patent protection on pharmaceuticals. His conception of "quality control" is to test his final product to determine whether it contains the required amount of active ingredient at the time it was manufactured. He then offers this product, usually hiding behind the cloak of anonymity, under a generic name and sells primarily to large volume purchasers. His interest in the product ceases when it leaves his packaging line. His package circular (if he has one) and his product information in medical reference books (if he uses this) are stripped-down versions of the *Innovator's* material, long on benefits, short on precautions, warnings, etc.

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He normally doesn't feel that a medical director is a necessity. After all, how many inquiries concerning the use of his brand of tetracycline can he expect to receive, when hardly anyone in the profession knows that his product, and not some other manufacturer's product, was used in a particular case?

The *Copier* in Canada considers one benefit-risk relationship (not the medical benefit-risk equation that concerns the *Innovator* and the F.D.D.)—namely, the risk of a patent infringement suit brought by the *Innovator* to collect the profits obtained from his marketing effort. But he usually doesn't worry too much or too long. He knows, from experience, quite a bit about Canadian drug patents—quite often, the prime subject of his "original research" expense. He knows that infringement of a process patent in Canada is exceedingly difficult and expensive to prove, that public and often political opinion are on his side in a patent fight and that time is with him.

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The *Copier's* chief marketing weapon is the differential between his price and that of the *Innovator*. The net difference between the two kinds of business for all operations is a vast difference in the magnitude of their costs. For this

reason, the *Innovator* must sell his new drugs at a higher price than that at which the *Copier* is able to sell his duplicated drugs.

We realize that in the foregoing we have outlined the full spectrum of pharmaceutical companies by comparing the two extremes. It is entirely possible that such an outline does an injustice to some companies at the lower end of the scale, and possibly distorts the image of some companies at the upper part of the scale. Such distortion is unintentional, but we feel that it is vital in the discharge of our responsibility to this Committee that at least this basic distinction between *Innovators* and *Copiers* be described.

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PHARMACEUTICAL SALES DOLLAR

In our previous sections we have drawn your attention to some of the unique problems of the pharmaceutical industry in Canada, particularly of its *Innovators*. Because of these problems, the cost of doing business in the pharmaceutical field is special to that industry alone.

On the following page we present a breakdown of our pharmaceutical sales dollar, and in the subsequent sections we shall attempt to explain in detail the various components of each item in this breakdown.

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PHARMACEUTICAL SALES DOLLAR

Cyanamid of Canada Limited
Year 1965

Manufacturing and Quality Control		.34
Materials	.19	
Direct Labor	.05	
Supervision and other costs	.10	
Warehousing and Distribution		.06
Royalties		.05
Research and Development in Canada		.02
Professional Service Representation, Marketing and Medical Information		.31
Field Sales Expenses	.15	
Sales Planning and Education	.04	
Advertising and Sales Promotion	.12	
General Administration		.06
Income Tax		.08
Net profit after tax		.08
		$ 1.00
Outward freight		.02
Sales Tax		.07
Returns		.05
		$ 1.14

MANUFACTURING AND QUALITY CONTROL

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Grave responsibilities are imposed on a pharmaceutical and biological business which is dedicated to the advancement of medical knowledge, the discovery of products for the conquest of human disease, and their supply to the medical profession.

Cyanamid conducts such a business and accepts these responsibilities as an implicit condition of its endeavour.

Possibly the most important responsibility is in the area of Quality Manufacture and Quality Control. This is the *sine qua non* of the research-oriented pharmaceutical company.

Every medicinal product identified by the Lederle label must be as near perfect as possible. Cyanamid has accepted the burden of this responsibility. Where the health of people is concerned, nothing less is acceptable.

Certainly, manufacturers in every kind of industry want to turn out the best products possible; but with most kinds of products, if something goes wrong or if someone does make a mistake, there is usually a service department to help rectify the error or replace a faulty part.

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The pharmaceutical industry does not get an opportunity to correct mistakes through a service department. An error can cost lives. Cyanamid stakes its reputation and existence on every package of every product on which it places the Lederle label. It is for this reason that Cyanamid manufactures according to the highest quality standards possible, and then on top imposes the most rigid quality control assays.

Although the government of Canada has established *minimum* standards for testing drug products, the self-regulation imposed on Lederle products usually goes beyond these basic standards. Incidentally, most of the government tests have been devised by the reputable drug firms themselves. But the government simply cannot test *all* drugs.

In Canada, the regulations governing a new drug require that a manufacturer obtain clearance from the Food and Drug Directorate before clinical trials may be initiated. The Food and Drug Directorate also passes on the effectiveness and safety of a new drug *before* it is marketed in Canada. It issues approval for marketing if the drug is shown to be safe and effective for use under the conditions recommended in its labelling. This is the result of a long, painstaking compilation of research and clinical data which is provided, again, by the Innovator of the drug. Also included in a new drug application submitted to the Food and Drug Directorate is the manufacturer's procedures for the manufacture, control, identification, and assay of the drug.

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While the maintenance of these minimum standards is inherent in permission to market a drug, the Directorate cannot possibly check the quality of every lot of every drug. Thus, in the interest of the public and the manufactur-

er's reputation, the vital check on the quality of drugs has to be by the pharmaceutical companies themselves.

These standards indicate the quality level below which no product may fall in order to be acceptable. In general, regulatory agencies can condemn only those drugs falling below the established *minimum*, but cannot indicate which are excellent, good, or fair.

Lederle products are tested far beyond minimum standards established by government agencies responsible for public safety. As an example, on one of our injectable antibiotic products, we do a total of 59 specific quality control tests during its manufacture, while the tests required by the F.D.D. number 20. These figures themselves can be very misleading since not the number of tests, but the extent, uniformity and regularity of testing, and the effort in both manpower and money involved, are more important. This comprehensive checking program protects the public as well as the Lederle reputation.

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In the pharmaceutical manufacturing processes carried out at Cyanamid of Canada's plants in Montreal and at Niagara Falls, Ontario, there are 130 full-time employees. Of these, 13 are engaged in quality control activities: of which group seven are university graduates, three are technical assistants, and three are occupied in clerical non-technical capacities. Although these figures vary from time to time, the figures quoted can be accepted as a fair average.

Naturally, the manufacturer who competes primarily on the basis of price is concerned only with not violating official *minimum* standards and requirements. Frequently, he does not go beyond that and usually cuts corners in a variety of ways to keep his costs low enough to underprice his competitors. Thus, by not performing all of the essential tests, he introduces the element of chance into the pharmaceutical equation. Herein lies a major danger in the use of "cheaper" pharmaceuticals.

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Drug manufacturers who compete primarily on the basis of price often ignore or dismiss as being unimportant the key phase of the drug producing process of pharmaceutical development, quality manufacture and quality control. But these processes, while extremely costly, cannot be dismissed as "frosting on the cake". *They are precise scientific disciplines and are inextricably linked with the research process.*

Frequently, entirely new tests have to be developed for each drug. A detailed knowledge of the interactions of the bulk chemical and the vast number of ingredients employed in formulations must be known under a variety of changing physical conditions. Improper particle size, poor selection of vehicles, inattention to stability and compatability under a wide variety of changing circumstances, and a lack of knowledge about disintegration times and degradation products are just some of the factors that have rendered drugs inactive or frankly dangerous.

No one assumes that all manufacturers have an equal investment in research competency and facility. It is equally foolhardy to assume that all manufacturers have equal sophistication in these important disciplines.

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The task of the Quality Control group is to determine whether the active ingredient in the product will be stable throughout normal shelf-life. Therefore, tests must be set up to answer all such questions.

Specific tests are set up to check the drug at every stage of production. From raw materials, through intermediate stages, to the final product, literally hundreds of tests are run to assure a perfect product. This is particularly apparent with some of Lederle's vitamin products where as many as 20 or more individual ingredients must be blended in precise amounts into one capsule. Tests are conducted all along the line to determine that each ingredient is present in exact measure. And when the product is packaged and labelled, the whole batch is placed in quarantine until Quality Control completes its final testing and releases it for general distribution.

Quality Control does not stop at the plant gate. As stated earlier, every batch of drugs marketed by Cyanamid of Canada has a lot number which is used to keep track of its distribution. The Quality Control group could determine the whereabouts of every shipped vial, bottle, or tube distributed by his Company and, if necessary, can recall any drug should a question arise.

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As a further protection Cyanamid retains several samples out of every batch of medicine manufactured or packaged. Spot checks are run on these samples to determine stability and also changes in flavor, color, etc., while sitting on the pharmacies' shelves in different parts of the country under different climates.

These test methods are constantly being improved and increased in umber as Cyanamid develops more sophisticated assay procedures. In some cases we find that testing a product is more expensive than its manufacturing costs. Because of these precise control and testing procedures, we have been able to produce a line of Lederle products over the years on which the physician and his patient can depend.

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WAREHOUSING AND DISTRIBUTION

As a responsible manufacturer of ethical pharmaceutical products, we feel we have a responsibility to our Canadian partners in the health profession—the physicians and pharmacists—and through them to the Canadian people, to insure that our products are readily available throughout Canada. To discharge this responsibility, we maintain warehouse stocks of our pharmaceutical products in Vancouver, Calgary, Winnipeg, Toronto, Montreal and Saint John, N.B. This network of distribution centers makes it possible for our pharmaceutical customers—the hospitals and drug stores—to obtain their supplies promptly, and also allows local emergency situations to be handled effectively. All depots are connected by telex with our Montreal plant, where a 24-hour service is maintained.

Only a few of our pharmaceutical products can be considered truly as emergency items, where a delay of a few hours would threaten human life.

However, stocks of those that are, such as Botulism Antitoxin, Amicar and Gas Gangrene Antitoxin, are carried in each of our warehouse locations. Several times a year, emergencies arise where our local medical representative, working in conjunction with the hospital and medical personnel involved, and occa-

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sionally with the all-out cooperation of the police, military and transport personnel, is able to provide our products on an emergency basis. A recent example is the experience of one of our Saskatchewan representatives in delivering a supply of Amicar from the Saskatoon airport to North Battleford, to save the life of a man suffering from internal hemorrhage. Other representatives have frequently been involved in equally dramatic efforts to rush Gas Gangrene or Botulism Antitoxins to victims in urgent need.

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ROYALTIES

Cyanamid's drug research is carried out largely by more than 1,000 scientists and technicians at its Pearl River, New York, laboratories. Economic considerations have dictated the concentration of the principal pharmaceutical research effort at a single location because of the heavy investment required in specialized facilities and personnel. It must be obvious, too, that fragmenting such an operation is not feasible.

The fruits of all this research are made available promptly to the Canadian operation. Cyanamid of Canada must pay its share of this work, and it is made through the payment of royalties to our parent, American Cyanamid Company. We would like to point out that these royalty payments amounted to only five per cent of our sales dollar, whereas on the basis of world-wide sales, the cost of American Cyanamid's pharmaceutical research and development was over eight per cent. Thus, Cyanamid of Canada is indeed getting a bargain for its research dollar.

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Rather than group payments for the Canadian share of the basic research, with costs for research, development, etc., conducted in Canada, we have set it out in this submission as a separate item so that the information would be completely detailed for the members of the Committee.

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RESEARCH AND DEVELOPMENT

Cyanamid World-Wide Medical Research

Cyanamid's research objectives are progress in the diagnosis, prevention, control and cure of disease and the alleviation of symptoms of disease.

There are three major research concepts:

Basic Research—involves looking for new scientific knowledge without a specific commercial application in mind.

Applied Research—covers investigation and experiments in which a practical or commercial end is more or less in sight.

Development—is the long period in which a scientific discovery or concept is translated into an actual product or process.

To conduct its pharmaceutical research program at Pearl River, N.Y., Cyanamid has a professional staff of 1000 scientists and technicians.

The financial risks of such research programs are enormous. The research and development costs for the broad spectrum antibiotics described in Appendix A totalled more than $15 million, while the costs of subsequent improvements have exceeded $14 million. For each new important product that reaches the pharmacy, it is estimated that almost $5 million is spent on its research and development.

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Cyanamid's medical research is concerned with most aspects of infectious diseases—bacterial, parasitic, fungus and virus; also nutrition, cardiovascular—renal ailments, mental health, endocrinology and cancer. This medical research is global in practice since it is aimed at diseases which occur in different parts of the world.

Cyanamid has been in the mainstream of pharmaceutical research and development since its work with sulpha drugs dating back to 1939. Subsequent developments include the discovery and synthesis of folic acid, which made possible the development of several compounds that have proved to be helpful in treating leukemia and other forms of cancer; the discovery and development of the broad spectrum antibiotics, Aureomycin, Achromycin, Declomycin; the first non-mercurial diuretic, Diamox (acetazolamide), an important steroid drug Aristocort (triamcinolone); vaccines, biologicals, cancer chemotherapeutic agents, and many others.

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Large sums have been invested in research on other products which did not turn out successfully. This money, however, has not been wasted. The scientific findings are published so that others will not have to wander down the same fruitless paths, thus contributing to the world's pharmaceutical knowledge.

Since no marketable products have resulted from these projects, the cost has to be borne by the relatively few successful discoveries. Otherwise, Cyanamid would have had to stop trying to solve the riddles posed by cancer, heart disease and other scourges.

Cyanamid of Canada Research Policy

Many critics of the Canadian pharmaceutical industry have charged that research expenditures incurred outside Canada, paid for in the form of royalties to or research allocations by parent organizations, should not be included in determining the price at which a pharmaceutical product is sold in Canada. Others have expressed concern over the relatively small amonuts of medical research performed in Canada by many large companies, although there has been a significant increase in recent years in the development of pharmaceutical research facilities in Canada by a number of companies.

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As an extremely diversified company with a very extensive capital investment in manufacturing facilities in Canada, the whole question of research in Canada is certainly one of real concern to us. We have taken the position that

we would be short-sighted if we attempted to duplicate medical research that is already being done, or research facilities that already exist, on a scale that we could not achieve. To develop the fully integrated research teams that would be necessary would be prohibitively expensive, in view of the particular research options available to our particular company. If we were involved solely or even principally in the pharmaceutical business, our attitude and reasoning might be substantially different. The decision as to where one spends his research dollars is obviously a decision that rests with the individual company, and must take into account many factors, some of which are common to only a particular company.

We have taken the position that we should direct our research efforts in Canada to those areas in which we are basic, such as organic and process chemicals, which are building blocks for the pharmaceutical industry as well as other chemical industries. We believe the research dollar invested in this manner will yield better returns to us, and to Canada, than if we were to construct a medical research laboratory. We believe that by so concentrating our research effort, we will be best able to achieve our long term objectives.

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This philosophy, we believe, is consistent with the thought expressed by the Economic Council of Canada in 1964 as follows:

> "...it has already been indicated that in the years ahead much of Canada's growth must come in the secondary industries and that a large part of the expansion in exports will have to be in the form of processed and manufactured goods. Over the past several decades the fastest growing secondary industries in all the main industrial countries have been the science-based industries. Also, the products of these science-based industries have been the fastest growing element in world trade. In order to achieve our economic objectives it will be necessary for Canada to participate adequately in these developments and to find a basis for effective and profitable specialization through her own efforts and skills."

For the year 1966, Cyanamid of Canada Limited will spend approximately $900,000 on research activities conducted entirely in Canada on projects for which the Company is specifically equipped, which takes into account the raw materials, climatic conditions, and other factors pertaining specifically to Canada.

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Canadian Research and Development

(a) *Canadian Clinical Investigation*

While Cyanamid of Canada maintains a duplication of the manufacturing, quality control, marketing and administrative facilities of Cyanamid in the United States, there is no duplication of the medical research facilities described in the preceding section.

Cyanamid of Canada contributes to the support of Lederle's total medical research effort through the medium of royalty payments. As indicated in our pharmaceutical sales dollar, such royalty payments represent approximately five per cent of our net sales dollar. In addition to these royalty charges, an

additional two per cent of our sales dollar is spent on research and development activities in the medical field in Canada.

While we do not maintain medical research laboratories in Canada, this does not mean that no medical research activities are conducted by Cyanamid of Canada. There is a popular misconception that all medical research activities of the industry are confined to and conducted within the four walls of a pharmaceutical research laboratory. Much of the vital clinical human testing on new drugs and new therapeutic concepts is done outside a company's own research laboratory. When a decision is reached that a drug is ready for clinical testing, it is Lederle policy to ask the men most highly regarded as authorities in the field of medicine to which the drug relates to do the clinical testing.

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Through the years Lederle has endeavoured, wherever and whenever possible, to have clinical testing of its research results carried out in Canada. To cite a few representative examples:

Antibiotics	—Dr. K. J. P. Wightman, Professor of Medicine, University of Toronto.
Temposil Calcium Carbimide	—Dr. Gordon Bell, Alcoholism Research Foundation, Toronto.
Cancer Chemotherapeutics	—Dr. G. M. Delage, St. Sacrament Hospital, Quebec City.
Aristocort (Triamcinolone)	—Dr. Jacques Genest, Director of Clinical Research, Hotel Dieu Hospital, Montreal.

Currently, two separate but related clinical investigation projects relating to the use of Tetanus Toxoid in the prevention of tetanus are underway at the Royal Victoria Hospital in Montreal. One is under the direction of Dr. Thomas Primrose, Associate Professor, Department of Obstetrics, McGill University; and the other is under the direction of Dr. Bernard Perey, Director of Emergency Clinics, Royal Victoria Hospital. The combined cost of these two projects will exceed $20,000, with the costs incurred at the Royal Victoria Hospital being covered by a Lederle research grant.

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Based on the actual experience of the past several years, we have every reason to be optimistic concerning the potential increase in such Lederle research activities in Canada.

(b) *Cyanamid Assistance to Canadian Medical Education*

On an international basis, the Cyanamid organization regularly provides substantial financial support to research institutions, medical schools and universities, and individuals for medical study, particularly in the field of research.

Lederle Medical Faculty Awards contribute to the support of faculty members of major medical schools in the United States and Canada. These Medical Faculty Awards are given to assist able men and women who aspire to full-time academic carers in the preclinical and certain clinical departments of these medical schools. This program provides financial aid for the support

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of individuals who have demonstrated their capacity both as teachers and investigators in the disciplines of anatomy, biochemistry, biophysics, genetics, microbiology, pathology, pharmacology and physiology in order to encourage them to remain in these disciplines. These awards are administered by an independent committee composed of professors representing various preclinical and clinical sciences drawn from the various medical schools from applications submitted to the committee through the office of the dean of the medical schools.

Since this Lederle Faculty Award system began twelve years ago, awards totalling approximately $150,000 have been given to the following Canadian medical schools:—

	No. of Awards
Laval University	2
McGill University	2
Queen's University	2
University of British Columbia	1
University of Montreal	1
University of Saskatchewan	2
University of Western Ontario	1
Total Awards	11

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(c) *Medical Student Research Scholarships*

Cyanamid of Canada, through its Medical Products Department, also makes available each year two medical student research fellowships of $700 each to undergraduate students in each of twelve schools of medicine in Canada. This contribution of $16,800 annually enables such students, who are selected by the university, to work on university sponsored research projects in the summer months.

These activities expand the medical profession's knowledge of drugs and therapy, and thus benefit the public, the medical profession and the pharmaceutical industry, although Cyanamid of Canada gains no specific benefits therefrom.

(d) *Medical Symposia*

As a contribution to the continuing education of practicing physicians, Cyanamid of Canada supports financially, and assists in the organization of, medical symposia sponsored by local medical associations. For example, in October 1965 a Symposium on Iatrogenic Illness was held in Ottawa under the sponsorship of the Academy of Medicine, Ottawa. This symposium was attended by approximately 260 practicing physicians, hospital staff physicians, interns, residents and senior medical students.

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The financial support given by Cyanamid of Canada is used to defray the costs of meeting rooms, travelling expenses and honorariums for guest lecturers, etc., and makes it possible for the sponsoring medical society to provide this educational program without charging attending physicians a registration or course fee.

The lecturers chosen by the sponsoring medical society are internationally recognized authorities in their specialized fields, as evidenced by the program of the Ottawa Symposium on Iatrongenic Illness reproduced on the following page.

These symposia are held at least once every two years. The next will be in Vancouver during 1967.

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MORNING SESSION

Banquet Room

9:00 .....Registration—All Day

Moderator: J. Burke Ewing, M.D.

Professor of Surgery, University of Ottawa, Faculty of Medicine

10:00—10:40 .....Iatrogenic Diseases in Children

RONALD DENTON, M.D.

Associate Professor of Pediatrics, McGill University, Assistant Physician in Chief, Montreal Children's Hospital, Montreal.

10:40—11:20 .....Iatrogenic Illness in Surgery

LLOYD M. NYHUS, M.D.

Professor of Surgery, University of Washington, School of Medicine, Seattle.

11:20—12:00 ..... The Many Problems of Medical Progress

WALTER C. ALVAREZ, M.D.

Emeritus Professor of Medicine, Mayo Foundation Graduate School, University of Minnesota Medical School, Chicago.

12:00—12:30 .....Question and Answer Period

12:45—2:30 .....Luncheon for physicians and wives—Drawing Room

Chairman J. F. HAMEL, M.D., President,
Academy of Medicine, Ottawa.

Speaker "Getting Along With Our Teenagers"

BEVERLEY T. MEAD, M.D.

Professor and Chairman, Department of Psychiatry, Creighton University School of Medicine, Omaha.

All physicians are invited to attend.

No fee is required for attendance at scientific sessions, luncheon or reception. The College of General Practice of Canada has approved a credit of five hours of study of category 1 to this Symposium.

AFTERNOON SESSION

Banquet Room

Moderator: T. L. FISHER, M.D.

Secretary Treasurer, Canadian Medical Protective Association.

2:45—3:25 .....Glands, Not To Monkey With

ROBERT B. GREENBLATT, M.D.

Professor and Chairman, Department of Endocrinology, Medical College of Georgia, Augusta.

3:25—4:05 .....Illness of Laboratory Origin

MARTIN M. HOFFMAN, M.D.

Associate Physician, Royal Victoria Hospital, Montreal.

4:05—4:20 .....Recess

4:20—5:00 .....Hazards In Counseling

BEVERLEY T. MEAD, M.D.

5:00—5:30 .....Question and Answer Period

5:30—6:30 .....Reception—Quebec Suite

Wives of physicians are welcome and encouraged to attend.

Recording of all or any part of this program is prohibited without written permission of the sponsor and speakers.

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(e) *The Role of a Medical Director*

Closely allied with the research and development function within Cyanamid is the role of the Medical Director. For that reason we have deemed it advisable to set out in some detail the specific activities of Dr. Claude P. Gendron, who has that responsibility within this Company.

Dr. Gendron was a prominent Montreal practitioner prior to joining Cyanamid and is a former president of the College of General Practice of Canada. He is the Company's prime contact with clinical investigators and the staff of the Food and Drug Directorate in the course of arranging for clinical

investigations and new drug submissions. Additionally, he acts in a liaison capacity with the medical profession at large, and we consider the exchange of information which takes place between Dr. Gendron and the members of the profession at medical seminars and symposia, as well as at various medical conventions, an extremely important segment of our two-way communications program.

Inquiries from the medical profession for additional technical information over and above that available in our published literature or through our medical representatives are directed to the Medical Director. Similarly, reports

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relative to clinical results and possible adverse reactions are received by him from practicing physicians. He plays the additional role of lecturer at our sales training courses and is a constant source of advice for the Company's field representatives.

In our operation, the Medical Director has absolute power of veto over the material used by our advertising department with respect to such published information as medical claims, dosage conditions, precautions, contraindications and official warning statements appearing in our package circulars, labels, brochures, etc.

The economics associated with the office of a Medical Director are such that smaller companies often find it impossible to retain such services, and many "generic manufacturers" deem them unnecessary. Cyanamid believes that in this era of increasingly potent and complex drugs, a Medical Director who is in frequent contact with the medical profession, and available in urgent situations, is a major contribution and a vital safeguard to the Canadian public.

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PROFESSIONAL SERVICE REPRESENTATION, MARKETING AND MEDICAL INFORMATION

Marketing expenses include selling, sales planning and education, advertising and sales promotion. These expenses are incurred to overcome a severe communications problem.

The problem is to convey a considerable amount of very important information about our pharmaceutical specialties to more than 20,000 doctors and 6,000 pharmacists, who are spread out over 4,000 miles of country. To disseminate this information, we utilize a "marketing mix" that includes personal calls by our staff of qualified, well trained, medical representatives, medical journal advertising and direct mail advertising. We consider these functions to be interdependent, but for the purpose of this brief each will be described separately.

To perform these functions, we employ 87 people in our medical products marketing department, 72 of whom are medical representatives spread throughout Canada on the basis of population. Of this group, 76 per cent of their time is spent on ethical pharmaceutical products, and the balance of 24 per cent on surgical products.

These 72 medical representatives include seven district managers who directly supervise the field force. An additional 15 people are located in Montreal and perform various head office marketing functions.

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The role that a medical representative plays in providing vital information to the medical profession is often misunderstood. He forms a particularly important link in the vital two-way flow of information between the pharmaceutical manufacturer and the professions of medicine and pharmacy. No responsible pharmaceutical manufacturing company will claim that the medical representative does not perform the commercial function of creating a demand for his company's products. He does this by providing information about his company and its products, yet he is not, nor can be expected to be, a professor of medicine. That he is a prime source of information concerning pharmaceutical products is confirmed, in our opinion, by the results of a 1964 survey conducted by an independent market survey firm. In this survey, 128 practicing Canadian physicians scientifically selected to be representative were asked to name the prime source of their information concerning pharmaceutical products. The replies were as follows:—

Medical Representatives	88
Another Physician	16
Medical Journal Articles	12
Direct Mail Literature	3
Medical Journal Advertisements	2
Medical Conventions	1
All other means	6
Total	128

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Field Sales Expense

The Lederle Medical Representative

The average medical representative is 35 years old, has a university degree, and has been employed for six years. His function is to present to the doctors and pharmacists in his territory complete information about all Lederle products, and by conveying this information, to create a demand for our products. He also makes sure that Lederle products are well distributed throughout his territory, and arranges credit for all out-dated products. To give greater insight into the activities of medical representatives, we have outlined what he might do on an average day.

For our medical representative, his car is his office. Here he keeps all the territory records, literature and drug samples needed for a day's work. His morning calls are most frequently on drug stores and hospital pharmacies, advising the pharmacists of new products or changes in older products, insuring he has adequate inventory and arranging credit or exchange on any out-dated or obsolete products.

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He also makes sure the pharmacists' product information records are up to date and advises the pharmacists of the specifics of new drugs or improvements in older ones. In hospitals he also calls from time to time on specific nursing

personnel and dietitians, so they too will be familiar with current changes in therapy.

He calls on doctors in his territory whenever it is most convenient for the doctor. This could be most any time and frequently comes at the end of the day when the doctor is finished seeing patients. This is the most important part of his job. Our representative must discuss products with all doctors, be they general practitioners, surgeons, obstetricians or otolaryngologists. He discusses products, the uses of which vary from prenatal care of pregnant women to the treatment of pneumonia and ulcerative colitis. Our representative must be knowledgeable, otherwise doctors will not continue to rely on him.

During his call, a representative will introduce a new drug, a new form of an existing drug, or present new indications or contraindications of existing drugs. He also follows up on a doctor's experience with these drugs and, if significant, reports them back to our medical director.

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To aid him and the doctor, we provide literature which outlines the salient points about our products. This literature is frequently left with the doctor, and it contains a complete product description outlining indications, side effects, contraindications and a suggested dosage schedule. We also have booklets available which summarize the complete clinical and laboratory experience of a drug, pointing out all its good and bad properties.

The representative also has samples of some of the drugs he is detailing. Upon request from the doctor, samples are left. A signed receipt is obtained, as prescribed by law.

Most of our medical representatives have territories encompassing both rural and urban areas, and a considerable amount of travelling is necessary. It is the rural physician and even the urban general practitioner who are best served by our representatives, for these groups do not have the same access to hospital ward rounds or therapeutic meetings, where drug therapy is reviewed and discussed, as do urban specialists.

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At the day's end, our typical representative has visited three or four drug stores, a hospital pharmacy, perhaps one or two other hospital people, and five or six doctors. He has had to plan his day precisely, adjust his presentation to the individual he is addressing, plus update his records and often drive many miles.

Sales Planning and Education

This includes the normal budgeting, control and supervision needed of a large sales organization, plus costs involved in the program of sales education.

Because of the critical need for well informed representation, we spend a great deal of time and effort training our representatives. We have a sales training manager whose duty it is to organize the training needs of our salesmen.

When a new representative is hired, he is given intensive training by his district manager, both in the classroom and in the territory. Here, the new

employee is taught about the diseases for which our products are designed, how they work, and what they can and cannot do. The trainee never works alone until his district manager is satisfied that he is competent to do the job. After three or four months of training and close supervision in the field, he is brought to Montreal along with other representatives, where he is again given intensive classroom instructions on product information.

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Every three months, district refresher meetings are held to review the products to be highlighted during the following three months.

Every medical representative attends the Montreal classroom refresher courses at least once every 24 months. All medical representatives are visited by their district manager according to their needs, but always for two or three days per quarter. During his visit the district manager will make doctor, hospital and drug store calls with the representative, so that on-the-job supervision of the representative is maintained.

With these programs we have developed a highly skilled and competent sales staff. Yet the job is never-ending.

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Advertising and Sales Promotion

(a) *Medical Journal Advertising*

Medical journal advertising makes an important contribution to the doctor. These professional journals provide a medium of communications whereby, through the editorial columns, the most recent results of pharmaceutical and medical research are made available to the busy practicing physician. Current information on drugs and drug therapy is also featured.

The pharmaceutical industry utilizes the advertising space to communicate information to doctors through these journals, and by so doing assures the very existence of the publications. Without the advertising revenue, it would not be possible to publish the journals unless high fees were imposed on the recipient.

(b) *Direct Mail Advertising*

We utilize direct mail advertising from time to time to bring certain products to the attention of a *selected* category of physicians, or to announce a new product. It is directed only to those physicians who have a particular interest in the products or indications being featured. It usually takes the form

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of a descriptive brochure, with or without a covering letter, giving a complete description of the product. We include also in this category the distribution of reference material such as our "Literature of Dermatology", which is a reference and abstract of articles of particular interest to specialists in dermatology. Also included are letters from our medical director to practicing doctors advising them of newly-found side-effects or contraindications to one of our existing products.

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(c) *Samples*

All our medical representatives carry a supply of samples of some of the products they are detailing. These samples are usually in the form of starter doses, but this may vary depending on their intended use.

Samples are well received by the medical profession and play an important role in the marketing of a product.

Samples are used in many ways by doctors:

1. As an immediate dosage for a severely ill patient, or when another supply of drugs isn't quickly obtainable.
2. To test an individual patient's tolerance to a particular drug. Every drug doesn't act the same with every patient, and by the use of samples a doctor may economically find the one best for his patient.
3. To allow a physician to judge the clinical response of a drug he has not previously used.

Samples are distributed only to doctors who have indicated a wish for them. For every sample given, a signed receipt is obtained. Samples are costly but are an indispensable part of our marketing mix.

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GENERAL ADMINISTRATION

Similar to many other large corporations, economy dictates that some services be supplied on a centralized basis. These services can be broken down into several major categories:

General Management

Employee Relations Administration

- recruitment of technical personnel
- job and salary evaluation
- administration of employee benefit programs
- safety and industrial hygiene
- secretarial functions

General Services

- purchasing
- traffic
- tariffs and customs clearance

Manufacturing Services

- engineering
- project evaluation
- industrial engineering

Financial

- comptroller and treasurer functions
- credit management
- computer programming
- budgetary control
- cost analyses and control

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Pensions and Group Insurance

Most of these activities are regarded by us as services to each of our operating groups. Where practical, such as in cost analysis and control, some of these charges are direct to the Medical Products Department. The remainder are allocated to our various departments on the basis of sales volume. It is not practical to attempt to provide services of such a broad scope economically for an individual product group such as pharmaceuticals.

We believe the charges for these allocated expenses are very modest.

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NET PROFIT AFTER TAXES

As indicated in our Pharmaceutical Sales Dollar, our after-tax profit on sales is eight per cent. We consider this figure modest and somewhat below the profit on sales in many other types of business.

Our return on investment is 10 per cent. Investment has been calculated at cost of facilities, less depreciation, plus working capital. This return on investment ratio is lower than the average reported by Dun and Bradstreet of Canada Ltd. for 1965 of over 19,000 reporting manufacturing firms in Canada.[1]

Both profit ratios are improvements over those experienced in 1964, and illustrate the latest data we have available.

When considering the risk involved in the pharmaceutical business, we believe these ratios are low.

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THE COST OF RETURNED GOODS

All antibiotics, vitamins, biologicals, and many other drugs sold in Canada must, by law, carry on the label a specific expiration date, based on stability data developed by the manufacturer.

Since we assume the responsibility of accepting for credit or exchange any unopened container which becomes out-dated, the cost of returned goods for a company with a product line such as our own, becomes a significant element in our total cost picture. Returns of out-dated material consistently amount to five per cent of our gross sales. Virtually all returned goods represent a total loss, since only 10 per cent of the value of total returns can be salvaged.

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PHARMACEUTICAL PATENTS IN CANADA

The basic reasons for the existence of a patent system in any country are as follows:

1. To act as an incentive to stimulate an inventor to discover new and improved products, and develop new applications of knowledge.

2. To induce the inventor to disclose his improvement for public benefit, thereby eliminating secrecy in the practice of the invention and assisting or stimulating research by others and/or avoiding research duplication.
3. To create and maintain a climate which encourages individuals and commercial organizations to invest in research, development and production facilities, at the same time providing a mechanism by which the successful inventor may recover his necessary and unavoidable costs.
4. To assure that the invention is developed in experienced and responsible hands.

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In the brief submitted to this Committee on July 9, 1964, we discussed the manner in which drug patents and the patent system in general contribute to drug safety and effectiveness. The incentives and safeguards provided by the patent system have made it economically possible for Cyanamid and other research oriented firms to invest large sums of money in plant, property and equipment and research programs designed to develop safer, more effective pharmaceutical products.

Further, with regard to the importance of patents, we presented our views to the Restrictive Trade Practices Commission concerning its specific recommendations relative to the abolition of drug patents in Canada. That presentation is reprinted in Appendix B.

There are special and discriminating provisions in the Canadian Patent Act that relate to drugs. If a drug is produced by a chemical process, the inventor cannot obtain a patent on the product itself, but only on the process. This limitation also appeared in the patent laws of Great Britain until 1949, when it was abolished in that country and a new drug *per se* was restored to patent-ability. The Ilsley Commission in 1959 recommended that the limitation similarly be abolished in Canada, but legislative action to implement this recommendation has not been taken. The continued existence of this limitation dilutes the effectiveness of the Canadian Patent Act insofar as drugs produced by chemical processes are concerned, and by its very existence leads to substantial and costly complications in the legal administration of the Patent Act.

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The second limitation in the Canadian Patent Act relates to the provisions of Section 41 (3) regarding the granting of compulsory licenses on food and drug products. This section had its origins in the English Patent Act of 1919, and originally was designed to circumvent the danger of a post World War I shortage of these products, a condition which certainly does not exist today either in England or in Canada.

This compulsory license provision is applicable to all drug patents, whether process or product, and application may be made immediately after the patent issues. The application is made to the Commissioner of Patents, who is obligated to order a compulsory license unless he sees good reason to the contrary. The commissioner has the absolute power to order a license to be issued, even to the extent of not requiring an oral hearing or cross-examination on evidence filed

in support of the application. The Courts have not established a clear or concise guideline on this matter, and as a result, the basic purpose of the Patent Act has been subverted.

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Some defenders of Section 41 (3) advance the argument that such compulsory licensing provisions are necessary to prevent the abuse of a patent. Section 68 of the Canadian Patent Act provided for licensing as relief for abuses contrary to the public interest, which abuses are well defined in Section 67 of the same Act. The public interest is further protected by Section 19, which reserves to the Government of Canada the right to use a patented invention for governmental purposes on payment of reasonable compensation to the patent owner.

Some of the hazards to public health developing from the use of compulsory licensing in Canada are well outlined in the Hilliard Committee Report, tabled in the House of Commons on May 12, 1966. We support these recommendations, although we are completely opposed to the principle of compulsory licensing.

Those who support the outright abolition of drug patents, or the reduction in the term of the patent, or the present or more elastic version of compulsory licensing provisions, usually do so on the basis that such actions, or a combination thereof, may reduce drug prices to the public. They ignore completely the fundamental principles of the Patent Act and disregard the long term effect of such actions on Canada's economy and its important role in the affairs of the international economy.

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The proponents of the abolition of drug patents, as a means of reducing prices, also completely ignore the potential consequences of such action. When, during the Mussolini regime, Italy abolished drug patent protection in 1939, it became the only country with a traditional patent system that had been subverted in such a way. Since then, despite her advanced chemical technology and her many talented scientists, Italy has not originated a single new drug of significance.

Mussolini, in effect, turned Italy into a drug haven where pill producers could copy the successful work of others, while bypassing the costs of research and development. They could also save themselves the substantial expense of new drug informational and educational programs. The copiers would produce only the "winners", those products most often prescribed by physicians, which had been developed and introduced by a research oriented pharmaceutical house.

But even copiers have their problems. With the tetracycline antibiotics, efficient quantity production bacame a major stumbling block. This is understandable. At Cyanamid, where three of these drugs had originally been developed, substantially as much money has been devoted to developing and improving the manufacturing processes as to discovering the drugs.

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The result was international piracy on a grand scale. Cyanamid became one of the principal victims of an international conspiracy to steal research secrets

and confidential "know-how" valued at many millions of dollars from established pharmaceutical laboratories for sale to unscrupulous competitors.

Some of the details of this conspiracy have been published in an article which has been reproduced as Appendix C, attached.

The abolition of drug patents in Canada, without question, would spawn a situation similar to that which developed in Italy. The "fly-by-night" firms would enjoy a field day and certainly the quality of drugs would deteriorate, despite the efforts of government agencies to maintain even minimum standards of quality. In taking such action, the Canadian government would be moving in precisely the opposite direction to that being taken by governments of most industrialized countries of the Free World. In fact, even Italy is slowly but surely moving toward the re-establishment of a pharmaceutical patent system.

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Althouth we feel that the question of drug patents should be considered primarily from the standpoint of drug safety and incentive to invent, the effect of drug patents on prices and the underlying reasons for such effects, must also be considered by your Committee.

It must be realized that an effective patent system is the means provided by the government to the inventor to recover his development costs. On the other hand, the pricing of a new product, even though it may be protected by a patent, depends on many other factors, including the nature and price of competitive products already on the market, the possibility that the patented product may be rendered obsolete very quickly by the introduction of a new and superior product, and the desire of the manufacturer to protect against prospective competition by pricing the patented product low enough to gain a foothold in the market before a newer competitive drug is introduced. A patented drug, for instance, may face immediate and vigorous competition from other similar patented drugs. Certainly this was the case with Aureomycin, where several price reductions followed its introduction, arising out of prospective or existing competition with Chloromycetin and Terramycin, both of which were patented.

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It is not in the manufacturer's self interest to demand an excessive price for a new patented drug, because he may thereby lose the opportunity to establish broad market usage against competitive drugs before the new and superior drug is introduced. If the manufacturer introduces the drug at a reasonable price, he may gain a share of the market immediately.

Summarizing our position on drug patents, we believe the long term interest of Canada would be best served by:

1. The elimination of Section 41 (3) of the Patent Act.
2. The amendment of the Patent Act to provide product patents as well as process patents on drugs, whether produced by chemical or biological processes.

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CYANAMID OF CANADA PHARMACEUTICAL PRICES

In establishing the initial selling price of a new drug, a number of factors must be considered. Among these is the price of our own related products and those of our competitors. In every case to date where we have introduced a new drug, there have been existing, competing products or other methods of treatment that established a price level.

Some of the other factors to be considered in pricing a new product include the following:

1. The probable market life of the product before it is replaced by a new preparation.
2. The investment needed to produce and market the product and acquaint the medical profession with its therapeutic qualities, side effects and use.
3. The possibility that initial costs may be reduced by process improvements, increased volume and other factors.

There are also many factors that determine the price history of a pharmaceutical product after it is introduced. Changes in costs of labor, raw materials, packaging supplies, sales and income taxes, and process improvements, all must be taken into account along with the competitive situation in the market place in determining the selling price of a product.

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In spite of consistent increases in many cost factors over the past decade, many of our Company's more important pharmaceutical products have been reduced in price. The attached table, for example, indicates the price history of our Aureomycin, Achromycin, and Declomycin Capsules in bottles of 16's from date of release to the present time. The prices listed are our prices to the retailer, with Federal Sales Tax included.

From this table, it can be seen that Aureomycin prices have declined some 75 per cent in 15 years. Achromycin has been reduced 42 per cent in 10 years, and Declomycin is down 37 per cent in five years.

The older two products have, in their own day, been the most highly prescribed broad spectrum antibiotic. Each one has been replaced, at the peak of its success, by a better product of our own development, and when the improved product was released, it was priced exactly the same as the older product in spite of its superiority and the huge investment necessary to make it available.

This illustration of antibiotic price decreases refutes the accusation that drug prices are increasing. It is also an excellent example of the benefits that can accrue to society when the forces of a free economy are allowed to act.

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The only instances of a price increase for these products involve the increase in Federal Sales Tax from eight per cent to 10 per cent in April, 1951 and from 10 per cent to 11 per cent in April 1959.

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PRICE HISTORY

Product	Comments	Date	Price to Retailer—Federal Sales Tax Inc.
CHLORTETRACYCLINE			
Aureomycin Caps., 250 mg. 16's	Released	Feb. 5, 1949	$12.84
	Price Decline	Feb. 1, 1950	10.27
	Price Decline	May 2, 1950	7.71
	Fed. Sales Tax—10%	Apr. 10, 1951	7.85
	Price Decline	Oct. 1, 1951	6.68
	Price Decline	Oct. 5, 1953	5.61
	Fed. Sales Tax—11%	Apr. 10, 1959	5.66
	Price Decline	Oct. 24, 1960	4.74
	Price Decline	May 25, 1961	4.27
	Price Decline	June 14, 1962	3.63
	Price Decline	Dec. 21, 1964	3.24
TETRACYCLINE			
Achromycin Caps., 250 mg. 16's	Date of Release	Feb. 1, 1954	5.61
	Fed. Sales Tax—11%	Apr. 10, 1959	5.66
	Price Decline	Oct. 24, 1960	4.74
	Price Decline	May 52, 1961	4.27
	Price Decline	June 14, 1962	3.63
	Price Decline	Dec. 21, 1964	3.24
DEMETHYLCHLORTETRACYCLINE			
Declomycin Capsules, 150 mg. 16's	Released	Oct. 2, 1959	5.66
	Price Decline	Oct. 24, 1960	4.74
	Price Decline	May 25, 1961	4.27
	Price Decline	Dec. 21, 1964	3.57

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The pricing philosophy used in pricing our pharmaceutical products in Canada is extremely simple. We have two types of customers—those who buy tax included (such as drug stores) and those who buy tax exempt (such as hospitals). We therefore have two prices—tax included and tax exempt. The difference between the two prices is the amount of the Federal Sales Tax.

An example of these prices is as follows:

Declomycin Capsules 150 mgm.

Package Size	*Price to Retailer (F.S.T. Included)*	*Price to Hospital (F.S.T. Exempt)*
16	3.57	3.22
100	21.29	19.18

Section III of the Excise Tax Act lists the following as exempt from Federal Sales Tax: Adrenocorticotrophin (ACTH) cortisone, insulin, radium, liver extract for use exclusively in the treatment of anemia and vaccines for use in the prevention of poliomyelitis. Should Parliament expand the Sales Tax exemption to include all prescription drugs, our prices would be decreased immediately to those customers who pay the tax. Removal of the Federal Sales Tax would mean a decrease in our price to retailers of approximately 10 per cent.

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We have illustrated the dramatic decrease in price of our major antibiotic products. We might add that there has never been a price increase on major Lederle products except due to an increase in the sales tax. How long this history of always reducing prices and never increasing them will continue is unknown, especially in the face of spiraling wage and material costs without compensating increased productivity. Pharmaceutical preparations are no different from other goods in this inflationary squeeze.

We urge you to recommend that the Federal Sales Tax be eliminated on all pharmaceutical preparations.

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BENEFITS TO CANADIANS

The following excerpt from the Pharmaceutical Manufacturers Association of Canada's booklet, "This is Canada's Prescription Drug Industry" illustrates the other side of the cost-of-drugs coin, that of the benefits of drugs.

"Drugs have played a major role in the control of diseases that were formerly often fatal, such as diphtheria, pneumonia, tuberculosis and syphilis. Reductions in death rate and in working time lost through sickness have contributed great economic benefits to Canada. New drugs developed by the industry have been estimated to save billions of dollars worth of man-hours annually in the United States, and Canada benefits as much in proportion to population. One authoritative study indicates that the national output in the United States alone has been expanded by as much as $7.4 billion in a single year as a result of improved medical treatment and drug usage for just four diseases.

New improved pharmaceuticals have helped to sharply curtail infant mortality rates and hospitalization time giving a dramatic boost to average life expectancy of almost 20 per cent in the past twenty years."

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The opinion expressed by the Royal Commission on Health Services in its first report in 1964 stated on page 340, "The outstanding progress made in medicine in the present generation would not have been possible had it not been accompanied by major advances, and in some cases by a breakthrough in the discovery of new drugs and the development of improved pharmaceuticals to help physicians to combat and in many instances prevent disease and illness. . . The dynamics of progress in the drug field are illustrated by estimates which indicate that 90 per cent of the drugs prescribed in 1960 were introduced in the previous two decades; 40 per cent could not have been prescribed in 1954."

Lederle products have played a major role in making these advances possible. The tetracycline antibiotics as an example are the most widely prescribed broad spectrum antibiotics which cure many of the heretofore common bacterial infections.

We believe that the prices we charge for Lederle pharmaceuticals are reasonable and, when compared to the results achieved through their use, as

well as to the far greater and steadily increasing costs of hospitalization, one of the greatest bargains available.

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Our present system of free enterprise has benefitted our society immeasurably. It would be a great disaster if, for the sake of a minor cost saving, the flow of new and improved drugs were to be altered.

CAN OUR PHARMACEUTICAL MARKETING COSTS BE SAFELY REDUCED?

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In the foregoing sections we have, to the best of our ability, detailed our methods of operation and our philosophy relative to the research, development, manufacture, marketing and distribution of our ethical pharmaceutical products. We have attempted to outline the dimensions of the medical information problem which faces the pharmaceutical manufacturer today, particularly the research-oriented innovator, and we have discussed the methods which have been developed over the past half century in an attempt to solve the many and continuing problems of communication with the physician and the pharmacist.

It is obvious that it is expensive to maintain an effective two-way communication network to provide the health team with the necessary scientific information concerning our products, and to obtain from them the equally important information concerning their experience in the use of these products in actual practice.

We realize that our marketing expense ratio may appear high, and we speak from first-hand experience in this respect due to our extensive marketing experience in other product areas. For example, our Industrial Chemical Division operates with marketing costs of less than 10 per cent of gross sales where they are selling bulk commodities. It would obviously be advantageous to use a less costly marketing process for our pharmaceutical products if an effective and safe alternative were available.

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We have, over the years and by different means, tested and experimented with various marketing concepts, and with few exceptions have found it necessary to continue to employ the procedures which we use today. The article published in the Harvard Business Review, September-October 1962, entitled "Ironic Contrast: U.S. and U.S.S.R. Drug Industries", contains some information pertinent to this subject, as follows:

> "The Russian method of dissemination pharmaceutical information appears to be one of general announcements in the medical and sometimes in the lay press or other media of mass communications. The belief that people (doctors) automatically will make use of information or products if these are available, is not borne out by the evidence."

As a remedy for this problem in the U.S.S.R. the article continues:

> "Even more interesting and significant, however, is the fact that representatives from the pharmacies or from the pharmaceutical warehouses or sub-depots, are now being sent to the clinics to inform physicians about what new pharmaceuticals are available and, in turn, to

find out their needs and requirements. In the particular case of physicians, it would be closer to the truth to assume that in many instances, they are much too busy to give a careful reading to the little flyers that flutter across their desk or even to peruse the medical literature systematically in search of new drugs."

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After comparing the two systems of drug manufacturing and marketing, the authors come to the following conclusion:

"1. *Vigourous promotion of drugs is not necessarily socially undesirable.* In the Soviet Union where drugs are even today only mildly promoted, there are substantial lags in the introduction of new drugs and delays in the dissemination of information about those drugs which have been made available."

"2. *Brand naming of drugs, in itself, is also not undesirable.* By brand naming, the responsibility for quality control is placed with the manufacturer, and the customer is enable to exert pressure on the manufacturer of inferior products. In the U.S.S.R., where quality control is enmeshed in government bureaus separate from the factory quality consequently suffers."

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"3. *Customer preference, which branding allows, serves in the United States to stimulate brand manufacturers into carrying reasonably full lines, even if some are sold at a loss.* In the Soviet Union, factory managers apparently protect their budget by avoiding highly unprofitable items, much as generic drug manufacturers do in the United States."

"4. *Finally, if reach is separated from production, as in the Soviet system, the process of getting laboratory items into production and out to the consumer is drastically slowed.*"

We believe that our prices, our profits, and our return on investment of and from our pharmaceutical operations are entirely reasonable. We would be as reluctant to reduce the quality of our marketing effort as we would to reduce the quality control of our production or the extent of our research effort.

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Based on our own experience, and the available published surveys and reports, we do not honestly feel that our marketing expenses can be *significantly* or *safely* reduced.

APPENDIX A

BRIEF HISTORY OF DEVELOPMENT OF CYNAMID ANTIBIOTICS

AUREOMYCIN

1. *Its history, and the difficulties and cost involved in discovering it*

The discovery of Aureomycin by Dr. Benjamin M. Duggar, of Lederle, involved four years of intensive effort during which a group of Lederle scientists isolated over 30,000 strains of actinomycetes before discovering it and then subjected it to countless laboratory and clinical tests on animals, and finally humans, before it was ever made the subject of a new drug application or announced to the public. Over five million dollars were invested in this gamble, after which much more money had to be spent in developing a process that would turn out the drug in sufficient quantities to be able to offer it at a reasonable price.

Here are a few of the highlights:

In 1944, Lederle Laboratories Division, American Cyanamid Company, began a large scale program of screening molds for antibiotic activity. To head up this program, Lederle gained the services of a retired professor from the University of Wisconsin, Mr. Benjamin M. Duggar, who had established himself as one of the world's outstanding botanists, and was an internationally recognized authority on molds and fungi.

— 2 —

Penicillin was then being produced by a large mold and Dr. Duggar was convinced that a more effective antibiotic could be found among the smaller molds. From all over the world, hundreds of soil samples were sent to him at Pearl River, New York, for extensive screening and evaluation. To handle this important screening operation, Lederle organized an antibiotic research group, consisting of teams of chemists, bacteriologists, pharmacologists and other specialists.

In 1945-47, while the Lederle scientists were working on the problem, other scientists had only reported about 30-35 antibiotics. But except for one or two, like streptomycin, they had no significant value. By 1948, about 100 antibiotics had been identified, indicating the vast amount of research that was being conducted in the search for new antibiotics.

The systematic testing of soil samples for antibiotic activity is a long, tedious and expensive task. For every success, there are thousands of failures. Dr. Duggar and his staff had to devise new methods of extracting the molds from the soil before they could even begin the intricate test procedures. If the screening process did establish that a mold had an antibiotic effect against a certain disease-causing organism, then further tests were conducted.

— 3 —

In 1946, after isolating 30,000 strains of actinomycetes, 3,400 of which survived initial tests, Dr. Duggar found one that looked promising. It had been isolated from a timothy field in Missouri. In its first try-out against deadly

microbes, it proved effective against more than 50 different germ species. Designated A-377, it was called Aureomycin because of its golden yellow color.

Aureomycin performed brilliantly in agar dishes, but some of its animal tests were slightly disappointing in respect to what had been anticipated. This led some investigators to express pessimism concerning its value. However, it is well known that drugs which fail in animals may work on humans, since humans and animals may not respond identically to chemotherapy. Undulant fever (Brucellosis) was a case in point. The drug was not successful in the laboratory in curing animals with the disease, but it did work in humans.

Even after its discovery, several more years of careful laboratory testing followed before Aureomycin was ready for use in human patients. Extensive clinical trials followed, in which Aureomycin proved itself highly effective. For the first time, physicians were able to treat diseases that had never before responded to chemotherapy. For instance, the first effective cure of any virus disease in humans was attributed to Aureomycin. Dr. L. T. Wright, of New York used it successfully to fight the disabling and painful venereal infection called lymphogranuloma.

— 4 —

Rocky Mountain Spotted Fever, a rickettsial disease which formerly claimed 20 per cent of its victims, also succumbed for the first time to Aureomycin chlortetracycline. A four-year old boy with a seven-day history of high fever, headache, muscle pains and five-day-old rash was among the first such patients treated. The child was given Aureomycin four times a day for four days. On the second day, his fever subsided. On the third, the rash disappeared. In one week, he was well. Other rickettsial diseases such as typhus and parrot fever also were conquered for the first time by Aureomycin.

The drug proved effective against all the bacterial infections that penicillin and streptomycin controlled. Its ability to attack both gram positive and gram negative bacteria, plus some viruses and rickettsia, led to its being called a "broad spectrum" antibiotic.

— 5 —

2. *The further work required to make it available to the public*

The clinical work which had been gathering in the course of studying and testing Aureomycin was next presented to the government authorities in support of a new drug application. Some idea of the mass of material involved can be gathered from the new drug application itself, which consisted of over 1,190 pages.

After receiving government approval, the new antibiotic was introduced at a symposium sponsored by the New York Academy of Sciences. The enthusiasm with which the clinical studies and findings were received, led us to take another gamble. We had a drug that could save millions of lives if we could only find a way of producing it in sufficient quantities to offer it at a reasonable cost.

After much further study, our production people advised they could do it, provided we were willing to make a heavy investment in a great deal of new, expensive equipment and buildings, and were prepared to hire and train a new

group of professional chemists and engineers for this highly technical job. It was decided to go ahead.

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3. *Aureomycin's benefits and therapeutic advantages*

Upon its introduction to the public, Aureomycin had been judged effective in many, many infections, among these yaws and trachoma. These two diseases are generally found in tropic and sub-tropic climates. Their response to Aureomycin was extremely dramatic. Yaws is a skin disease of venereal origin which has plagued Africa and parts of South America for centuries. It is currently being controlled by the World Health Organization. Even far-advanced ulceration and marked deformity stemming from this malady, have responded quickly to Aureomycin.

Trachoma is an eye disease which affects about 100 million people around the world. Its principal victims are children. In some areas, Aureomycin cut the incidence of the disease from 60 per cent to less than 10 per cent. In one experimental region in Africa, the test period was called "saif balash ramod"—the summer without eye disease.

Today it is estimated that Aureomycin and its descendants, Achromycin and Declomycin, control about 100 human diseases.

Aureomycin represented a major discovery and accomplishment in medical history. Effective against both gram positive and gram negative bacteria, the rickettsia, large viruses and some protozoa, its broad range of activity made it much more useful to the practicing physician than penicillin or streptomycin, the two most important antibiotics available at that time.

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A most important utilization of the broad spectrum aspects of Aureomycin was found in peritonitis cases, which usually involve more than one type of infection. Some mixed infections, which could not be reached by any one of the earlier antibiotics, could be wiped out by Aureomycin, with the result that we now rarely hear any more of deaths due to peritonitis.

As production increased, physicians were able to utilize the golden wonder drug in other infections. By 1950, Aureomycin had added many other infections to its list of indications.

ACHROMYCIN—TETRACYCLINE

1. *History of the discovery of tetracycline*

In the course of extended research being pursued simultaneously, but unknown to each other, Lederle and Pfizer were both engaged in work that led to the discovery of Tetracycline through the dechlorination of Aureomycin.

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Actually, Lederle had begun work back in 1948, long prior to Pfizer, but it failed to pursue the project to a conclusion and—in the words of the patent attorneys—"reduce the invention to practice", until after Pfizer's Dr. Conover completed his experiment in June of 1952 and for the first time isolated Tetracycline in pure form.

There were so many difficulties faced in discovering and isolating tetracycline that it is somewhat extraordinary that two scientific groups working separately, were able to produce it. First of all, until the publication by Pfizer of a postulated chemical structure for Aureomycin and Tetracycline in October 1952, the exact structure of Aureomycin was not known. Pfizer had a team of top scientists working on the puzzle over many months. The structure was finally postulated by Prof. Woodward, of Harvard, a member of this team.

Many scientists believed that an attempt to remove the chlorine atom was doomed to failure because such a selective reaction could not be devised. Even if one were successful in removing the chlorine atom, there was no assurance that the end product would have *any* therapeutic effect, much less the superior qualitites later found in Tetracycline.

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Nevertheless, both research teams flowed on, with the result that we do have the superior benefits resulting from their discoveries.

2. *Therapeutic superiority of Tetracycline*

The therapeutic superiority of Tetracycline over both Chlortetracycline and Oxytetracycline was testified to by leading experts on the subject of infectious diseases and their treatment with antibiotics.

It is significant that these eminent doctors testified that, after treating thousands of patients with Chlortetracycline, Oxytetracycline and Tetracycline, they found that Tetracycline was definitely superior in several vital respects. Tetracycline produced much less toxic side effects than the other two, some of which had been serious prior to the introduction of Tetracycline. It was more stable than the others at body temperatures. It did not deteriorate as rapidly in the human body, with the result that the blood level required for combating diseases could be maintained much more easily than with the others.

Dr. Dowling futher found that Tetracycline diffused more rapidly into certain parts of the human body, such as the cerebrospinal fluid, than did the other two and that, whereas Aureomycin sometimes caused damage to the liver, no such injury resulted from the administration of Tetracycline. He also found that Tetracycline was far superior to Aureomycin in the treatment of amoebic dysentery.

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By 1958, Tetracycline represented over 70 per cent of all new prescriptions for broad spectrums sold, whereas Chlortetracycline, which in 1952 had accounted for over 40 per cent of all new prescriptions for broad spectrums, dropped to less than five per cent and Oxytetracycline dropped from over 30 per cent to less than 10 per cent.

DECLOMYCIN

1. *Origin, history and development*

Declomycin was first discovered in 1953 by a group of Lederle scientists —biochemists, microbiologists, cytologists and enzymologists. *It was not found in the course of a search for a new antibiotic.* The scientists found it in the

course of investigating the life processes of certain molds which produced antibiotic substances. This is frequently the way with research. Science involves the study of nature and how it operates. New drugs are by-products of that study. They cannot be found without much deeper probings into the work of nature itself.

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The organism which produced Declomycin was one of thousands of mutants of the strain originally discovered and isolated by Dr. Benjamin Duggar, as the source of Aureomycin. It produced a compound which evidenced a degree of antibacterial activity that could not be accounted for by any then-known compounds.

A research group was formed to pursue the investigation of that particular organism, labelled S604, and the antibiotic compounds produced by it. The organism was subjected to every conceivable kind of testing and study. First, the original test flask fermentation had to be stepped up to tank proportions in order to recover a sufficient amount of the mixed end-products to permit work to be done on isolation of its components. Then, as each component was isolated, it had to be studied and tested. One of these components proved eventually to have remarkable qualities: a far greater stability and greater potency than any existing known antibiotic. It was called A-VIII.

All of this work is not as easy as hindsight makes it appear, which is another characteristic of research.

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Although A-VIII was a new compound, and showed promise of producing greater activity against disease bacteria than other drugs of the Tetracycline family, it was still a long way from being a marketable antibiotic. Lederle scientists had to know more about it—a lot more. Before A-VIII could become a Cyanamid product, chemists had to know exactly what it was, pharmacologists had to know exactly what it would do in a healthy body, and doctors had to know just how it would act in a body infected with disease. On top of all this, Cyanamid management had to be convinced that the compound showed enough activity over and above that of the other broad spectrum antibiotics to justify its manufacture. The new drug, was found to have a structure like Chlortetracycline, except that it lacked a single methyl group. Hence, it was called demethylchlortetracycline, or Declomycin.

These experiments went on for months. The pharmacologists had to widen their scope. They had to observe the effect of Declomycin during the complete life cycle of certain animals. Mice were tested, so were hamsters. The scientists began working out the complicated matter of dosage, and they had to produce studies of the "acute toxicity" of the drug—that is, they had to determine the point at which a dose of Declomycin could be considered lethal.

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On the basis of their extensive experiments, the scientists concluded that "a preliminary clinical trial of A-VIII can be safely undertaken".

The next step, of course, was human clinical trials. The object was not at this point to find out how well Declomycin acted against disease, but what its

effect was in healthy human beings. These trials were conducted with the assistance of a small number of healthy volunteers from laboratories and offices at Lederle. Results confirmed the lack of toxicity of Declomycin and indicated that the drug had unusually high and prolonged antibacterial activity in the human body.

Cyanamid's management, convinced it had an important and useful new product, authorized the extension of clinical trials outside the company.

2. *Therapeutic superiority over earlier broad spectrums*

Dr. Maxwell Finland, of the Harvard Medical School, one of the world's most respected antibiotic authorities, was among the first to make clinical tests of Declomycin. In March 1958, a shipment of Declomycin powder was sent to his laboratory in Boston. His tests confirmed the work of the Lederle scientists and led him to publish an enthusiastic report of the drug. "Demethylchlortetracycline", he wrote, "should prove to be superior to tetracycline in the treatment of susceptible infections, in that comparable antibacterial effects should be obtainable with smaller doses".

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By August of 1959, over 200 doctors throughout the world had used Declomycin. Over 15,000 patients, ranging from 22 months to 91 years of age, had received the drug before it was released for sale in the fall of 1959. Lederle kept a close watch on what happened. Case histories and clinical tables poured into Pearl River. The drug was found to be effective against 175 different diseases. In almost all instances, it worked better or as well as the other broad spectrum antibiotics. In addition, some infections which had always resisted the action of the older compounds, succumbed to Declomycin.

The only drawback found in the drug has been the fact that certain patients treated with it, upon exposure to the sun's rays, developed an irritating skin rash. This photosensitivity had not been detected earlier, for the reason that nearly all patients suffering from diseases requiring treatment with broad spectrum antibiotics are confined indoors, either in the hospital or at home. Immediately upon discovery of this phenomenon, Lederle collected the clinical data involved, notified the appropriate government agencies and amended its literature to advise the medical profession at once of this effect and the precautions to be taken.

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Today, the assembled mass of additional clinical data confirms, beyond any reasonable doubt, the superiority of Declomycin over all earlier broad spectrums.

APPENDIX B

Memorandum from Cyanamid of Canada Limited re Recommendation No. 6 of Restrictive Trade Practices Commission Report concerning the Manufacture, Distribution and Sale of Drugs

In the "Summary of Recommendation" at the conclusion of the RTPC Report (pp. 524-526), The following recommendation is made in paragraph 6:

> "As the Commission believes that close control exercised by patents has made it possible to maintain prices of certain drugs at levels higher than would have obtained otherwise and that such patent control has produced no benefits to the public of Canada which would outweigh the disadvantages of the monopoly, the Commission recommends that patents with respect to drugs be abolished. In the opinion of the Commission this is the only effective remedy to reduce the price of drugs in Canada." (underlining added)

The following arguments against this clear and almost unprecedented recommendation should be seriously weighed.

1. *World Experience.* Virtually all countries in the world presently have, in one form or another, statutory patent protection for the manufacture, use and/or sale of drugs. Even Italy, one of the two or three countries where, since 1939, there has been no such patent protection (and where, since that time, there has not originated a single new drug of significance), seems to have realized its shortsightedness and is now introducing legislation to reinstate patent protection of drugs under Italian law.

— 2 —

And here in Canada, at one of the Hearings held by the RTPC, Commissioner of Patents, Michel, not only testified that "the patent system, if it is a factor in the high price of drugs, is certainly not the main factor," but also said that he wondered "if to drastic a treatment of the patent system would not harm the modest, but bona fide, efforts of those doing research in Canada more than the portion of the high price of drugs which might be attributed to the patent system." (p. 341).

2. *United States Experience.* In the United States, even after a two-year investigation of drugs by the Kefauver Sub-committee in the Senate (including the basic problem of drug prices and the effect thereon of patent protection), and after legislation was introduced in the Congress of the United States last year to provide for the compulsory licensing of drugs (to qualified applicants after a three-year interval) there was so much and such persuasive testimony against the proposal for compulsory licensing that the resulting Drug Industry Antitrust Act of 1962 was finally passed without any provision for compulsory licensing—let alone any provision, or even any serious proposal or consideration, of the complete abolition of patents with respect to drugs.

— 3 —

3. *Research Incentive.* Patent protection, which guarantees to inventors a reward for their labors by giving them the right for a limited time to exclude others from practicing the invention, acts as an incentive for further costly research and for the discovery of new drugs. It is not unlike the tax incentives now being offered by the Canadian Government for industrial research and expansion. Both devices are designed to stimulate new ideas and are helpful in preserving our system of free enterprise as distinguished from Government intervention and control.

4. *Quality Control.* The abolition of patents would clearly have a detrimental effect on the quality and safety of drugs. Pirated and bootleg drug would be imported into the Canadian market by non-inspected distributors, with the resulting lack of that degree of quality control that attends the Canadian manufacture and distribution of patented drugs under brand names.

5. *Effect on Prices.* Although it is possible that the complete abolition of drug patents might reduce the price of drugs to the consumer (by freely opening Canadian markets to the "coat-tail riders" to copy the drugs invented by others without having to recoup heavy expenses for successful as well as unsuccessful research), it is irrefutable that any such reduction would be minor. This is what Commissioner of Patents, Michel, pointed out in his testimony before the RTPC.

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Similarly, at Hearings last year on the proposed Drug Amendments before the Congress of the United States, the world-renowned scientist, Dr. Vannevar Bush, testified as follows:

> "I believe the cost of drugs to the user can be reduced. But the way to do this is not to knock out the source of new and better ones. The reason for the high cost of drugs does not lie in undue profits realized by the pharmaceutical industry. If an individual goes into a drug store and pays a dollar for a prescription, four or five cents of that dollar represents profit to the concern which made it. If we knocked out all the manufacturer's profit, we would not reduce the cost much, and soon we would have an industry in distress. Personally, I never want to buy a drug made by a company that is losing money and is therefore tempted to cut corners. We need a healthy industry if we aspire to a fully healthy population."

Further on this point, at the same Hearings in the United States, Mr. John T. Connor, President of Merck and Co. Inc. in New Jersey, testified as follows:

> "By withdrawing the incentives of the patent system from the discovery of new drugs, the bill . . . would mislead the public by promising something for nothing. It dangles before the consumer the glittering promise of lower drug prices at no seeming cost to the Nation. It offers no proof that lower prices will, in fact, result. And it conceals the high cost in human lives and suffering of the death sentence it would pronounce on pharmaceutical industry research."

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6. *Discrimination Against Drugs.* Not only does it seem inequitable to single out drugs as the only product category form which it is recommended that patent protection be removed, but also for Canada to take any such step would inevitably be a start toward the destruction of the entire patent system which is and has been for decades a basic tenet of this country's economy and of the economy of the free countries of the world. Furthermore, it seems particularly shortsighted to tamper with the quality of existing drugs and the discovery of new drugs, both so important to human life and health, by removing the time-tested protection and stimulus that the patent laws give, and by forcing Canada to take and use the drug discoveries of other countries (even if they should continue to be available to Canada after the removal of patent protection) rather than attempt to promote drug research within this country.

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APPENDIX C

THE $100 MILLION DRUG THEFT

Reprinted in full with permission from the April 1966 issue of "Waiting Room Digest"

"...At about 8 or 9 p.m., one evening toward the end of November, Fox drove me to the plant and told me how to get to the sixth floor of Building 110, to Dr. Bishop's and Dr. Goodman's microbiology lab, and the big chill room located there. I went in and found nobody in the laboratory but janitors in the halls. I became quite excited when I got to the microbiology lab, and quickly went to the chill room. Fox was right. There I saw some samples in yellow boxes, among many others, and though I did not know the code numbers, I believe I saw some marked 'A-8' which was the code number for Demethylchlortetracycline (DMCTC) and grabbed four to eight of these samples. I rushed out and gave them to Fox." With these words, a young chemical engineer named Jahn Cancelarich confessed his part in what has been called "the greatest burglary in history," the stealing of micro-organisms and production data used in the manufacture of four "wonder drugs" at American Cyanamid's Lederle Laboratories in Pearl River, N.Y., and their sale to six pharmaceutical firms in Italy.

The stolen drug cultures—which Lederle spent $20,000,000 and 20 years developing—enabled the Italian companies to swing quickly into production and undersell Lederle, and other American firms, in the U.S. and Canadian markets at an estimated loss to North American firms in excess of $100 million.

— 2 —

The story of foreign intrigue, stolen samples and top secrets smuggled out at night and duplicated, reads like a motion picture or television script, with a cast of characters to match.

Key figures in the industrial espionage organization were Dr. Sidney Fox and Cancelarich, former employees of Lederle, and Elio Salvetti, an Italian engineer who acted as a "middleman" in the U.S.-Italian piracy.

In all, seven men were brought to trial in the States. Three other alleged conspirators—a prominent member of the American business colony in Rome, a fast-talking Italian go-between and contact man, and a Milanese count who directs an Italian pharmaceutical company—have been indicted but remain in Italy beyond reach of U.S. law, protesting their innocence.

What makes the story even stranger than fiction is the fact that it was brought into the open, not by the F.B.I., but by a relaxed, elegant Wall Street lawyer and wartime guerilla fighter, Walter Mansfield.

Mansfield pieced together a four-year history of bizarre industrial espionage in which the principals double-and triple-crossed one another with a gay abandon that would startle crooks of lesser breed and intellectual attainment.

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Their final downfall was brought about by a disgruntled accomplice who exposed his confederates when they cheated him out of his share of the profits.

But until the case broke, the Americans involved in the conspiracy lived well on the road, taking frequent trips to Milan, Naples and Rome, where their Italian counterparts entertained them lavishly, flashing them around the country in sleek Ferrari sports cars. Little Leonard "Lenny" Fine, a former chemist for General Electric in Syracuse, N.Y., who was drawn into the plot by his old friend Fox, testified wistfully about the "champagne breaks" at the Italian firms' beautifully appointed offices.

Briefly here is the background of the great drug theft:

From 1954 to 1959, Dr. Fox was employed by Lederle Laboratories to work on the development of broad spectrum antibiotics. His position and duties required him to keep fully posted on Lederle's current antibiotic production procedures, and he regularly received reports pertaining to Lederle's newest and most important research and production activities.

Fox systematically removed a vast quantity of highly secret research and production data involved in production of antibiotics, steroids and other drugs. In addition, he gradually stole and armed himself with a full set of Lederle micro-organisms (cultures) used in the production of the broad spectrum antibiotics.

— 4 —

These seizures prepared Dr. Fox for a series of transactions involving the peddling of the fruits of Lederle's costly research. Fox concealed his illicit "consulting" activities from Lederle by forming a business, Kim Laboratories, which was registered in his wife's maiden name.

By September 1959, just prior to the departure from Lederle's employment, Dr. Fox made contact with an agent interested in buying his stolen secrets and cultures for resale to Italian drug firms.

After leaving Lederle, Fox ran into a problem. He needed a constant flow of fresh drug information. He turned to John Cancelarich, a chemical engineer employed by Lederle, whose confession begins this story.

Cancelarich started by stealing Lederle's secret procedures, which the pair microfilmed in Fox's basement. He went on to take micro-organisms' drug samples, thousands of documents, all of which were microfilmed. Most were returned before they could be missed. Nearly all concerned the four wonder drugs, including tetracycline.

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Tetracycline is regarded by medical authorities as one of the greatest wonder drugs ever developed. It is the most widely prescribed drug in the world. The Food and Drug Administration credits tetracycline with saving the lives of 500 to 1,000 patients daily. The antibiotic is used against a broad range of infectious diseases, including pneumonia, dysentery, gonorrhea, meningitis, typhus, scarlet fever and many skin infections and abscesses.

In November 1960 the American conspirators met with Salvetti who informed them that two Italian drug makers were interested in two of their stolen cultures.

Cancelarich's affidavit states:

"an agreement was finally reached whereby Fox and Salvetti would be paid $50,000 for the micro-organisms and know-how...plus a royalty for one year of 25 lire per bottle..."

The Americans agreed to go to Italy to help set up the operation, but had to use aliases because Fox had already sold the same material to another Italian firm.

In preparation for the agreed-upon trip to Italy, the men worked feverishly in Fox's basement, according to Cancelarich, writing up summaries from the microfilm and photostats. They had stolen so much information by this time that they obtained a dealership in photocopy machines to give the conspirators access to necessary supplies for reproduction.

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The Cyanamid processes and culture samples were allegedly sold for prices ranging from $50,000 to $110,000 to an estimated eight Italian firms. Over and above this, the men involved are said to have received $5,000 a month each with a bonus of $15,000 after three months and an increase to $7,000 a month after a year for consultation services and assistance in setting up the manufacturing processes.

"This was more than just counterfeiting or duplicating of a final product," John Bertrand, manager of medical products, Cyanamid of Canada, told Waiting Room Digest.

"This was not only piracy of material, but of complicated technical knowledge that took years to develop. It's the first time we've encountered anything of this magnitude. Our manufacturing techniques are so involved that no one person would have full knowledge of our operation. There had to be a definite conspiracy."

One of the primary reasons that this unprecedented theft of drug cultures and research information was possible, was the availability of a market for such material. When Mussolini rescinded patent laws, it gave the Italian manufacturers freedom to avail themselves of the fruits of research without investing research dollars.

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Lyman Duncan, the tall, tough head of Cyanamid's drug division, who worked with Mansfield on the case, described the Italian situation as "a nest of pirates operating in a sanctuary established by this lack of a patent law."

He explained that when a new product is brought out, "these people simply have someone pick up the product, fly it to Italy and they start duplicating it."

Because of the serious threat to further research if allowed to continue, American drug companies have begun to take measures to protect themselves. Although handicapped by the lack of any laws specifically outlawing theft of trade secrets and know-how, both federal and state law enforcement agencies have taken steps to prosecute such conduct under existing criminal laws.

Meanwhile some measure of justice has been served. Fox, Cancelarich and Fine were each given six-month prison terms, three other conspirators were sentenced to two years, and the seventh man was given a suspended sentence.

The CHAIRMAN: The meeting is open for questioning of the witnesses.

Dr. HOWE (*Hamilton South*): Mr. Chairman, I think we should attempt to question the witnesses with some semblance of order on this brief.

The CHAIRMAN: We always do it that way, Dr. Howe.

Dr. HOWE (*Hamilton South*): I said "attempt".

The CHAIRMAN: Do you mean you have some particular order?

Dr. HOWE (*Hamilton South*): It is lengthy, as you have already pointed out, and it might be a little bit difficult if we just simply question. I do not know what your intention was in this regard. I have several questions in mind, which are mixed up throughout the brief and some are not included in the brief.

The CHAIRMAN: Yes.

An Hon. MEMBER: Take it by sections.

The CHAIRMAN: Certainly this is what we have done in the past—to do it by sections. If this is agreeable to everyone here, I suggest we carry on that way. Is that satisfactory to everyone?

In keeping with that, are there any comments or questions on the introduction, pages 1 to 8?

Mr. MACKASEY: Mr. Chairman, I understand pages 1 to 8 simply trace the relationship between the head office and the Canadian subsidiary.

Mr. CHAIRMAN: Would you please repeat that?

Mr. MACKASEY: I believe that pages 1 to 8, as I recall reading it simply trace the relationship between head office and the Canadian subsidiary, or have I oversimplified it?

Mr. STOVEL: Our company in Canada is a wholly-owned subsidiary of American Cyanamid.

I think our relationship with our parent differs very little from that of most industries in Canada which are also wholly-owned subsidiaries.

Mr. MACKASEY: You mention that you are wholly-owned. Would you define that for me because it is important when we get into research?

Mr. STOVEL: We do not have stock on the Canadian market. In other words, American Cyanamid is the sole shareholder of Cyanamid of Canada.

Dr. HOWE (*Hamilton South*): Mr. Chairman, on page 3 you are talking about the importation of partially manufactured and wholly manufactured drugs from your parent company. What determines the price that is paid for these raw key chemicals purchased from your parent company, and for your partially manufactured drugs?

Mr. STOVEL: Largely they are determined by the fair market value of the ingredients involved.

Dr. HOWE (*Hamilton South*): Is a financial statement from your parent company available to this committee?

Mr. STOVEL: The financial statement is published and available to any shareholder, and we will be glad to send you a copy.

Dr. HOWE (*Hamilton South*): Could we have one for our records here?

Mr. STOVEL: Yes, fine.

Dr. HOWE (*Hamilton South*): Thank you.

The CHAIRMAN: That is, of the parent company?

Dr. HOWE (*Hamilton South*): I am talking of the parent company, so that we can see the purchase price and see where this goes in.

Mr. STOVEL: I am afraid that the financial statement of the parent company will not show the actual purchase price of any individual product. We handle about 2,500 products in Canada.

Dr. HOWE (*Hamilton South*): I do not mean individual products. Will this show a break down of prices paid by your Canadian subsidiary to your parent American company.

Mr. STOVEL: I think that what you are getting at in a general way, is this: We say that our raw material, used in our manufacturing operations in Canada, amounts to 19 per cent of our sales dollar. Actually, eight cents of the sales dollar is purchased from the American parent company, and if you assume they have a profit on that eight per cent of maybe 12 per cent on sales, this works out to about one cent per sales dollar of our Canadian net.

Mr. HOWE *(Wellington-Huron):* This is the over-all average of all our Canadian purchases.

Mr. STOVEL: This is the over-all average.

Dr. HOWE *(Hamilton South):* In other words, to be brutally blunt, is there any ballooned price in the United States to allow American companies to conceal some of the profits in the Canadian company?

Mr. STOVEL: Absolutely not.

Mr. MACKASEY: A supplementary question, Mr. Chairman: Mr. Stovel, is duty paid on raw material that is brought into Canada?

Mr. STOVEL: Is duty paid on it? Finished items carry a fair market value.

Mr. MACKASEY: Yes; but on the raw material is duty paid? Who sets the value of the raw material?

Mr. STOVEL: The value of the raw material?

Mr. MACKASEY: That the duty is calculated on?

Mr. STOVEL: It is usually the fair market value in the country of origin, and where it is clear cut and there is a pattern in the trade, where that can be established, a fair market value for subsidiaries is covered in section 6 subsection (6) of the dumping laws in the tariff act.

Occasionally, on semiprocessed materials, you have items that are not normally commercially available. Then we have to sit down with the Department of Revenue and establish the reasonable fair market value.

Mr. MACKASEY: Are these the same prices that you use in your calculation for expenses to arrive at the selling prices. In other words, the price you arrive at, agreed between the Department of Revenue and the firm shipping the goods into you, is the same price that you use for calculating the cost of your product.

Mr. STOVEL: Right.

Mr. TARDIF: Is the reason for bringing these raw materials from the United States because they cannot be manufactured in Canada.

Mr. STOVEL: If I could refer you to page 3, it says that 60 per cent of our Lederle line is manufactured entirely in Canada. Twenty-two per cent is manufactured in our Montreal plant, using imported pharmaceutical material; and in those instances the raw materials are not readily available in Canada. Fifteen per cent is packaged in Canada but not processed; and only three per cent, or the highly speciality items which have very little volume are imported in the finished dosage form. Therefore, we have the three categories of imports. But the bulk of what we do in Canada is made, from the ground up, right in Canada.

Mr. TARDIF: What I would like to know is this; where the raw products not available in Canada, and is that the reason for importing them, or were they available in Canada to be manufactured in Canada?

Mr. STOVEL: I think I should pass this one to Mr. Bertrand who is more familiar with the details.

Mr. J. A. BERTRAND *(Manager, Medical Products Department, Cyanamid of Canada Limited):* I would think that they would not be available simply because most of these are relatively low-volume products. If it were available we would certainly be buying it in Canada. These, in most cases, are active ingredients where the volume required to support the Canadian market is simply too low for us to consider manufacturing it economically ourselves, or for anyone else to consider manufacturing it.

Mr. TARDIF: I presume this covers drugs which are used by your firm only or is it drugs which are used by other pharmaceutical firms in Canada?

Mr. BERTRAND: I think you would have examples of both categories in the same example. A considerable number of them are products which are manufactured only by our company.

The CHAIRMAN: Mr. Bertrand, for the guidance of the Committee, could you give one example by name of drug of each of those categories.

Mr. BERTRAND: Well, I believe that we would be using imported bulk sulfadiazine powder in the manufacturing of sulphadiazine tablets, for example, because sulphadiazine powder is not, to my knowledge, manufactured in Canada.

I could give you an example of a product which has been developed by Cyanamid, which we import. It is a chemical, acetazolamide, which we in turn compound into tablets and other dosage forms and sell as Diamox on the Canadian market. This is a case where we would be most happy to manufacture it in Canada if the volume of our requirements warranted going into the fine chemicals business of making acetazolamide. These are examples of the two kinds.

Mr. MCLEAN *(Charlotte)*: I would like to ask a leading question—a more general one. Would the witness say what are the economic considerations of an American firm establishing a wholly-owned subsidiary in Canada? Is this entirely due to tariff considerations and matters of that sort, or is there some

other reason that makes it economically sound to have a subsidiary in Canada, or is there some reason other than a purely economic one?

Mr. STOVEL: Perhaps I could answer that in a general way. Our company operates in many countries across the world in all kinds of businesses. We have drug operations in 19 different countries. We have attempted, wherever the volume warranted, to set up and manufacture domestically, which we have done in Canada as soon as the volume seemed to warrant our doing it. I do not think tariff was the sole consideration.

The CHAIRMAN: I would like to remind members of the Committee that the proceedings are being taped, and if, when they are asking questions, they could lean towards the microphones on the table it would help the tape recorders.

Dr. HOWE (*Hamilton South*): Mr. Chairman, I think we are more or less at this point: You say that you have companies in various countries in the world and I presume that England would be one of them.

Mr. STOVEL: Yes, sir.

Dr. HOWE (*Hamilton-South*): I have asked this question before of the P.M.A.C. and I am going to ask you now, and I am going to be specific: Folvite tablets is one of your manufactured drugs, is it not?

Mr. STOVEL: That is correct.

Dr. HOWE (*Hamilton-South*): Folvite tablets sell in England for 53 cents a hundred; that is the five milligram size, and in Canada they sell for $10.38.

There are two other drugs. One is Achromycin which is yours—am I correct?—which in England sells for $3.51 and in Canada sells for $5.40; another one is Aureomycin which sells in England for $2.34 and sells in Canada for $5.40. Can you in any way explain this discrepancy, particularly, of the Folvite tablets. I have the price books here.

Mr. STOVEL: The Folvite one is obviously the serious one to you. It is a product that England is going out of the business in, and it is an end-of-line disposal situation. They are withdrawing it.

The other two lines are ones which they intend to keep manufacturing in both countries.

Dr. HOWE (*Hamilton-South*): Why is there this much discrepancy on Achromycin and Aureomycin? In one case it is almost twice as much here, and in the other case—just roughly calculating it—it is 50 per cent more.

The CHAIRMAN: Could you identify the size of package?

Dr. HOWE (*Hamilton South*): Yes, certainly; the Achromycin is 16 capsules at 250 milligrams, selling in England for $3.51, and selling in Canada for $5.40. The other is Aureomycin which is a 250 milligram capsule, 16 capsules, selling for $2.34 in England and $5.40 in Canada.

Mr. BERTRAND: Dr. Howe, what kind of prices are you quoting? Are those consumer prices?

Dr. HOWE (*Hamilton South*): Yes; I presume that these are consumer prices—retail prices.

Mr. BERTRAND: Well, I think it is only reasonable that we would talk in terms of our price to the retailer. On Achromycin our price to the retailer, tax included, in Canada, for 250 milligram 16 capsules is $3.24. It is $2.31 in the United Kingdom.

Dr. HOWE (*Hamilton South*): But there is still a discrepancy.

Mr. STOVEL: Could I comment on that? We have tried here to explain how our costs of doing business in Canada have evolved. We have not got complete breakdowns for every part of the world, but there are such factors as the average monthly rate which in England is less than half what we pay in Canada. The average is now $135 per month in the U.K. versus $361 per month in Canada for hourly employees.

Mr. ORLIKOW: The wage rates, yes; but you yourself say on Page 19 that the direct labour cost in a dollar is 5 cents.

Mr. STOVEL: Yes, but we did not carry that on. The average salesman's salary is part of our cost. It is less than half in England what it is in Canada. The average salesman's travelling expense in England, again, is less thn half what it is in Canada. The concentration of population means far less coverage per doctor in England than it does in Canada. Therefore, all through the piece you have to compare the relative standards of living when you compare the relative end product's price.

Mr. MACKASEY: Mr. Chairman, I have a question arising our of Mr. Stovel's remarks. You mentioned a drug that they are withdrawing in England. Why are they withdrawing it?

Mr. STOVEL: I think the reason is lack of volume.

Mr. MACKASEY: And yet there is sufficient volume in Canada to retain it?

Mr. STOVEL: Well, the reason is lack of volume at a price at which they can make money.

Mr. MACKASEY: Why lack of volume? Is it because the drug is not fulfilling its function, or because there is a better substitute, or because it is unsafe? What is the reason for the lack of volume?

Mr. STOVEL: I think I should pass this to Mr. Bertrand.

Mr. BERTRAND: Mr. Mackasey, it is primarily due to the fact that they do not have a great incidence of the condition that this drug is designed to treat. As a matter of fact it is marginal in Canada. It is certainly—I think Dr. Howe knows this—not in the same category as our Achromycin.

Mr. MACKASEY: I am not a doctor, as you know, so perhaps you would explain to me what this drug does in England that it cannot do in Canada, or vice versa? What is the purpose of the drug? Is it a wide spectrum antibiotic?

Mr. BERTRAND: It is not a wide spectrum antibiotic. Possibly Dr. Gendron, who is with us, is best qualified to answer the question about what it is designed to do.

Dr. Claude GENDRON (*Medical Director, Cyanamid of Canada Limited*): You are referring to folic acid, Mr. Mackasey?

Mr. MACKASEY: I beg your pardon?

Mr. GENDRON: Your are referring to folic acid?

Mr. MACKASEY: I do not pretent to be able to pronounce it, but I know that Mr. Stovel mentioned it.

Mr. GENDRON: Folvite is a drug which is used in special kinds of anemia, and more so in pregnancy and where there is malnutrition and other types of anemia. I quite agree with you that probably there are some cases of anemia of the same type in England as there are in Canada. In fact there is a big controversy about the product itself in the medical world. We realize it is not being used as it should, and probably it should be used more.

Mr. MACKASEY: This is the point I am interested in because we in this committee, are interested in safety as well as cost. There is controversy in what sense—that it is not safe?

Dr. GENDRON: Oh, it is absolutely safe, sir.

Mr. MACKASEY: What is the controversy about?

Dr. GENDRON: The controversy concerns the use. If it is used as one product, as folic acid, or Folvite, then it serves its purpose; but if it is used in what we call a cocktail preparation, with iron and other things, then it is not thought to be as good.

Dr. HOWE (*Hamilton South*): It has shotgun characteristics?

Dr. GENDRON: Shotgun characteristics.

Mr. MACKASEY: What I am trying to get at is why is it being discontinued or withdrawn in England and not in Canada? This shotgun process of diffusing it with other products seems to me to be as relevant an argument as to why it should be withdrawn in Canada as well.

Mr. STOVEL: There are two reasons why we withdraw a drug. The first reason is if there is any question of its safety or effect. The second reason is if we cannot make money on it. I think a competitive situation has arisen in England where our company could no longer make money.

Mr. MACKASEY: That is a very honest answer, I have to accept that.

Dr. HOWE (*Hamilton South*): But we still have it here?

Mr. STOVEL: The volume we have is not significant.

Dr. HOWE (*Hamilton South*): Is it going to be withdrawn in Canada?

Mr. STOVEL: No; not as we see it at the moment.

The CHAIRMAN: What you are saying, if I may clarify it, is that because you are withdrawing the drug in England does not mean that it is coming off the market. It is being manufactured by other companies.

Mr. MACKASEY: It is no longer profitable to sell in England but it still is, at the moment, in Canada?

Mr. ENNS: Are these other companies still competing in this line? Are they manufacturing the same product?

Mr. STOVEL: Yes, they are, in Canada; and I can only say I believe they are in England. But, I cannot say that with any assurance of being completely accurate; I really do not know.

Mr. ENNS: I was just wondering if they are doing it more successfully in England than is your company. Is this why you are withdrawing?

Mr. BERTRAND: We have no way of knowing.

Mr. MACKASEY: I just want to make certain of one point. Does the competition which is making this particular drug unprofitable in England exist in Canada? Do we not have the same degree of competition here?

Mr. BERTRAND: This is not a terrifically competitive field simply because the volume for this product is very low. This is a marginal product in Canada. This is a product that we have looked at two or three times.

There are some physicians who believe implicitly in this particular product. We would have second thoughts before we withdrew it. But it is not a large volume product even in Canada. Obviously it is not a large volume product in the United Kingdom.

Mr. MACKASEY: My last question is: The physicians are obviously prescribing some competitor's product, which is normal and natural.

The CHAIRMAN: If they are prescribing it at all; that is the point.

Mr. MACKASEY: Yes; but if they are not I do not understand why we still have it here, if there is a beter product. Presuming that some other company is producing the equivalent and is outselling your product, which is normal in a free society, what I want to know is if your competitors in England are producing the same competition in Canada? Do they produce the same alternative to your product?

Mr. BERTRAND: I believe they are marketing it. I cannot say, whether they are marketing it more aggressively in the United Kingdom than they are in Canada.

Mr. MACKASEY: But it is available?

Mr. BERTRAND: Yes.

Mr. MACKASEY: There is no possibility of collusion between drug companies, that because there is such a small volume they leave the field? This is blunt speaking, but it is part of the reason for the committee's existence. That is not the case in this particular instance?

Mr. BERTRAND: There is certainly no collusion between the companies in Canada.

Mr. MACKASEY: Not on this particular matter?

Mr. BERTRAND: Absolutely not.

Dr. HOWE (*Hamilton South*): At 53 cents a hundred, which is the selling price in England, is there still a profit in that?

Mr. BERTRAND: No, or they would not be going out of business.

Dr. HOWE (*Hamilton South*): May I introduce some more subject matter?

The CHAIRMAN: Are we still on the introduction?

Dr. HOWE (*Hamilton South*): We referred to page 19 which has the breakdown of prices.

The CHAIRMAN: Before we get into that can we finish off up to there.

Are there any other questions relative to pages 1 to 8, the introduction?

Dr. BRAND: Well, apropos what has just been said, Mr. Chairman, I wonder if some of the witnesses would care to comment on the differences in retailing between the U.K. and here in view of the fact that the drugs are covered under the scheme in Great Britain, and what difference this actually makes so far as the cost in Great Britain are concerned when compared with those in Canada.

Mr. STOVEL: I do not think any of us here today are in a position to really talk sensibly about retailing drugs in England. We have a hard enough job talking today on what we are doing here.

Dr. BRAND: Surely it is an important point. This is where the state is paying for the drugs; there is the factor of cost alone which largely comes into the type of drugs they would recommend be sold.

I think, Mr. Chairman, perhaps it would be very wise if, later on, we heard some witnesses who are familiar with the differences in the two, particularly in view of what is going on in Great Britain at the present where you can get a prescription from a doctor and get your drug free of charge from the pharmacist.

The CHAIRMAN: I am aware that one of the companies coming before the committee will be bringing representatives from several European countries.

Dr. BRAND: I was thinking of the United Kingdom, not necessarily Europe.

The CHAIRMAN: I think this includes the United Kingdom.

Dr. BRAND: I am sure they would be glad to know they are included in the European community.

The CHAIRMAN: Are there any other questions relative to this section?

Mr. MACLEAN (*Queens*): I have a supplementary question on the introduction on page 1. It states "Cyanamid of Canada has eight manufacturing plants" and so on.

The CHAIRMAN: Would you speak a little louder into the microphone, Mr. MacLean?

Mr. MACLEAN (*Queens*): It says that Cyanamid of Canada has eight manufacturing plants, employs approximately 3,000 people, with gross assets having a value of $100 million. This is the total operations of Cyanamid of Canada. Could you give us some indication of the relative importance of pharmaceuticals to the total operations?

Mr. STOVEL: I will be glad to try. In general, pharmaceuticals represent about 5 per cent of our activity in Canada. It represents perhaps far more than 5 per cent of our management concern but 5 per cent of our total people—and our total mix is in pharmaceutical products.

In terms of general business activities, we operate in five broad areas in Canada: agriculture; basic industrial products which include products for the mines, the paper mills, the refineries, the chemical industries, the rubber industry—a whole host of basic industrial products; the building products

industry which is largely concerned with architectural specialities and decorative products; the medical field, and the consumer field. Among those five groups, our medical activity rates fourth both in size and in contribution to earnings.

Mr. MACLEAN (*Queens*): Do you include products used for veterinary service in pharmaceuticals?

Mr. STOVEL: No, we do not. We include them in the agricultural field.

Mr. MACLEAN (*Queens*): Thank you.

Mr. HOWE (*Wellington-Huron*): Mr. Chairman, I was rather interested in this partnership of local businessmen operating 30 fertilizer bulk blending plants. What control do you maintain and how is this partnership set up?

Mr. STOVEL: This is a very interesting exercise which we pioneered here. We have associated companies where we and a local businessman jointly put up enough equity capital to start a company. We, at Cyanamid, loan to that enterprise enough capital to erect a plant. The plants vary from quite small, say, $150,000 maybe with working capital to $400,000 up to about $1.5 million with working capital of maybe closer to $2.5 million. To each one of these, Cyanamid undertakes to provide a certain function; the local businessman also undertakes to provide certain functions. We sell our products to this local businessman. He, in turn, sells to the farmer in the local area. The profits from this local business are divided, 50 per cent for the partners and 50 per cent for ourselves.

We have found this willingness to capitalize on the initiative and aggressiveness of the local entrepreneur quite a successful device for improving the total farm fertility program in which we are interested as we have four areas of the farm business, fertilizers, pesticides, veterinary products and feed additives. We are in the process of enlarging these 30 plants by another 15. We are also in the process of expanding the service to cover other fields and have these local partners manage them. But they are, in every sense, 50 per cent owners. They have the responsibility of running the day to day business, of making the collections, of getting credit and all this kind of thing which a big company finds unwieldy to do.

Mr. HOWE (*Wellington-Huron*): What is the proposed length of time for which the agreements are drawn up?

Mr. STOVEL: We, at Cyanamid, have two members on the board and the partner has two members, usually himself and his lawyer or accountant. They run evergreen unless it becomes a deadlock between the partners and the Cyanamid representatives. If there is a deadlock which we have not had as yet, there is a procedure whereby the company can be dissolved and each partner to the agreement can submit sealed bids and the highest bidder buys out the other one.

Mr. HOWE (*Wellington-Huron*): Do the individual partners eventually own their own business? Do they have the opportunity of controlling the ownership of these plants some time in the future?

Mr. STOVEL: I doubt this.

Mr. HOWE (*Wellington-Huron*): Or is this a permanent arrangement?

Mr. STOVEL: We hope it will be a permanent arrangement. Obviously we would not be expanding the program if we did not feel it was worthwhile and if our partners did not feel it was worthwhile.

Mr. HOWE (*Wellington-Huron):* I do not know, Mr. Chairman, whether this has very much to do with drugs as it is in the agricultural area; but, in connection with this, has your company been before the investigation that is taking place in conjunction with the Department of Agriculture to investigate the cost of farm machinery and related products?

Mr. STOVEL: We do not make farm machinery.

Mr. HOWE (*Wellington-Huron):* No, but you make farm products.

Mr. STOVEL: We are before committees constantly. We have not been before this one, as yet.

Mr. HOWE (*Wellington-Huron):* No doubt, you will be called to appear, though.

Mr. STOVEL: There is an investigation going on in Quebec at the moment.

Mr. HOWE (*Wellington-Huron):* This is sort of an integration program. How far do you carry the integration through? When you talk about feed additives, do you go right to the farmer and integrate in the broiler business, so to speak?

Mr. STOVEL: We do not own any chicken farms.

Mr. HOWE (*Wellington-Huron):* Do you assist in the purchase of any?

Mr. STOVEL: Not at this point.

Mr. HOWE (*Wellington-Huron):* Or hogs?

Mr. STOVEL: No. Primarily our business in feed is through feed additives which is done through the feed manufacturers.

Mr. HOWE (*Wellington-Huron*): Thank you, Mr. Chairman.

Mr. O'KEEFE: Mr. Chairman, I believe Mr. Stovel said that general pharmaceuticals at present total about 5 per cent of their overall production.

Mr. STOVEL: About 5 per cent of our overall activities.

Mr. O'KEEFE: Can he give us any indication of what the percentage of your overall profits would be from this particular category?

Mr. STOVEL: I mentioned it was fourth among our groups and fourth in volume.

Mr. O'KEEFE: And you gave a figure of 5 per cent.

Mr. STOVEL: I am not saying exactly 5 per cent.

Mr. O'KEEFE: Can you give us the average profits from that?

The CHAIRMAN: I think this comes under the pharmaceutical sales dollar a little later on in the brief.

Mr. O'KEEFE: Just one more question, Mr. Chairman; Mr. Stovel, do you feel that drugs are too expensive in Canada?

Mr. STOVEL: No, I do not, generally speaking.

The CHAIRMAN: Are there any other questions on this subject?

Mr. MACKASEY: You say that the pharmaceuticals represent, was it 5 per cent?

Mr. STOVEL: Roughly 5 per cent.

Mr. MACKASEY: Do they represent more or less than 5 per cent of your profit?

Mr. STOVEL: At any given time, they will represent either slightly more or slightly less. Bear in mind, we are a private company which does not publish total statistics. We have laid bare our soul on drugs and if we start talking in absolute numbers, all our competitors in the whole chemical industry will know exactly what we are doing.

Mr. ORLIKOW: They are all charging the same price anyway. The evidence is very clear.

Mr. STOVEL: Could I put it this way. On page 8 of our brief we state it is our policy in the pharmaceutical business:

> To conduct an ethical pharmaceutical and biological business so that contributions to medical knowledge may be made and products for the conquest of human disease can be marketed at a rate of return consistent with the resources committed and the risks involved, while maintaining the highest standards of business and community conduct.

In some of our business, the risks involved, the resources committed and the degree of obsolescence are not as high as in pharmaceuticals.

Mr. MACKASEY: I am not questioning your right to make a profit. We have figures in the Hall Commission report and in your brief of the over-all profits of the industry in general. I do not think my question is inappropriate and I intend to ask it of all companies that come here.

You mentioned, and we all know that Cyanamid is a big company, that 5 per cent of which its products or activities are devoted to the pharmaceutical end of production. I simply would like to know whether in your total picture of profits the same relationship continues. The conclusion I arrive at is just part of a general picture, whether you make 3 per cent out of your 5 per cent activities, 4 per cent or 10 per cent. I cannot see what disadvantage you would be putting yourselves at competitively by emphasizing this point.

Mr. STOVEL: The pharmaceutical products are somewhat higher than our average mix, but that average mix includes some basic plants that are still in operation after 25 years.

Mr. MACKASEY: That is a good reason for it. You said in a given period, I presume that means a business year?

Mr. STOVEL: I am talking of business years.

The CHAIRMAN: May we now move to the next section—the nature of the pharmaceutical business—which is, really a discussion of generics versus brand name manufacturers, if I may use those terms or, innovators versus copiers.

Mr. MACKASEY: Am I fair in presuming, Mr. Stovel, that this section is put in to justify the expense you people associate with quality control?

Mr. STOVEL: I do not think this is a right assumption at all. We attempted to develop this brief to be of help to you in understanding our business, not to justify anything.

Mr. MACKASEY: If I may say so, I think you are getting very touchy on certain words. Let me ask this question. This section is devoted to copiers—and I do not know if you used the word "innovators"—and I think your main argument is that you people control quality and the copiers do not. Am I right in presuming that?

Mr. STOVEL: That is one of the arguments.

Mr. MACKASEY: What are the others then? What else does this section from 9 on state or discuss?

Mr. STOVEL: Do you want to read it?

Mr. MACKASEY: I have read it twice already.

Mr. STOVEL: It discusses quite a number of areas and perhaps again, as it is getting specific to our pharmaceutical business, I will turn this question over to John Bertrand.

Mr. BERTRAND: Mr. Mackasey, I think in addition to what Mr. Stovel has said—

Mr. MACKASEY: He has not said anything yet; this is the point.

Mr. BERTRAND: He said quality control was one of the factors in this section. I would also think that one of the main factors and the main reason for this section being in this brief is simply to acquaint your Committee with the reasons why a copier, some 10 or 15 years after an innovator has put a drug on the market, can come out with a copy without spending the money needed to do the clinical work, to get the new drug application without spending a nickel or very few nickels to acquaint the medical profession with the quality, characteristics, the precautions and so on of the drug. This is really an answer to why occasionally, some copier sells a product at 20 or 30 per cent below what the innovator sells it at; this attempts to tell you why he can do that economically.

Mr. MACKASEY: That is the point I was making in the beginning and which probably Mr. Stovel did not understand. Part of your costs would be justified; the spread between the generic firms and the brand firms is the question of quality control.

Mr. BERTRAND: But you have to look at it very broadly, because we are not talking about quality control in the sense only of that that exists in the manufacturing operation. This is quality, if you will, of the marketing effort.

Mr. MACKASEY: Mr. Bertrand, do you put a percentage value on this additional expense that you have that generics do not have?

Mr. BERTRAND: Mr. Mackasey, on page 19, we have outlined what it costs us.

Mr. MACKASEY: Would you read it to me?

Mr. BERTRAND: It is the table. In other words, we are saying that it costs us 31 cents out of our dollar to provide all of the services that we detail as professional service representation, marketing and medical information.

Mr. MACKASEY: But you do not break down the 31 cents to say how much of it is specifically for quality control.

Mr. BERTRAND: It would be impossible to do that.

Mr. MACKASEY: How did the Hall Commission report come down to not only percentages, but to decimal points? I will read from page 678:

> On the basis of information received from 22 of the 27 companies, the director concluded that expenditures on quality control represented 3.62 per cent of the cost of goods sold. The survey conducted on behalf of the Canadian Pharmaceutical Manufacturers Association, and so on.

Further on it says:

> However the expenditures as described for the 35 companies amounted to 4.2 per cent of the total production costs.

Mr. BERTRAND: Mr. Mackasey, I think on that I would be doing a little guessing if I attempted to justify every figure that is in the Hall Commission report. I was not a party to some of the statistics and I do not know of our own company participating. However, I think they very definitely are talking about quality control in the production sense, not in the marketing sense. We have said somewhere in this brief that when you have an organization operating as an innovating research oriented pharmaceutical company, it is extremely difficult to pinpoint in dollars and cents what your quality control costs. You can walk into a plant and you can say: How much do you pay your chief chemist in quality control? How much do you pay the secretary? How much do you allocate to that room? But that is not the real cost of quality control. The real cost of quality control is that plus the procedures that are built in throughout the manufacturing operation and throughout the marketing operation. I do not see how we can even talk in terms of the Hall Commission report statement on what quality control costs.

Mr. HOWE (*Hamilton South*): Mr. Chairman, may I ask a question at this point. Really your quality control comes under the top figure of 34 cents, does it not?

Mr. BERTRAND: This is a production factor.

Mr. HOWE (*Hamilton South*): But under your 31 cents for professional services representation, and so on, is your promotional cost?

Mr. BERTRAND: This is our marketing professional service representation account.

Dr. HOWE (*Hamilton South*): The Hall Commission report recommends that this be reduced to 15 per cent. Would you, as a company, be agreeable to reducing it to 15 per cent of all the other drug companies agreed to the same thing?

Mr. BERTRAND: We do not think we could do a marketing job at 15 per cent, Dr. Howe; I do not think it makes a bit of difference what other companies

might do or might not do. We simply say that we cannot see a significant safe reduction in marketing expenditures.

Dr. HOWE (*Hamilton South*): What do you mean by "safe"?

Mr. BERTRAND: By safe? Could I refer to the Vademecum? I would like to pass this out because I thought the question might come up. This is an exercise which might take just a few minutes. If I may, Dr. Howe, I will speak to you and the others can follow along. The top sheet of that is a photo copy of page 128 of the 1966 edition of the Vademecum, in which Empire Laboratories described their tetracycline. Now if you will turn over the first one you will notice there is half a column. If you turn over the flyleaf you then find the Cyanamid description of Achromycin which is our tetracycline, and the rest of that photo copy for three full columns of the Vademecum describes Achromycin. It talks about the composition; it talks about the specific uses, it talks about the administration and dosage in very great detail, it talks about the precautions and warning. If you just take a look at the warning and precautions section which is at the bottom left column of page 178, and you look back to the Empire tetracycline Vademecum section, you find only a general statement about counter-indications; nothing about warnings, nothing about precautions. Now if we wanted to reduce the expense that we incur in a Vademecum—I do not say we do it, but if we had to do it—we would be forced into this kind of a disclosure about our products, and I do not think that is safe marketing.

Dr. HOWE (*Hamilton South*): May I interject and disagree. I must commend you first on this. I agree that what is in the Vademecum is absolutely necessary and I would be the last one to see that reduced in volume; but what percent of your 31 per cent is involved in your Vademecum insert. Is this not a very small per cent of the over-all promotional cost when you consider what must be tremendous cost in mailing to doctors, in detail men who go to doctors, and many, many other costs which are involved of which this, surely, is a very small cost, or a small percentage which would not have to be reduced for safety's sake?

Mr. BERTRAND: Admittedly, it is simply an example, Dr. Howe, but we have given you a breakdown of what makes up this 31 per cent. We have said that it costs us 15 per cent for our field sales expense. Now this is fundamentally the cost of our detail force. We happen to think that a well-trained, well-qualified detail force is just as important to us as a well-trained production staff. Now, if someone comes along and say you have to reduce either the quality or the numbers of your detail force, I personally think the medical profession in Canada is going to suffer.

Dr. HOWE (*Hamilton South*): But is there not a great deal of his time spent in detailing a product in a purely competitive way against an identical drug from another company, rather than the introduction of new drugs and the explanation of their uses? Could this not be a means of reducing expense without sacrificing the educational values that a detail man passes on to the medical profession?

Mr. BERTRAND: Dr. Howe, when a medical representative goes in to see a physician we are not known as a "me too" house. We do not send our people in to doctors' offices and into pharmacies and say, "Look, we have the same

product as our competitors, only it is a little bit better." Most of our products are specialty products that have been developed in our own research laboratories. Now, occasionally other people come along and put out what we call a copy, and if our people are going in and talking about tatracycline, talking about newly discovered things about tetracycline, I do not think that is pushing brand "A" versus brand "B".

Dr. HOWE (*Hamilton South*): Well then, in your advertising and sales promotion, will you admit that there is a lot of unnecessary mailing done to doctors that is not read, and serves no useful purpose?

Mr. Bertrand: Dr. Howe, I will take your judgment that there is a lot of direct mail that is not read by doctors. I think that this is understood by everybody in the business.

Dr. HOWE (*Hamilton South*): Would this not be a more intellectual approach to finding out the properties of a drug than some of the mailing that goes out? It is very costly.

Mr. BERTRAND: This is the reason that I personally feel that we should hve full disclosure in the Vademecum. We do it as a matter of policy. We have done it for a number of years. We have something like twenty pages, column after column, describing Lederle products. I agree with you. This is an extremely valuable document. I do not think you would agree with me that every physician in this country has read this book from cover to cover. He simply has not got time.

Dr. HOWE (*Hamilton South*): No, but it is a reference. That is all it is intended to be, is it not?

Mr. BERTRAND: It is a very important reference. I do not think our products would be in it unless we felt that.

Dr. Howe (*Hamilton South*): But you will admit that there is some possibility that some cost could be reduced by the limitation of the direct mailing that would not affect in any way your over-all sales, provided other drug companies were to do this, too.

Mr. BERTRAND: Well, wait a minute. We are jumping from one element to another. Have we left this question of the detail man?

Dr. HOWE (*Hamilton South*): Well, I had for the moment but I had not excluded it from everybody else. I am just trying to break this down and see if there is any way that this can be saved, because 31 per cent promotion is a large portion of the prescription dollar.

Mr. BERTRAND: All right, Dr. Howe, if you will allow me. Now you are talking about the third line in that breakdown. You are talking about something that we include as advertising and sales promotion. Now, you have talked specifically about direct mail. Direct mail makes up 1.3 per cent of our sales dollar. In other words, 1.3 per cent of that 12 is direct mail, and if you will allow me I would like to show you a sample of the kind of thing that we put out as direct mail. I do not have enough copies for every particular individual here. I will just pass them around at random. Dr. Howe, this is a piece of Lederle direct mail on a continuing basis. It is called "Literature of Dermatology". There are approximately ten issues put out per year. We usually skip the two summer

months, but this is virtually a monthly document. It is a world wide monitoring job on all medical journal articles—not advertisements—that relate to the practice of dermatology. It simply indicates the recent publications, in what journal they appear on a world wide basis, with a short paragraph indicating the gist of the article.

Now, these are not articles reviewing Lederle products. They are mostly reviewing conditions. We started this about a year ago and it goes to a limited group of people, only the specialists in dermatology. We were concerned about what this was costing us, so we sent a letter to each one of these people along with a particular issue and we said, in effect, this is a costly proposition for us. We want to be sure you are getting this. We want to be sure that you are finding it of value and of use. We sent out 220 letters. We got back answers to 210 of those. Ninety-eight percent of them were favourable, said they like it, they enjoyed it, they wanted it to continue. One or two percent said they were no longer in practice—this was taken from a mailing list from our mailing house of specialists in dermatology. Since they were no longer in practice it was of no great interest. We asked them to fill out and return to us a questionnaire that had three questions on it: Do you find the subject matter interesting and up-to-date; is this information of value in your specialized practice; do you wish to receive this literature in the future? And we ask them to make any comments and suggestions. I pulled at random a few replies. In all cases, it was yes, yes, yes to each question. The comments were "appreciate receiving this publication", Dr. Gibson E. Craig, Montreal. "Very helpful", Dr. Donald Montgomery, Ottawa. "I think you are doing a real service in providing these abstracts", Dr. Norman Wrong, Toronto. "In view of the overwhelming number of publications today, we need more of this kind of information so that one may know where to look for the comparatively small number of articles which we would have time to read in their entirety", Dr. Kenneth Baird, Lancaster, New Brunswick. "A meritorious and valuable service to busy practitioners. The most useful literature I receive in the mail", Dr. Ronald M. Bremner, Saskatoon. "I think this is an excellent service you are rendering to dermatologists", Dr. Mercantini, Ottawa. "Gives us a nice concise resumé with the references which we would not receive otherwise for a year in other publications", Dr. Fournier, Vancouver. "Very useful in conducting by practice", Dr. Jean Paul Foisy, Montreal. "An indispensable review. Thank you very much", Dr. Jean Dufresne, Three Rivers.

I simply cannot agree, on a basis of this kind of reply, that this is junk.

Dr. HOWE (*Hamilton South*): I did not call this junk.

Mr. BERTRAND: Or not useful to the medical profession.

Dr. HOWE (*Hamilton South*): If I grant you that Lederle's direct mailing is certainly more ethical than are some of the other companies, does this 1.3 per cent include the amount it would cost to have this written? This is not just the printing and mailing price?

Mr. BERTRAND: We are in a rather unique position there, Dr. Howe. Some of the material that we have used on direct mails, such as this, is printed by our parent company in the United States, supplied to us without specific charge except for duty and transportation and, of course, the cost of mailing.

If I may, I have one other illustration of direct mail. We were forced, by our own policy, to put this out in this form. Late in 1964, we introduced to the medical profession in Canada, a product known as amicar, epsilanaminocaproic acid which is a product that has been developed for use in acute life threatening situations where haemorrhage results from an overactivity of the fibrinolytic system. This is a product that in conjunction with and in discussion with the Food and Drug Directorate in Canada, we agreed was a necessary product that should be restricted to use in hospitals only because there are a number of precautions. In order to alert the medical profession of all that we knew about this drug, precautions, warnings, toxicity, we printed in French the American brochure and mailed it to a very wide list of hospital specialists and specialists outside of the hospitals who might come in contact with this product. We could not afford, frankly, to turn this product over to our detail force. We used direct mail in this particular case. I do not think a specialist in this area who receives this kind of a document from Lederle, would throw it in the waste basket. I think he read it and profably kept it. This is not all of our direct mail. I would remind you that our direct mail is 1.3 per cent of our sales dollar, so if we eliminated every piece of it, that is how much we would reduce our advertising costs.

Dr. HOWE (*Hamilton South*): In your advertising and sales promotion, what makes up the other 10.7 cents?

Mr. BERTRAND: It is made up of of a variety of things. As an example, we do a certain amount of medical journal advertising, particularly when we are introducing a new product. This is the introductory issue in October, 1965, of Declomycin B.I.D. therapy where we introduced the 300 milligram tablet that could be used on a B.I.D. basis for the first time. It is a four-page insert.

The CHAIRMAN: For the information of members of the Committee, B.I.D. means twice a day rather than the usual four times a day dosage.

Mr. BERTRAND: *This Describes what the product does, what it looks like.* You have full disclosure as part of it; the complete disclosure with respect to warnings, precautions, indications, the same type of thing we put out in vademecum. We do not continue to do this month after month. As a result, I show you the September 16, 1966, issue, of the same Journal where we are advertising the same product. It has dropped back from a four-page insert to this kind of an advertisement. The space and time cost are part of this 12 per cent. The cost of creating, printing these inserts and advertisements is part of the 12 per cent.

Dr. Howe (*Hamilton South*): Do you advertise also in these free magazines such as *The Canadian Doctor, M.D.* and others?

Mr. BERTRAND: I think, Dr. Howe, in our brief we said that we do use journal advertising, utilizing just about every national publication in Canada plus the two publications that are somewhat regional in French. So, virtually every national publication to the medical profession would, at one time or another, have an advertisement. Obviously, every issue does not.

Dr. HOWE (*Hamilton South*): So a large portion of this 12 cents is actually a journal type advertising, magazine type advertising rather than direct mail by about ten times?

Mr. BERTRAND: We are not holding back anything here. So I do not think it is necessary to ask us for each individual one. I will tell you what the 12 per cent is. It is 5.4 per cent samples; it is 1.7 per cent space and time in the journals; it is 1.3 per cent direct mail; it is 7/10 of a per cent on price books and catalogues. In case there is any question of what they are, we publish for the benefit of pharmacy and any physician who requested a Lederle product description, which is in looseleaf from updated with supplemental new pages whenever we change the description of a product for any reason, whenever we change a package style, whenever we introduce or delete a product and, in what we call all other forms, we are talking about 2.8 per cent. This adds up, according to the arithmetic in front of me, to 11.9. We have taken the liberty of rounding it off to, say, 12 per cent.

Dr. HOWE (*Hamilton South*): You do not feel then that any of this could be reduced as far as your business is concerned or as far as the medical profession is concerned?

Mr. BERTRAND: Not on a broad general basis. Dr. Howe. If you are going to say to me, "Could you live in this country if this particular advertisement had not appeared in this particular journal I would have to say probably.

Dr. HOWE (*Hamilton South*): My question was not suggestive. I was just merely inquiring.

Mr. ORLIKOW: Mr. Chairman, I think we should make it clear, in case representatives of this company do not understand it, the reason we are here, the reason we are spending all this time, the reason there was an inquiry, first of all by the director of investigation under the Combines Investigation Act and then a report by the Restrictive Trade Practices Commission and then a big part of the report of the Hall Commission is that rightly or wrongly the people of Canada are concerned with what they think is the high price of prescription drugs. This is why we are here. I would like to come to this question of 31 cents out of every sales dollar which are spent as this brief says for professional service representation, marketing and medical information. I would like to ask, is this not really paid, not by the company, but by the consumer, the person who buys the prescription and every dollar that he pays retail—

Mr. STOVEL: We would be out of business if we were selling at a loss, so obviously all our elements of expense have got to be paid for by the ultimate consumer.

Mr. ORLIKOW: The Hall Commission has suggested that, and I imagine you surely want other companies that will come here to give all their figures. If they are not all 31's probably companies like yours will range between 25 and 35, just rounding out the figures. The Hall Commission suggested that this be reduced, as Dr. Howe says, to 15 per cent. You have given some answers to Dr. Howe but there is a very large amount in the direct mail advertising, an example of which you mentioned in the advertising, some of which you pointed out in the medical journals and so on. Every other company is doing exactly the same thing. Now are they not all doing it with the hope—and I am not being critical: this is the way our competitive system works—that they can not only increase their total sales but increase the percentage of the total business which each company does? Is that not why your company does it?

Mr. STOVEL: I think we ought to get to fundamentals. We are in the business to make a profit. On pages 76 to 80 of our brief we try to detail our position on whether it was sensible in our particular case—we cannot speak for others—to reduce marketing costs, and we came to the conclusion that the whole medical health scheme would not benefit if we did.

Mr. ORLIKOW: It would be unreasonable to expect you to do it by yourself, but now would the health of the people of Canada be affected—I am just speaking from memory, but I can find the figure—if, as you yourself say in the brief that you have either 83 or 88 detail men.

Mr. STOVEL: I would like to correct that. We have a total of 87 who are covering the products lines in the medical field, about three quarters of their time is spent in the pharmaceutical field and one quarter in the surgical suture field, so that, in effect, we have about 66 people.

Mr. ORLIKOW: Fine. Sixty-six people for one company and this is duplicated by every company which is doing the same type of business as yours. This is a very substantial number of people. If you think of 1966 costs, salaries and expenses, this is a very substantial amount of money, running into millions of dollars not for your company but for all the companies in Canada. Certainly your detail man is explaining to the doctor your problem; that is understandable, but he is also, I am sure, explaining to the doctor that in the field of antibiotics he should be using your product. Aureomycin or Achromycin, and the Parke Davis man is explaining to the doctor why he should be using Parke Davis' antibiotic Chloromycetin, both of which sell for exactly the same price, although there is no consultation between you I know. One of the government reports lists about five companies, each of which sells 16 capsules, 250 milligrams, at $9.44 which is an amazing coincidence, I think. After all the person who is sick cannot do what he does with groceries, go if he wishes to Steinbergs, or to A & P or to Dominion. He goes to his doctor and his doctor writes a particular antibiotic or a particular tranquillizer which the doctor wants him to use and that is the prescription that the person gets. How could your company compete, and how would the consumer be hurt, if instead of spending 31 cents there were regulations which were of equal force for every company and which said you could spend only 15 per cent?

Mr. BERTRAND: This is a rather involved answer but let us take a shot at it.

Would you say that the health of Canada is benefited by the existence of such reference books?

Mr. ORLIKOW: Of course, it is. But let me say one more thing, because we are getting it on the record. I have also read enough of the testimony by very competent medical people, particularly people who teach in the medical colleges, to know that the amount of material like this which they see is very small compared to the tremendous amount of material which comes in the form of advertising and the rest which we have talked about.

Mr. BERTRAND: If I might, I would like to show you some additional information which we include, that some of our men pass out, sometimes we mail it; it is not always specifically designed for a particular product, but sometimes it is. We are the originators of Declomycin. We think, quite modestly, that we probably know more about Declomycin than any other company in the

world. We pull together—after the product has been on the market—Declomycin compendiums. We pass them out in the medical profession. This is all part and parcel of this 31 cents over-all marketing costs. This is the kind of thing that we have to cut out if you start saying, can you market pharmaceutical at 15 per cent. We have a guide to the recognition and treatment of overdosage of Lederle pharmaceuticals. In fact, of our copier friends, I do not know any of them that have anything like this. This is the kind of thing we have got to do away with. We are talking about bulletins on routine immunohistology that are given out, antibiotic treatments. I think we are the company with the largest medical film library in Canada. We put out a film catalogue. This is expensive to print. It goes to every hospital, every director of nursing, each year. We are showing about 3,000 or 4,000 prints per year. This is expensive. We think that it is part of the Lederle, Cyanamid, Davis and Geck names.

We send out medical advisory department booklets to physicians who request information in depth concerning a particular condition or product; cancer control through chenotherapeutics, tuberculine tine test, tetanus antitoxin and tetanus toxoid, common questions and answers; amicar I mentioned a little earlier, aristocort, a compendium of clinical and laboratory information. This is not four colour work designed to sell a particular product, and this is the kind of thing that you are saying you are going to have to do away with. Can you reduce it? We said on pages 76 and on in our brief we do not think so.

Mr. ORLIKOW: But my point is this, and I am sure this is exactly what the Hall Commission had in mind, because your company—and I am not being critical of your company—and each other company doing the same type of business as you are, wants to make a good impression, wants to go into the doctor who in the final analysis is the person who makes the decision which product will be used, you are putting out a great deal of this stuff which is tremendously expensive. If you read the testimony before the Kefauver committee you will note that a great deal of this material which is very expensive and which, in the final analysis is paid for by the consumer, goes to doctors who do not have the time to read it. There was all sorts of evidence before the Kefauver committee, and I am sure that when we get the doctors here from the various medical colleges and the various hospitals they will tell us the same thing. I do not think doctors are any different from members of parliament. The wastepaper basket of every member of parliament at the end of every day is filled to overflowing, and I am sure doctors are in the same boat. And I suggest to you, along the same line as the Hall commission did—not that you exercise restraint, because this is asking the impossible in a competitive society—that some outside agency, which I suggest is the government, should lay down ground rules which would apply to everybody, not for your company particularly.

Mr. STOVEL: You can not take attitudes and apply them and make sense. Many of the other people in the industry do not do this kind of thing. Our total philosophy at Cyanamid is that service is good business, and we do our utmost to try to provide a service to the medical profession.

Mr. ORLIKOW: I do not question that but I suggest to you, as one who worked in a retail drug store in a working-class, lower-middle-class area, that

many times when a doctor prescribed sixteen antibiotics and the customer saw the price, he walked away and said, "I will leave it" or "I will take eight". This is not doing the ordinary person very much good when he can not afford it, and the cost he is charged is, to a large extent, determined by the amount of money which you people feel you have to spend to get your message across, 31 cents out of every dollar.

Mrs. RIDEOUT: I am a little reluctant to even ask a question, with this esteemed group present. I am trying to follow this very carefully in my own mind. I find this portion about the innovator and the copyer most interesting and because I am a consumer I am wondering just what part I play in it. Now, it just sounds unbelievable to me that you, as a company, can spend vast amounts of money on research and come up with a product that is going to be to the general benefit and welfare of all of the people, and then somebody can copy it. Are you not protected in any way?

Mr. BERTRAND: No.

Mrs. RIDEOUT: Now, am I protected when my doctor writes a prescription for medication that I might need? I trust his judgment and he sends me on to the pharmacist and I must trust his judgment. Now what am I getting, the innovator's product or the copyer's, or am I protected?

Mr. BERTRAND: It depends on how your physician writes the prescription. You have to have confidence in your physician; you have to have confidence in your pharmacist.

Mrs. RIDEOUT: Which I do, but how do I know? What I am trying to find out is, are we protected legally in any way? Are you protected? When you spend all this money on research and then somebody copied your product it just sounds reasonable to me that somewhere along the line you should be protected. I admit I am probably asking a stupid question.

Mr. STOVEL: That is why we have to repeal that tariff, as stated in our brief that there are desirable changes in the patent law.

Mr. O'KEEFE: Is your firm always an innovator and never a copyer?

Mr. BERTRAND: We are known pretty well throughout the business as not being a "me too" outfit.

Mr. O'KEEFE: But are you always an innovator and never a copyer?

Mr. BERTRAND: To the best of my recollection and knowledge, yes sir.

Mrs. RIDEOUT: But, I am not protected and you are not protected under the law?

Mr. BERTRAND: Well, I think what Mr. Stovel was saying is that we feel the Patent Act in Canada is discrinimatory against drug manufacturers and drug researchers. It does not allow for a product patent; it allows only for a process patent. We have detailed it in here, that a copier, after a certain length of time, can start producing a product, and whether or not he infringes our patent we have a very, very great difficulty in following that through. So our protection through the patent act is very weak in Canada.

Mrs. RIDEOUT: This is what I wanted to know. Simply because a great proportion of your cost is in research naturally you want to come up with a new

product so you can sell it to the consumer, and this is business. So, in effect, you must spend a large portion of your cost in research.

Mr. STOVEL: I think our table shows 7 per cent.

Mr. MACKASEY: Mrs. Rideout has brought up a very good point, and I think we should delve into it. Mr. Bertrand, you mentioned that the patent laws are not conducive to research. Why should the patent laws in Canada encourage research if you do not do any here anyway?

Mr. BERTRAND: Well, obviously, on page 19 there is a breakdown on what is involved in expenditures for the research and development of new products.

Mr. MACKASEY: Yes, but where is that research done, Mr. Bertrand?

Mr. BERTRAND: Most of the research done to develop new Cyanamid products is done in a centralized medical research organization at Pearl River, New York.

Mr. MACKASEY: There is none done in Canada?

Mr. BERTRAND: There are clinical investigation programs going on in Canada. We do not have a research laboratory as such—bricks and mortar and chemists working in a research laboratory— in Canada.

Mr. MACKASEY: I understood, Mr. Chairman, that we were going to get into a further discussion on patent laws later, but I would like to make the point that I am a little perplexed why the patent laws of Canada should protect new discoveries through the medium of research. You do not do any research here in Canada. You make a very valid point all the way through your brief for centralizing research in the United States but unfortunately for Canadians, this central point is not in Canada, and I am wondering why we should worry about protecting new discoveries made in the United States and produced in the United States through our patent laws. It is a blunt question, but this is exactly what the Hall commission report asks.

Mr. BERTRAND: We are licensed under patents granted in Canada to American Cyanamid Company to market products produced under those process patents, so I really do not think it makes a great deal of difference whether the research that led to this particular patent was performed in Montreal, Pearl River, New York, Switzerland or where it was performed.

Mr. MACKASEY: Well, it makes a big difference to the Canadian scientist, Canadian university graduates, and Canadian universities where the research is done. I think you would agree to that. I think this is one of the problems with dealing with an international company. Pharmaceuticals is almost an international industry. I am quite willing, Mr. Chairman, to refrain from further questioning in this area, if you feel it is desirable.

The CHAIRMAN: As you know, we are hoping to have certain people before us to discuss patents, but I am sure it would be impossible at that time to have representatives from every individual drug company before us. A large portion of the brief does deal with patents.

Mr. MACKASEY: Could I get rid of a little question first, then, Mr. Chairman? I will revert to the detail man, Mr. Bertrand. This is a thorny question that I ask all companies. What is the method of remuneration?

Mr. BERTRAND: I can not speak for any general method but I can tell you what our company does. We pay these people a salary; we do not have a commission system. We do have a sales incentive program that varies from time to time.

Mr. MACKASEY: What does sales incentive mean to your company?

Mr. BERTRAND: It means that we attempt to set up a program—and this is exceedingly difficult to do—that will judge the effectiveness of our people. This does not represent, off the top of my head, a greater amount than 10 per cent of their annual salary, on the average.

Mr. MACKASEY: How do you judge their success? In other words, are these bonuses tied in with increased volume?

Mr. BERTRAND: In some cases, yes; in some cases they are tied in with the introduction of a new product, as to how rapidly it is accepted and known about by physicians in various areas.

Mr. MACKASEY: You say in some cases it is tied in to volume. Do you not think this could lead to abuse in that the detail man may get a little exuberant, a little over-zealous and a little ambitious to reach his quota and could conceivably misrepresent the product.

Mr. BERTRAND: Well the sales figures on which this is usually based is the sales amount to either pharmacies or hospitals, not to the physician. In other words, are you asking is there a danger of our men going in and being over-zealous in their detailing of a particular product so that a physician will write more prescriptions? These cannot be based on that because, frankly, we do not know how many prescriptions an individual doctor writes for our product.

Mr. STOVEL: I would like to enlarge on that, if I could. As I mentioned before, we operate as a company in many different fields and throughout we have a consistent policy. We have our sales representatives on a basic salary. We do have an incentive which averages out to about 10 per cent of their sales salary, which is tied not so much to sales quotas but specific objectives; new accounts that they have been able to open, new product lines that they have been able to develop and sometimes specific introduction of new products. I think this is pretty general throughout industry.

Mr. MACKASEY: Mr. Chairman, I would like to go back to research if I may and if you want to go from page 19 to research, research begins around page 30.

The CHAIRMAN: Unless it is directly related, I think there are some questions on other matters.

Mr. ISABELLE: You were talking about copiers. Do you think if they were thrown out of business this would help to reduce or decrease the price of drugs?

Mr. BERTRAND: I think this is a long-term thing, Dr. Isabelle. I do not think if they are thrown out of business that it would have an effect tomorrow morning.

Mr. ISABELLE: I mean in the long-run.

Mr. BERTRAND: I think in the long-run it would certainly lead to genuine competition. The question is how are you going to throw them out of business? If you strengthen the Patent Act you create a better climate for companies to invest in not only research but in manufacturing facilities in Canada. I think this in the long term will lead to economies.

Mr. ISABELLE: What is the percentage of copiers in Canada? Would it be 50 or 65 per cent?

Mr. BERTRAND: You mean in terms of volume. Frankly, I do not know and I think it would vary greatly from product to product. We have many products on the market, Dr. Isabelle, that the copiers have not copied yet. They may have looked at them but for various reasons they have not copied them.

Mr. HOWE (*Wellington-Huron*): We are here to investigate the cost of drugs and I would like to ask the witnesses if, in their research, there are not drugs discovered which can be put on the market at a very reasonable price and do you sometimes find that there is a reaction from the consumer that the drug is so cheap it cannot be any good?

Mr. BERTRAND: I do not know of any instance where that occurred.

Mr. HOWE (*Wellington-Huron*): In modern marketing methods we know that in some of our big chain-operated departmental stores they will take things they have had in their bargain basements that would not sell and put them up in their exclusive areas and cleared them right out. This happens time after time in marketing. Some people may think this is ridiculous but I know of a specific case where it happened.

Now one other question. Do you set the same mark-up on every drug that you produce? Do you have a 10 or a 20 per cent mark-up across the board?

Mr. STOVEL: I think we covered how prices were developed in Canada on pages 67 to 72.

Mr. HOWE *(Wellington-Huron):* You say you do not use the same mark-up and I would like to know why?

Mr. STOVEL: I think it is covered in that section but there are many factors that enter into the pricing of a drug. This would include the potential volume, how much effort can you afford to put behind it, how long do you think it is going to last until it is replaced by another one, what are the potentials for improving the process. All these factors have to be weighed individually on each item and a price established. We think our over-all return is not unreasonable.

Dr. HOWE *(Hamilton South):* Then why do all antibiotics end up at the same price?

Mr. STOVEL: They do not. We introduced each of these products and in time the earlier one was partially replaced by a second one and in time both were partially replaced by a third one. It shows that the price of our first product in the antibiotic field which was introduced, and which we pioneered or developed as a company, reduced 75 per cent over the period from its introduction until today. It shows a similar but not quite so dramatic price decline on the one that was introduced in 1954 and a further decline in the one that was introduced in

1959. Now in some cases competitors have either found a means of making this or a somewhat similar product, and may have chosen to price it at the prices we established.

Dr. HOWE *(Hamilton South):* Is that true of all the manufacturers of the tetracycline group that you are the originators and others have copied, and that this price that has been established is the same because, basically speaking, most antibiotics sell now on the market for the same price except some of the newly established ones. I am thinking of Chloromycetin, which is possibly one of the oldest of all the antibiotics made by Parke Davis. Then there is Tetrex and others in the tetracycline group which sell at an identical price to yours. Is there any reason for this except that they have all copied you? For example, this would not apply to Parke Davis, that Chloromycetin—

Mr. BERTRAND: Dr. Howe, I would like to correct an impression here without getting into other companies. Our company developed the first tetracycline;—Chlortetracycline. This does not mean that there are not other analogues of tetracycline on the market by other companies that our company did not develop. I am thinking now of oxytetracycline. I am afraid when you said we developed all the tetracyclines that would be somewhat inaccurate. We did not develop, and we do not market oxytetracycline.

Dr. HOWE *(Hamilton South):* But it does sell for the same price?

Mr. BERTRAND: I do not know about that. I would be very surprised if it did not sell for approximately the same price.

I think you are getting into an area such as, for example, gasoline which various companies tend to sell at the same price. You have a competitive situation. I do not think we could live too long with a drastic, price differential between our major antibiotics and the major antibiotics of other reputable companies.

Now, this does not imply, at all, in my feeling, that there is any collusion or a conspiracy to keep prices at a certain level. This is part of the competitive life of the economy. If we have price reductions it puts the other company under pressure to determine whether they can continue to sell their products, or whether they would be better advised to reduce their price to our level.

Mr. ORLIKOW: I wonder if I could read into the record here—because I think this is an opportunity for Cyanamid to explain—from pages 511 and 512 of the report of the Restrictive Trade Practices Commission published in 1963 which dealt with the question of drugs. I would like to read one paragraph because it deals specifically with this question of antibiotics and with this company:

> What has given the Commission some concern is the later history of prices of drugs as indicated in the Green Book, Chapter XV. In respect of the older penicillins, for which no patents were obtained, and the streptomycins, for which licences were freely given, prices soon began to decline and over a period of some years reached a level that appears to have been very close to costs. However, in respect of later drugs controlled closely by patents, notably the five broad spectrum antibiotics, the story is quite different. Chlortetracycline (Aureomycin), chloramphenicol (Chloromycetin) and oxytetracycline (Terramycin) came on the market in Canada successively within a year or two, beginning in

May 1950. Price reductions occurred down to 1953, due largely to improvements in methods of production. From 1953 till late in 1960 no reductions occurred. When Cyanamid introduced tetracycline (Achromycin) in 1953 and demethylchlortetracycline (Declomycin) in 1959 it adopted the prevailing price of the three earlier broad spectrums. When price reductions did occur late in 1960 there may have been several contributing factors, but the Commission is of the opinion that the lower prices of imported European drugs constituted the most important one. During the intervening years, notwithstanding that all of these drugs enjoyed large sales and that the costs of both basic drugs and finished dosage forms showed remarkable variations between companies, no company thought it desirable to reduce its prices. It was as if the price established in 1953 had come to be regarded as the right price.

The prices did not come down until the very people you complain about, the copiers, started to bring stuff in.

Mr. STOVEL: I do not think our table on page 72 agrees with that. If you look at the number of price declines there were from 1949 down to 1964—

Mr. BERTRAND: Page 70.

Mr. STOVEL: I am sorry, page 70. There has been a whole succession of price declines.

Mr. ORLIKOW: Well, between 1953, which is what they say, and 1960, the price decline, to say the least, is minimal. It was after 1960 that they came down very sharply. These are your own figures, and they show, at October 1953, $5.61, and in 1959—I am talking about Aureomycin—it is $5.66. It is not until 1960 that it comes down. Therefore you have that period from 1953 to 1959 when the price stays pretty constant.

Mr. BERTRAND: Mr. Orlikow, I think you will see here, although there are variations, pretty much the price pattern of a modern pharmaceutical which is used in very large volume as this one was: You will find it coming out at a particular price; you will find it perhaps coming down in price pretty rapidly for some time and then levelling off for some time; and then resuming the long downward trend. It is just the nature of business.

Mr. ORLIKOW: Here is a photocopy of a page from "Business Week" of August 15, 1964 which says—and they are referring to tetracycline that McKesson and Robbins cut the price of tetracycline to $6.00 a hundred tablets in the United States from the $17.00 which your company and Pfizer Company were charging; and your company, in retaliation, cut McKesson and Robbins off—you refused to sell them. I think you sued them. Now, this is the copier, and you stated to Dr. Isabelle that if they were out of business perhaps the prices would come down. I think that if the copier went out of business the price would stay up, not come down.

Mr. PAPE: Mr. Orlikow, if I could mention the McKesson thing and the tie-in with the copier, it was all connected with patents and the fact that the innovator without patents goes out of business. I think we all have to bear this in mind. Someone like McKesson and Robbins comes in as a copier, without the research expense, without the marketing expense which is put into the product

to begin with, and they are able to put a price like this on it. I believe Lederle had every right not to do business with them even though it was reversed in the courts.

Mr. ORLIKOW: Of course, that is a legal matter. I do not think you are going out of business. I have a copy of "Moody's Industrials" for the six months ending June 30, 1966, which shows that your company made a net profit of $53,847,000. I do not think your company is going out of business.

Mr. PAPE: I think you are talking about American Cyanamid in total.

Mr. ORLIKOW: Yes. I cannot talk about the Canadian Company because you do not talk in Canadian figures.

Mr. PAPE: But this, of course, is not all drugs in the United States.

Mr. ORLIKOW: The drugs are not losing money, I am sure of that. All the evidence is that—

Mr. PAPE: I would say that if they were losing money we would drop them; we would have to.

Mr. STOVEL: I think you will understand that we are constantly getting into new business, or getting out of old business. We have an obligation to our shareholders, and that is to make money; and have an obligation to the consumers to see that they get a good deal.

Mr. MACKASEY: Mr. Chairman, I think it is our obligation to find out whether they are, or are not, getting a good deal. We cannot presuppose one or the other.

Earlier we were discussing research, Mr. Stovel, and I think we were discussing patent laws at the moment. I would like to say, just to reassure you, that I am certainly not an advocate of the elimination of patent laws—on the contrary. Would you invest in more manufacturing in Canada if the patent laws were adjusted upward, theoretically?

Mr. STOVEL: There are lots of factors you have to take into consideration in investment, such as the availability of capital, the tax rates, but basically it comes down to the potential return on investment. If tariff laws are strengthened, and you do see a chance to eliminate some of the potential risk in a business, your tendency would be more to go into it.

I would like to raise a more general point. Cyanamid started in Canada —its very first operation was in Canada—as a chemical company. About 1930 our company took advantage of an opportunity to get into the drug business. We acquired a company—the Lederle organization.

As Cyanamid, for about 18 years we dumped back and ploughed back profits we were making from our chemical activities, until we began to get the first kind of pay out. These things have to be looked at in a long-term way.

Mr. MACKASEY: Well, the argument keeps coming up, through all the briefs, that the patent laws of Canada are unfair to the pharmaceutical industry and not conducive to research in this country; the reason being, logically, that if you discover something through research, under Canadian laws you are not given adequate protection to regain or recoup your expenses—and this is research not only in a successful product but in unsuccessful products. What I am trying

to establish, for my own benefit, perhaps, is how this applies to firms which do their research outside of Canada and which annually, according to your balance sheet, pay for your share of research done outside the country.

Mr. STOVEL: How do we pay for it? We pay for it in the form of royalties, which is 5 per cent of our Canadian sales dollar.

Mr. MACKASEY: What I am trying to get at is why the Canadian government should concern itself about patent law protection to stimulate research, because of the reason you are giving, that there is no research done here because of the patent laws—when you do not do any anyway. How do you answer that argument which appears in all commission reports?

Mr. STOVEL: I think that we might find out that we do do in Canada about $900,000 of research. We have consistently tried to evaluate on our research where, with the amount of talent we can get and the modest opportunity available to us, we can do this most constructively.

We have felt that in Canada we would be better to concentrate our efforts on research in those areas which are particularly significant to the Canadian situation—the raw materials situation, the export situation, the climatic conditions.

I think, as we show on our brief, we are a sizeable exporter of chemicals, and part of that has come out of our research. Now, we cannot, in a broad business like this, do research in every area and do it well. We felt that, insofar as drugs were concerned, we could do it more effectively in our particular case at Pearl River, New York, than we could through attempting to duplicate it here and having, perhaps, to reduce it in some other area.

Mr. MACKASEY: If, by some turn of fate, patent laws were adjusted to provide more adequate protection for the pharmaceutical industry in Canada, what effect would that have, if any, on the amount of research you would do in Canada?

Mr. PAPE: There are a couple of angles to your question, which I would like to comment on.

I think Canada would benefit by stronger patent laws. I think that if you were to ask each copier, off on the side, if he would like to be an innovator, he would. He would want to contribute more, and he would like to be protected. I do not think you will ever, unless you have strong laws in the country, develop innovators.

We are in a peculiar position in that our research effort is concentrated in Pearl River, and hence we have a large investment there and it is very difficult to break this up; it is inefficient to do so; but that does not mean that perhaps other companies, will not be encouraged to do research in Canada. I cannot say what the future might be.

Mr. STOVEL: May I comment? We show in our brief that we are doing 2 per cent of our research in Canada. If the patent law were strengthened my personal opinion is that we would tend to do more in Canada.

Mr. ORLIKOW: Is it not true that, with the exception of one company, all the large pharmaceutical companies in Canada are similar to yours—that they are subsidiary organizations of American organizations?

Mr. STOVEL: I believe there are other countries involved.

Mr. ORLIKOW: All right; I am sorry, I will correct that: that they are companies owned in the United States, or Britain, or France or Switzerland.

Mr. STOVEL: I think the drug business tends to be international by nature.

Mr. ORLIKOW: The point I am making, though, is that what is true of your company is probably true of every other company. They will say, it does not pay us to—

Mr. PAPE: I cannot speak for the others.

Mr. ORLIKOW: Well, I am just curious, because, you see, your company is mentioned specifically in this report, and they say here on page 91—I will not read the whole thing—that the parent organization in 1959—to give the last figures had spent twelve to fifteen million dollars on research, compared with the total in Canada, for 21 companies, of $2 million, and then they end up by saying—and I will quote exactly:

> For the year 1959 the parent U.S. company (that is your company) spent $1 million on research for each $100 spent on research by its Canadian subsidiary.

Now, that is a fantastically low comparison. I am not very good at arithmetic, but the percentage would be very, very small in Canada as compared to the United States. How would the patent law change that?

Mr. PAPE: My point was that it probably would not drastically affect our behaviour. I was trying to get the point across that it would, perhaps, encourage others.

Mr. ORLIKOW: They are in the same boat as you are.

Mr. PAPE: I thought I had brought up the point—

Mr. MACKASEY: The point, as I understood it—and perhaps you can correct me—was what you simply said was that it would be harder for the generic firms to do business.

Mr. PAPE: This sums it up in a sentence.

Mr. MACKASEY: It would be harder for the copiers to copy.

Mr. PAPE: I tried to suggest that it would encourage them, perhaps, to do some research.

Mr. MACKASEY: Why do you people not do some? What encouragement must we give your firm to do some research in Canada? Never mind the copiers. What about the innovators? What steps would you recommend we should take to induce your company, and all the so-called big companies, to do a little more research in Canada?

Mr. BERTRAND: Mr. Mackasey, if I could comment on that for just a second, we are in an unusual position in comparison to most of the other companies in the sense that we are a very large, diversified organization. Many of the other companies are specifically pharmaceutical companies. Some of them have diversified, but not really to the extent that we have.

I think that if the patent laws are strengthened, I think you are seeing and you will have documented—as I believe the P.M.A.C. brief indicated—that

there is a steady gradual growth of pharmaceutical research in Canada. I think the strengthening of patent laws would certainly accelerate that.

In our particular company, because our research organization had its roots and grew at Pearl River, New York, we cannot say to you that if the patent laws are strengthened we are going to chop Pearl River up into nineteen little bits and scatter it all over the world. This just is not feasible.

On page 35 there is an indication that Cyanamid of Canada's research expenditure is something of the order of $900,000 for 1966.

Mr. MACKASEY: This is not necessarily just pharmaceuticals. This is your general operation?

Mr. BERTRAND: That is right.

In our philosophy of doing business we have been continually looking to expand our clinical investigation work in Canada. All drug research is not carried on within the four walls of a research laboratory.

The CHAIRMAN: Gentlemen, I have two points to raise. First of all, I should point out that from the evidence before the Committee previously, there is one major drug company doing all of its research in Canada—the opposite applies here—and this company will actually be before the Committee.

The other thing is that I wondered if it might not be useful to the Committee to have Mr. Laidlaw say a few words about the differences between the American patent system and the Canadian patent system so that we can really understand the basis of this argument.

Mr. MACKASEY: I do not disagree with you, Mr. Chairman. However, I am more interested in research because you yourself have ruled that we would deal with patents later on.

The CHAIRMAN: I said this morning that I had no objection to pursuing the question of patents, because Cyanamid are not going to be before us again, and they are prepared—and I hope the Committee members are prepared—to sit most of today on this brief.

I am sorry if I confused you. There are certain groups which are coming to talk about patents, but I think that the individual drug companies will not, and as this brief, and some of the other briefs we have looked at, deal to a great extent with patents, I think the Committee should have the opportunity of going into this now if they so wish.

I wonder if Mr. Laidlaw would like to say a little bit about the American system versus the Canadian system.

Mr. A. M. LAIDLAW (*Legal Counsel for the Committee (Ottawa)*): Mr. Chairman, I think when the briefs are read and we discuss patents it would be helpful to the committee to know exactly how the patent situation stands in this country. I do not know whether most of the members of the committee are aware that approximately 93 per cent of all the Canadian patents are owned by foreigners. Of this large number about 85 per cent are held by American inventors and American corporations.

The Canadian subsidiaries license these patents from their parent corporations and therefore they have the protections that the patent system offers. Our patent system relating to pharmaceuticals is different from that of the United

States. It followed, until recently, the United Kingdom system. In the United States you can get a patent on a chemical process from which a drug results, and you get the patent on the drug. This means that in the United States, which has the strongest patent system in the world, if you obtain a product patent—a certain specific drug—anyone who discovers a new process must make an arrangement with the owner of the product, if the new process can be used. In Canada, in the case of any invention which leads to the discovery of a new food, or medicine, and which is made by a manufactured process, you can get the patent only on the process. This is why Mr. Bertrand made it quite clear that from his point of view he felt that this protection should be increased, and that patents should be given in Canada on the products, quite apart from whether or not the products are made from one particular kind of process.

Having said that, there is another element in Canada which is specifically tied in with pharmaceutical patents. That is, that any person can apply to the Commissioner of Patents in Canada for a compulsory licence to manufacture that drug in Canada. The Commissioner, unless he sees good reason to the contrary, will grant that licence. I have the numbers here in my brief case. I was in touch with him about the number of compulsory licences that have been issued.

Naturally, the drug companies who have these drugs, and who have their licences through their parent corporations do not like this aspect of our patent laws either, where any person who proves himself competent to the Commissioner can apply for a compulsory licence. That is what is at present the basis of our Canadian patent law in this respect.

The United Kingdom recently changed its patent laws and allowed a patent to issue on the pharmaceutical product. This problem came up before the Royal Commission on Patents which was held in Canada not so long ago. This was thoroughly studied, with regard to whether Canada should or should not do the same thing. The Commission, in its wisdom, said that they saw no reason why patents should not issue on pharmaceutical products in Canada.

This, I believe, is mentioned in the report of the Ilsley Commission. However, I think it is only fair to the Committee to point out that this royal commission report, although it said this on the one hand, said that the compulsory licensing system must stay and, in fact, be improved; that the situation should stay so that as much competition as possible should be concentrated in this particular industry. Therefore what the commission suggested on the one hand they seemed to take away on the other.

The Fair Trade Practices Commission report suggested the abolition of patents altogether, and, as all of you know, the Hall Commission report rejected this on the grounds that this would create international furor and certainly disharmony whereever the patent system enters into the economics—and it enters into the economics a great deal—and suggested that perhaps competition should be encouraged by allowing licences of importation; in other words, a person could apply to the Commissioner of Patents, or a responsible tribunal, and could import the drug which was even being manufactured in Canada. I think you will want to make enquiry on this of the gentlemen who are here, and others who will be coming.

I think the theory behind this is that means have been suggested to improve competitive efforts between Canadian-owned companies or subsidiary compa-

nies, even with the so-called importers who do not do anything else and who contribute nothing to the economy.

Going back to Mr. Mackasey's question on research,—does the patent system promote research—well, it might, and it might not. In my view, Mr. Chairman, if I am allowed to express an opinion here, I do not think that by strengthening the patent system along the lines of the United States Cyanamid of Canada is going to do more research in Canada.

In discussing and thinking through the patent system, there are two important areas. It was initiated as a reward to an inventor, and to give the inventor a monopoly so as to reward him for his efforts. This was the original patent system. It is now changing considerably, where the patent system is now being used as a form of market control. I think that in the United States, for example, the great development there, industrial-wise, has been to some extent—perhaps to a considerable extent—due to the patent system. But here, in this country, knowing that we have only about 7 per cent of all Canadian patents owned by Canadians or Canadian firms, I do not think that the same rules or thoughts apply.

Therefore, just to wind this up, Mr. Chairman, I would think that the Committee would be well advised indeed, whenever it reads about patents throughout any of the briefs, no matter by whom presented, to bear this particular situation in mind.

The CHAIRMAN: Thank you very much, Mr. Laidlaw.

Mr. MACKASEY: I have one or two questions I would like to ask Mr. Laidlaw. I appreciate his contribution.

Why, Mr. Laidlaw, was there a recent change made in the United Kingdom from one system to the other in the patents?

Mr. LAIDLAW: Affecting pharmaceuticals? The whole patent act was under review and this was one particular section.

Mr. MACKASEY: Yes; but why? There must have been a reason for the change. Why would they change from the method to the product?

Mr. LAIDLAW: I could give you the details of the Swan committee report which set out those changes, Mr. Mackasey. They are very technical.

Mr. MACKASEY: I would like a copy so that I could compare them. If the United Kingdom found it practical to issue patents on the products, as opposed to the Canadian methods which, I understand, were identical until very recently, they must have had very good reasons, and I would like to know what these reasons are.

Secondly, I would like you, perhaps, to do a little research on whether or not the reduction of duties, tariffs and patent laws would not produce what we have got to concede to be a very sizable manufacturing industry in this country—certainly, when you look at Cyanamid and many others—that we would not, in effect, be saying to the pharmaceutical industry, "As of Monday you might as well close up shop and become importers and set up warehouses." I would like to get your views on this.

The other point I have is merely a comment, Mr. Laidlaw: How can we expect Canadians to own a greater share of the licences when there are practically no Canadian firms in this industry at the moment?

Mr. LAIDLAW: We are dealing, in this particular industry, with a peculiar industry, and very few Canadian firms are involved. As I understand it from you, you would like to see some of this business switched, and I am wondering whether the patent system will aid and abet in this.

Mr. MACKASEY: I would like to see the Canadian government increase the protection under the patent law—contrary to the Hall Commission report—but at the same time, from the same type of legislation, obtain guarantees from the industry in general that a greater share of the product that is now being used in Canada would be manufactured in this country.

What I had in mind, perhaps, is that an increase in research facilities in this country would not only, as is now the case, result in tax incentives, but also that, as a result of research done in this country, and as a result of increased protection, the patent laws would protect ultimate findings under this research done in Canada, and that some guarantee would be given to us, through legislation, from the pharmaceutical industry, that these discoveries would result in more actual production in this country. This is what I am interested in.

Mr. LAIDLAW: I believe there are certain research incentives now given by the government, and I would not be at all surprised that the fact that $900,000 of Cyanamid of Canada is spent in Canada is of some assistance, taxwise to—

Mr. MACKASEY: I am sure they take advantage of the 150 per cent, but there is nothing that guarantees Canadians in Canada that any of the discoveries from that research will result in increased manufacturing in this country.

Mr. LAIDLAW: There is no such guarantee.

Mr. MACKASEY: No; and this is what I would like to see done; and it could be done through some type of an agreement that would make the patent laws of this country more receptive to increased manufacturing and increased research in Canada.

This is the point I am making, and it is an area that I had intended to pursue a little more vigorously when we get into the facts. In other words, if the pharmaceutical industry wants increased patent protection, then it is time they increase production in this country. That is the way I see it. They cannot have the best of two worlds. They cannot be charging off royalties to head office and be absorbing part of the research costs at some international centre. This is all money which, as Mr. Orlikow mentioned, is paid by the consumer in Canada, and which goes out of the country, logically or otherwise.

I think the time has come for Canadians and the government to look upon the pharmaceutical industry as a legitimate industry, not to be badgered constantly by these committees, but rather an industry which through some joint project, we should encourage to foster and grow in this country. We need more primary and secondary manufacturing in this country, and the only way we are going to get it is to encourage manufacturers who now exist. This idea of licence of importation, which appears in the Hall Commission report, leaves me with the impression that all we are doing is telling the pharmaceutical industry to close up shop and go home and set up warehouses.

Mr. LAIDLAW: May I say, Mr. Mackasey, that things have been done, and our Patent Act contains certain features that would try to help along the lines that you suggest.

If I could pose an example. If Cyanamid of Canada developed, in Canada, an invention which was patentable—Mr. Stovel mentioned that the patent system is international in character, and this is quite right—this would mean that Cyanamid of Canada would own this patent, would take out identical patents in other countries, and certainly in the United States. I think we would have to jump to an assumption now, that the American parent company would develop that invention from that point on and give to the owner of that patent the right to use it in Canada.

To answer the second part of your question, the problem that is bothering you, I think, Mr. Mackasey, is this, that the Patent Act contains certain compulsory licensing provisions that if a patent is misused, or abused, or is not being developed in this country, then any person, after a period of three years from the date of the patent issue, has a right to go to the commissioner of patents and say: "Here is a Canadian patent and I want to manufacture it, because this person who made it is not developing it. It is being developed in the United States and being imported from the United States." This has not happened many times. These sections have not been used very much, for the simple economic reason that the country is not large enough to develop, from the beginning, a sizable industry to fill the Canadian market. This is a problem of straight economics.

Mr. MACKASEY: May I interrupt you, Mr. Laidlaw? I agree that the Canadian market is too small but there is nothing to prevent a company from, let us say, Montreal manufacturing a product for a market much wider than Canada. It does not have to be duplicated by a manufacturing process in the United States, in England or in the Caribbean countries. There is no particular reason why something discovered through the medium of research in Canada could not be manufactured here for a predetermined international area, that would include some products of the United States.

In conclusion, Mr. Chairman, what is bothering me is that the Department of Industry is trying to stimulate manufacturing and research in this country on the one hand, and other departments of the government are nullifying that action. There does not seem to be any dovetailing of the reference or any correlation of the reference. You cannot turn around and say to the manufacturing industry that, because they are suspect in their prices, the solution is to get out of the country and to bring in second-rate products from Europe, which, admittedly, will sell.

I am more interested in the long-range effects—in case of war and disaster, or the day when our population is sizable. Instead of driving industry out of this country we should be stimulating it, which is what the Department of Industry is doing.

Therefore, if I were given a mandate tomorrow to bring down the cost of drugs, I would run to some of these European countries like Poland and the others, and bring the products into Canada where they are available. But I think this is a short-range policy and this is why I think the government has the stick. We can go to the pharmaceutical industry and say: "Certainly we will increase patent protection; certainly we will stimulate research through tax incentives; but what we want in return is more research in Canada and more manufacturing in Canada. If you cannot accept that, then do not expect us to help you in the other areas."

The CHAIRMAN: Ladies and gentlemen, we have been sitting for almost 2½ hours. I think it would be reasonable if we now adjourn for lunch, with the understanding that we will meet again after Orders of the Day, which will be approximately 3.30.

As I expect the questioning will continue, we will probably meet again this evening at 8 o'clock, in the event that we have not finished the brief.

Before we adjourn, I would like to ask Mr. Laidlaw if there is any difference in the length of time of patents between the United States, Canada and the United Kingdom?

Mr. LAIDLAW: Seventeen years; in the United Kingdom it is 16 years, but from a different date. Therefore, in effect, the term would be the same.

The CHAIRMAN: The meeting is now adjourned until after Orders of the Day, and we will meet in Room 209.

AFTERNOON SITTING

The CHAIRMAN: Gentlemen, we have a quorum. I apologize to the witnesses for the members being unavoidably detained because of the delay in the question period in the House today. I am sure they understand.

We would like to go on from where we left off this morning. I think Mr. Stovel would like to make a few remarks pertinent to what was said this morning and I thought we might have Mr. Laidlaw say a few more words about patents and compulsory licensing, and then the meeting will again be open.

Mr. STOVEL: Thank you, Dr. Harley. It seemed to me when we broke off at lunch we were really getting down to the heart of the question: what is in the best interest of Canadians? Do you change the patent laws or the tariffs encouraging industry to come to Canada or do you put arbitrary curbs on the working of the free enterprise system, or do you ensure that unreasonable profits are not being made?

In considering these items we come up against some perplexing factors, one of which is the role of the international corporation as it exists among most of the drug companies. Also, upon considering these factors, I think you come up against the goals of the economic council. You are all aware of them: the need to create more jobs, the need for federally increasing productivity, the need to develop secondary industry, particularly a science-based industry where productivity is high. As a Canadian, these are problems that I personally wrestle with a good deal and so do my associates in Canada. It is a subject that the officers of our parent company also pay a good deal of attention to.

The drug industry is truly international, as is the chemical industry to which it is so closely related. In the case of our particular company it has been truly international from the start. An English scientist foresaw the need for synthetic nitrogen products. A German scientist developed a process. An American promoter saw a market opportunity and was able to secure the risk capital. Our particular company was located in Canada because raw materials and energy were available but, I think, more because there were strong patent laws and there were general conditions that encouraged this kind of an export-oriented industry.

In the past 60 years our company has grown from one plant in Canada to one of the major international chemical companies of the world, and this year the international sales will amount to about one billion dollars. The Canadian operation is the oldest, largest and most diversified of any of the parent company's foreign operations. It is also the largest exporter of materials among any of the company's foreign operations. In considering the problems of the international corporation, I think it imperative that we examine the guidelines developed by the government and sent by Mr. Winters, as Minister of Trade and Commerce, to the presidents of the leading subsidiaries. I would like to put these on record and discuss them in the light of the way we operate, and particularly in the way we operate with respect to drugs.

The CHAIRMAN: I think all the members are familiar with the guiding principles of good corporate behaviour.

Mr. STOVEL: It is something that we spend a good bit of time doing and, if we are not careful, by looking at one segment of the industry you may destroy other general objectives of the government and of the economic council.

Item 1 is pursuit of sound growth and full realization of the company's productive potential, thereby sharing the national objective of full and effective use of the nation's resources. I think here our prime business in Canada is upgrading Canadian raw materials. We export about four times as much as we import. We add about $25 million to Canada's favourable balance of trade. We are a science-based organization. We have about 3,000 employees, 10 per cent of whom are college graduates; doctors, chemists, lawyers, physicists, engineers —all through the piece; approximately 10 per cent are technicians or partial graduates; over 50 per cent of them are high school graduates, and we find this is an increasing thing. We think this is good for the economy; it is developing the highly productive sector.

Item 2, and I think this is very pertinent to drugs, is realization of maximum competitiveness through the most effctive use of the company's own resources, recognizing the desirability of progressively achieving appropriate specialization of productive operations within the internationally affiliated group of companies. In our particular case we have tended to specialize in the basic drug research in the U.S. There are other types of research, as we tended to locate in Canada which are particularly connected with our export-oriented products, or products that are upgrading Canadian raw materials. I think this kind of specialization is desirable.

Item 3 is maximum development of market opportunities in other countries as well as in Canada. As I have explained, I think there are some 700 chemical companies. We, as one company, export 10 per cent of the chemicals out of Canada. We are doing our best to extend processing of our natural resource products to the extent practical on an economic basis. We do that in two ways: we do a great deal of development work with the extractive industry, the mines particularly, and with the tar sands. We did this by upgrading energy and raw materials into plastics.

Item 5 is pursuit of a pricing policy designed to assure a fair and reasonable return to the company and to Canada for all goods and services sold abroad, including sales to the parent companies and other foreign affiliates. We fell we comply, in looking our case over, in that instance.

Item 6 is matters of procurement, to search out and develop economic sources of supply in Canada. We do buy or do make in Canada wherever possible. We have a definite policy that we prefer to buy Canadian. In the matter of drugs, we told you this morning that 60 per cent of our drugs are manufactured wholly and completely in Canada.

Item 7 is to develop as an integral part of the Canadian operation wherever practicable, the technological research and design capability necessary to enable the company to pursue appropriate product development programs so as to take full advantage of market opportunities domestically and abroad.

I think our record on export speaks for itself. We mentioned this morning some of the things we are doing in the farm field which we hope will lead to total fertility. In the drug field, certainly our brief should have left you with that impression. We are also attempting to offer a service to the medical and educational fields in health.

Item 8 is retention of a sufficient share of earnings to give appropriate financial support to the growth requirements of the Canadian operation, having in mind a fair return to shareholders on capital invested. In recent years we have retained for further investment in Canada 97 per cent of our earnings.

Item 9 is to work toward a Canadian outlook within management, through purposeful training programs, promotion of qualified Canadian personnel and inclusion of a major proportion of Canadian citizens on its Board of Directors. We are doing this. We have considerably Canadianized our management; it will only be a short time until the majority of our board of directors will be Canadian citizens.

Item 10 is to have the objective of a financial structure which provides opportunity for equity participation in the Canadian enterprise by the Canadian public. We are working toward that objective but we have to time it right. We have to make sure that we do not dilute the shareholders' equity in American Cyanamid by putting it on the market at a time when there is enough money available to make it sensible to bring it up.

Item 11 is periodically to publish information on the financial position and operations of the company. This is the one item we are not doing but we think this cannot be directed solely to subsidiary companies. If all Canadian companies are asked to do this, or if the law is changed, we would be more than willing to do it.

Item 12 is to give appropriate attention and support to recognized national objectives and established Government programs designed to further Canada's economic development and to encourage and support Canadian institutions directed toward the intellectual, social and cultural advancement of the community. I think the mere fact that we volunteered three times to appear before your committee, and we have appeared before many other committees, indicates that we are conscious of the social need. We have a strong program going, not only in the drug field but in a lot of other areas of medical assistance, grants, aid and general support to universities. In connection with centennial year, we have gone out—perhaps even farther than we should have—to try to support Canada's centennial and have chosen to put most of our support in Expo '67, where it will do more good than if it were scattered all across the country. In that particular case we are doing it in several ways: we are one of six

co-sponsors, of a major pavilion; we are joining with a drug association in sponsoring part of the health program; through our agricultural associates we are supporting the agricultural program and we have a part in habitat '67. In addition to that, we are acting as hosts to four international conferences, which will bring people to Canada from other parts of the world and thus exposing them to the opportunities available here, and so on.

I thought I would like to get that on the record. These are the general terms of reference which the international companies face.

The CHAIRMAN: Gentlemen, I was just wondering if there are any pertinent questions on those items? I think Mr. Blakely had an inquiry of you, which probably could be covered under what you have said on item 8. I think this would be an appropriate place.

Mr. W. J. BLAKELY, C.A., (*Accountant for the Committee*): I think, perhaps, you are referring to the statement on page 57. You indicate that your return on investment is 10 per cent and you indicate how you calculate investment. I am interested in the comparison of this to the rates quoted by Dun & Bradstreet, where you say that your rate of 10 per cent is lower than the average of some 19,000 reporting manufacturing firms as reported for 1965 by Dun & Bradstreet. I wonder if you could tell me if you are quoting from the Key Business Ratios published in 1965?

Mr. STOVEL: I personally did not get into the detail of this, but I do know that Dun & Bradstreet gave us permission to use this quotation.

Mr. BLAKELY: I would assume that this is probably the source document that you are referring to.

I have a copy of it here, and again I would assume that the ratio you are referring to is the one which they define as profits on tangible net worth, where the average for the over 19,000 manufacturing industries is indicated at 12.47 per cent. Do you know whether or not that is, in fact—

Mr. STOVEL: This, I think, is the figure of our 10 per cent.

Mr. BLAKELY: I assumed that it probably would be. It seems to me that the ratios are not directly comparable, because tangible net worth, as used in the Dun & Bradstreet percentages, is defined and, I think, quite naturally defined, as the sum of preferred and common stock surplus less deficits. This is different from your definition of investments, and I would naturally expect a difference in the ratios. Can you comment on that?

Mr. STOVEL: I am sorry; as part of our team—we do not have accountants with us—this was supplied by our treasurer. I questioned it, naturally; it was factual; but the difference in what we state ours is based on, versus what Dun & Bradstreet bases theirs on, I cannot tell you.

Mr. BLAKELY: I would suggest that they are on different basis, and I naturally would expect the ratios to be different. Since the individual who is responsible for this statement is not present, we cannot go any further on that particular item.

Before we pass from it, perhaps it might be noted that in the same publication of ratios, the figure for the pharmaceutical preparations is 21.93 per cent. This is considerably different from the 10 per cent being quoted by your

company on page 57; and this ratio is the sixth highest out of something like 52 classifications.

Mr. STOVEL: Perhaps to be factual on that, I will have to get our treasury people to submit a reply to your Committee. I am beyond my depth.

The CHAIRMAN: I would suggest that you take a copy of the minutes to your treasurer and let him read what Mr. Blakely has said, and then he can comment on it. Mr. Blakely can then bring back any correspondence to the Committee if it is required. This has been done in the past.

Mr. ORLIKOW: Mr. Chairman, I wonder if the report is of a size that it could be printed as an appendix to today's evidence?

The CHAIRMAN: Perhaps Mr. Orlikow could look at it.

Mr. ORLIKOW: I do not think it looks too big to print as an appendix.

Mr. MACKASEY: Mr. Chairman, we have already had the brief printed as an appendix. If we are going to print these figures, I think we should print them all, not just extracts.

Mr. ORLIKOW: That is exactly what I am suggesting.

Mr. MACKASEY: When you get into this type of work, it is quite a problem. Perhaps it would be better if we were to get 30 or 35 copies from Dun & Bradstreet.

Mr. ORLIKOW: Since it is referred to in the brief, and since our accountant questioned some of the figures, and since I presume we are not going to get a chance to come back to Cyanamid, I cannot see why this document, which does not look to be very big, could not be printed as an appendix so that we and anyone who is interested could have a look at it at a later date. I move that this be done.

The CHAIRMAN: Is there a seconder for this?

Perhaps you could let Mr. Orlikow have another look at it and see if he would still like to have it printed as an appendix.

I do not think Mr. Blakely mentioned that while the Dun & Bradstreet of Canada Limited report was printed in 1965, it actually refers to the year 1962. Is that not correct?

Mr. BLAKELY: That is correct.

The CHAIRMAN: They are always a few years behind.

Mr. ORLIKOW: So are most of the figures we get.

There are only six pages, Mr. Chairman, and I cannot see what objection there can be to printing it. It has been referred to in the evidence and in the questioning which has been going on. I think it will add to the knowledge of members of the Committee.

The CHAIRMAN: Does anyone have any objection to this being printed if permission is granted by Dun & Bradstreet?

Mr. MACKASEY: I have no particular objection, Mr. Chairman.

The CHAIRMAN: Perhaps this is a good time to mention also that there is another publication which I have in my hand, which was sent to me by Dr.

Wigle of P.M.A.C., which is very relevant to what we are discussing today, on a study of Canadian physicians' attitudes toward medical mail advertising and pharmaceutical literature, September, 1966. The special study was done by a company called the Canadian Facts Company Limited.

We could print this as either part of today's proceedings, in addition to all the others, or we can get copies and send them around to all members.

Mr. MACKASEY: What was the name of the firm, Mr. Chairman?

The CHAIRMAN: Canadian Facts Company Limited.

Mr. MACKASEY: I would like to know a little of the pedigree of this firm, to see what their background is.

Mr. ORLIKOW: Mr. Chairman, apart from the pedigree of the firm, this brief was not presented to us.

The CHAIRMAN: When they appeared before us, this was discussed, and it was mentioned at that time.

Mr. ORLIKOW: Since we have not had a chance to question it, I would suggest that copies of it be sent to members of the Committee.

The CHAIRMAN: Fine.

Mr. LAIDLAW: Mr. Chairman, this morning I gave a brief dissertation on patent law, generally, in an endeavour to assist the Committee members when they are reading the section dealing with patents in the Cyanamid brief.

This particular section in the brief calls for two changes to be made in the Patent Act. One is that we allow patent protection, *per se*, on the pharmaceutical products. In Canada, as you know, you can protect only a patented process; the drug that is derived from that particular patented process you cannot protect, *per se*. In the United States this is quite different. In England the law was the same until 1949, when it was changed, and the Patent Act of 1949 removed what you might call this restriction, or inhibition, and allowed drug patents, *per se*, to be handled in exactly the same way as were all other product patents. The question was raised: Why has not Canada changed its legislation?

Coupled with that statement, I would like to bring expressly to the attention of members of the Committee that both in England and in Canada we have this form of compulsory licensing by which any party can go to the Commissioner of Patents and apply to manufacture—and we will refer to drugs only here—that particular drug in Canada, and the Commissioner awards this licence unless he sees some good reason to the contrary.

In England they did not change this. The brief, then, requests that drug products should be patented, *per se*, and also requests the removal of the compulsory licensing provision.

In answer to a question raised by Mr. Mackasey this morning I have brought a copy of the Ilsley Commission report which went into section 41 and which deals with the drug part of patents, and I would like to read, if I may, one or two paragraphs from this report, which indicate the views of the Ilsley Commission and, which, I think, form the basis of what we are now discussing, which is of extreme importance to Cyanamid and the others companies and also

of extreme importance in the public interest. I am now quoting from page 94 of the Ilsley Commission report which reads as follows:

> The Patents Act 1949 (United Kingdom) makes no exception of chemical products or foods and medicines from the range of patentable products. They can all be protected regardless of the processes by which they are produced. This horn of the dilemma, if such it can be called, was recommended by the Swan Committee and the reasons for its recommendation are to be found in paragraphs 92 to 101 of its final report.
>
> While the reasons given by the Swan Committee for its recommendations are not all equally convincing, we have come to the conclusion that we should make a similar recommendation, particularly—

and then they cite the compulsory licensing provisions which the commission wishes to retain.

Then it goes on as follows:

> Under our proposed section as drafted it will still remain the duty of the Patent Tribunals—

—this is another recommendation of the commission—

> to consider, on an application for an order for grant of a licence, whether there are good reasons for refusing the application, or, as it is expressed in our present section 41, whether "he sees good reason to the contrary."

As it was pointed out by one of the witnesses this morning, this provision throws on the patentee opposing an application for a compulsory licence the burden of proving that good reasons for refusing it exist. We would expect that ordinarly the patent tribunal would make an order for the grant of a licence, or licences. It is almost, though not quite, as if patents relating to foods and medicines were licensable as of right.

Now, it should be mentioned that in the brief it referred to the one segment of the proposal to grant patents, but it did not refer at all to the continuing of compulsory licensing provisions.

I will read further:

> The question whether a provision for compulsory licences of substances and processes relating to foods and medicines should be enacted was argued at length before us. The arguments of those against such provisions have been fully considered. And while we realize that such a provision may have a tendency to encourage some manufacturers of pharmaceutical products to sit back and wait for research to be done by others with the comfortable feeling that if a new wonder drug, for example, is invented, they will be able to obtain compulsory licences for its manufacture—"to suck the blood" out of research by others, to use the language of an argument advanced in the British Drug Houses case (1954) 72 R.P.C. 2 as quoted on p. 10—we nevertheless think the weight of the argument is in favour of a system of compulsory licensing so far as foods and medicines are concerned. The absence of such a provision would enable patentees of new drugs and medicines to profit unduly from the suffering or ailments of others. Foods should be coupled with medicines mainly because it is in some cases hard to say whether the substance is a food or a medicine.

So much for the Ilsley Commission Report, Mr. Chairman.

One would think that a lot of compulsory licences would be granted but such is not the case. I have before me a letter written to me at my request by the Commissioner of Patents, dated September 22. It reads as follows:

> As you are aware the licensing provisions for medicines have been in the Patent Act since 1923. Up to 1949 no applications had been made. Since 1949 we have had 34 applications for licences on medicines.
>
> Fourteen were granted, 13 were abandoned or withdrawn, one was refused, six are pending.

Of the fourteen cases listed the time taken varied from 5½ months to 2½ years in order to get a particular licence. I mention that because the Ilsley Commission felt that these applications were taking too long a time and, in the interval, too much benefit was being obtained by the patentees.

Mr. Chairman, I will just sum this up as best I can, because the Committee, possibly, or even the witnesses today, of course, may wish to make some comments on it.

The CHAIRMAN: Thank you, Mr. Laidlaw.

Mr. MACKASEY: I am wondering if Mr. Laidlaw has had an opportunity of dovetailing this Ilsley Commission report with the Hilliard report. The two worked hand in hand, if I am not mistaken. On the basis of the Hilliard report—it seems that somebody could, under this clause of the Patent Act, take advantage of a product already on the market to enter into production. I think it was only the vigilance of a former member of Parliament—Mr. Jones—that it was pointed out that this firm, which had acquired these rights, was ill-prepared to manufacture these products, or, at least, that they would be violating the safety factor.

As a result of that Parliament set up what is known as the Hilliard Committee. The Hilliard report, which, I think, appeared in the back of the pharmaceutical brief, for those who have it, does deal with compulsory licences.

I am not trying to dispute what Mr. Laidlaw said. I am just trying to supplement it and point out that there is also another aspect to this thing, that because the patent law deals strictly with the law, in very cold terms, it seems to me that what we need in government is someone who sees the whole picture. The Hilliard Commission saw another aspect of compulsory licences, Mr. Chairman, and that was the safety of the people. In other words, to me, the paradox in the whole situation is that certainly any company could come along and take advantage of the patent laws of Canada and start production of a product that has proved successful on the market. Our law seemed very lax, certainly until the Hilliard report came down, in making sure that this firm applying for permission to produce the drugs had the necessary qualifications—the necessary standards—that the food and drug department insists upon.

Mr. Chairman, I think that one of the recommendations which has to come out of this is that all aspects of the Hilliard report be implemented as soon as possible.

The CHAIRMAN: Are there any other comments from members on this aspect of patents?

Mr. MACKASEY: Mr. Chairman, I would like to refer to page 59 of the brief which I think Mr. Laidlaw was asking us to do.

The CHAIRMAN: Page 59?

Mr. MACKASEY: It was written in layman's language and therefore I can read it.

Earlier, Mr. Chairman, the witness covered briefly, but thoroughly, I thought, the 12 points of the guiding principles of good corporate behaviour in Canada. I think you mentioned, sir, the degree of Cyanamid's exports around the world. Am I right in presuming that this is not from your pharmaceutical division?

Mr. STOVEL: Basically it is in organic chemicals, which are used sometimes as drug intermediates and in the agricultural field. There is very little in the drug field.

Mr. MACKASEY: The difficulty here, Mr. Chairman, is that all Cyanamid, as a general corporation, is certainly a wonderful asset to Canada. We know your record, and we know of the thousands of people who are employed and the millions of dollars you spend weekly. But basically we are interested in the pharmaceutical end of it. When you talk about exports, I am sure you do not want to leave the impression that these exports come out of the pharmaceutical end of your enterprise?

Mr. STOVEL: No; there was no intent on our part.

Mr. MACKASEY: No; I am sure of that. This is why I would like to refer to page 59, because you have outlined four very basic reasons for the existence of a patent system in any country. The first one, of course, is to stimulate an inventor to discover new and improved products; secondly, to induce the inventor to disclose these things; and, thirdly—and this interests me—"To create and maintain a climate which encourages individuals and commercial organizations to invest in research, development and production facilities, and at the same time providing a mechanism by which the successful inventor may recover his necessary and unavoidable costs."

I just throw this at you, that the pharmaceutical industry has not met this criterion; that their record of investment in research in Canada is pathetic. You can hide under the aspect that you are an international concern, or an international industry—I am not talking about Cyanamid in particular—but the fact still remains that the time has come for the pharmaceutical industry to start investing in research in Canada.

I question witness after witness and company after company and I find, with one exception, very little real research being done in Canada. There is a logical reason from an international aspect. You certainly have wonderful facilities in Pearl River and others in Switzerland and other countries, but what does that do for Canadian research? What does that do for the young man coming out of university? What does that do for research in Canadian universities? That is what interests me.

Mr. STOVEL: I would refer to this morning's statement that 2 per cent of our sales dollar is now being spent in research in Canada. A few years ago it was very little. I think—and here I give a different answer from what Mr. Laidlaw gave—anything that is done to strengthen the patent situation in Canada, strengthen the trade mark situation, will inevitably lead to more research by more companies.

Do not forget that over the whole country we do not spend anywhere near the amount of money on research that is spent in the United States. Therefore, so how can any individual company do this? I think we started from zero; we are up to a little over 2 per cent now; and this will continue to grow if the climate is right. But it may not be in our own buildings; it may be farmed out to universities.

Mr. MACKASEY: You said "If the climate is right". Would you care to give us a capsule summary of what you think is the right climate?

Mr. STOVEL: If the whole economic climate is encouraging to investment in secondary manufacturing, in all aspects, apart from patents.

Mr. MACKASEY: Do you feel that, other than patents, the atmosphere is not conducive?

Mr. STOVEL: We could not be investing as much in Canada as we are and saying it is a bad risk. We have a great belief in the future of Canada.

I think the things that make it difficult for a company to operate are things like patents, where they get whittled down. I think another factor in drug patents, which was not brought out this morning, is that 10 years ago it took two years to get a new drug application patented, and perhaps, on the market; now it probably takes seven years. Your length of patent is much less.

Mr. MACKASEY: Your first section refers to an incentive to stimulate an inventor to discover new and improved products. Has Cyanamid discovered any new products in the pharmaceutical field as the result of research in Canada?

Mr. J. A. BERTRAND *(Manager, Medical Products Department, Cyanamid of Canada Limited)*: We have one product, Mr. Mackasey, which was researched partly in Canada, and part of the research was farmed out to the United States. It was ultimately run through all phases of animal study and clinical trials and eventually marketed in Canada as a drug for use in the treatment of alcoholism, called Temposil by trade name in Canada and called Dypsan by trade name in most foreign countries. It is made completely in Canada for all of the markets of the world at the present time.

This is the only example that I can give you of pharmaceutical exports from Canada.

Mr. MACKASEY: I am sure this 2 per cent allocated to research and development in Canada rather than in the United States is an improvement, but what percentage of that, if any, is the result of compulsory clinical testing by law, as a result of the Food and Drugs Act? Does that fall in that category?

Mr. STOVEL: That does not fall in that category.

Mr. MACKASEY: In what category does it fall?

Mr. BERTRAND: I may have misunderstood you, Mr. Mackasey, but I am not aware that there are any specific regulations concerning the amount of clinical

investigation work that has to be done in Canada to support a new drug application. Was this your question?

Mr. MACKASEY: Yes.

Mr. BERTRAND: I am not aware of any specific regulations.

Mr. MACKASEY: Are all your tests done outside of the country before the application is made under the Food and Drugs Act? Do you do all your testing outside the country?

Mr. BERTRAND: At one time we certainly did.

Mr. MACKASEY: But now?

Mr. BERTRAND: Now we try to do more and more of it in Canada.

Mr. MACKASEY: What portion of it is done in Canada? Where is it allocated? Where is the dollar broken down on page 19? Is it under research and development?

Mr. BERTRAND: Yes, that it where it would be.

Mr. MACKASEY: Therefore, this 2 per cent is not research in the traditional sense? It also includes this type of tests that are needed?

Mr. BERTRAND: You mean you would not consider to be research the clinical investigation which is required to support a new drug application?

Mr. MACKASEY: I would if we want to split hairs, but it is not the type of research we are thinking about, and you know that as well as I do. I am talking about research for new products, particularly.

Mr. BERTRAND: I am sorry, I am not sure I do know what you mean by "research", if you define it in those terms. Is the research that you are talking about only the research that is conducted within the four walls of a research laboratory?

Mr. MACKASEY: That is the part I am primarily interested in, very definitely.

Mr. BERTRAND: I think you will find that that definition will not stand up in normal pharmaceutical usage. In other words, you have research that goes on inside a research laboratory. All of the research on a new drug product to bring it from a chemical compound to the market cannot be carried on within the walls of the pharmaceutical research laboratory.

Mr. MACKASEY: No; but theoretically this can all be done outside of Canada and then brought into the Food and Drug Directorate in Ottawa.

Mr. BERTRAND: Yes; that is theoretically correct. This is the point I am trying to make.

Mr. MACKASEY: Are you doing more of this in Canada and is this why your figure of 2 per cent is increasing?

Mr. BERTRAND: Yes; Mr. Stovel said, this is true.

Mr. MACKASEY: Are you doing any pure research in Canada?

Mr. BERTRAND: Your are speaking of pharmaceutical research?

Mr. MACKASEY: Yes. Similar, for instance, to your operation in Switzerland.

Mr. BERTRAND: I would have to say that by most standards we would not be doing pure pharmaceutical research in Canada.

Mr. STOVEL: I would like to comment on that. I do not think that anywhere in the world do we do the kind of research that we are doing in Switzerland. This is really moving out into a fundamental field, like a university. Whether or not it is going to pay off, nobody knows. It has been going about five years with no tangible results as yet.

Mr. MACKASEY: What I am really saying is that the research for new products, which your pharmaceutical industry, I presume, is always looking for—and I am not referring to a variation of a competitor—has to be done somewhere. It is not being done in Canada?

Mr. STOVEL: While we did not claim it in the competitive part of our general research, one of the derivatives of one of the chemicals we make is used in the drug field and we have done research in Canada on that chemical. We have not done the final research on the matter of compounds because we are not equipped to do it.

Mr. MACKASEY: Coming back indirectly to research, Mr. Chairman, how is the figure of 5 per cent for royalties determined? I know it must have the approval of the government but in looking at some of the balance sheets during lunch hour of some of the other companies I notice they do not have this category of royalties of 5 cents on the pharmaceutical dollar.

Mr. STOVEL: The system is very simple, really; during the life of the patent we pay 10 per cent and when the patent expires we pay nothing. It happens that ours, as of now, averages out to 5 per cent.

Mr. MACKASEY: During the life of a patent in Canada, for instance, you pay 10 per cent to the parent company?

Mr. STOVEL: Right.

Mr. MACKASEY: And after the patent expires you pay 5 per cent in the form of royalty?

Mr. STOVEL: We pay nothing, but there are other ones. This happens to work out as a numerical average between the nothing ones and the 10 per cent ones.

Mr. ORLIKOW: I may have misunderstood Mr. Mackasey, but surely the government of Canada or no government department has anything to say about that. Is that not an internal business arrangement between the Canadian company and—

Mr. STOVEL: The Department of Revenue looks quite strictly at these internal transactions of subsidiaries and parents.

Mr. MACKASEY: I was going to say it would attract them in matters of income tax.

Mr. Chairman, I am sure there are others who would like to ask questions here.

Mr. ISABELLE: Speaking about that 2 per cent that Mr. Mackasey put forward, do you mean in the existing situation that you will have to spend more than 2 per cent on research in Canada for building new laboratories and increasing research staff and medical staff?

Mr. STOVEL: I would like to be quite clear on that, as far as we see it in the immediate future—we do not know what the long term holds—and we have no plans and see no particular advantage to our Canadian company or to Canada in putting up a research facility on the drug end of our business. We think, following Mr. Winter's guideline, that international companies should achieve appropriate specialization of productive operations within the internationally federated group of companies. In our particular case we can do it more effectively by leaning on them. But I do think that if research incentive is continued or made firmer and if the patent laws are, shall we say, strengthened, we probably would do more of the research in Canada, although not necessarily in our own building.

Mr. ISABELLE: If you increase this existing 2 per cent for research in Canada, this would automatically increase the price of drugs.

Mr. HYMMEN: Mr. Chairman, I am sorry I was not here this morning but I had to attend another committee. However, I re-read the brief, which I think is excellent, and also glanced at a brief which is to be presented tomorrow dealing in greater detail with some of the problems involved in patents.

I do not entirely agree with Mr. Mackasey. I appreciate his concern about trying to establish research in Canada. I know you mentioned in your brief you have a thousand people working in your research headquarters in the United States. Whether 5 per cent of the cost is allocated to that operation or to the operation here, to me has not a great deal of bearing on the cost of drugs.

You mentioned the climate. Having read your brief and the one to be presented tomorrow, I think I know what you mean by the climate: the copiers type of operation that seems to have developed, where fly-by-night operations are gobbled up and regobbled up, and the whole situation is rather confused. If the climate—and I think I know what you are referring to—were such that you could develop research operations in Canada compared to our two populations as between Canada and the United States, you might have 100 or 200 research employees with a year on different teams and different lines of research than you could in the United States. Is that entirely possible in regard to relations between Canada and the United States?

Mr. STOVEL: You cannot factor our drug business between Canada and the United States on a population basis. There are perhaps more competitive companies in the field here than there are in the United States.

Mr. HYMMEN: I have another question, Mr. Chairman. There is reference in the brief to some problems in Italy which resulted because of the complete elimination of patents, and also there was a suggestion that some thought is being given to reintroducing patent legislation. Is there substantiation of that fact in relation to Italy?

Mr. F. W. PAPE (*Executive vice-president*): I do not have this in any direct way but certainly we have been led to believe that there is serious thought being given to it.

Mr. MacLEAN (*Queens*): With regard to the royalties of 5 per cent paid by your company to the parent company, I suppose that this is a standard pratice. Is this the same amount that is paid by all the subsidiary companies around the world? I realize this is an estimate to begin with but it is comparable? Are all subsidiary companies around the world treated exactly the same?

Mr. STOVEL: I think each company may have its own operating philosophy. We can only speak for Cyanamid of Canada and our parent relationship. You are going to meet a number of other companies and undoubtedly through them you will get a cross-section. I cannot speak for what they do.

Mr. MacLEAN (*Queens*): Perhaps my question was not clear. I meant subsidiaries of your company.

Mr. STOVEL: Of our company? Yes, they are all treated the same.

Mr. MacLEAN (*Queens*): The second part of my question, and you may not be in a position to answer, but can you give us any indication of the cost of basic research which is carried on by the parent company in the United States which is paid for out of this 5 per cent? For example, is it a profit from one stream or, in addition, does the parent company heavily subsidize the research, apart from the relief they get from that subsidiary company in royalties?

Mr. STOVEL: World-wide; the company's research runs to about 8 per cent of sales. They charged us 5 per cent of our sales so, in effect. I think Canada is getting a bit of a bargain.

Mr. ENNS: My question is related to the patents and yet I am not quite sure in what way. The statement in the brief relates to the patents and on page 62 they say that we support these recommendations of the Hilliard Committee, but we are completely opposed to the principle of compulsory licensing. I was under the impression that compulsory licensing would, in fact, add to the safety and be a control or be a protection to the consumer, and that drug manufacturers, whoever they may be, would at least have to conform to licensing and would have to apply to a licensing board. I am not sure just why you combine these two sentences in the same paragraph about patents and licensing.

Mr. BERTRAND: I think I can clarify that and I think you have raised some confusing issues about compulsory licensing in the Hilliard Committee report.

The compulsory licensing provisions of the Patent Act with respect to drugs, have been in existence for a very long time. The Hilliard Committee report was looking at what would happen when companies did acquire compulsory licences under these provisions, and the Hilliard Committee report deals fundamentally with what they consider to be extremely valid safeguards that should be built into the system, if compulsory licences are to be granted on drug products. Obviously, we support entirely what the Hilliard Committee said in effect that certain safeguards should be maintained before compulsory licences were issued for the manufacture of pharmaceuticals. However, that does not mean that we support the concept or the principle of compulsory licensing but as long as the principle is there, and as long as the provisions are in the Patent Act, we think the Hilliard Committee report contains some very important recommendations.

Mr. ENNS: I think under the present system, anyone, if he has the technical skill and knowledge and ability to manufacture drugs or chemicals, is able to do so without the government or anyone really knowing about it. The reason why I felt there was some support for the idea of compulsory licensing, is that there would have to be at least a divulging of every manufacture in the business.

Mr. BERTRAND: This is getting a little bit mixed up.

Mr. MACKASEY: Mr. Chairman, on a point of order, I think I can help Mr. Enns, because I fell in the same trap. The compulsory licensing that Mr. Bertrand refers to and the brief refers to, and the Hall Commission refers to is something independent from the recommendations we took of compulsory registration. Compulsory licensing, as we have discussed it refers to new firms coming into operation and having to acquire a licence to register, as I understand it this concerns the Patent Act.

The CHAIRMAN: Compulsory licensing means the allowing of other companies to manufacture a drug that is patented by another company.

Mr. ENNS: Yes, I can see we are speaking of two different aspects of licensing.

With such a disastrous experience in Italy, which is explained here and the very interesting appendix about the million dollar theft, there seems to be no move in that country to a return to patents. Is this correct?

Mr. BERTRAND: I do not believe it has happened yet, but there has been evidence submitted in the Pharmaceutical Manufacturers Association brief. We have not documented it exactly, but there is no question that there are strong moves in Italy to return to a patent system on pharmaceuticals.

I am not sure of this, but I think some of the companies who are appearing before you later on, are a little more familiar with the Italian situation and could spell it out in detail. We have been led to understand by all that has been written on the subject, that the Italian government is seriously considering reinstituting a patent system.

Mr. ORLIKOW: I would like to come back to the question of research and development in Canada. It is very obvious that Cyanamid, and it is not alone, feels that it suits them, it is more efficient and more profitable to concentrate their research organization in the United States.

I wonder if this company and all the drug companies should be giving consideration to the interests of this country. The whole slant of the Economic Council report emphasizes the need for more education and more training in Canada. And yet, for the last five years at least, Canada has been exporting at least 500 doctors a year and over 500 professors a year, if my memory serves me right. A substantial percentage of those professors are in the sciences and particularly in medical research. It is obvious, if medical research—a large percentage of which is done by the pharmaceutical companies which, because of being big business are highly profitable—can afford to hire the best, we are going to have a continual movement from Canada to the United States. It seems to me that it would be good for Canada and good for these companies and I am not suggesting that they duplicate the same kind of research or that they research the same products in Canada, as they do in the United States, but I suggest it would be good for Canada and good for the Canadian subsidiaries of

Cyanamid if they could convince their American parent that it is time to invest money in basic research in Canada. Whether it be done of premises owned by Cyanamid, or whether it be done in co-operation with independent organizations like the universities, really does not concern me too much. Mr. Chairman, I certainly think that this country has had enough of simply being the end product, the end of the line for international concerns which sell in this country and make a profit. I am not thinking of Cyanamid; I think all the drug companies have been very remiss in this respect. I just wonder if we can hope within the next couple of years there will be a much more substantial improvement than there has been up until now.

Mr. ISABELLE: Mr. Chairman, could I ask a question of Mr. Orlikow?

Did you say that 500 doctors go to the United States every year?

Mr. ORLIKOW: Yes.

Mr. ISABELLE: Medical doctors? Last year we produced only 806 graduates.

Mr. ORLIKOW: Well, Dr. Isabelle, the figures have been tabled by the government every year in answer to questions asked in the House of Commons.

Mr. ISABELLE: Last year 118 doctors went to the United States. This is what I saw.

Mr. ORLIKOW: The figure is 500 and, I will send you the answer to the question later.

The CHAIRMAN: I think Mr. Orlikow perhaps is also including biochemists and—

Mr. ORLIKOW: No, no 500 physicians, 500 engineers and 500 professors.

Mr. ISABELLE: I will send you the figures I have.

Mr. ORLIKOW: They are not my figures, they are figures which the government of Canada has provided. I wonder if this question has been discussed with your parent company?

Mr. STOVEL: You made an assumption that it was our parent company's unwillingness to do drug research in Canada. Up until now, it has been our position as local management that we can do a more sensible and a more effective job in Canada if we concentrate what efforts we can put in research in lines that are more uniquely connected with Canada's resource position. We have pushed for more research in other fields, but we have not pushed for more research in medical fields.

Mr. PAPE: Mr. Orlikow, if you fragment this type of drug research, it can very well get more expensive. It is no longer economical; it gets more expensive and hence by pushing ahead on this if it is not on an economical basis, the costs will go up and this will not be the right direction to get prices down.

Mr. ORLIKOW: I do not think the price of insulin was raised as a result of the fact that the initial research was done at the University of Toronto. I do not think that the price of drugs is being increased, for example, by virtue of the fact that the department of pharmacology at the University of Manitoba has been increased somewhere in the neighbourhood of 1,000 per cent in the last ten years. I think this is good for the country and good for basic research in the

field of medicine. If you have the impression that I said this was forced on you by your parent company, I certainly did not mean to give you that impression. I am not really interested where the decision is made. I just think the fact that we have virtually no basic research done by Canadian pharmaceutical companies, particularly the ones which are internationally owned, but it is done elsewhere, is bad for Canada. That is all I am suggesting and I express the hope that after you look at it, you will agree with me and try to get your parent company or whoever makes the decisions, to adopt a different policy.

Mr. BLAKELY: I wonder, Mr. Chairman, if we might return just for a moment to the question of royalties. I think, in reply to an earlier question concerning the basis on which the amount of the royalty payment is determined, the answer was 10 per cent of the sales value of those drugs for which there are patents. Is that correct?

Mr. STOVEL: That is my understanding.

Mr. BLAKELY: Yes. For those drugs on which you would have paid royalties, would any of the raw material or, for that matter, the finished product, have been purchased from the parent or a subsidiary company?

Mr. STOVEL: A large part of what we pay patents on is made in Canada exclusively.

Mr. BLAKELY: A large part of this? I would understand, then, that some of it would be purchased either in raw material form or as a finished product from the parent company.

Mr. BERTRAND: Most of the royalty that you have here applies to our tetracycline antibiotics. In this respect we are the only basic producers of tetracycline in Canada at Niagara Falls and Montreal. In respect of those, I cannot offhand think of a single thing that we import from the parent company. This is a licence which we have under their tetracycline patents in Canada. It is a licence to manufacture and sell, and the manufacturing licence carries with it the complete production "know how" and the on-going research in process development which they make available to us.

Mr. BLAKELY: Then you are saying that with respect to those drugs which you sell and on which you pay a royalty, a very small portion of them may have been imported either from a parent or subsidiary either in raw material form or in finished dosage?

Mr. BERTRAND: No, I do not think we are saying that. We are saying that when we have a licence under an American Cyanamid Canadian patent it is a licence to manufacture and market. Now, if we are not manufacturing we do not have the licence. I think what you are trying to find out is, do we pay a royalty on a particular product and at the same time import raw materials? My answer to that is categorically, no.

Mr. BLAKELY: I thought this was the question.

Mr. MACLEAN (*Queens*): I have a rather general question but I hope it might be helpful. There has been considerable discussion on the things which might bring about further research in Canada and make the pharmaceutical industry more self-supporting—if I could use that word—in Canada, or could assist in the further development of the pharmaceutical industry in Canada.

Perhaps if one of the witnesses could give us a brief history of the development of pharmaceutical industries in other countries—by that I mean over the last 50 years—it would give us some indication. It would seem to me that the pharmaceutical industry is not a compartment by itself; that it is not truly an industry of its own, and that it tends to develop in countries which have been well advanced in the chemical industry generally. I am thinking of the development in Germany of dyes and this sort of thing, and in the process there was a fallout—to use this horrible expression—which was beneficial to the pharmaceutical and drug industry. As a result of this the drug industry grew up as a subsidiary or as a sideline, if you like, of some other large chemical industry.

Are there cases where there are large pharmaceutical industries developed, as it were, in isolation or do these developments take place in every case in association with the chemical industry generally?

Mr. STOVEL: I do not know which of us had better try to answer that question.

I do not have enough personal background and enough years in the drug end of our business to make a very sensible appraisal on the back history of drugs. I came up through the chemical side of our business.

Mr. F. W. PAPE (*Executive Vice-President, Cyanamid of Canada Limited*): I think you have examples in any of the large pharmaceutical houses which have subsidiaries in Canada. That is what we are talking about. Take our own Lederle line, for example, which was a research oriented company with a patent system which has encouraged people to invest money in research; it was successful and grew. I think there are any number of these companies which operate in this same way. I think this is what I was trying to get across this morning; if Canada has the proper atmosphere to encourage people to invest money, some of these firms, whom we term "copiers" today, will be encouraged perhaps to do some research in Canada and they will grow as a pharmaceutical innovator.

Now, perhaps this is a little bit apart again from the approach that many of you have been asking of Cyanamid namely to fragment our research right now, which would be uneconomical and would raise the cost of drugs. I do not know whether I am making myself clear on this.

Mr. MACLEAN (*Queens*): You are a little beside the point I was trying to reach. Suppose Canada, for example, created the almost perfect climate for research in pharmaceuticals. I have a suspicion that that in itself would not be good enough; most of this research is on a sounder basis if it is associated with a general chemical industry and that you have to have the proper climate for a rapid development of the chemical processing industry on a wider front than just pharmaceuticals to obtain the optimum situation.

Mr. PAPE: I do not know the history of many of the other pharmaceutical houses in the United States but many of them were not allied with a large chemical interest. I can think of a number of them, but I do not know too much of their background. Many of them were strictly pharmaceutically oriented houses and they grew and were innovators in this field. Maybe I am still not answering the question.

Mr. MacLEAN (*Queens*): There is a highly developed general chemical industry in the United States which is probably advantageous to those companies.

Mr. PAPE: There is no doubt that if you are a widespread organization you have a whole host of talents which certainly help in this area. Each one of these starts small at some time or other.

Mr. MacLEAN (*Queens*): My other question—and this again may not be clear because it would be better put to the area—to the parent company, I suppose—where most of the research is done. There must be considerable cost involved in keeping abreast of developments all over the world in pharmaceutical research so that you are not doing research in a field that has already been covered or trying to develop a drug for a disease or situation that someone else has just found the answer to and this sort of thing.

Mr. PAPE: You are absolutely correct.

Mr. MacLEAN (*Queens*): Now, I presume that this is calculated in as part of the general research cost.

Mr. PAPE: This is another reason for the advantage of a central research location where you can have your information flow in. This is another important feature of patents, that information gets disseminated by people getting patents. The computer is in on it now. I do not know the statistics on the flow of new information which the scientists of today have to keep up with, but you are certainly right that this is an area that takes considerable time and energy. If you picture fragmenting this—it is hopelessly expensive already; but if you fragment it it will get worse.

Mr. MACKASEY: What you are really saying is that we should have done what we are trying to do today 20 years ago. Is that correct?

Mr. PAPE: Yes.

Mr. MACKASEY: We are rapidly becoming a satellite in this field of research. We are not doing anything, on the argument that it is better centralized in some other countries.

Mr. PAPE: Let us put it in another way. Mr. Stovel has said we are actually putting money into research in other areas of our endeavour.

Mr. MACKASEY: My questions, in all fairness to you, should be asked of the pharmaceutical manufacturers associations in general rather than to Cyanamid.

Mr. ISABELLE: Mr. Chairman, I would like to ask a question. With respect to this two per cent of research you are doing in Canada do you have any difficulties in finding biologists, bacteriologists, physicists and chemists?

Mr. BERTRAND: Dr. Isabelle, I think, perhaps, Dr. Gendron is in a better position to answer that question than any of the rest of us. He is struggling with clinical investigations and that type of thing all the time.

Dr. GENDRON: Yes. I think this is a point which we ought to look at. Tomorrow, if Cyanamid was organizing the most wonderful research laboratory, basic research, as Mr. Mackasey refers to it, where would we get the people?

Mr. MACKASEY: To work in the Canadian laboratory that Mr. Orlikow was referring to—

Dr. GENDRON: You see day after day in the Canadian newspapers—and I do not care which ones they are—pages requesting bacteriologists, physiologists, biochemists and so forth without even as much as an answer to it. I think that Canada, being such a young country, does not have the human possibility or the manpower to really do what is known as basic research. I think every one of us would like to. It is not just a matter of setting up a building and a lab and wonderful equipment which, as Mr. Pape says, would definitely tend to raise the price somewhere because somebody would have to pay for all this equipment. It would then have to be staffed. When I, as medical director of the company, and this applies to a number of other companies, I presume, want to set out clinical investigations, you do not think that I can just pick up the phone and call Dr. So and So and go and meet with him. It is terribly difficult at this stage of the game to get clinical investigations which is known as phase 4, not the basic research, sir, which you are referring to. It is difficult not because of their unwillingness to do so, by all means no, but they do not have the time to do so. All the practising physicians we know have more business than they can cope with and, I know, myself, if I now changed my habits and went back to my practising—I was approached a number of times by the pharmaceutical industry to do this so-called phase 4 clinical investigation. It means that they bring you a drug which is on the market; they would like to know a little more about it; they would like to know how the drug works and they would like to be certain of some of the indications. I had to turn down many of these gentlemen who would come to me and say: "Well, look, Claude, we would like you to do this." I do not have the time. I am sure I am not the only one. There was published not so long ago a list of what was known as available clinical investigators in Canada. When I mean available, these gentlemen are professors or practising physicians, and so forth. there was a list of about 75 people. Now, if you take 75 available people for investigations and send them out into the pharmaceutical industry, you will not have enough.

Mr. MACKASEY: Well, it is more or less a defeatist's attitude. What you are saying is that we cannot have more research until we get more people. Students do not go to university and say: "There is no use taking up the skill because when we graduate if we want to practise what we have learned we either go to the United States or we go to Europe". It is a question of the chicken and the egg.

Mr. Chairman, if I may get off that particular topic I would like to get back to my favourite and that is the federal sales tax. I get a different answer from every witness.

The CHAIRMAN: I thought Mr. Blakely answered that question for you last week. He is sitting beside you.

Mr. MACKASEY: I do not agree with his figures either.

Mr. Bertrand, in the Hall Commission Report they estimate the relationship between the price that the drug industry sells the product to the drugstore for and what we pick it up over the counter for is 219 per cent. In all fairness to the druggist, this includes a professional fee. I figure that this would at least, under the present circumstances, establish the relationship at 150 per cent.

Now, on page 71 you have a short column which states: "Price to Retailer, $3.57, Price to Hospital, $3.22". The difference, I presume, is the federal sales tax. Am I right.

Mr. BERTRAND: That is correct, Mr. Mackasey.

Mr. MACKASEY: Do you consider the retailer here the drugstore?

Mr. BERTRAND: Yes.

Mr. MACKASEY: Well, in other words, would you not agree with me that this tax is pyramided?

Mr. BERTRAND: Mr. Mackasey, I have heard many hours of testimony here, and I am going to avoid the trap by saying I will not agree or disagree. However, if you would like I will run through—and I think you have the right to ask the question of a manufacturer, particularly if the manufacturer has—

Mr. MACKASEY: Particularly, since in your brief you recommend we remove the tax, I raise the question.

Mr. BERTRAND: What I was going to say was that since we do have suggested list prices. Now, if you will allow me I will talk in terms of a product which we would sell. I want to straighten out the numbers. I could use these numbers and come to the same conclusion. If we have a product which would sell for 54 cents to the hospitals, when we sell that to a drugstore, that means the federal sales tax is now applicable—we would sell it at 60 cents. Now, that is a difference of six cents. Correct?

Mr. MACKASEY: That is right.

Mr. BERTRAND: The six cents, of course, we pay to the government. Now, if you are talking about the retail druggist who operates on a mark-up system, so that we do not get mixed up with this professional fee business—let us forget about the druggist and talk about our suggested list price in this case. In this particular case our suggested list price would be $1.00. Are you with me?

Mr. MACKASEY: Yes, I am with you.

Mr. BERTRAND: Fine. Now, let us suppose that there is an elimination of the federal sales tax on this particular drug. Our price, over night, to the retail druggist, would drop from 60 cents to 54 cents. If you apply the same mark-up relationship, that is going to be a suggested list price of 90 cents. You have saved six cents tax and are going to remove ten cents from the suggested list price.

Mr. MACKASEY: Exactly, but your figures conflict with the bible, as I call the Hall Commission. They have worked out a survey that the relationship between your 60 cents—it is easier to calculate than 54 cents—and what the consumer gets is 219 per cent, say 200 per cent. Therefore, if the Hall Commission is right, that 60 cents item which you sell to the drugstore, sells at $1.50. That is the 250 per cent actually that they got. Even at 200 per cent it sells many more times than you suggest at retail price.

Mr. BERTRAND: Mr. Mackasey, in this particular area, this was a difficult area because you are asking a manufacturer to comment on a flexible retail

price situation that involves not only a suggested list price, in some cases, but a professional fee; it involves all sorts of things. It is very difficult for us to do anything more than say to you, "here is what we would do on a suggested list price basis". The figures I am quoting you, we can back up with published data in our published price list.

Mr. MACKASEY: Have you ever sought to determine whether the druggists sell at your suggested retail price or not?

Mr. BERTRAND: I have too many problems to run around the country worrying about what he sells it at.

Mr. MACKASEY: That is fine. No one is asking you to but you have not. You could quite easily have said, "no, I have not". But the Hall Commission has and the Hall Commission tells us—and we are interested in costs here to the consumer, to the poor soul who buys from the drugstore—that, the relationship between the price that I go into the corner drugstore and buy that product at and the price you sell it to the drugstore is well over 100 per cent, not the 40 per cent.

Mr. BERTRAND: I am sorry. I do not know where the figures came from. I cannot comment on their survey. All I can tell you is what we do.

Mr. MACKASEY: You said the suggested retail price was 40 per cent and hoped the man would buy it at that price.

Mr. BERTRAND: I do not even hope. It is there for convenience. If he wants to follow it, that is fine. If he does not, that is his business.

Mr. ORLIKOW: Mr. Chairman, I do not think it is our job to defend either the manufacturers or the retailers, but if the manufacturing group did anything but suggest the government would be prosecuting them for violating the anti-trust laws. He may even be violating the law when he put that suggested price on. I do not know. I think if Mr. Mackasey has a complaint—and we all have complaints about the price of drugs—we should take it up with the people who sell them.

Mr. MACKASEY: My point, Mr. Chairman, is, I think, obvious to everyone here, that the federal sales tax plays a greater role than the straight 10 per cent that you mentioned. In the first place it would be a minimum of ten per cent, if they abided by your suggested retail price, which is less 40 off your price but the Hall Commission and other reports that we have indicates this is not the case. Even if you bring them down 100 per cent that doubles the effect of the federal sales tax. It means that we are paying closer to 20 per cent. In the final analysis, it seems to me the first area to bring cost of drugs down is to get rid of the federal sales tax.

Mr. BERTRAND: We certainly agree that that is a very good move.

Mr. MACKASEY: I do not want to injure the pharmaceutical—

Mr. BERTRAND: What I am concerned about, Mr. Mackasey, is getting all tangled up in mark-ups of percentages and mark-ups of dollars and guessing on what individual resale druggists are selling a particular product for. I am simply saying that on our suggested basis, taking an example where we now have six cents of federal sales tax built into the example, this would create a reduction in our suggested list price of 10 cents.

Mr. MACKASEY: I agree that the question would be better directed to the druggist. There are one or two questions here that I should like to ask in order.

The CHAIRMAN: Could I ask him a question? It is relevant to the same thing, really. We often hear the charge made that drug companies sell more cheaply to hospitals than they do to the average person. You say here on page 71 that the only difference between your price to the hospital and your price to the retailer is the federal sales tax?

Mr. BERTRAND: That is correct.

The CHAIRMAN: There is no special discounts for hospitals?

Mr. BERTRAND: No, sir, but let me say this, Dr. Harley. I would like to be very careful here because I could get a couple of letters tomorrow morning saying what you said is not quite true. We have quantity prices. In other words, the price per capsule in a bottle of 100 is less than the price per capsule in a bottle of 16.

The CHAIRMAN: Your retailer can get that same discount?

Mr. BERTRAND: The retailer can get the same discount on the same quantity.

The CHAIRMAN: Thank you. I am sorry, Mr. Mackasey.

Mr. MACKASEY: I presume that your company is a wholly owned subsidiary—I would like your comment on this statement from page 656 of the Hall Report: "A corporation operating a wholly owned subsidiary company will normally try to manage the affairs of both the parent and subsidiary so as to maximize profits. As a result, the price charged by a parent with a subsidiary in the drug industry may be an arranged price in the sense that it may not be the same price which the parent would charge an independent firm." Would you like to comment on that, Mr. Bertrand?

Mr. BERTRAND: I think Mr. Stovel might. I think in the case of prices between American Cyanamid and Cyanamid of Canada, these are prices that are either set on the basis of fair market values in the United States or in the event that there is not an established fair market value, they are set in accordance with a directive set up by your Department of National Revenue. I do not know how else to say it.

Mr. STOVEL: I think we can go a little further on this. As we have a big stake in the export-import fields, we as a company lean over backwards that we do not, in any way, violate dumping regulations or the special regulations that are set up to deal with subsidiaries so that, in effect, we are paying what the like customer is paying in the United States plus the normal tariff rate.

Mr. MACKASEY: I have one last question. You have answered the one on royalties. Just for the record, on the section under supervision, does this include the payment of any supervisory help outside the country at head office?

Mr. BLAKELY: Further to that last question, are there any management fees paid to parent or subsidiary?

Mr. STOVEL: No.

The CHAIRMAN: Could the Chairman ask another question? Do Cyanamid of Canada normally bid on government tenders for drug purchases?

Mr. BERTRAND: It is like carrying coals to Newcastle, but we do bid on government tenders. We do not do a very significant amount of government business. We do grant, in some cases, discounts based on quantity, and sometimes these quantities are higher than are normally in our published price list. You may see Cyanamid, under certain conditions, bidding with discounts of 15 per cent or 10 per cent off their standard price for one reason or another. Sometimes we bid the same price that we sell to hospitals, assuming the quantity is the same. We do not do any significant business with the government.

The CHAIRMAN: I smiled and I was going to ask you: Is that the reason?

Mr. BERTRAND: I think the reason comes back to the fact that there are a few copiers active in some of the areas that we are active in, and they usually have first crack at government business.

Mr. ORLIKOW: And often.

Mr. BERTRAND: Quite often; you are right.

The CHAIRMAN: Are there other questions for the witnesses? Has the Committee finished questioning the witnesses?

Mr. MACKASEY: If you would like, Mr. Chairman, we can open up another avenue.

The CHAIRMAN: It is up to the Committee, of course. It is ten to six. If there are no other questions we would like to thank Cyanamid of Canada Limited for coming and for presenting their brief. We should ask them what part of their dollar went to the preparation of their brief.

Mr. BERTRAND: That is homework.

The CHAIRMAN: I would like to thank you for coming and for bringing your colleagues with you and for answering the questions in the Committee.

APPENDIX "A"

KEY BUSINESS RATIOS IN CANADA

(Reproduced with permission from Dun & Bradstreet of Canada, Limited)

Retailing
Wholesaling
Manufacturing
Construction
Service
Transportation
Mining
Agriculture
Fishing
Forestry

KEY BUSINESS RATIOS

CANADA-CORPORATIONS

Line of Business (and number of concerns reporting)	Cost of Goods Sold — Per Cent	Gross Margin — Per Cent	Current Assets to Current Debt — Times	Profits on Sales — Per Cent	Profits on Tangible Net Worth — Per Cent	Sales to Tangible Net Worth — Times	Collection Period — Days	Sales to Inventory — Times	Fixed Assets to Tangible Net Worth — Per Cent	Current Debt to Tangible Net Worth — Per Cent	Total Debt to Tangible Net Worth — Per Cent
ALL COMPANIES—(113,641)	69.1	30.9	1.75	4.71	8.35	1.77	59	6.5	71.9	65.7	104.7
RETAIL TRADE —(17,759)	76.8	23.2	1.18	2.08	12.79	6.15	26	7.4	50.2	80.2	135.1
(1801) Automobile accessories, Tires, Service Stations	71.8	28.2	1.14	2.34	14.67	6.26	33	9.2	100.0	122.9	178.0
(2420) Clothing and Dry Goods	68.6	31.4	1.53	2.14	9.34	4.35	35	4.6	45.0	98.0	129.0
(434) Department and Variety Stores	67.9	32.1	2.18	3.36	14.75	4.39	35	6.1	49.7	56.1	129.6
(1180) Drug Stores	67.8	32.2	1.65	3.41	16.73	4.90	—	4.7	55.1	81.1	113.3
(1562) Food Stores	81.0	19.0	1.41	2.08	15.09	7.25	—	18.9	57.8	43.0	85.3
(514) Fuel Dealers	76.7	23.3	1.67	3.25	14.80	4.54	65	22.3	42.1	69.1	122.9
(2064) Furniture and Appliances	71.6	28.4	1.95	1.80	8.03	4.45	92	5.7	26.2	102.6	148.4
(1050) Hardware	73.2	26.8	2.06	1.35	4.73	3.49	46	3.6	34.6	74.3	116.6
(423) Jewelry Stores	56.9	43.1	1.97	4.45	14.33	3.22	75	3.1	35.7	89.7	142.0
(3328) Motor Vehicle Dealers	86.5	13.5	1.51	1.18	13.84	11.72	17	8.2	48.7	137.4	200.3
(763) Motor Vehicle Repairs	70.7	29.3	1.39	3.13	18.12	5.78	34	9.3	93.1	94.4	140.0
(404) Shoe Stores	65.6	34.4	1.61	2.14	10.74	5.01	—	3.1	57.5	114.0	163.5
WHOLESALE TRADE—(16,525)	82.8	17.2	1.82	1.75	8.56	4.88	42	7.8	46.4	70.2	119.1
(682) Clothing and Dry Goods	83.2	16.8	1.75	2.07	8.97	4.32	67	5.6	13.4	94.6	136.3
(501) Coal and Petroleum Products	66.4	33.6	1.84	1.25	1.82	1.45	57	7.9	67.2	23.8	54.2
(346) Drugs	80.4	19.6	1.79	2.23	12.77	5.71	42	6.7	26.4	89.2	116.7
(706) Electrical and Farm Machinery	79.0	21.0	2.28	2.80	13.86	4.93	63	6.6	20.8	76.1	143.1

(1710) Food Products	91.1	8.9	1.54	1.06	11.63	10.95	18	14.3	40.0	90.5	128.5
(620) Hardware, Plumbing and Heating Equipment	80.7	19.3	2.10	1.48	5.65	3.81	52	5.2	23.7	63.8	85.1
(329) Livestock and Grain	91.4	8.6	0.94	1.14	8.04	7.01	27	4.1	46.8	245.8	285.8
(2348) Lumber and Building Materials	80.9	19.1	1.90	2.16	8.15	3.77	63	6.3	39.3	69.9	103.8
(960) Motor Vehicles and Accessories	85.9	14.1	2.66	1.70	17.25	10.10	21	8.3	43.4	71.9	198.4
(1660) Machinery and Equipment	76.2	23.8	2.06	2.52	11.61	4.59	66	4.2	33.3	100.7	173.2
MANUFACTURING—(19,666)	73.7	26.3	2.39	6.06	12.47	2.06	42	5.2	67.1	29.5	75.5
(79) Agriculture Implements	77.4	22.6	2.37	3.88	5.84	1.50	64	4.1	22.0	26.9	59.4
(57) Aircraft and Parts	82.4	17.6	2.57	5.29	10.59	2.00	42	3.7	41.5	30.8	71.4
(97) Alcoholic Beverages	53.1	46.9	2.60	16.06	24.09	1.50	26	2.9	66.3	26.7	95.0
(476) Bakery Products	61.7	38.3	1.51	3.52	10.54	2.99	16	18.8	70.3	26.7	80.8
(110) Boat and Ship Building and Repairing	78.9	21.1	3.66	2.84	5.16	1.82	66	1.8	53.4	40.9	60.6
(182) Boilers and Fabricated Structural Metal	82.5	17.5	2.17	1.12	2.66	2.37	70	3.2	51.9	56.7	88.5
(211) Boots and Shoes	80.1	19.9	1.86	2.11	9.40	4.44	52	5.0	38.7	85.5	128.4
(808) Cement, Clay and Stone Products	64.4	35.6	1.76	7.95	14.22	1.79	58	7.5	94.8	36.0	88.7
(1271) Clothing—Men, Women, Children	78.6	21.4	1.78	2.01	9.86	4.90	61	5.2	23.5	102.9	127.3
(1022) (Commercial Printing	67.3	32.7	1.69	4.14	11.52	2.78	56	9.0	71.7	50.1	80.5
(75) Confectionery	66.6	33.4	2.12	5.20	10.56	2.03	41	4.9	71.8	33.2	68.0
(49) Cotton Goods	73.9	26.1	2.11	5.62	12.85	2.29	39	4.1	40.1	41.4	60.5
(720) Dairy Products	76.5	23.5	1.51	3.01	15.30	5.07	17	14.1	84.0	48.3	82.5
(139) Engraving, Stereotyping, etc	60.9	39.1	2.23	10.40	18.36	1.76	52	10.3	39.3	23.2	42.1
(121) Fertilizers and Industrial Chemicals	70.3	29.7	2.96	10.01	12.42	1.24	47	6.3	85.4	15.9	68.7
(92) Fish Products	81.2	18.8	1.39	3.06	12.01	3.92	25	5.3	108.8	75.5	138.2
(181) Fruit and Vegetable Canners and Preservers	75.1	24.9	1.75	3.93	9.66	2.46	25	2.9	62.4	60.5	97.2
(295) Fur Goods	75.4	24.6	1.53	0.48	2.36	4.83	80	3.4	29.1	170.9	210.2
(764) Furniture	75.1	24.9	1.64	2.67	9.84	3.68	63	5.4	47.3	86.4	112.6
(151) Glass and Non-Metallic Materials	72.0	28.0	3.20	7.09	13.29	1.87	48	5.2	70.2	23.1	74.4

KEY BUSINESS RATIOS (Continued)

CANADA-CORPORATIONS

Line of Business (and number of concerns reporting)	Cost of Goods Sold	Gross Margin	Current Assets to Current Debt	Profits on Sales	Profits on Tangible Net Worth	Sales to Tangible Net Worth	Collection Period	Sales to Inventory	Fixed Assets to Tangible Net Worth	Current Debt to Tangible Net Worth	Total Debt to Tangible Net Worth
	Per Cent	Per Cent	Times	Per Cent	Per Cent	Times	Days	Times	Per Cent	Per Cent	Per Cent
MANUFACTURING (*Continued*)											
(302) Grain Mill Products	84.0	16.0	1.85	1.60	7.25	4.54	36	8.3	44.4	55.6	91.0
(395) Hardware and Tools	69.2	30.8	2.79	8.13	19.86	2.44	47	3.7	53.1	39.2	88.5
(148) Heating Equipment Manufacturers	76.9	23.1	3.15	4.53	11.02	2.43	62	4.2	44.0	33.5	67.6
(191) Hosiery and Knit Goods	76.2	23.8	1.85	1.55	4.71	3.02	50	4.7	44.8	61.1	91.8
(155) Household Electrical Appliances	77.2	22.8	2.40	3.96	12.88	3.25	66	3.8	42.3	63.8	119.5
(222) Industrial Electrical and Communications Equipment	81.4	18.6	2.76	3.67	12.72	3.46	50	4.1	45.0	51.3	124.7
(220) Iron Foundries	82.7	17.3	3.56	3.48	7.12	2.04	48	4.7	54.5	23.3	74.1
(122) Iron and Steel Mills	75.4	24.6	3.14	8.45	10.73	1.27	49	4.2	79.2	17.1	55.8
(454) Machine Shops	73.5	26.5	2.14	4.84	13.23	2.73	54	6.1	48.3	47.1	66.4
(588) Machine Tools and Misc. Machinery	76.8	23.2	2.90	4.38	12.07	2.75	64	3.2	55.6	49.0	103.3
(227) Metal Smelting and Refining	74.7	25.3	3.28	4.00	5.59	1.40	34	3.6	163.4	17.1	167.6
(562) Metal Stamping, Pressing and Coating	79.6	20.4	2.22	4.74	13.37	2.82	48	5.9	65.0	42.5	81.2
(645) Metal Fabricating	73.6	26.4	2.05	3.72	9.99	2.68	56	4.9	77.5	52.0	104.7
(97) Motor Vehicles	83.2	16.8	2.10	9.56	32.38	3.38	18	8.6	46.9	32.5	62.7
(162) Motor Vehicle Parts and Accessories	78.5	21.5	2.21	9.76	23.26	2.38	31	5.2	35.7	33.8	61.5
(77) Office and Store Machinery	53.4	46.6	3.50	12.71	28.87	2.27	50	5.4	66.5	24.5	84.3
(147) Paints and Varnishes	63.8	36.2	3.22	4.14	10.80	2.60	53	4.4	38.8	32.0	65.7
(226) Paper Boxes and Bags	79.2	20.8	2.13	5.46	8.58	1.57	40	7.7	42.2	19.4	42.8
(55) Petroleum Refineries	66.8	33.2	2.84	4.66	4.84	1.04	54	5.8	75.2	13.1	51.5

(224) *Pharmaceutical Preparations*	49.1	50.9	3.85	8.89	21.93	2.47	56	5.3	53.3	25.6	79.0
(672) Plywood and Planing Mills	77.4	22.6	1.43	2.78	9.37	3.37	47	5.2	67.6	83.0	138.1
(930) Publishing and Printing	51.9	48.1	1.55	7.86	18.03	2.29	38	17.5	74.4	33.2	77.9
(68) Pulp and Paper Mills	70.4	29.6	3.08	13.98	13.53	0.97	25	4.3	62.1	11.5	49.4
(68) Rubber Products	74.8	25.2	3.22	3.76	9.03	2.40	58	4.0	52.7	31.5	71.2
(877) Sawmills	75.1	24.9	1.68	7.48	15.19	2.03	24	6.1	100.8	35.7	105.4
(259) Slaughtering and Meat Packing	84.8	15.2	1.75	1.36	13.95	10.26	14	17.9	56.7	56.5	76.3
(140) Soaps and Toilet Preparations	53.7	46.3	3.15	8.42	22.75	2.70	28	7.1	49.9	22.3	49.7
(342) Soft Drinks	44.5	55.5	1.57	8.81	19.87	2.26	25	8.4	82.3	35.0	55.9
(19) Tobacco and Tobacco Products	74.3	25.7	2.38	6.59	19.90	3.02	11	4.3	18.6	42.8	104.9
(88) Wire and Wire Products	75.2	24.8	3.07	8.12	16.43	2.02	37	4.2	47.2	25.6	45.0
(64) Woolen Goods	79.9	20.1	1.84	2.59	8.37	3.22	47	3.2	64.3	79.3	133.5
CONSTRUCTION—(12,716)	81.1	18.9	1.47	1.59	9.64	6.03	65	6.3	91.1	153.9	248.7
(6305) Building Construction	85.2	14.8	1.51	1.27	8.37	6.58	62	5.0	97.5	179.6	306.4
(567) Highway, Bridge and Street Construction	70.0	30.0	1.04	0.22	1.03	4.65	52	14.9	132.9	113.9	199.3
(5502) Special Trade Contractors	75.6	24.4	1.50	2.37	13.72	5.78	73	9.4	70.1	129.1	173.2
SERVICE—(13,481)	—	—	0.65	3.98	10.56	2.65	34	—	147.5	76.7	177.1
(318) Advertising	46.5	53.5	1.19	4.27	30.98	7.24	69	59.3	43.7	155.4	190.1
(814) Engineering and Scientific Services	—	—	1.65	7.05	20.84	2.95	75	—	29.2	63.7	96.0
(355) Funeral Directors	35.0	65.0	1.05	8.74	18.47	2.11	78	18.5	137.5	68.5	135.9
(2402) Hotels and Lodging Houses	—	—	0.27	4.53	12.07	2.66	10	—	269.6	99.5	222.2
(1179) Laundries, Cleaners and Pressers	—	—	0.53	2.19	8.55	3.89	20	—	167.2	88.2	148.9
(490) Motion Picture Theatres	—	—	0.86	4.35	5.49	1.26	21	—	69.2	23.9	71.1
(2178) Restaurants and Taverns	52.0	48.0	0.50	1.63	11.58	7.07	7	29.8	224.2	127.1	260.5

KEY BUSINESS RATIOS (Concluded)

CANADA-CORPORATIONS

Line of Business (and number of concerns reporting)	Cost of Goods Sold	Gross Margin	Current Assets to Current Debt	Profits on Sales	Profits on Tangible Net Worth	Sales to Tangible Net Worth	Collection Period	Sales to Inventory	Fixed Assets to Tangible Net Worth	Current Debt to Tangible Net Worth	Total Debt to Tangible Net Worth
	Per Cent	Per Cent	Times	Per Cent	Per Cent	Times	Days	Times	Per Cent	Per Cent	Per Cent
TRANSPORTATION, STORAGE AND UTILITIES—(5,009)	—	—	1.13	10.47	8.37	0.80	44	—	163.0	20.1	111.4
(281) Air Transport	—	—	0.84	1.40(L)	5.65(L)	4.01	42	—	197.5	117.7	249.1
(60) Bus Transport	—	—	0.44	9.80	20.00	2.04	12	—	101.2	64.7	183.5
(113) Electric Power	—	—	0.97	22.22	11.59	0.52	38	—	179.6	9.8	107.0
(65) Gas Distribution	49.4	50.6	0.98	7.50	6.05	0.81	69	11.9	202.5	23.9	159.6
(40) Grain Elevators	—	—	1.03	17.19	9.43	0.55	123	—	36.0	146.1	158.9
(50) Pipelines	29.1	70.9	0.66	13.06	12.51	0.96	49	30.5	335.9	35.0	310.0
(312) Radio and Television Broadcasting	—	—	0.74	5.76	17.09	2.96	61	—	176.9	103.7	210.2
(78) Railways	—	—	2.34	8.76	3.65	0.42	42	—	120.8	7.3	57.5
(202) Storage and Warehouse	—	—	0.55	4.89	6.17	1.26	52	—	151.3	45.9	131.7
(115) Telephones	—	—	1.96	24.09	12.06	0.50	43	—	168.9	6.4	88.6
(2317) Truck Transport	—	—	0.81	2.72	13.30	4.89	41	—	145.0	93.3	175.5
(382) Urban Transportation and Taxicabs	—	—	0.70	4.65	13.10	2.81	29	—	107.6	45.5	84.8
(414) Water Transport	—	—	1.02	0.63	1.04	1.63	33	—	115.7	36.9	120.7
MINING—(1,786)	27.9	72.1	1.56	6.97	4.79	0.69	40	5.6	74.4	19.0	77.6
(64) Coal Mines	67.9	32.1	2.80	0.12	0.14	1.20	41	5.3	87.2	17.0	52.3
(109) Gold Mining	5.8	94.2	2.93	7.40	2.92	0.40	24	11.2	18.6	5.7	7.5
(447) Oil and Natural Gas	19.5	80.5	1.20	3.92	3.00	0.76	66	12.7	155.3	24.0	237.3
(329) Quarries	49.0	51.0	0.78	3.72	10.66	2.86	58	13.7	176.1	105.1	196.3
(498) Prospecting and Contract Drilling	—	—	1.05	3.81	10.96	2.88	59	—	113.4	75.8	165.2

AGRICULTURE, FORESTRY AND FISHING—(2,695)	53.5	46.5	0.78	2.43	5.69	2.34	28	5.7	138.1	96.2	175.6
(1725) Agriculture	52.7	47.3	0.60	1.02	1.61	1.57	36	4.3	142.4	104.3	168.9
(146) Fishing	37.3	62.7	0.49	4.00	7.59	1.90	12	13.6	82.3	59.5	87.3
(1094) Forestry	55.2	44.8	1.20	3.41	12.98	3.81	24	7.1	137.1	85.7	198.9

— Not applicable.
(L) Loss.

HOW THE RATIOS ARE FIGURED—WHAT THEY MEAN

These ratios are based on an analysis of a composite sample of corporation income tax returns for the taxation year 1962 as compiled by the Canadian Department of National Revenue. These ratios are averages and include both profitable and unprofitable concerns.

Cost of goods sold

This includes the cost of inventory which has been sold or used, freight or transportation, customs duties, direct labor and factory overhead. Discounts on purchases are deducted. The ratio is a percentage of sales.

Gross margin

This ratio is derived by deducting the cost of goods sold from the sales figures. It answers the question "Is the markup on cost to selling price sufficient to show a profit?"

Current assets to current debt

Current Assets are divided by total Current Debt. Current Assets are the sum of cash, accounts receivable, inventories including supplies, and Government securities. Current Debt is the total of bank loans, accounts payable, tax liabilities and amounts due to shareholders. This ratio is one test of solvency.

Current year profits on sales

Obtained by dividing the profit declared by the companies, by total sales. This important yardstick in measuring profitability should be related to the ratio which follows.

Current year profits on tangible net worth

Tangible Net Worth is the equity of stockholders in the business, as obtained by *adding preferred and common stock plus surplus (less deficits) and then deducting intangibles.* The ratio is obtained by dividing Profits by Tangible Net Worth. The tendency is to look increasingly to this ratio as a final criterion of profitability. Generally, a relationship of at least 10% is regarded as a desirable objective for providing dividends plus funds for future growth.

Sales to tangible net worth

Sales are divided by Tangible Net Worth. This gives a measure of the relative turnover of invested capital.

Collection period

Annual sales are divided by 365 days to obtain average daily credit sales and then the average daily credit sales are divided into accounts receivable. This ratio is helpful in analyzing the collectability of receivables. Many feel the collection period should not exceed the net maturity indicated by selling terms by more than 10 to 15 days. When comparing the collection period of one concern with that of another, allowances should be made for possible variations in selling terms.

Sales to inventory

Dividing annual Sales by Inventories. This quotient does not yield an actual physical turnover. It provides a yardstick for comparing stock-to-sales ratios of one concern with another or with those for the industry.

Fixed assets to tangible net worth

Fixed Assets are divided by Tangible Net Worth. Fixed Assets represent depreciated book values of building, leasehold improvements, machinery, furniture, fixtures, tools, and other physical equipment, plus land. Ordinarily, this relationship should not exceed 100% for a manufacturer, and 75% for a wholesaler or retailer.

Current debt to tangible net worth

Derived by dividing Current Debt by Tangible Net Worth. Ordinarily, a business begins to pile up trouble when this relationship exceeds 80%.

Total debt to tangible net worth

Obtained by dividing total current debt plus mortgage and other funded debt by Tangible Net Worth. When this relationship exceeds 100%, the equity of creditors in the assets of the corporation exceeds that of owners.

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 11

THURSDAY, OCTOBER 20, 1966

WITNESSES:

Representing Hoffman-La Roche Limited: Mr. John S. Fralich, of Montreal, President; Mr. Robert Hunter, of London (England), Chartered Accountant, Director of Roche—England; Mr. C. A. Nowotny, of Montreal, Assistant Secretary; Mr. R. G. McClenahan, Solicitor, of Ottawa.

ROGER DUHAMEL, F.R.S.C.
QUEEN'S PRINTER AND CONTROLLER OF STATIONERY
OTTAWA, 1966

24878—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

Vice-Chairman: Mr. Patrick T. Asselin (*Richmond-Wolfe*)

and

Mr. Brand,
Mr. Clancy,
Mr. Côté (*Dorchester*),
Mr. Enns,
Mr. Howe (*Hamilton South*),
Mr. Howe (*Wellington-Huron*),
Mr. Hymmen,
Mr. Isabelle,
Mr. Johnston,
Mr. MacDonald (*Prince*),
Mr. Mackasey,
Mr. MacLean (*Queens*),
Mr. O'Keefe,
Mr. Orlikow,
Mr. Pascoe,
Mr. Prud'homme,
Mrs. Rideout,
Mr. Roxburgh,
Mr. Rynard,
Mr. Tardif,
Mr. Whelan,
Mr. Yanakis—24.

(Quorum 10)

Gabrielle Savard,
Clerk of the Committee.

MINUTES OF PROCEEDINGS

THURSDAY, October 20, 1966.

(18)

The Special Committee on Drug Costs and Prices met this day at 9.50 a.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout and Messrs. Harley, Hymmen, Isabelle, Johnston, Mackasey, MacLean (*Queens*), Tardif.

In attendance: Representing Hoffmann-La Roche Limited: Mr. John S. Fralich, of Montreal, President; Mr. Robert Hunter, of London (England), Chartered Accountant, Director of Roche—England; Mr. C. A. Nowotny, of Montreal, Assistant Secretary; Mr. R. G. McClenahan, Solicitor, of Ottawa.

Also in attendance: Messrs. W. J. Blakely of Kingston, Accountant for the Committee, and A. W. Laidlaw of Ottawa, Legal Counsel for the Committee.

The Chairman introduced Mr. Fralich who, in turn, introduced his associates.

Mr. Hunter made a preliminary statement and brought to the attention of the Committee corrections that should be made to pages 7 and 31 of the brief.

Messrs. Fralich, Hunter and Nowotny were questioned by the members and by Mr. Blakely.

Agreed,— That the Brief presented by Hoffmann-La Roche Limited be printed as part of today's proceedings, with the exception of Appendix IV being the Final Report of the Committee on Cost of Prescribing, of the Ministry of Health, London, England, called THE HINCHLIFFE REPORT. *(See Appendix "A")*

At 12.20 p.m. the Committee adjourned to 3.30 p.m. or after the Orders of the Day.

AFTERNOON SITTING

(19)

The Committee reconvened at 4.15, the Chairman, Mr. Harry C. Harley, presiding.

Members present: Messrs. Asselin (*Richmond-Wolfe*), Harley, Howe (*Wellington-Huron*), Hymmen, Isabelle, Johnston, Mackasey, MacLean (*Queens*), Tardif, Yanakis (10).

In attendance: Same as at morning sitting.

24878—1½

The Committee resumed consideration of the submission of Hoffmann-La Roche Limited.

At 4.20 p.m. the members were called to the House for a division and the Committee adjourned until 5.00 p.m.

The Committee reassembled at 5.00 p.m.

Mr. Laidlaw and the members asked further information respecting certain points of the brief.

Answers were supplied by Messrs. McClenahan, Nowotny, Hunter and Fralich.

At 6.20 the questioning being concluded, the Chairman thanked Hoffmann-La Roche and the officials of the Company for their presentation, and the Committee adjourned until 9.30 a.m. Tuesday, October 25.

Gabrielle Savard,
Clerk of the Committee.

EVIDENCE

(*Recorded by Electronic Apparatus*)

THURSDAY, October 20, 1966.

The CHAIRMAN: Ladies and gentleman, I think it would be reasonable to start the meeting at this time.

We have with us this morning the representatives from Hoffmann-La Roche Limited. I would like to introduce Mr. Fralich who is the president of the company and ask him to introduce the members of his delegation.

Mr. J. S. FRALICH (*President, Hoffman-La Roche Limited*): Mr. Chairman, and members of the committee, I have with me today on my immediate right, Mr. Robert Hunter, Chartered Accountant, who gave the key evidence for Roche, Canada in various compulsory licensing cases as to costs, prices and profits and which are referred to in our brief. He has largely supervised the submissions made to you in these respects in the brief and its supplements. He has been a director of Roche, England since 1943, and has played a leading part in the negotiations with the U. K. Ministry of Health about costs, prices and profits not only for Roche but for other Swiss drug businesses.

On his right is Mr. C. A. Nowotny, Assistant Secretary of our firm, to whom was assigned the task of preparing our brief and endeavouring to anticipate what you required.

Mr. Graham McClenahan of the legal firm of Gowling, MacTavish, Osborne and Henderson has represented Roche before the Courts in our various compulsory licensing cases referred to in the brief, and as such is qualified to answer questions in this area.

Mr. Hunter would now like to make a statement.

Mr. R. HUNTER (*Chartered Accountant, Director of Roche-England*): Mr. Chairman, Roche comes here and is really addressing itself to more than one audience and more than one interest. In the first place, it is addressing itself to the public interest which is represented by the members of the committee; in the second place, of course, it is concerned with another interest which is the private interest not only of Roche but also of the other members of the drug industry. Now, that sets some kind of dilemma because while we must answer every question which the Committee puts to us in the public interest, we must also have some regard to the private interest; so we thought we must not put too much information forward in public because we might appear to be trying to take the lead or appear too much on stage or even, perhaps, appear to be suggesting that we are holier than thou. Therefore, there was a dilemma about this.

The dilemma, of course, is not confined to Canada. It exists in the United Kingdom where, at the very moment, there is a committee called the Sainsbury

Committee, investigating these very same questions. The terms of reference of the Sainsbury Committee are practically the same, almost word for word, as the terms of reference of this Committee, although in the United Kingdom case it is not a parliamentary committee. Perhaps it would help if I just explained briefly the things the Sainsbury Committee are doing in this respect.

It has, first of all, asked every member of the industry to put in information for five years at least of its costs, prices, accounts and so forth. It is exactly the same questionnaire for every member of the industry and every member of the industry has put that in, just about a month ago. In addition to the people whom Lederle called the "innovators" the committee has also asked the "copiers" to give the same information. "Copiers" is the word used by Lederle.

Now, like this committee, Sainsbury needs to examine some of the members of the industry, and, similarly to this Committee, it has asked eight members of the industry to appear before it next month and the beginning of December. It has decided that the information that is provided in the questionnaires should be confidential. It is very detailed and they have decided to treat it as confidential. They have said specifically that if they have to refer to particular cases or particular arguments in their public reports, they will first consult with the members of the particular firm concerned before they publish the information.

This dilemma seemed to present itself to us in this case. So, we put in, so far as the figures were concerned, a somewhat shortened summary in the brief and we supplied a lot more detail to Dr. Harley and to Mr. Blakely, much like the information that we have been required to put before Sainsbury. Furthermore, of course, we are now going to be publicly examined on the facts and what we say about the facts. In Britain, we shall appear before the Sainsbury Committee on November 17, and in that appearance we shall be examined privately, so to speak, by the committee. That appearance will not be public.

So, this is the dilemma that we thought we had to solve. We tried to solve it by putting in, as I said, a shortened version of the brief and supplying Mr. Blakely and the Chairman with all the details to support what we have put briefly in the brief. Of course, it is very likely that in trying to do this, on the public appearances we may be appearing to say that the copiers do not provide much information, and on the public statement that we put in perhaps somebody could say that we are not providing very much ourselves. The point about that is that all the detail of the costs and prices of certain drugs and our total position was discussed in the courts. So, a lot of this information is really publicly available if anyone wants to look at it, somebody who would perhaps have the time and the patience to do so.

Of course, in this dilemma we understand that we may very well end, as is the common case, by trying to please everybody and, in fact, pleasing nobody. At any rate, we have tried in the more detailed confidential statement to give the facts. We also understand that in these circumstances we must answer fully every question about costs, prices and so on, that you may put to us. But we do think, as in Britain, that the actual confidential information that is being given and which, no doubt, will be made available to the members of the Committee, should not be printed in the proceedings. It seems to us that it would put us in a position that is not quite necessary.

• (10.00 a.m.)

Thank you very much, Mr. Chairman.

The CHAIRMAN: Are there any other comments to be made by Roche?

Mr. FRALICH: I do not have any.

Mr. HUNTER: Mr. Blakely, who has seen the information behind it, has pointed out to me that there was an error on page 7 of the brief where we say wrongly that the $7.5 million was provided from outside the group. Of course, he quite rightly pointed out that it is quite wrong because the schedule itself shows that $2.5 million were ploughed back profits which were not drawn from the company outside Canada, and so $5 million odd is what was actually being sent to this country to finance the business here.

There is also, I gather, a misstatement on page 31 of the brief, in the particular paragraph referring to the Hinchliffe Report. It should not be 258(ii), it should be 256.

Mr. TARDIF: Did you say on page 31?

Mr. HUNTER: Page 31, paragraph 48, the fifth line.

Mr. TARDIF: It should be 258 instead of 228?

Mr. HUNTER: It should be 256, not 258(ii).

The CHAIRMAN: Thank you very much. The meeting is now open for questions.

Mr. MACKASEY: I should like to quote from page 670 of the Hall Report and I would like the comments of Mr. Fralich who has the reputation of being honest and open. It says: "This state of affairs in Canada leads us to the conclusion that if the existence of patents on drugs contributes to a substantially higher level of drug prices than would exist in the absence of such patents, it is difficult to see with respect to the Canadian drug industry, that the patent system can be defended on the usual grounds that it is necessary to provide incentives for research."

Mr. FRALICH: What is your question?

Mr. MACKASEY: Do you agree with it? I presume you do not, and I would like to know why you do not.

Mr. FRALICH: No, I do not agree with it, as was brought out Tuesday. Research is an international thing in the drug industry as in many industries. If you do not provide the wherewithal for research by means of a patent, you do not have research.

Mr. MACKASEY: In other words, you do not agree that patents necessarily produce more research.

Mr. FRALICH: I think that without a patent you do not have research.

Mr. MACKASEY: In other words, you do agree that patents are conducive to research?

Mr. FRALICH: That is right.

Mr. MACKASEY: Do you do any research in Canada?

Mr. FRALICH: Not in the sense of a laboratory developing a new chemical which then has to go through the various stages.

Mr. MACKASEY: In other words, you share the same characteristics of most pharmaceutical industries, similar to Cyanamid?

Mr. FRALICH: That is correct.

Mr. MACKASEY: Mr. Fralich, can you visualize a situation in Canada where the position could be altered? What type of climate is needed in Canada to be conducive to the creation of research?

Mr. FRALICH: That is quite a question. Speaking for Roche, we do our research in three main centres, as I think appears in my testimony to the R.T.P.C., that is Switzerland, the United States and England. Research, in the sense of pure research, i.e. somebody developing a new chemical, has to be developed in a place that will generate the funds locally to support it. There have also to be the scientific disciplines available that will provide the background for that beyond your own internal facilities. I think, in this respect that Canada is, we might say, on the verge; our economy is growing. Contrary to that, as the Lederle people said, if you fragment research you run into tremendous communication problems and duplication of expense and as a businessman I realize that communication is probably the most difficult thing in business. Poor communications in research are practically catastrophic.

Mr. MACKASEY: Fundamentally and basically you do no research in Canada?

Mr. FRALICH: That is right, in the sense that we defined it.

Mr. MACKASEY: I am not trying to say it is right or wrong, but you do not do any?

Mr. FRALICH: No.

Mr. MACKASEY: In other words, I keep coming back to one of the arguments advanced by Cyanamid; there is no necessity to quibble on it but as a general principle that without patent protection there cannot be research, there should not be research. It is hardly logical to expect firms to set up research facilities in Canada if in their opinion the patent laws do not protect their end result.

Mr. FRALICH: That is correct.

Mr. MACKASEY: It is the little question of the chicken and the egg. You do not have any research so, to me, it is illogical to appeal on this ground, as Cyanamid did in their brief and as you do in your brief, that it is hurting the cause of increased research in Canada if you do not do any, anyway. You have to attack the patent laws from a different angle.

Mr. FRALICH: Could I say this, Mr. Mackasey? If, God forbid, any of us were suffering from cancer, I am sure that we would not want to be cured merely by a cancer compound that was discovered in Canada. So, why fragment research? Let me say this. If our company grows, and I hope it will, it is entirely possible that we will get into specialized areas of research when the wherewithal to pay for that is generated in Canada. Research is a long range thing. There is no use going into a million dollar project where you may have to spend, to make it easy should we say, $100,000 a year for ten years, if you

can only foresee the first $100,000, because you are just throwing that away if you stop it at the end of the first year. As I said, in spite of all modern science can do, it still takes nine months to have a baby—

Mr. MACKASEY: Thank God.

Mr. FRALICH: —and I think research is something similar in that it grows.

Mr. MACKASEY: I agree that once it is started it grows and you cannot control it. With respect to your analogy of the cancer victim, I could not help but think that a cancer victim in the United States would have no objection to a cancer cure discovered in Canada. It works two ways.

Mr. FRALICH: A cancer cure discovered anywhere.

Mr. MACKASEY: The point is that the chances of it being discovered in Canada are very remote because no research is going on here. I am interested in research because I think, hand in hand with increased research by the pharmaceutical industry would come increased employment, not only for people in research but in the actual manufacturing of products.

I am just trying to find out from you people some suggestion, which seems very hard to get from the industry, of the type of climate they would like to see in Canada, not just for selfish reasons but for Canadian reasons. As a Canadian I would like to see an industry that is already established in Canada grow and prosper.

I admire your brief because it is open and frank, but all the way through it, it attacks the patent laws of Canada for various logical reasons, from your point of view. I am just asking, and I am going to ask all firms when they come before us, what atmosphere they would like to see created in Canada from a selfish motive—from your motive—and what return can we, as Canadians, expect if that atmosphere were created. In other words, what would happen if we strengthened the patent laws other than give you more money?

• (10.10 a.m.)

Mr. FRALICH: Let us take the reverse of that coin and say if you do not strengthen the patent law, it is my personal opinion you will not develop research in Canada. This is based on history elsewhere. If you do strengthen the patent law you improve the climate a little bit for people to consider research in Canada.

Mr. MACKASEY: Well, Mr. Fralich, you mentioned you were nervous at the beginning but you are fielding the questions very well. You say: "improve the climate". You sound a little bit like Paul Martin. You said: "To improve the climate so that research could be considered." I want to know under what climate would research not only be considered but would be implemented.

Mr. TARDIF: Mr. Chairman, I think that question has been answered several times. I think the gentleman said that he needed a bigger market for that.

Mr. MACKASEY: Well, I have known the gentleman for a long time, Mr. Tardif, and he never needed someone to speak for him.

Mr. TARDIF: I do not think it is based on how long you have known the gentleman. I have listened to the same questions and the same answers ten times.

Mr. MACKASEY: When did you listen to it, Tuesday all day?

Mr. TARDIF: I have been listening to it right now.

Mr. MACKASEY: Mr. Chairman, you are running the meeting. Is my question out of order?

The CHAIRMAN: No, you can go ahead for a minute.

Mr. TARDIF: It is just repetitious; that is all.

Mr. MACKASEY: I am sorry if I bore you.

Mr. TARDIF: The feeling is mutual.

The CHAIRMAN: It is a different witness, Mr. Tardif.

Mr. TARDIF: I beg your pardon, Mr. Chairman.

Mr. FRALICH: I wish I could give you a definite yes or no answer. I hate to use this term but it is an "iffy" question and as a consequence, as a businessman, I have to give an "iffy" answer. I believe in doing more than I promise; therefore, I am not about to promise something I cannot deliver.

Mr. MACKASEY: Well, in other words, at the risk of offending anybody in the room, if we increase the capacity—

Mr. TARDIF: Tell me, because I would like to know.

Mrs. RIDEOUT: Paul, would you like to come over here and sit by me?

Mr. TARDIF: Not necessarily.

Mr. MACKASEY: Mr. Chairman, if we were to increase patents to give more protection as you ask for quite openly in your brief, we have no guarantee it would help the cause of research in Canada. We would create an atmosphere that would be favourable but in return you people would not come out and say: "Increase patents and we will increase research".

Mr. FRALICH: I see your point but I do not think it is a fair question. Perhaps my associate, Mr. Hunter, would care to make a comment because I seem to be going in circles and that is not my intention.

Mr. HUNTER: I think that the problem is really being discussed by this gentleman over here.

The problem is that the scale of research is so great that you have no hope actually of getting back the cost or making a really worth while discovery unless you spend a lot of money, in the first place; in the second place, you have to get it back from the world market.

You can see that very clearly from the experience in Britain. You will remember that penicillin was developed in Oxford during the war. I happen to know personally, my wife's cousin, one of the people on that team, and you will also remember that it was not patented. The result was that that team was completely broken up; they only got back into the penicillin thing ten years afterwards, with the product of Beecham's.

Now, in the meantime, there was a government sponsored movement to research into all kinds of things in the National Research Development Corporation and one of the things they developed about ten years ago was an antibiotic. Of course, they did not have all the facilities to get the product to the

point where it could be marketed and for that purpose they had to have the help of Glaxo in England—quite a large firm—and also a large American firm. Finally, it was marketed about a year or so ago, and the National Research Development Corporation granted exclusive licences under the Patent Act to Glaxo for a large part of the world and to the American house in the rest of the world.

It is quite clear from the statements of the Chairman of the National Research Development Corporation that they have no hope of getting back even their primary research costs unless those exclusive licences stand.

Of course, any country like Britain and, I think, Canada which itself embarks upon this research, whether it is by a private individual or by the State, clearly wants the Patent Act to recover his money. If he does not have that, I do not think either the State or the private individual will undertake the research. It is really as simple as that.

Mr. MACKASEY: Recover the money in the country where the discovery was made and the first patent was issued or recover the money in a world wide operation?

Mr. HUNTER: They have to, as you can see from the statements, recover it from the world wide operation. This is the point. It is not so much, as I see it, that you will say: "We will encourage research here"; it is rather looking at it the other way in that you will totally discourage it without a remedy of the Patent Act.

Mr. MACKASEY: Perhaps I am a little dense in that I cannot see how you can discourage something that does not exist. I think my ten minutes are up, Mr. Chairman.

Mrs. RIDEOUT: Mr. Chairman, I will be the first one to admit I have not come to indulge in any questions on the Patent Act, because I am here as a member of the Committee and as a consumer. I am interested in the cost of drugs and how we can resolve this dilemma. Possibly you would tell me if I am asking questions that are not pertinent to the brief.

I noticed your breakdown on costs and, of course, I could not expect you to have any breakdown on the cost to the retail pharmacist. You people represent one drug company and we have had various witnesses here from other drug companies. Is there competition in the price if you have a similar product? Can you go to the retail people and offer to sell your product for less than somebody else who has the same product? Is there any competition in price?

My point is this, as a consumer I do not have any idea when I have a prescription whose product I am getting. I do not know, as this is between the doctor and the druggist. So actually I really do not know whose product I am buying but is there any competition in prices to the druggist?

Mr. FRALICH: Well, first, a very minor point; when you go to a doctor and he gives you a prescription, I would say that is between you and the doctor.

Mrs. RIDEOUT: But I cannot read his writing so I do not know what he has prescribed.

The CHAIRMAN: Of course, it is something exceptional.

Mrs. RIDEOUT: I am sorry, Mr. Chairman.

Mr. FRALICH: As far as Roche is concerned we have no products to my knowledge that identically duplicate chemically another product on the market with the exception of the copiers, if you will pardon my saying so, who have legally stolen our industrial property by means of a compulsory licence.

• (10.20 a.m.)

Mrs. RIDEOUT: This is what I wondered about because I do think that the pharmacist is in a very difficult position because as you look at the shelves in a drug store it is fascinating. There are just thousands of bottles of pills and liquids and he has to keep so many of these products. I just wondered how on earth he could cut his prices when he is in the position that he must be able to fill the doctor's prescription.

Also I wanted to have an opportunity to ask a question of the Lederle people but I unfortunately had to be in the house. I think, Dr. Harley, you asked about bulk purchasing by hospitals. Of course, they are in a position to get a better price than the retail pharmacist. One thing that has concerned me for some time is this. I just look in my own medicine closet with all the various bottles, and take one every three hours or four hours. I do not know what the pills are. Is there any way in which you as manufacturers can sell to the retail pharmacist prescription size bottles, identifying what is in the bottle and the name of the drug? Is this possible?

Mr. FRALICH: I would like my associate to answer that, but first I would like to come back to one unfinished part of your first question.

I think if the doctors present will excuse me we should recognize that medicaments are not like house paint. If you paint a house red, it is red. Medicine is a fine science but an exact science. A drug that will help me may cause reactions in you, for the same conditions, so then the physician has to pick another drug in the same therapeutic category. When you speak of the numerous medicaments in a retail pharmacy, I think it would be well to keep this in mind. Life would be too simple, I think, because it would be reducing the human body to a machine, a computer if every time a certain indication turned up the doctor could press a button and a pill would come out and that would cure a hundred per cent of the people. Do you follow me?

Mrs. RIDEOUT: Yes, I understand.

Mr. FRALICH: With regard to your second question of identification of a product from the retail drugstore to the consumer, the patient, I would like Mr. Nowotny to comment on that.

Mr. NOWOTNY: Mrs. Rideout, your question is, can we as manufacturers sell our products in containers of a certain size which will permit the pharmacist to dispense the size as such. Was that the question?

Mrs. RIDEOUT: Yes.

Mr. NOWOTNY: That system, of course, is in use in many countries in Europe. We personally are in favour of it, because we think that this eliminates, in our opinion, any possibility of error on the pharmacists' level. Of what it does to the costs of the pharmacists, of course, I cannot speak. That is a question that you must address to the pharmacist. Whether this will make it less costly for him to operate, I do not know. I think you should ask that of the retail pharmacist, but certainly the system is in use in Europe. We think it is a good

system. The doctor knows what you are getting. The pharmacist knows exactly what he is giving to you, and, of course, you as a consumer know what is being given to you. Should an emergency arise, whatever physician has to step into the emergency, would immediately know what product you have taken. We certainly are in favour of that system.

Mrs. RIDEOUT: I was thinking purely on a cost basis because retail pharmacists must charge a service charge, I presume, for putting up prescriptions. I am just wondering who would be absorbing this extra cost, whether the manufacturer would be charging more to the pharmacist for putting the drugs up in smaller packages, or who is going to have to pay?

Mr. NOWOTNY: I do not think that on the manufacturers level this would make it more costly. In other words, I do not think it would increase our price necessarily.

Mrs. RIDEOUT: Then why is bulk buying so much cheaper?

Mr. NOWOTNY: I am sorry, I do not understand.

Mrs. RIDEOUT: Hospitals buy in bulk and it is a lot cheaper for them or so I would presume. I am not knowledgeable on this at all. I am asking for my own information. If you had to put these pills up in small packages it would certainly cost you more money then, would it not?

Mr. NOWOTNY: Yes, but not to any appreciable extent. When you speak about hospital buying, institutional buying or government buying, it is not only the bulk package which enters but of course the quantity. In other words, one druggist may purchase from a manufacturer a bottle of one hundred while a hospital may buy a hundred thousand tablets at a time, and that, of course, makes a difference, particularly in the distribution costs. In other words, you make one shipment rather than making a thousand shipments of one hundred tablets. That makes a difference, particularly in a country like Canada which is so vast.

The CHAIRMAN: I was going to say to Mrs. Rideout, as a practising physician, the labelling on a prescription is a doctor's prerogative. If the doctor wishes the product labelled with its proper name, the pharmacist does that under the doctor's direction. Often the medical profession do not want the patients to know what they are getting. Sometimes if you are given a prescription for a certain drug, you might go to a book and look up this drug and then when it says the drug is commonly used for six different diseases, you may assume that you have one disease that you do not have. This can be a great source of anxiety, so that right now the labelling is done at the doctor's discretion.

Mr. MACLEAN (*Queens*): I have a supplementary question to begin with and it is one that is no doubt generally known by many of the Committee, but as a layman I do not know the answer. When a doctor prescribes the same exact drug that is manufactured, for example, by your company and also by a copier, who has the choice to decide whether the patient uses the product of the original company or the copier's product? In other words, does the doctor specify the exact drug down to the detail of manufacturer, or is this an option that the pharmacist has?

Mr. NOWOTNY: If I may answer that, I think of course, the principle is, and I think Dr. Harley and Dr. Isabelle would confirm this, that when a doctor writes a prescription he expects the patient to receive exactly that medication which he has prescribed. He will mention the name of the product, possibly the name of the company, if that is necessary to further identify it. He expects that the patient will receive that medication from that pharmacist. I think the principle really is that the pharmacist must dispense the drug as prescribed. If for some reason or another he does not have that product, or for whatever reason he may have for not wanting to dispense that product he should get in touch with the physician and obtain his authorization to change the prescription and supply a substitute if I may use the term. But he should not do it without the physician's authority.

Mr. MACLEAN (*Queens*): This would, of course, apply to the substitution, one drug for a slightly different drug in the same category, but it also applies, I take it, to the actual brand of a drug which may be an exact chemical compound and the two products are identical but one is manufactured by a copier and the other by the originator. It seems to me that this puts a great deal of power in the hands of the doctor with relation to the selling of drugs as to whether they are manufactured by copiers or by the original innovators.

Mr. NOWOTNY: If I may again answer that. You say that this gives a lot of power to the physician. I do not think that the physician would consider this as a power but as an absolute must; may I say that. You say that one brand is the same as the other. I must disagree with you on that, with respect. I do not think that you can say that one brand is therapeutically exactly the same as the other. There are many, many factors which influence the drug. You must not be confused by the chemical substance or the active ingredient. The active ingredient may be the same but when it is put into dosage forms there are many factors which will influence the effect of the drug. There have been papers written on that. There was a paper published, I think some time ago. In the *American Pharmacist.* I think the authors listed about twenty-four factors which influence the therapeutic effect of a drug. Everything from potency to the inert substances which are used, of course in the compounding of the tablet; let us say the cornstarch may be of a different quality or something, or the hardness of the tablet, and all these things influence it, so you have no such thing as therapeutic equivalency as between two brands. I think if you would ask the Food and Drug department, they would confirm this to you. They would say there is no such thing. That is one point.

• (10.30 a.m.)

The second point is that when a doctor prescribes the drug, brand "A", which he knows, he has confidence in that brand "A"; that is why he prescribes it. He also knows his patient. If he would prescribe brand "B", or if the pharmacist substitutes brand "B", and I am not using the term substitution in any derogatory sense, if he does that, that patient may for some odd reason react differently to brand "B" than to brand "A". Dr. Isabelle and Dr. Harley I am sure can tell you that it is difficult enough to have to deal with the individual reactions of each individual patient, if you introduce then the factor of the different drug, of a different drug in the sense that they are not

therapeutically the same, you are running, of course, graver risks. That, I am quite sure the physicians do not want.

Mr. MACLEAN (*Queens*): This leads me to another question. It would seem to me that doctors and the medical profession generally become acquainted with drugs first when they are produced by the innovator of the drug. What is the process, in the case of a drug that has to be prescribed, by which the copier convinces doctors that their product is one that could be prescribed. They must sell them somewhere.

Mr. NOWOTNY: That is the $60,000 question. Perhaps again, a doctor would be in a much better position to answer than I because I am obviously not in the doctor's office when the copier walks in.

I imagine what he does is the following. He will say, "Doctor, do you know brand "A"? Well I have the same thing but it will cost you "x" many cents or dollars less." That is all that he says. He will use the information about the drug which we have provided, and will continue to provide to the doctor, and claim that he has an exact therapeutic copy of our drug. That is what he does. He may even go to the extent of copying the form, size, shape and colour of our pharmaceutical product. That is all, I think, that he does really. He does not service the drug, Mr. MacLean; he only refers to what the doctor knows about our product and says he has a copy of it, and that it will do the same thing but that it will cost less.

Mr. MACLEAN (*Queens*): I presume that the pharmacist who sells the drug has to keep stocks of both the copier's product and the innovator's product as soon as some doctors begin to prescribe the innovators' product. Is that right?

Mr. NOWOTNY: I imagine so. The question should be addressed really to the pharmacist, because that is one of the pharmacist's costs, that he should have in his drugstore, readily available, a supply of any of the products which the physician in his area will prescribe. That is his part of the service that he renders to the community.

Mr. MACLEAN (*Queens*): It would seem to me, perhaps you will not agree, that if the patent rights were more stringent you would eliminate the costs of (a) the copier merchandising his drug by going to very considerable cost of convincing doctors that it is equal to the innovator's product; and, conversely, (b) the expense that the innovator must have to go to to retain his market for the drug. He has certainly, I would think, to keep up a steady barrage of counter propaganda, if you like, to the medical profession trying to persuade them that the original product is more meritorious than the copied one.

Mr. NOWOTNY: You are speaking now of our costs or the cost—

Mr. MACLEAN (*Queens*): I am speaking of the cost of providing drugs generally, the over-all costs.

Mr. NOWOTNY: Yes, I think you are right. Yes, in principle you are right.

The CHAIRMAN: Mr. MacLean, as a member of the medical profession, I wondered if I might make one point.

It depends on how the doctor writes his prescription. Sometimes the doctor does not really come into this area at all. It is very simple. If I, as a doctor, write for a certain brand of penicillin, the druggist by law in most of the

provinces has no alternative but to supply that drug. This is not true in Alberta, I think, where they have the power to substitute legally. But if I, as a doctor, write "penicillin 500,000 units; tablets 12", the pharmacist can really fill that prescription from any brand of penicillin that he wishes, and this is true really of any drug. In other words, if I, as a doctor, write the generic name or the chemical name for a drug, the pharmacist had the power to fill any of those prescriptions by whatever brand he wishes, provided that it is exactly what I ordered in that name, and the prices here vary a great deal.

Mr. MACLEAN (*Queens*): Well, I think the witness said a little while ago that these things are never exactly the same.

The CHAIRMAN: No, but chemically they might be. Their chemical formula might well be the same.

Mr. MACLEAN (*Queens*): Yes, I realize that.

The CHAIRMAN: I am not saying that their activity would be the same but their chemical formula is identical. Is this correct?

Mr. NOWOTNY: Yes. That was my statement.

Mr. MACLEAN (*Queens*): I wanted to revert for a minute or two to the line of discussion that we were having prior to this, in discussing the problems of research and patent protection.

It would seem to me that there are two problems that were being discussed as one, or at least, two facets of the same problem. It seems to me that first there is the question of stimulating research, and that most important breakthroughs in pharmaceutical developments are done by companies which are dependent on a world market. They must be protected in the entire world market, or in as much of it as possible, for them to have the required stimulation. It seems to me that is one problem.

Then if I followed the discussion properly I think there is a subsidiary problem which is an economic one chiefly, as to where or in what country the research should be done. I believe that if Canadians are paying "x" amount of money more for drugs because they are patented, even if there is no research done in Canada, but research is stimulated somewhere else in the world, on account of that, Canadians, as patients, receive a great benefit from the result of this continuing research, regardless of whether it is in the United States, Canada or Switzerland. This is a world advance in the treatment of disease. Have I followed the discussion properly?

Mr. FRALICH: I agree completely with what you say, yes.

Mr. ISABELLE: First of all I should make a little comment about research personally, being a practising physician. I do not care where research is carried on. I do not care whether it is Canadian or whether it comes from France, or England. I do not care at all. What counts is the result of research.

To me research in Canada is about the same as poetry or literature; we are in our infancy. We are in our childhood so we cannot produce what the adults can produce. This is only a small comment I wished to make on this topic.

I have another topic which I would like to take up and ask, a few questions which I believe may be of great importance to the pharmaceutical industry. As I said before, we have two pharmaceutical industries in Canada. We have the

reliable companies and we have what I would call the racketeers, or the small companies or the copiers, which is a more polite word for it. I will ask a few questions here.

• (10.40 a.m.)

I am going to take as an example, your company. You discovered a drug which in my opinion, is one of the best medications that has ever been discovered in the world called chlorodiazepoxide as the generic name or librium, known the world over and which is one of the best products, I think, as a tranquillizer. You brought that on to the market about 1960, if I am right. Now less than five years later, this drug is still looked upon in Canada as a new drug; but after four or five years under our law it becomes what we call an old drug, so that means that anybody could copy this without having gone into years and years of expensive research. Here they take the whole drug and produce a replica of the same thing and put it on the market, take your literature and work up a big business without having even sometimes an office, just a telephone on a desk somewhere, and make the same money as you are making now without having to invest as much money as you did. Do you think if this law could be amended, or if this five years of protection could be made ten years, I would say—I am not a legal man; perhaps it should be taken up with a legal authority later on—do you think that you could lower the cost of librium, after ten years, by half or even after five years, by half? This is what counts for the public, I think, because it is the consumer in whom we are interested. We are here to represent them.

The second question is this. How much does it cost your company in dollars to protect your company as innovators of certain products? Let us take an example. How much does it cost you roughly to protect yourself against copiers before the five years are up in the case of a new drug? Maybe you could tell us also the story about the drug, Rimifon, which has been discovered by your company and which today is selling away below what is supposed to be the normal price. I think it would be a good thing to brief the Committee on Rimifon because this thing to me is a scandal.

I have another question here. I put a question on the order paper the other day, and all I am interested in is lowering the cost of drugs if it can be done, and if it can be done, how should we proceed?

You have been in court often with copiers. I have seen your name many times in the newspaper, but one thing strikes me. I saw about a year ago I think, in the paper that you were prosecuting Barlowe-Côté Laboratory in Quebec city because they had forgotten to label properly a copy which is the sulpha—or a copy of this, and this is an explanation I wish to have on this last question. What do you think our law is for, to protect your racketeers or to protect intelligent, important, serious companies?

The CHAIRMAN: These are biased questions.

Mr. ISABELLE: Another point, if I may; I know this is true but I want you to tell everyone. Despite all we have said on important companies, do you have a service for indigent people, those who cannot afford capsules, let us say, of librium, or any other drug you have as a specialty? Do you provide them free of charge, if the doctor realizes that he has one patient who is indigent? Do you

have a service if a doctor sends you a prescription? Do you have a service for those people, in Canada, free of charge.

Mr. FRALICH: Dr. Isabelle your first questions were in a legal area that I would like my associate, Mr. Nowotny to answer. With regard to your last item, our company has what we call the indigent patient program that covers eight or nine different drugs at the moment under which we will supply a physician, free of charge, medication for the physician's indigent patient or patients that the physician is treating without charge. We feel that if the physician makes this contribution, and we know many physicians do, we could make the other contribution. That was the program you had in mind, was it Dr. Isabelle?

Mr. Nowotny, do you wish to carry on with the other items since they are all in the legal area?

Mr. NOWOTNY: Yes. I will take your questions, starting backwards. You were referring to Barlowe-Côté which is being operated by one J. Harry van Ular in Cap Rouge, and you were referring to the mislabelling of a product. The situation arose where we had to take court action against this person in respect of one of our drugs for patent infringement. In settling this case, we also asked Harry van Ular to agree not to sell another one of our products which he had been selling, namely, the product called sulfadimethoxine generically, or "Madribon" under the brand name. About a year later, we found that Harry van Ular was still selling the product sulfadimethoxine so we wrote him and asked for explanations. He replied, and the Food and Drug were, of course, advised of all this, that he had made an error; that the product in the bottle or bottles he was selling was not sulfadimethoxine but sulfamethoxypyridiazine which is a completely different product. This product is known under the name of "Kynex". He said this had been a simple error in his own, well, in what I suppose Dr. Isabelle would call, his own garage. That was one instance. We have had many other areas of conflict with Mr. Harry van Ular; for instance, in respect of our product Chlordiazepoxide known under the trade mark "Librium". Again we had to take action against him for a patent infringement. The Food and Drug Directorate also entered the picture because "Librium" at that time was still a new drug under the Food and Drugs Act and its regulations. There was a judgment against Harry van Ular ordering him to cease and desist from further infringing our patent. He, however, continued selling that product. We were obliged to take contempt of court proceedings against Harry van Ular. In these contempt of court proceedings it was found that the product which he was selling, which was in tablet form at this time and supposedly containing ten milligrams of chlordiazepoxide actually contained less than one milligram of chlordiazepoxide. I think that Food and Drug probably could tell you more about him than anyone else. We will not go into this further but it is all a matter of court records, so I am not saying anything which is not known.

• (10.50 a.m.)

On the question of "rimifon," this is, of course, referred to in appendix nine on page two. That was a drug which, under the patent laws of Canada, could not be patented. On Tuesday Mr. Laidlaw explained the difference between the United States and the Canadian patent law. Consequently we had, within a very short time, a considerable number of copiers in this field which depressed the

price to a level which is absolutely extraordinary. Rimifon or isoniazid, as it is known, was being marketed by us in tablet form as well as in injectable form. None of the copiers, of course, was interested in the injectable form because it does not sell enough and, secondly, it requires a little bit more care in producing it. Today, the copiers are no longer interested and one after the other have dropped out of the isoniazid market because the price has been depressed too far. I do not know whether this answers your question on "Rimifon"?

Mr. MACLEAN (*Queens*): You did not say what it was used for?

Mr. NOWOTNY: Isoniazid is, of course, used in the treatment of tuberculosis.

Mr. MACLEAN (*Queens*): I have a question in this field which may have already been answered somewhere in the course of the sittings of the Committee. I am a new member on the Committee. When an innovator develops a new drug and puts it on the market, is there any general guidelines with regard to patent law in most countries in respect of the length of time free to him when he must try to recoup his research costs or a fair amount of them? In other words, what is the period of time when there is some element of the cost of a new drug going towards defraying the cost of developing it. At what time does it become purely a production problem so far as costs are concerned?

Mr. HUNTER: I think it would be extremely difficult to say at what point of time you really recover your research costs. This has been debated many times and I think you will find, for instance, in one of the paragraphs of Hinchliffe, which went into this question quite deeply, there was no real answer to this problem except somehow to allow people, who indulge in the long frustration of pharmaceutical research, to recover their current costs out of their current sales. Nobody has yet, at least in my experience, been able to arrive at a formula whereby you can say you ought to recover your cost within a certain number of years. The point which you make, I think, is generally accepted. For instance, in the United Kingdom, under the Voluntary Price Regulation Scheme which is referred to in the Hall Report, one of the provisions is that the innovator or the patentee is completely free to fix his own price without any question from the Ministry of Health whatever for four years. That does not mean that he is going to, afterwards, have his price chopped down to nothing but it is in fact a recognition of the sort of point that I think you are putting Nobody would agree that four years is the right period for complete freedom. You could have other periods of years. This is just a compromise. Of course, nobody would then, even agreeing to that, have solved the other problem as to what should be the price after that period, so it really is a very difficult question to answer.

Mr. MACLEAN (*Queens*): What I am trying to get at is this. I think in some cases there is a fear in the mind of the public that if patent laws are too stringent sometimes a company comes up with some new, very effective drug which may be cheap to manufacture and they will then be in a position to go on forever charging an exorbitant price for this drug and make a killing, as it were, ad infinitum. I would just like your comments on this. I do not agree with this point of view but I think some people hold it.

Mr. HUNTER: Of course, that is a general charge made against the industry that the industry is trying everywhere to answer. You will see that in this brief

it has been suggested that the price of one particular drug cannot really be determined without association with all the other drugs of this particular firm. Every drug firm makes profits on some lines and not very good profits on the others. This is why, as I said, Hinchliffe said that probably the profits must be such over the whole field of manufacturers' drugs to enable him to carry on with his research. So, we have stressed it in this brief. All we could do was to say this. There are, of course, other ways of doing this. But one of the things we said was that the Ministry of Health in Britain has been looking at this problem ever since 1950. It is in the general context, I think, of Canada which has compulsory licenses and which has this kind of inquiry into drug prices. As I said, it is exactly the same, so far as I can see, as this inquiry, the same problem approached in the same way. What I think you can say is, quite clearly, that the Ministry of Health has concluded, after this long time of struggling with the problem, that the only way is really to have some supervision of the profits of drug firms so as to prevent the public from imagining that it makes fantastic profits, and that really every debate that there is about drug prices, is in the long run—sometimes in the very short run—a debate about profits, not about prices. It is incredibly difficult to price a drug in the sense that most people think, because the content of the variable cost in the drug is so low. What is important is how you recover your research costs, how you cover your cost of detailing, and so on, which is a kind of fixed charge. And therefore almost invariably, I think, you can find in every debate, in every discussion of this problem, people really judge the industry, not as it says on its prices, but really, from Kefauver onward, they are asking, are the profits too high? And so far as I know that is the only test that one can ever realistically make of drug prices—are the drug manufacturers earning too much money to cover their legitimate current costs including research, to enable them to go on, to finance expansion, and so forth.

• (11.00 a.m.)

Mr. MacLEAN (*Queens*): I would like to raise as an example headache tablets. I know it is not a prescribed drug but I think the general public often think the principle is the same. You can go into a drug store and pay 18 cents for twelve if it bears a brand name, whereas you can buy almost a pint what is said to be exactly the same thing, although perhaps our previous witness would not agree with me, for a few cents, or for a very much lower price. Now, in a situation of this sort is the manufacturer of the brand name able to charge his extra price as the result of brand name advertising only, or is it because of some patent right? Now, this is outside of the field, but I think it may have some bearing.

Mr. FRALICH: I think, sir, what you are probably referring to is aspirin.

Mr. MacLEAN (*Queens*): Yes, as an example. I pick it as an illustration.

Mr. FRALICH: We at Roche are not in this field, so I am speaking from hearsay, not from experience. I think, under the circumstances, the best answer I can give you is what Dr. Morrell said when he was head of Food and Drugs, that when you buy medicaments of this nature you depend on the reputation of the manufacturer. The manufacturer puts his name on a product, not only for identification—his trade mark, if you will—but also he is risking his reputation thereby, and his reputation is the only thing that determines whether he is in

business next month or next year if something goes wrong. You might also say you can buy a pair of shoes, perhaps, for six dollars of for sixty dollars—you take your choice, the difference being, of course, if the shoes hurt your feet that is uncomfortable but they are not too bad; if the medicament gets in your system and causes damage, that is bad. Have I given you two parallels that help you understand this problem?

Mr. MACLEAN (*Queens*): I think so, but the point I am getting at is that a lot of people, when they discover that they can buy aspirins, or what they are told is exactly the same thing, for a fraction of the cost, they think they have been made suckers of in some way, and this creates a bad image for the drug business generally. I think a lot of people perhaps still buy the brand name out of choice, but there are a lot of people who think they have been fooled for a long period of their lives, not knowing that the same drug was available much cheaper from some other source. There is a kind of feeling that there is something unethical about it somewhere, and I think this creates a bad image. I do not want to pursue this.

Mr. HUNTER: Yes, that of course, is one of the dilemmas of the drug industry, and of course you will find these great differences are usually in such things as aspirin, for example. But the point is, of course, that none of those kind of products have the volume money-wise and so on really to enable the industry to go on with what it does; the whole heart of the problem really lies in, for example, whether you allow compulsory licences or not, which is your other question as to how long you are going to be free reasonably free to earn sufficient profit to enable you to carry on. It would not be in respect of such things as aspirin.

The CHAIRMAN: I would like to revert and have Mr. Nowotny answer Dr. Isabelle's one question.

Mr. NOWOTNY: I think, in fact, there were two questions. I will deal with his second question first. If I understood Dr. Isabelle correctly the question was, how much money did we spend to protect ourselves against the copiers before the five-year period? When we talk about a five-year period I want to be sure that I understood correctly. He was referring to the Food and Drugs Directorate's practice of considering a drug as new under the Food and Drugs Act and its regulations for approximately that period of time—it is really not quite that exact—and afterwards classifying the drug, if I may use the term, as an old drug. That is a very difficult question to answer. Certainly, in the case of one of our products, which is cholordiazepoxide, we had, within a very short period of time, two types of attacks. One was clear-cut patent infringement, including passing off—by "passing off" I mean copying even the shape, size and colour of our dosage form, tablets or capsules; and secondly, of course, we had the compulsory licence application. The first compulsory licence application was filed within about fourteen months of the day the patent issued, or not quite two years from the time we introduced it. The costs, of course, are considerable when defending our proprietary rights. Perhaps the best way to explain it is that from that time on I had to spend most of my time on that particular matter. I cannot give you exact figures, but it runs into tens of thousands of dollars.

Now, your first question was if this five-year period were extended, let us say, to ten would this help, and would this permit us to decrease our prices?

This is very difficult to answer, I think, because it is not so much the five- or ten-year period—and I repeat it is not exactly that; there is an official here from the Food and Drug Directorate and I am sure he will agree with me when I say that the Food and Drugs Act is in this respect quite specific. Perhaps I can read the section and then you will understand it better: It says in Section C.08.001 of the Regulations:

> For the purposes of the Act and this Division, "New Drug" means
>
> (a) a drug that contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating, excipient, menstruum or other component, that has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug;

You are dealing here in terms of "sufficient time" and "sufficient quantity", what is sufficient and what is not sufficient, and I am quite sure Food and Drug will agree with me that this depends entirely on the drug. There are many drugs, as is well known, where there have been no problems, no serious new problems, side-effects and so on, in the first five years, and problems suddenly develop in the second five years, or even after 10 years.

• (11.10 a.m.)

I do not think that is anything which can be specifically set down at five or 10 years, and I do not think that that would affect our price so much. We do all this research; we have all this constant watch on our products, this constant calling on physicians like Dr. Isabelle to get his opinion and his experience of our drugs, whether or not the Food and Drug regulations are there; we have to do it. We would not be in business if we did not do it.

What affects the price of drugs would be the patents. I think Mr. Mackasey asked the question: If patents are strengthened in Canada, will this increase or decrease the price? If patents are abolished, or if the patent laws are left as they are, then, of course, we have problems—very serious problems. If the patent law is strengthened, as he suggests, then, I think, in the long run, as Cyanamid suggested to you, there could be a decrease in prices, because in that case this will stop the excessive splintering of the market, which we have today.

We have, as we say in our brief, two effective licences already against us. We have always said that a licence to one is really a licence to all, because some of these people who have licences actually are unable to market the drug themselves. They will make the substance and sell it to anyone who comes along, perhaps even to someone like Harry van Ular. Whether that is safe in his hands or not, is not a question for me to decide, but rather for the Food and Drug Directorate.

I do not know whether I have answered your question, Dr. Isabelle.

Mr. ISABELLE: I imagine that the policy of the Food and Drug Directorate would be within the four or five years, but I agree with you and with Mr. Mackasey that we are talking the same language, but are not using the same language, because I am not a lawyer and you are.

Mr. MACKASEY: I have been called a doctor and now a lawyer, but I am neither.

Mr. ISABELLE: Therefore, what has to be done in order to decrease these prices would be a change in our bylaws, whatever they are, even if it is by patents, by licence, or by Food and Drug.

The CHAIRMAN: Mr. Johnston, do you have any questions at this point?

Mr. JOHNSTON: No, I do not.

Mr. MACKASEY: Mr. Chairman, before Mr. Blakely gets into the patent section of this, I have a few related questions on the very interesting testimony.

The CHAIRMAN: If Mr. Blakely gets into the patent section, I think we have got the wrong consultant.

Mr. MACKASEY: I would not want to appear as the villain of the piece, because the drug industry has had a lot of compliments thrown its way this morning. I could add a lot to that if that was my role, but it is not at the moment.

There has been reference made to copiers—I presume these are generic firms—as racketeers. Is this not a rather blanket statement? Would you not say that there are some exceptions?

Mr. NOWOTNY: May I answer that, Mr. Mackasey? I would not use the term "racketeers" at all. Perhaps some are and some are not, but that is not for me to decide. I think Dr. Isabelle's reference to "racketeers" was, in particular to that one man we were talking about a little while ago, but I do not think this term applies to them, in general; no, certainly not.

Mr. MACKASEY: In other words, all generic firms are not racketeers?

Mr. NOWOTNY: No; of course not.

Mr. MACKASEY: And all copiers are not obnoxious and unnecessary?

Mr. NOWOTNY: Of course not.

Mr. MACKASEY: Are there many so-called—I cannot use the word "respectable" because we have just both agreed that many generic firms are respectable—members of the Pharmaceutical Manufacturers' Association, who were once considered generic firms? Is this not the logical way of beginning in the industry?

Mr. NOWOTNY: Yes, I think so. You have had it in the brief of the Canadian Drug Manufacturers. They have said themselves that they are copiers today and that they may become innovators tomorrow.

Mr. MACKASEY: Naturally your objection is that they are innovators on their own instead of taking your innovation.

Mr. HUNTER: Mr. Mackasey, I think that if one is realistic, and as we have tried to write in this brief, the truth is that what it was possible to begin 50 or 60 years ago is probably not possible now. Of course, as individuals, most of us would, I think, regret that. Originally the automobile firms were almost all started by small men in small garages, but no one would think of starting in the automobile business today with a limited amount of money. I think that if you are realistic you will realize that that is what the position really is with the drug firms now, they have got to be so large.

The president of Roche said to me one day he thought that the drug industry probably would wind up with only a few in it, rather like the automobile industry. Unfortunately, I think it is quite unrealistic to think that an individual could start a business today as Roche did 50 or 60 years ago. I think it is beyond reason to suppose it.

Mr. ISABELLE: Mr. Chairman, I have one comment to make on what I said about racketeers. They are legal robbers, if you like that term better.

I am going to give you an example. You were talking about generic drugs. There is in Quebec a firm which is called Generic Drugs, and I don't think they have ever put a new drug on the market. Therefore, they should be called "Generic Copyer Company Limited."

Mr. MACKASEY: Your point is well taken, Dr. Isabelle. I am fairly aware of these arguments, because I sat through all the hearings we had on safety. These are things which are second nature to you, as a doctor, but to a layman they were very revealing.

I personally have said many times, and Dr. Morrell, as a director of the Food and Drug Directorate has said himself, when I asked a question directly, that, everything being equal, he would want to buy a brand name rather than a generic name. He has stated this.

I happen to think that there is room in Canada for generic firms, where the purchaser has the built-in protection that the hospitals have. The Department of Industry has set up standards of production, set up safety standards and set up all the other checks, which the consumer does not have, as an individual, and, therefore, he must rely on brand name products.

I think that there is room in Canada for both types of industry, except that I do not think generics should be above the law, or should circumvent the law. They should be just as stringently surveyed as you people are.

In all fairness, I do not think the patent law does this, because I think the Department of Justice looks very coldly at the facts. For instance, they do not take into consideration the Hilliard report, and I think that if we are going to be logical, and if we are going to get fair value for our dollar—I am talking about the market and the consumer—not only should the copyer have to apply, as they do, for a licence, but also, at the same time, before that licence is granted, the courts must take into consideration the firm recommendation of the Hilliard report, that, in addition, these firms who are making this application must also be able to meet the standards of the Food and Drug Directorate.

• (11.20 a.m.)

Mr. FRALICH: Could I make a comment on that?

In this area we are dealing in the health of human beings.

A propos of what Dr. Isabelle said about this nebulous transition point between a new drug and an old drug, before Roche put a new drug out on the market we have first satisfied ourselves that it is safe, and that a physician using it will get a known, predictable reaction in his patient under certain conditions. In addition, we satisfy the Food and Drug Directorate that what we have learned about the drug is acceptable to them.

Let us take a very potent drug which has been on the market for five or six years. Let us say that this drug, for some reason or another, is not patented, so

that we can keep the legality out of it. If I want to start the Fralich Drug Company I can start it, I can put the drug on the market, and now I have to notify the Food and Drug Directorate of the fact; but I do not have to satisfy them that my pharmacology, toxicology, pharmaceutical manufacturing, and so on, are suitable. I do have to satisfy them if I want to sell to the federal government under the federal government regulations.

I do not propose to volunteer for the Food and Drug Directorate that they should take on more arduous tasks than they now have, but I think an innate sense of fair play would require that any drug going on the market goes through this same procedure if we want to protect the health of Canadians.

An example with which some of you may be familiar: an ex-official of the Food and Drug Directorate, Dr. Pernarowski, now at the University of British Columbia, made some rather extensive tests on, I think it was, 23 different brands of the same drug, which is unpatented. He presented a paper to the Canadian Pharmaceutical Association—the retail pharmacists group—at Saint John a few months ago, which showed that a considerable number of those drugs produced no therapeutic effect in humans. He concluded that there is no such thing as a generic equivalent drug.

I think we must always keep in mind the difference between chemistry and pharmacology. Two substances can be chemically identical—this you can prove in the laboratory—two dosage forms of the same drug produced by different people can be chemically the same, but the pharmaco-dynamics of those two drugs can be entirely different.

Mr. MACKASEY: Mr. Fralich, may I interrupt you at this point? I will agree that there is no generic equivalent, but does the same argument apply between your product and, say, the products of Ayerst, McKenna and Smith, Kline & French—not simply because the alternate product is a generic; it could also be a branch name equivalent.

Mr. FRALICH: I am not sure I follow your analogy there.

Mr. MACKASEY: I think your accountant does. The point I am getting at is that you mentioned the generic equivalent as being outwardly identical to the brand product, but its effect on the human body is not necessarily the same. This is equally true, I submit, of all respectable firms and the rival firm could be as legitimate and as worthy as Ayerst, McKenna and Smith, Kline & French and some of the others.

Mr. FRALICH: Yes, that is true. I did not attempt to differentiate there. If I did, it was not intentional.

Mr. MACKASEY: I just brought it up.

Mr. Chairman, I would like to get down to the Hall Commission because they had an opportunity to do a little deeper research than we have. I do not necessarily, Mr. Fralich, share their opinion, but I would like to get the other side of the argument. On page 656 it says:

> A corporation operating a wholly-owned subsidiary company will normally try to manage the affairs of both the parent and subsidiary so as to maximize profits.

Before you comment, earlier a gentleman mentioned that we inevitably get down to profits rather than price. I am not a Chartered Accountant but it seems to me your profits do come from prices—that there is a direct relation. I think we are splitting hairs. I would just like to repeat the statement:

> A corporation operating a wholly-owned subsidiary company will normally try to manage the affairs of both the parent and subsidiary so as to maximize profits.

Do you have any comments on that?

Mr. HUNTER: I think the statement, as you quoted it, is very wide.

Mr. MACKASEY: Did you say wide or wise?

Mr. HUNTER: Wide.

Mr. MACKASEY: I thought you said wise.

Mr. HUNTER: The part which you quoted, of course, could apply to every single business there is.

I think the paragraph goes on, does it not, to talk about considerations relating to tax or tariff advantage and so on and so forth. It says: "—while in other cases it may be to the advantage of the international organization for the supplying firm to sell to related firms at prime cost—", and so forth. It goes on to say: "As a result the price charged by a parent to a subsidiary in a drug industry may be an arranged price in the sense that it may not be the same price which the parent would charge an independent firm". I think that is the point you are probably asking. Am I right?

Mr. MACKASEY: The point I am getting at is this: Is there a practice within your industry, in general—and in your company, in particular—for profits to be skimmed off the subsidiary company and hidden in the general balance-sheet of the parent company, to the detriment of our picture and so forth?

Mr. HUNTER: Well, yes; this is, of course, a common question, and it is particularly being asked in Canada. It is being investigated by the Ministry of Health in Britain of which you have no equivalent yet.

In order to deal with that, generally speaking, I think the charge, as levied against the whole industry, is probably very much exaggerated.

So far as we are concerned we have tried, in the information which Mr. Blakely had, to cover this point. We did an exercise. It is, of course, as he says a little technical to people who are not Chartered Accountants, but we tried to deal with this by looking at our own profits and at this charge and saying: "Well, what do we do about that?"

First of all, the business of Roche is divided into two parts. It began in drugs, and then it made a good breakthrough—if you would like to call it that—in vitamins. Therefore, it really has two businesses. It has vitamins and drugs. Vitamins are a highly competitive business. In the large, you could say that the products are not patented. It is large scale seller, and, generally speaking, there is not a great deal of money to be made in vitamins. As far as Roche is concerned, it has imported its vitamins at, broadly speaking, world market or independent prices. It has to do that because it is supplying a fairly large number of other firms in this country, which make up those vitamins into—

Mr. MACKASEY: Excuse me. It is an interesting sideline which we are getting into. But, in other words, so far as Roche is concerned, you are not guilty of this charge.

Mr. HUNTER: No, we say we are not.

Mr. MACKASEY: That is all. I just wanted to get it on the record.

One page 677 of the Hall Commission it says: "The cost to the Canadian company—" Here you can provide our accountant with statistics, and it does not have to be today; but I would like to have the statistics.

> The cost to the Canadian company of acquiring a particular raw material may be a more or less arbitrary figure.

This is exactly what you were presuming.

> As we have seen, most of the major Canadian drug companies are affiliated with companies in the United States or Europe, who supply the Canadian companies with their requirements of basic drugs.

Now, the inference here is that again the value of raw materials becomes arbitrary. I would just like to know what your accounting policy is in regard to raw materials coming into your parent company.

• (11.30 a.m.)

Mr. HUNTER: The problem, as you say, is extremely difficult. Whenever you export from one country and import into another all kinds of people have a right to challenge your price—the tax people of the exporting country, the tax people of the importing country; moreover, you always have in the importing country—not always but very often, as in this country—you have another aspect of the tax gatherer, which is the customs duty. I think, as you saw from Mr. Benson's testimony, that the income tax view is really in conflict with the customs duty view. The income tax people naturally want the value of the imports as low as possible, the customs people naturally argue that it should be as high as possible. Really, that is what the Hall report is referring to.

Moreover, in this country you have also the Dumping Act. So you have to have a price which is high enough not to get you into trouble with that. As Mr. Benson said—I think—I read his testimony very carefully—just how you price the thing, how you cost it, is extraordinarily difficult. I do not think any accountant, whoever he may be, would say that he knows how to price these kinds of things. Classically, in taxes, as you know, you use the test: What would an independent person pay? That is also referred to in the passage I read just now.

Therefore, for that purpose, we did an exercise which shows what you could pay for drugs, for example, to Italy, which was mentioned by Lederle. It is probably again a highly debatable price. In my opinion, the prices which are quoted by the Italians would probably be challenged by the Customs people here, if we were to use that, for Dumping Duty purposes. It is a very complex, difficult subject. But, if you take those prices, as I have tried to demonstrate in the exercise which is summarized for Mr. Blakely, and if on the other hand you take what ought to be paid for research we should come out more or less in balance.

Mr. MACKASEY: All right; I will accept that for the moment. I think there is much stress, and advisedly so, placed on the fact that the pharmaceutical industry, as opposed to the generic firms, stresses quality control. What value do you place on that in your mark-up?

Mr. HUNTER: I think, personally, that Lederle gave a very good answer about this. Like everything else in the drug industry it really cannot be detached.

Mr. MACKASEY: Well, this is a question—

Mr. HUNTER: Yes, I am going to answer it, Mr. Mackasey, As they said, it depends on what type of quality control. Personally, as far as I am concerned, I think they might very well have said—at least I would say—that quality control is very, very necessary; but if you mean strictly what is made, put into production, what are the rigorous tests, the constant tests, all the way through, you will find as a fact, reported in the P.M.A.C. submission and everywhere, that this is not, costwise, a major factor; but it is very important otherwise.

Mr. MACKASEY: But it is used all the time in the argument for the differentiation between your price and that of the generics—research and quality control. I could come back and quote you 50 different instances, particularly when we are discussing safety.

Mr. HUNTER: You were asking me how much, I think, and I was trying to say how much or I thought you were asking me how much. I would say, for instance, that for every drug firm the problem of recovering its research cost is infinitely greater.

Mr. MACKASEY: Yes, I agree, but I would have preferred you to have said 2.8 per cent or 6.1 per cent or something like that. Somebody in the company must know what your cost components are, including that area which is devoted to safety.

Mr. HUNTER: That is quite right, and I think in our case it is probably about two or three per cent.

The point I am making is that there is a vast difference between research and quality control, in this respect, that the copier has to have quality control all the time; he has to, to comply with the Food and Drug Directorate and in order to stay on the market; if he is caught with bad drugs he will not be there. Therefore, the generic house certainly has quality control and to a certain extent it may be more costly because of the small volume of that business it seems to me the indications are that for a generic house it costs more because of the volume, whatever the quality of the control. The difference between the innovator and the copier does not lie there, which has to be built in to the price of any drug, whether it is of a generic house or ours; the difference lies in the whole problem of how do you recover the research.

Mr. MACKASEY: You just made an interesting statement. You just mentioned that the generic firms, too, have a cost of quality control.

Mr. HUNTER: Yes.

Mr. MACKASEY: But, you said this contradicts the argument that we have been getting all through the safety section, that you buy a brand name over a generic because they have no quality control.

Mr. HUNTER: I was not trying to make an argument. I was merely trying to state a fact.

Mr. MACKASEY: That generics do have quality control.

Mr. HUNTER: They must have some kind. What quality of it, is another matter.

Mr. MACKASEY: But they do have it?

Mr. HUNTER: Yes.

Mr. MACKASEY: Therefore, the argument is not really valid, that you buy brand over generic strictly on the question of safety.

Mr. HUNTER: Not wholly on that, no.

Mr. MACKASEY: All right. I turn to the bottom of page 678. You have talked about the motor car industry and industries in general. I would like a capsule comment on this portion of it. At the bottom of page 678 it states as follows:

> In most industries foreign companies tend to supply their Canadian subsidiaries with know-how (including the results of research) and with capital, and to take the earnings of the Canadian subsidiaries as the return on their investment. In the drug industry it is evident that foreign parent companies prefer to be separately compensated for supplying Canadian subsidiaries with know-how on the one hand and with capital on the other.

In other words, you people stress separately the cost of research. Would you comment on that, please? Why are you different from other industries?

Mr. HUNTER: In my opinion, it is different because the quantum of the research in the price is very, very much larger. If you are in the large scale food business, of which I have had some experience, the cost of research is probably about half of one per cent, or a fraction of one per cent, of your sales volume. Therefore, if you are going to have your food product sold internationally under a brand and imported into a country, you do not really worry about recovering that because it does not make any difference. But, when you spend on drug research, as some firms do—I think this is clear from Lederle and it is certainly true at some point of time for Roche—anything between 15 to 20 per cent of your sales of drugs generally, well, you have a real problem.

Mr. MACKASEY: I will accept that. On page 680 there appears one of my favourite quotes. It is taken from the Restrictive Trade Practices Commission. I will cut down on it, but I will expand it if you think it is necessary. One of the paragraphs says:

> "This means that profits of Canadian subsidiaries are not an accurate indication of the actual profit resulting from the sale of imported drugs; they reflect the earnings of the Canadian subsidiary only and do not reflect any profit previously taken by the parent company."
>
> Support for the view that profits tend to be taken by the parent company rather than by the Canadian subsidiary may be found in other figures published by the Commission.

They are talking about the Restrictive Trade Practices Commission. Do you agree with that?

● (11.40 a.m.)

Mr. HUNTER: You ask do I agree with it. I agree that is what this question is, and the answer to the question, which is a perfectly proper one, we tried to provide in general terms in the figures that Mr. Blakely has, and on which, no doubt, I imagine he may be questioning us later.

Mr. MACKASEY: Mr. Chairman, I will move on rapidly. I have only a few more questions. I go to page 681. Of course, this is an unfair quotation and you can challenge it if you do not agree with it:

> Allowing for the understatement of profits made in the drug industry referred to above, we conclude that profits of pharmaceutical companies in Canada appear to be running at least twice the level of the manufacturing industry as a whole.

Mr. HUNTER: I think that the story, as told you by Lederle, and the story which was tried to be told you by Roche, shows that that is not so, and in my experience, is not so. It is a statement which has no limit in time. It says the profits were always higher. They are not. The figures which I have supplied to Mr. Blakely show—and Lederle said much the same thing—that during the period before you get the major advance to which it refers, you are probably going to be very badly off. You may even have to put money in from other fields of your business, if you have them, which is exactly what Lederle said in their brief. Therefore basically the problem is, as has been recognized, that you will have a very lean time, or may have a lean time, for some years, and you may have a better time as the result of discovering something which is big enough to carry—

Mr. MACKASEY: When was the last time you had a lean time?

Mr. HUNTER: We had a lean time right up until chlordiazepoxide.

Mr. MACKASEY: Which was 1961.

Mr. HUNTER: Yes.

Mr. MACKASEY: A final question—and I do not agree with this: "After examining the evidence..."—I have skipped all the evidence. The evidence refers to imported drugs...

The CHAIRMAN: Which page are you referring to?

Mr. MACKASEY: Page 692. "After examining the evidence, we have concluded that imports of drugs have had the effect of reducing drug prices in Canada in certain important areas. In our view the benefits accruing to society as a whole from lower drug prices outweight the possibilities of increasing manufacturing opportunities of such drugs in Canada where the smallness of the Canadian market makes production of such drugs in this country an uneconomic enterprise."

Before you answer, I would like to say that this viewpoint is shared, unfortunately, by certain senior civil servants in the Health and Welfare department. I am glad to say that I do not think it is necessarily shared by the Department of Industry.

It comes back to one of the frustrating things, Mr. Chairman, that I have found since I have come here, that one department does not seem to know what

the other department is doing all the time, like the example cited earlier about the Customs and the Revenue Department.

I would like Mr. Fralich to say what effect he thinks certain recommendations to increase the flow of imports into this country would have on his industry as it exists at the moment.

The CHAIRMAN: You mean cheap imports?

Mr. MACKASEY: I am not saying they are cheap. I am just saying imports.

Mr. FRALICH: I am sorry, would you phrase your question.....

Mr. MACKASEY: Presuming that the recommendations of certain people in this country and in this government were to encourage, to a greater degree, imports from countries such as Poland, or from people who have a reputation for inexpensive drugs, what effect would it have on your industry in Canada, eventually?

Mr. FRALICH: It would be catastrophic to it.

Mr. MACKASEY: How many people would it put out of work, if any? What would it do in the way of payrolls? In other words, what stake do you feel that you have in Canada, as an industry?

Mr. FRALICH: If that were implemented completely I would say it would be the end of the pharmaceutical manufacturing industry here. As somebody said Tuesday, the net result over a period of time would be that the Canadian pharmaceutical manufacturing industry would have no choice but to do the same. We would be employing labour elsewhere rather than in Canada.

I cannot make an estimate of the effect on employment in the total industry. I think the P.M.A.C. brief shows that our total employment is around 6,000. I would guess that at least half of those would disappear.

Mr. MACKASEY: In other words, we would destroy a Canadian industry?

Mr. FRALICH: Right.

Mr. MACKASEY: That is all for the moment, Mr. Chairman.

Mr. BLAKELY: I could follow up on some of the questions which Mr. Mackasey was asking.

You suggest that the innovator must be prepared to tolerate lean financial years, mainly due to heavy research costs which bear fruit only occasionally. I think your suggestion is that this situation actually existed for Roche in Canada, and in the supplementary information to which reference has been made this morning, it is noted that the years 1954 to 1962, I think, are not nearly as profitable as 1963, 1964 and 1965. I think the point you are making is that the last three years are profitable because of the introduction of your new drug, "Librium"; is that so?

Mr. HUNTER: Yes.

Mr. BLAKELY: Again from the information I have here, it appears to me that your sales level in 1954, in drugs, was a very modest one. I would not have any idea what percentage this may have been at that time of the total market. In comparison to your sales level in 1965, I think the 1965 level was something like fourteen times what it was in 1954. The point I am leading to is that I

would think it is entirely possible that, during those years, you may have been establishing your position in the Canadian drug market, and that if this is so it would not be surprising to see earlier years appearing less profitable than later years. Would you care to comment on that?

• (11.50 a.m.)

Mr. HUNTER: Yes; I think that what you are saying is generally correct. I think what you may be inferring, perhaps, is something else. I think that the rise in the volume of drugs is very considerable in any of the cases you look at, and what I think I have been trying to demonstrate in this case is the principle that is set out in Hinchliffe, namely, that you may get a major advance only every ten or twenty years. This, in my experience, is an absolute truth. It applies certainly to all the Swiss businesses, with which I am familiar, and it certainly applies to most businesses. If you look carefully at Lederle, you will see that their brief says that in effect this happened to them about 10 or more years ago. They spent a tremendous amount of money, then they got this famous aureomycin and so on, then they got profits, and I think you will be able to see from their general statement that their profit position has really platformed now. If you say, as I think you are, we were establishing ourselves in this market, well, an international drug firm, if it is in that business, has to establish itself, more or less, in every market. I think that Hinchliffe said, I think what the Roche case shows, and what any case shows, is you still have to wait patiently for another major advance to carry you on and therefore, profits, practically for everyone, fluctuate up and down over a period: their level is not flat. Whether you are looking at any particular firm on the rise or in the trough, is a hazard at the time at which you look at it.

Mr. BLAKELY: Were you, in fact, establishing your position in the Canadian market in those years?

Mr. HUNTER: Well of course we were, and one could have asked what would have happened had we not got "Librium".

Mr. BLAKELY: So you were developing from a relatively small portion position in the market to a much higher portion.

Mr. HUNTER: Yes, but that was not from choice. For example, in the earlier years of that 12 year period I have covered, Lederle and people like Cyanamid were in a very different position.

Mr. BLAKELY: Right, but in your particular case, is it not possible that in the nine years we are talking about, in comparison, they were not as profitable as the three years ending in 1965.

Mr. HUNTER: They were not, no.

Mr. BLAKELY: Is it not possible, to some extent at least, that this was due to the proportion of cost necessary to establish your position in the market.

Mr. HUNTER: Oh, yes.

Mr. BLAKELY: You did not have the sales at that point, did you?

Mr. HUNTER: No. I am awfully sorry but I missed the point at first. You are perfectly right. Just let me illustrate it. For instance, in order to be in this kind

of field, obviously, you have to have a certain number of detail men covering the whole country. There is a kind of irreducible minimum of this. If you are in one of these troughs that kind of cost may bear very heavily on you. It would seem that Lederle have a figure of 31 per cent. I imagine that perhaps 10 years ago it may not have been as much. This is the problem. You have a tremendous fixed cost and your volume is so undependable. That is why when there is so much talk about percentages and comparisons of percentages, it is really to most accountants almost meaningless, because what would happen if, as a result of compulsory licences, the price of chlordiazepoxide was slashed to half. Our percentage would then move the other way. This is the problem.

Mr. MACKASEY: Mr. Chairman, may I ask a supplementary question. I fail to gather the significance of the question in this respect. I do not see anything wrong with a company, in this case, Hoffmann-LaRoche Limited growing in a competitive world and getting a bigger part of the market. I think this is the name of the game.

Mr. BLAKELY: Mr. Chairman, obviously that is not the point. What I was trying to establish was that the reason for, as you call them, the lean years, may not have been solely the fact that you did not have any major success, which is the term you used, during those years.

Mr. HUNTER: I do not agree with you.

Mr. BLAKELY: And that, in addition to this, the financial operations of those so-called "lean years" were this way because of the relatively high cost of developing a stronger position in the market. I am not suggesting that it should not have been done, but just that once that position is established those results tend to be somewhat extraordinary.

Mr. HUNTER: I do not think that most people in the drug industry would agree with the way you put it. I see the point, and in many businesses it must be so. But as Hinchliffe said, and I keep repeating it, when you get a successful drug like chlordiazepoxide and it is very good, as Dr. Isabelle said, when you get a big demand. Since your fixed cost does not go up in proportion, that is when you get into the profit position; whereas, when you say you are developing the market, you can develop the market by having your organization, as you must, as the platform—it is like at Cape Kennedy; you have to have a platform to launch the rocket. Without the platform there is no rocket, but the rocket may not take off. When you say develop the market, you have to have the platform for it, but you are still dependent on whether the rocket takes off or not. Therefore, you are solely dependent on whether you get this major advance.

Mr. BLAKELY: Pursuing the point, that these "lean years" were due to the lack of drug success, if this was the case, I would expect that this was a condition that would be general throughout your total worldwide operations. Was it?

Mr. HUNTER: Yes.

Mr. BLAKELY: In other words, the consolidated statements would show the same pattern.

Mr. HUNTER: Yes.

Mr. BLAKELY: I did notice too in schedule 3 that the cost of sales as a percentage of sales has decreased from 1954, a rate of 82.6 per cent.

Mr. HUNTER: That includes our marketing.

Mr. BLAKELY: Down to 1965, when it is only 61.7 per cent. In other words, there are about 20 percentage points of a difference.

Mr. HUNTER: Yes.

Mr. BLAKELY: It seems to me again then that you had a high cost operation in the earlier years.

Mr. HUNTER: Yes, I think generally speaking, as I think we tried to explain somewhere in the brief, the Canadian market for most international business is very rarely the most satisfactory. It is a widely spread market; it has been rapidly expanding, and particularly for Roche in these lean years, it is a fact that no one in Roche was satisfied with the position in Canada of the Roche business. What do you do? Do you say, I will not have the detail men. It was suggested to me in one of the compulsory licence cases in Britain that you could hire and fire the detail men. But you cannot; you have to have them and you have to wait with them until you get your drug. For instance, in Britain, Roche has not had a very great number of increases in detail men and, so far as I can remember, there has not been a huge increase here. If we lost the drug tomorrow because it was a thalidomide, or you lost it in volume, or pricewise, do you withdraw the detail men from Dr. Isabelle?

Mrs. RIDEOUT: May I ask a supplementary question. I am very interested why you found it necessary then to bring in $7 million—this is on page 7, paragraph 14—to provide the funds from outside of Canada in what you consider to be the good years after the success of your new drug.

Mr. HUNTER: No. As Mr. Blakely will see from the detail it was mostly provided up to that point. This is the point I am making; you have to have the launching pad and it is a very costly business.

Mrs. RIDEOUT: But you do say that not even the greater earnings of 1964 and 1965 were able to provide the finances required for the continuing growth. You mean the lean years?

• (12.00 noon)

Mr. HUNTER: No, I am saying that we had to put all this money up to even the last two or three years and then even the fatter years, to use the biblical expression, were not enough to generate all the capital for the business. We still needed a bit more money, as Mr. Blakely can see, for 1965, which we had to borrow.

Mrs. RIDEOUT: Then is it presumptuous of me to anticipate that you are thinking you must increase the cost of your drugs?

Mr. HUNTER: No, I should not think so. At the moment I would think—and Mr. Fralich should answer this—they are keeping their fingers crossed and praying that the result of the compulsory licences will not slaughter them.

Mr. BLAKELY: Finally, on the question of the lean and fat years, as you put them, the average rate of returns before taxes on capital employed, over this 12-year span, is how much?

Mr. HUNTER: You mean only on drugs?

Mr. BLAKELY: I am referring to the total operation?

Mr. HUNTER: I think it is down here. It is 16 per cent before tax—

Mr. BLAKELY: On drugs?

Mr. HUNTER: On drugs, for the same period, it was 20 per cent.

Mr. BLAKELY: I would think that the idea in having to tolerate the poor years and make this up on the good years, that over a long span of years the rate of return would average out to a return that would be reasonably close to the average rate of return experienced by industry in general. What would be your view on that?

Mr. HUNTER: I do not think there is any real average. My experience is, I do not know what your experience has been, that it is very simple really. Every growth business earns a lot of money relative to the ones that are declining, it is relative, of course. It must, otherwise the growth does not take place. The source of all capital is unused income. Every growth business that I have ever looked at contains always the fact that it is making better than average profit; otherwise it would not be there. I am not admitting that this has been in Canada, what I am saying is that to argue from some general average, as if this was holy is rather like, in Dr. Isabelle's terms, arguing that old men like me are going to grow like my grandson is. This is not a human condition. So I think that to use the average, as if we are all an average age of 35 years, is a bit unrealistic. What you have to say is, having regard to the fact that it is a growth industry, was the profit, or will it continue to be, completely unfair because it is too high. This is really the problem. Again Mr. Blakely, supposing you should say, (this has been the dilemma for the Ministry of Health) "I do not think 20 per cent is right or that even 30 per cent is not right because it is above the average." All right; assuming that you are going to say that, then as the Ministry of Health knows you cannot guarantee that they will make even the average. You do not intend to guarantee it. You say there should be a norm of so many per cent. But how much difference will that make to the prices of drugs. And is that not a thing which is unworkable. What you really have to do is this. You have to tolerate this gamble, as it is, and let them win, when they do, and go through a jolly lean time when they do not. This is the pattern of the industry. Not everybody in the drug industry, not even, I should say, all in this room are entirely happy with their present position.

Mr. BLAKELY: I can appreciate where a higher rate of return in a risk industry would be experienced.

Mr. HUNTER: I am suggesting growth was the thing as much as risk.

Mr. BLAKELY: Right. I was going to say that a higher rate of return would be experienced in some of the years than would be in other years, but over a longer period, the average would come out reasonably close to what is being experienced by industry or manufacturing in general which, I understand, is about ten per cent.

Mr. HUNTER: I don't think I should repeat myself. I happen to know the figures of the four major Swiss drug firms at least in Britain and elsewhere and, of course, their profit patterns are quite different, it is all dependent on

when they last had a major advance which is exactly, I am convinced, the story behind Lederle's presentation.

The CHAIRMAN: I think this would be probably a good time to break for lunch. Would the Committee agree that the brief today be printed as part of the record with the exception, I think, of appendix No. IV which is the Hinchliffe Report which is to be sent to the members as a separate report.

Mr. MACKASEY: Is all this being translated or are we being provided with copies in both languages? Are we getting briefs in both languages or just simply unilingual?

The CHAIRMAN: Some of them are and some of them are not.

Mr. MACKASEY: Could you recommend that those who have not got it, it would be possible to submit them bilingually?

The CHAIRMAN: We have asked them all to do that. Some people have said they do not have the facilities nor the money to cover the expense. I am not talking here particularly of drug companies.

Mr. MACKASEY: I am thinking only of our staff. We are very hard pressed. These things are long and technical. I mean the House of Commons translation staff.

The CHAIRMAN: The meeting is adjourned until after orders of the day. Again, we will not put a time limit on, but it will be approximately 3.30 I would think, depending on activities. The meeting will be held in this room.

The meeting is adjourned.

AFTERNOON SITTING

• (4:10 p.m.)

The CHAIRMAN: Mrs. Rideout and gentlemen, perhaps we could proceed with the meeting.

I think at this point we might ask Mr. Laidlaw if he has any questions of the witnesses.

Mr. A. W. LAIDLAW (*Legal Counsel for the Committee*): Mr. Chairman, I would like to bring the subject of discussion back to what I feel is the intent of the brief. As I understand it, Mr. Fralich and his colleagues are here today for two reasons: First, because of an interpretation placed by the Supreme Court of Canada on our compulsory licensing provisions, specifically section 41, subsection 3 of the Patent Act; and secondly, the royalties and the amount of royalties that have been provided patentees by the Commissioner of Patents, which is claimed by the LaRoche Company and being entirely inadequate. If I am correct in this assumption, Mr. Fralich, I would like to carry on in this vein for a moment.

An hon. MEMBER: I think the bells are ringing.

The CHAIRMAN: If they are, I cannot hear them.

Mr. LAIDLAW: Shall I continue?

The CHAIRMAN: Yes.

Mr. LAIDLAW: If I may start with the first subject, which is compulsory licensing—

The CHAIRMAN: I am sorry, Mr. Laidlaw. Apparently the bells are ringing.

Mr. MACKASEY: It is either a fire or a vote, in which case it is not serious!

The CHAIRMAN: Unfortunately, for a Member of Parliament the ringing of the bell means that he has to leave.

We could meet again after the vote, which would probably be 5 o'clock, and perhaps we could be through by 6 or 6.30, rather than spending the whole evening here.

Some hon. MEMBERS: Agreed.

The CHAIRMAN: We will meet again after the vote.

• (5:00 p.m.)

The CHAIRMAN: Gentlemen, we will continue our meeting from where we were so rudely interrupted by the bell.

Mr. LAIDLAW: Thank you, Mr. Chairman. Before I was counted out by the bell I was suggesting that perhaps it would be suitable if we got back directly to the brief itself, as time is running out and I believe it would be only fair to Mr. Fralich and his colleagues from Roche to put forward any evidence which they might have and make any statements they might wish to make with respect to specific points.

As I understand it, the brief really came about because of a decision in the Supreme Court of Canada which interpreted section 41(3) of the Patent Act which deals with compulsory licensing of food, drugs and medicine.

The contention by Roche, as I understand it, is that this sub-section is no longer fair to the drug industry, and they have expressed reasons why in the brief.

Their second contention is that if, in the wisdom of the government, the section is retained, then some steps should be taken, by legislation or otherwise, to secure more reward for the patentee because of the fact that he has been "legally robbed", as was pointed out this morning by others in the drug industry.

Taking the first point first, dealing with compulsory licensing only, I would draw the attention of the committee to page 18, paragraph 29 of the brief, which is, I think, a very strong statement, and which I would like to have Mr. Fralich justify. I will read it: "Canada has accordingly chosen to adopt and follow the pattern of the drug industry in Italy rather than that of either the United States or the United Kingdom." Now, there is no patent in Italy at the present time concerning drugs, and Canada is not in that position. We are not in the position of the United States, in that the United States has no compulsory licensing system for drugs, but we are actually more gentle in Canada with respect to licensing when it comes to the United Kingdom, because the United Kingdom have similar licensing provisions as we have in Canada except that they also award licences to import drugs if this becomes necessary. This does

not appear in Canadian legislation. It had been recommended by the Ilsley Commission, and it has been recommended by the Hall Report.

Perhaps we could have some comment, Mr. Chairman, on the compulsory licensing system alone before we go into the royalty situation.

Mr. FRALICH: Thank you, Mr. Laidlaw. I think Mr. McClenahan should answer that for you.

Mr. R. G. MCCLENAHAN (*Solicitor, of Ottawa*): Mr. Laidlaw, to go back to the basic principle just briefly, a patent is a reward to an inventor for disclosing his invention to the public. The reward is in the form of an exclusivity in the market for a specified period of time, and by means of this exclusivity the patentee, or the inventor, has the means of controlling the market as you were pointing out on Tuesday, I believe, of this week. This is the principle that has existed throughout, since patents were first granted. The patent is, in effect, a shield whereby you can protect your exclusivity.

The latest decision of the Supreme Court of Canada has been to the effect that the purpose of section 41(3), which is the drug compulsory licensing section, is strictly to create competition, and since any licence is going to create competition then the grant of a licence has become automatic, and, in effect, the drug patents do not exist; a drug patent is a paper shield now, and it gives you no protection; and the recommendation of the R.T.P.C., that drug patents be abolished, and what was said in the Hall Report about drug patents, is no longer relevant because the Supreme Court of Canada has done this and drug patents just no longer exist. The meaning of the section being competition, then competition will always be created by a licence, and, therefore, licences will, in practically every event, be granted. For that reason we say that the drug patents have been abolished.

With regard to the royalties, the Commissioner of Patents has been granting a royalty of 15 per cent of the selling price of the bulk substance. This royalty has been upheld by the Supreme Court of Canada. This amounts to approximately 1 per cent of the patentee's selling price, and, as such, does not enable the patentee to recover his essential costs of research and medical information. If this were general throughout the world, in the United States and the United Kingdom, then it would not provide the means for maintaining the research incentive which, surprisingly, was the very thing which the Supreme Court of Canada said in the Parke Davis case, that it was one of the main considerations that the Commissioner should have in mind.

The Parke Davis case was in 1959 and is reported in the Supreme Court of Canada Reports. In that case both Mr. Justice Martland and Mr. Justice Rand, who were delivering the judgment of the members of the Court, said that one of the principal considerations in determining the royalty was the maintenance of the research incentive.

This 1 per cent on the selling price of the patentee is not going to maintain the research incentive, because it is not going to give the means for continuing that research.

Mr. LAIDLAW: Mr. McClenahan, going back for a moment to compulsory licensing, I am sure you are quite aware that this provision in Canadian patent law has been in existence since the 13th day of June, 1923. I want to make this

perfectly clear: Is it your contention, or the contention of Roche, that the government should abolish this legislation which has existed for such a long time and which was copied from the U.K. legislation earlier, and which is the same type of legislation which now exists in the United Kingdom? Are you suggesting that this should now be abolished, in spite of the examination of this particular section both by the Ilsley Commission and by the Hall Commission?

Mr. McCLENAHAN: Yes, I would recommend it, and it is the recommendation of Roche, that section 41(3), as it is now being interpreted should be abolished, and if there is to be such a compulsory licensing section then it should be replaced by a section which has all the guidelines so that it will be fairly administered.

• (5:10 p.m.)

The section is not being interpreted in the same way in Canada as the corresponding section is being interpreted in England. In Canada, as I have said, if the purpose of the section is said to be competition, *per se*, then the licence has become almost automatic and there is no real inquiry, whereas in England the Comptroller of Patents there, who is the counterpart of our Commissioner of Patents, assesses these compulsory licence applications in terms of balancing the public interest and he determines where the public interest lies in each application. So far as he is concerned, he has said that the main question involved in determining the balance of public interest is the selling price to the public, and where the patentee has a reasonable selling price then the chances of the licence being granted are radically diminished, whereas in Canada this is not the situation. All one has to look for in Canada is to see whether or not there will be competition and if that is so, then the licence will be granted.

Mr. LAIDLAW: May I ask two questions following from what you have just said?

First, you are aware that the cases you have quoted in your brief are cases that have been decided by the Assistant Comptroller in the United Kingdom who corresponds, presumably, to our Commissioner of Patents. These are administrative officials acting in perhaps a quasi judicial capacity. Are you absolutely convinced that if those cases which you quote were appealed that they would be upheld by the English courts? In my opinion, I do not think so.

Mr. McCLENAHAN: Well, in my opinion they would. In my opinion that is the real consideration that was intended by this legislation and I would expect that the English cases would be upheld by the United Kingdom courts, and I think that the way that the Comptroller or the Assistant Comptroller in England is handling these applications is the way in which the legislature intended that they be considered.

Mr. LAIDLAW: Then, I have another question on the same point. Would Roche be satisfied to follow the Ilsley Commission's proposal? I am assuming that abolition of our present section will not take place, but on that assumption would Roche be satisfied, as suggested by the Ilsley Commission, to replace our subsection 3 of section 41 with the corresponding section?

Mr. McCLENAHAN: There is not a great deal of difference in the wording between our section 41 and the corresponding English section. There is a great

deal of difference in the way that this wording is being interpreted. If we could be assured that the wording of the corresponding English section would be interpreted and applied in Canada in the way that it is being applied in England, then we would feel a lot happier than we are with the current situation.

Mr. MACKASEY: Including the interpretation in the field of imports?

Mr. MCCLENAHAN: The way that the imports is being interpreted in England is that a licence to import should not be granted unless the public interest demands it. Those are the words that the Assistant Comptroller used in the Pfizer case.

Under section 67 of the Canadian act and 37 of the U.K. Act, it is an abuse for the patentee not to manufacture in the country involved but rather to import the product. Now, in England the Assistant Comptroller has said that he does not like to grant a licence to import because he is authorizing the licence applicant to do that which if done by the patentee would be an abuse under the Patent Act. Therefore, he said, I will only grant imports if the public interest demands it which, I presume, to be a situation where the patentee for some reason or other is holding the price at an unreasonable level.

If this was to be the way in which it was to be applied in Canada, then I think we would have much less objection than we have to the way that the matter is now being applied.

Mr. MACKASEY: I am not an expert on Irish sugar but if it were Irish coffee we were discussing I could do a lot better.

The CHAIRMAN: Could I ask a question on a point of clarification. I think, Mr. Laidlaw, on Tuesday—and you were also in attendance at the meeting—listed actually the number of compulsory licences that had been applied for and issued during this period of time. You mentioned, "since the latest interpretation of the courts": on what date did that interpretation take place and how many compulsory licences have been applied for since that time?

Mr. LAIDLAW: Mr. Nowotny seems to have the date at his fingertips.

Mr. NOWOTNY: The Supreme Court judgment came out in January of this year.

The CHAIRMAN: So it is really too early to tell what influence this will have on compulsory licensing?

Mr. NOWOTNY: Well, yes, with the exception that there has been one application since then against us.

Mr. MCCLENAHAN: The decision is dated January 25 of this year. From the fact that the decision says that the purpose of section 41(3) is to create competition, then it becomes automatic that a licence is going to create competition and, therefore, the licences are going to be granted.

The CHAIRMAN: In view of that, I was wondering how many licences have been applied for since that date?

Mr. MCCLENAHAN: Just one that I am aware of at the moment, against us.

The CHAIRMAN: One in total or one against Roche?

Mr. McCLENAHAN: One against Roche.

The CHAIRMAN: One in total.

Mr. McCLENAHAN: I cannot speak for all the other companies. I do not know if that is one in total or not.

The CHAIRMAN: I am sure we will be able to get the precise information from the Commissioner of Patents.

Mr. McCLENAHAN: I believe there is another one out now—I am sorry, it has not been a compulsory licence request yet; it has been a request for a voluntary licence made from another company whose patent has not even been issued yet and presumably as soon as that happens, the request for the compulsory licence will be made. Now they are not even waiting for this time period, that was referred to earlier today, of three or four years before the request for the compulsory licence is made. This request is now starting off even before the patent is issued.

Mr. MACKASEY: I have a supplementary question. Have you found any indication in these judgments that the Hilliard Report is having any effect on the ease with which these compulsory licences are being granted.

Mr. McCLENAHAN: No. As I understand it, the recommendations of the Hilliard Committee have not been enacted yet and accordingly these recommendations are not being invoked for the protection of the public.

Mr. MACKASEY: Mr. Chairman, do we intend to have representatives of the Food and Drug Directorate before the committee?

The CHAIRMAN: I would think, again, that is up to the committee, if they wish to have them.

Mr. MACKASEY: Could I make a motion to that effect?

The CHAIRMAN: No motion is really required. We will be glad to talk it over with the steering committee.

Mr. LAIDLAW: May I speak, Mr. Chairman?

The CHAIRMAN: Yes.

Mr. LAIDLAW: Mr. McClenahan, there have been representations before this committee by one or more of the drug firms that if this compulsory licensing section referring to drugs and medicines was abolished, the drug companies would not object to being treated in the same manner as all companies handling anything are treated under the abuse sections of the Patent Act, which is section 67. Now, one of your recommendations is that no licence for a drug shall be granted under section 67 (2) (c) of the Patent Act. Section 67 (2) (c) of the Patent Act reads: "The exclusive rights under a patent shall be deemed to have been abused if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms." I would like an answer to that question. Why do you demand this much protection, which would exceed the protection any firm of any kind in Canada has?

• (5:20 p.m.)

Mr. McCLENAHAN: The drug companies are already subject to section 67. It is just that section 41 (3) seems to offer so much better terms, so that they do

not have to wait the three years to get their compulsory licence or to apply for in that section 41 (3) is relied on. Our reason for raising the question about section 67 (2) (c) is that if we obtain relief under section 41 (3) we can see ourselves being in the same position and subject to the same interpretation because of section 67 (2) (c). If you look at the section it says, "the demand for the patented article". This sort of phraseology is what the Commissioner of Patents has, in effect, used to justify a minimum or pittance royalty as he refers to it, under section 41 (3). He refers to the patented article as being the drug in its bulk form and therefore applies his royalty to the bulk form of the drug which is sold for far less than the dosage form. On that basis, this has been used to justify a very minimum or pittance royalty.

If we get relief from section 41 (3) and somebody applies for a licence under section 67 (2) (c) and the Commissioner comes to the conclusion that the patented article, that is the bulk substance, is not being made—I will just read the section; "If the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms"; supposing somebody comes to us and says we would like to buy the bulk substance and we say, "Sorry, we do not sell the bulk substance; we sell the drug in dosage form." Then we see the hazard of this person coming to the Commissioner of Patents under section 67 (2) (c) and saying that the demand for the patented article is not being met to an adequate extent at all because we cannot purchase the bulk. Therefore, we are subject to the licence being granted under this section and with the reference to the "patented article." We can see the same royalty being applied against us possibly under this section. Unless relief is given under both sections we could very easily be subject to the same treatment under Section 67 (2) (c) as we are now receiving under 41 (3).

Mr. LAIDLAW: In other words, you wish the same protection for the pharmaceutical manufacturers or for Roche, as the case may be, in Canada as the drug manufacturers in the United States now have; no compulsory licensing of any kind, regardless of abuse.

Mr. MCCLENAHAN: No. This is not a question of regardless of abuse because the abuse provisions are in section 67. We are subject to the abuse provisions. If we abuse the patent, then we are subject to the licence.

Mr. MACKASEY: Does Section 67 not pertain basically in a sense to the fact that you are not using your patent? Does not section 41 (3) bring in the question of costs? It protects your consumer. There is an argument there that is all for you.

Mr. MCCLENAHAN: That is what we argued that 41(3) did; that it brought in the question of cost, but the Supreme Court of Canada said no it did not, that all section 41(3) did was—

Mr. MACKASEY: The cost of manufacturing, I am talking about the cost to the consumer.

Mr. MCCLENAHAN: It speaks of what is being made available to the public so that would be the cost to the consumer. You are quite right. One of the principal provisions of section 67 is the question of whether or not the invention is being worked in Canada. Certainly, the whole section takes on this attribute or complex in view of subsection (3) of Section 67 which refers to the fact that

patents for new inventions are granted not only to encourage inventions but to secure that new inventions, so far as possible be worked on a commercial scale in Canada without undue delay. You are quite right that this atmosphere is created for section 67, although, quite frankly, there are other considerations, or other abuses than just non-working.

Mr. MACKASEY: A supplementary question for a moment, if I may. Do you have drugs that you are manufacturing to protect yourselves against section 67? Do you have drugs that normally you would not produce because there is just not a big enough demand for them, but you produce simply to prevent people from taking advantage of section 67?

Mr. MCCLENAHAN: I will have to pass that one on to Mr. Nowotny.

Mr. MACKASEY: I ask this because obviously the generics would not have this type of financial burden to carry.

Mr. NOWOTNY: I am trying to see if I understand your question. You are asking, are we manufacturing drugs to avoid coming under section 67(2) (a). Is that it?

Mr. MACKASEY: Yes, that is right, certain drugs.

Mr. NOWOTNY: First of all, of course, the copier would not be interested in the small volume drugs.

Mr. MACKASEY: If it is small enough he would. There is a point I meant to bring up which was that somebody, I thought it was black-mail frankly—offered to cease asking for a compulsory licence on your main product, if in return you would give him some other benefit from another product which you had which was rather nominal in volume but which would be satisfied easily. I think this is the inference I got here. I will come back to it later.

Mr. NOWOTNY: If you have a large volume product; let us take again chlorodiazepoxide. I said this morning that the drug patent issued in 1961 and about 14 months after we had the first compulsory licence application. On that basis alone, of course, it is quite out of the question for us to consider manufacturing the substance in Canada. I said, just on that basis alone. How can we justify any investment in manufacturing a substance if you are going to have in very short order a compulsory licence; that is problem number 1; we know, problem number 2, that the licence will be granted because anyone can apply, and anyone will get it, and good reasons to the contrary really, do not exist at this stage. And thirdly, the compensation is a pittance, as the Commissioner of Patents calls it, and that is of course, what worries us about Section 67 (2) (c). It speaks of a patented article and we compare Section 41 (3) and 67(2) (c). Section 41 (3) speaks of what is being made available to the public. What is being made available to the public is the dosage form and not the substance, and yet, the Commissioner of Patents feels justified to put the royalty on the basis of the bulk substance. Under Section 67(2) (c), here there is even a better excuse for giving a pittance royalty, and 67(2) (c) I think has to be read in conjunction with Section 72 (3) which reads: "For the purpose of Sections 67 to 72, the expression 'patented article' includes articles made by patented process." That very same term was used by Mr. Justice Abbott in the Supreme Court judgment in the Bell-Craig case. So there you see our dilemma.

Mr. LAIDLAW: Time is getting along, may I turn, Mr. Chairman, to the other aspect now, the royalty aspect. This is in the nature of asking for an explanation. I am not quite certain of it, but as I understand it now, Mr. McClenahan, the Commissioner of Patents in Canada in these applications for compulsory licences awards a royalty of approximately 15 per cent on the bulk substance and not on the finished dosage. Am I right in that?

Mr. MCCLENAHAN: That is correct, yes.

Mr. LAIDLAW: Going to the last two pages of Appendix 7, in the Pfizer case, the assistant comptroller gives a very learned dissertation on how he arrives at an appropriate award to the patentee in the case of a compulsory application, and just to quote briefly he awards 4.6 per cent to the patentee for research. He adds 1.43 per cent for promotional activity, he assesses an allowance for profit at about 1.8 per cent and he comes out with a royalty payable at 9.7 per cent in all, but to make it even he calls it a figure of 10 per cent which would be more than generous to patentees.

• (5:30 p.m.)

This royalty at 10 per cent of the price which he would have awarded, if he had had to award a royalty, is the price accepted by the Ministry of Health for the patentees' branded and unbranded drug respectively; the branded price being used to calculate royalties payable on the licensee's sale of the branded drug, and the unbranded price being used for sales of the unbranded drug. I am not certain what is meant by "the price accepted by the Ministry of Health". Is that on the final sale price or is that on the bulk substance? In any event, how does that calculation work out in comparison to the 15 per cent royalty that is now awarded by the Commissioner of Patents on an application of this type?

Mr. MCCLENAHAN: I will invite Mr. Hunter to answer that question. He is in a better position to answer it than I am.

Mr. HUNTER: There are two questions, I think. You first asked is the Ministry's price that for the bulk substance. Quite clearly, no. It is abundantly clear that the Comptroller was discussing the whole problem of price to the public, that is to say, the dosage form, and when he speaks about the branded and the unbranded price, on which there is a good deal of doubt, he really means the branded and the unbranded price of the dosage form. It must be so, because you can hardly have a branded form of the bulk substance. There could not possibly be any doubt that he is talking about the royalty on the dosage form. Now, the bulk substance, as we have illustrated in this brief, in today's terms is almost all these drugs that are attacked by compulsory licensees and is a price which is probably somewhere between 4 and 10 per cent—perhaps not even as much as that—of the dosage form and that, of course, was clearly spelled out by Mr. Justice Jackett in the Exchequer Court case of *Roche* v. *Bell-Craig*. This whole difference, which he understood, is clearly to be seen there and he, of course, awarded a royalty based upon the dosage form price. He even spelled out exactly in kilos what he thought Roche would get. In fact, he says Roche's average price was given in evidence, and it was not challenged, at about four thousand odd dollars a kilo for a combination of all the dosage forms, and it was found by the commissioner, through evidence given by Craig, that his price would be $3,500 a kilo which, of course, is the way the copier works. He always poses his price just a little below the price of the patentee,

but as high as he can. Mr. Justice Jackett said that he was awarding us 15 per cent of $3,500, which he spelled out as $525, and this is actually to be seen in exactly those terms in the judgment.

Now, the Supreme Court decided this was not so, that the Commissioner was right, and that the royalty was to be 15 per cent of the value of the bulk substance and, moreover, it was clear from the case—you can see it written there—that the cost of the bulk substance would be, according to the finding of the Commissioner, somewhere between $80 and $120 per kilo. And there is a compulsory licensee, as we have said here, who is, in fact, selling it to another distributor for $450 a kilo. So that even if we got the royalty, on the $450 a kilo, which we eventually would not; that is only one-tenth of our selling price and about one-ninth of the price that Mr. Justice Jackett referred to. This is what we have said here very clearly in this brief, and in point of fact the latest applicant that Mr. Nowotny referred to does day in effect that he claims that the right royalty following the Supreme Court's decision is $30 a kilo. He says it practically in those words and he says this is what the Supreme Court has authorized the Commissioner to award. Mr. Justice Jackett, on the other hand, with respect to the same drug said, in a kind of excusing way, that we were getting a fairly good royalty because it would be $525, so that the difference between these two things is spelled out in those cases if you read them carefully.

• (5.36 p.m.)

Mr. LAIDLAW: Could I interject one question. Is the price that is mention as 10 per cent in the United Kingdom, determined by the Ministry of Health, an end price to the consumer?

Mr. HUNTER: Yes.

Mr. LAIDLAW: Are you absolutely certain of that?

Mr. HUNTER: Absolutely certain.

Mr. LAIDLAW: In other words, it would be evaluated in the same as Mr. Justice Jackett did before he was overruled?

Mr. HUNTER: Yes.

Mr. LAIDLAW: Thank you.

Mr. ISABELLE: So the 15 per cent is only 15 per cent of the royalty. If I am the copier and I go to you, if I have the proper license, and buy some bulk substance, let us say chlordiazepoxide, I have to pay 15 per cent royalty to your company on one kilo but it is on the bulk substance?

Mr. HUNTER: Yes.

Mr. ISABELLE: That is not what was said the other night?

Mr. HUNTER: No. From the last two applications it is quite clear that the applicants expect to pay something like $30 or so, something less than $100 anyway, per kilo to obtain a license to sell a product which Mr. Justice Jackett said he would certainly sell for $3,500, but this remains to be seen, because when there is enough competition, as we have put in this brief, the price will not be that. I think somebody asked whether we expect the floodgates to be opened. I think everybody in the drug industry does. Of course, there has to be

a big enough product for the copier to want to ride on it. He is not really interested in a ride on small products. So he has got to have a big product. The man who made the last application was sitting in the Supreme Court, when we had our case, and he actually said to us afterwards, "now I know what to do; I am going to file an application next week", knowing where he stood, knowing he could not lose because he gets a ride on the back of this product into which is built all these costs which have to be sold, like the rest of the drug industry, at some very much greater markup than the bulk substance. He knows that he is going to get it at a cheap price and he says, "now that is the right price for my royalty and for the license". That is why we say in here, coming back to Mr. Laidlaw's point at the beginning, therefore in practice for the drug industry such a royalty, of less than one per cent of the selling price of the dosage form into which all the servicing costs have been built, is effectively abolishing patents. It must be so. If I may use, perhaps, an odd analogy, it is like taking a man's sausage away; you take all the meat away, you leave a few scraps inside the skin and give him back the skin and say, you still have a sausage.

Mr. HOWE (*Wellington-Huron*): Probably this is not in the same connection. I hesitate a little bit to ask questions at this stage of the game because it might be repetitious. I am rather interested in page 79, in connection with the same matter of copiers and licensees. I also note in your brief that it says that certain drugs depend for their existence not only upon the original introduction to doctors, but also upon the constant support by medical information upon the drug to doctors. Then it goes on to say that if that support were withdrawn because the number of licensees grew, it would not be possible for the original people who produced the drug to carry on this service, and that the drug would disappear from the market altogether. I was rather interested in this part where it says, then the drug would quite quickly disappear from the market altogether. It is rather an interesting statement that no matter how valuable the drug was to the health, if it becomes such an ordinary commodity on the market and was not carried forward to the doctors with the necessary information, it would disappear? Has this happened to any of the drugs that you have produced or that you know of?

Mr. FRALICH: It has not happened to any of the drugs we have produced because these compulsory licensees are too new in the field. Mr. Howe, I think you have to remember, first, that a drug's development does not stop abruptly. Drugs like sulfonamides are still being widely used and new uses are developed for them. The same applies with modern drugs. Here one of the physician members should be speaking rather than myself. It is necessary for us, the originators of the drug, to fulfill our obligation of bringing these new uses and contra-indications, warnings where not to use, to the attention of the using physician. If the price is deflated to the point where we cannot afford to do this, we do not do it and, taking an extreme case, if all of a sudden people started to die on drug A and nobody came to the doctors and said, "do not use this one on people who have some condition, because you will kill them", the doctors will stop using that drug very very quickly and the drug would disappear. The second aspect in this medical information field is the continuing maintenance of medical information. It has been our experience that even though a drug is well accepted by the profession, in fairly specific uses, if you stop reminding—if you will pardon my using the word—the physicians of the drug how it can be used, when it should be used, telling the physician that he can get a known

predictable reaction in his patient under certain conditions, physicians immediately react and say, something has turned up wrong about that drug because this company is no longer talking about it, and they stop using it.

• (5.45 p.m.)

Mr. HOWE (*Wellington-Huron*): In another committee of the House there is quite a lot of consideration being given to this high pressure advertising adding to the costs. It would appear that this type of servicing is a very expensive procedure because the cost of sales in your schedule (1) is the biggest item in your expenses. It is rather interesting to see that these levels of service are broadly the same as in other advanced countries, such as the United States, and it is not realistic to suppose that either the doctors or the public will tolerate lower standards of service in Canada.

In other words, you feel that this type of information and servicing is demanded by the people, or they will not use the product.

Mr. FRALICH: That is correct.

Mr. HOWE (*Wellington-Huron*): But, as I say, I was interested that when the cost came down, and this service was not economically sound to be continued to be used, the drugs could disappear.

Mr. FRALICH: That is correct.

Mr. HOWE (*Wellington-Huron*): Irrespective of how good it was, or how bad it was, for the health of the people?

Mr. FRALICH: As the head of Cyanamid said Tuesday: "You have to make a profit." If we do not make a profit—I have some very fine people who work for Roche for whom I am responsible, but they will not work if they do not get paid.

Mr. NOWOTNY: I just wanted to add that if you cut our prices down to a really low level then I think we have only two choices; that is, either to abandon the market, or to cut down on the servicing of the drug. With regard to the servicing of the drug—it is in our brief, and, of course, it has been said to you already by Cyanamid on Tuesday—this is a "two-way street". It is not just a question of bringing information to the doctor, but of taking information back from the doctor. The vital test on any drug is on the hands of the physician when he prescribes it for a patient. We can only support this kind of servicing if we get our price.

If we do not get our price, then, of course, we have to make the decision to abandon the market, or to cut down on our servicing. I do not think that the physicians in this country would want either of these two alternatives.

Mr. MACLEAN (*Queens*): Mr. Chairman, am I too naive when I suppose that even in a commercial company there are certain ethics which form guidelines other than just a profit motive? I am thinking now in the direction of research for the evolving of possible new drugs. If profit were the only motive you would only be interested in developing drugs for the treatment of widespread diseases, or conditions, whereas there must be cases where drugs can be found—or have been found—for diseases which are very limited in their occurrence.

If you look at the economics only, a company such as yours would not bother with this, because there would never be enough people—enough demand—for the drug to make it economically worth while manufacturing it.

This brings me to the question of, frosh, what is your policy in research of the parent company, or generally in the pharmaceutical industry, with regard to the developing of drugs which will never be really economic to manufacture, but which might be a boon to certain limited numbers of people who suffer from uncommon diseases. Secondly, if you do come up with a drug of this sort, do you take on the responsibility of marketing it and developing it regardless of whether you ever make any worth-while profit out of it or not?

I note with interest a statement on page 4 of appendix IX which says:

> But even among the "marketable" drugs there are failures in the commercial sense because there is no large need for these drugs. Although not of commercial significance enough is produced to supply the modest demand because some people need them.

Would you expand on that. If that is the fact of the case, I would assume that this is an added responsibility which falls on the shoulders of large innovators, and is something which never, or very seldom, is the responsibility of a copier. Is that an accurate supposition?

Mr. FRALICH: Yes, in answer to your last question. I want to thank you for correcting an impression which I may have created. Certainly every drug company, an innovator such as ourselves—I believe this came out by Lederle late on Tuesday—has the responsibility of aiding the health team—the physician, the retail pharmacist, the hospital pharmacist—in helping alleviate the ills of mankind.

From the research point of view, as in all research in drugs, while you have objectives it is not as easy as sitting down and postulating that a certain drug will do certain things. In your research you will find drugs for which there are very limited uses, and, as you stated, these are made available.

Under the economics of scale they do not pay for themselves. Perhaps, as the old grocer said: "What you lose on the carrots you make on the beans"—it has to be that way.

We have a drug called Fluorouracil. It is helpful in alleviating a very small percentage of certain types of cancer. Please, I do not want anybody to think that we have a cancer cure. This is a help in a very small percentage. It is a very toxic drug. We make it available on practically a non-profit basis in the hopes of helping physicians to help people who are in the terminal stages of cancer. If we were to endeavour to equate a profit and loss on that drug, it would come out of the list very quickly.

No others occur to me at the moment, but you will recall Lederle mentioned that they had one, the name of which escapes me, which is in a much similar category but for a much less serious condition.

We have another drug called Arfonad which is useful, in very limited types of surgery, in reducing blood pressure. Frankly, I think our sales on the product may be $3,000 a year. It is stocked in our depots from coast to coast in case any physician—any surgeon in this case—would require it.

I hope this has answered your questions.

Mr. MACLEAN (*Queens*): There was one other element of my question: I asked if I were correct in presuming that copiers do not have this obligation. Since they do not evolve new drugs they stay clear of these—

Mr. FRALICH: That is a truism. They do no research, they discover nothing new, therefore they have nothing to offer.

• (5.55 p.m.)

Mr. MACKASEY: I have just one question: Can you say that in no case has an effective drug for a rare disease—and I say "rare" only in the sense of not being—widespread been discovered and not manufactured, because it would be too costly from the company's point of view?

Mr. FRALICH: To the best of my knowledge, in Roche, this has not occurred. Often times we do produce small quantities of drugs for people in research, who have an idea that a certain drug under certain conditions may be of use. This may be in human clinical research and it may be in animal. This we do and I cannot give you numbers, but I would guess at least twice a week, 5 or 10 grams of various substances go from our medical director to researchers in universities, hospitals and so on, and none of this is charged for.

Mr. HUNTER: I would like to comment briefly on Mr. Laidlaw's reference to the Pfizer case in the United Kingdom.

I think the significance of that case is that it is the first one in which the decision really, basically and substantially, has been that one of the good reasons to the contrary, for refusing the grant of the licence is that the price is reasonable. This is the first time, in contrast to the Geigy case, where there was so such finding, that this has happened, and I do not think it will be the last. Roche has two cases coming forward in England and we have a good deal of confidence that, for the same reasons, the licence will be refused. This is, of course, totally different from Canada, where, as Mr. McClenahan explained, reasonable price has nothing whatever to do with section 41(3) and has nothing to do with whether a grant of the licence should be made.

Now, on this fundamental—because that is what this inquiry is about—the costs and prices of drugs, there is a wide divergence of view between the United Kindgon and Canada. In England reasonable price is the main factor in whether you grant a licence now, and here it has no relevance whatever to that.

The point, I think, is that the Assistant Comptroller in England has realized, from subsequent disputes about the award in the Geigy case—the many disputes in the courts—that in order that a patentee may be adequately protected, there must be a balance between the royalty granted, if his patent is taken away from him, and the price. There is no use awarding a royalty which leaves a copier with a wide margin to compete on unequal terms. It is my conviction that that is really the essence of the Pfizer case. Because the Ministry of Health is now charged with regulating drug prices, then, that is one of the substantial reasons for refusing the licence, because the price must be considered to be reasonable.

Mr. MACKASEY: I would like to get into the area of marketing. The service to doctors has just been discussed, and all that comes under marketing.

According to the Lederle brief on Tuesday, the cost of marketing for that firm is 31 per cent. According to the P.M.A.C. brief, which is a composite of the industry, the cost of marketing is about 30 per cent. We have, in this Committee, been trying to find ways and means of inducing the industry to save money there, or to see if it is feasible to save money there. You people then come up with a figure of 18 per cent, which is 12 per cent lower than the average, and 13 and a fraction per cent lower than Lederle. Can you explain how you do it?

Mr. HUNTER: It is not done by us. It is done by the consumer demanding the product. That is to say, it is solely a question of the ratio of the sales to the cost expense.

If I could illustrate it. Roche has, approximately, 43 detailmen today spread right across the country. A few years ago when chlordiazepoxide started, it probably had something in the order of 35 detailmen. Is it not self-evident that if you have 35 men detailing the drug, and your turnover, because of the success of one drug, goes up tremendously, the cost per unit of sale, per detailman, to take one example, goes down. Of course, it is an illustration of the fact that percentages are very deceiving things.

Mr. MACKASEY: I hope we are not being deceived by them, because they are yours.

Mr. HUNTER: What I meant to say was this, that the 18 per cent seems like a compliance with the Hall report suggestion that we should get down to 15 per cent. I think that it is very clear. Just suppose as a result of the compulsory licensing cases, that our prices come down to the kind of level which the Supreme Court evidently thought ought to be the case, without going into the facts. If our sales on the same volume drop to half, then this ratio becomes 36. To pay too much attention to percentages is a very shallow way of looking at the problem.

If the same volume of sales, that is, quantitywise, remained, but the price went down as drastically as I have suggested now, you could not then decide to cut the number of detailmen down to half. They would still have to be there.

Mr. MACKASEY: In other words, the success of "Librium" has brought down your cost of marketing considerably?

Mr. HUNTER: Yes.

Mr. MACKASEY: And, secondly, your percentage is low because your volume is huge. However, using the same argument, then, does it not work against you in the next item, research and development, where you have 12 per cent against the industry's 7 per cent?

Mr. HUNTER: I am not sure that the industry has this 7 per cent. If you look at the P.M.A.C. brief, you will see that they have three items in respect of research. In statement E-2 they have R and D of 7 per cent, if that is what you are referring to.

Mr. MACKASEY: Perhaps could you use the same table. I am using page 2-3 of their section of the brief marked "prescription dollar"?

Mr. HUNTER: I think it is better to look at Appendix E, where all these figures are set out. I think it is easier to see what is really the case.

• (6.05 p.m.)

In E-2 you see the sales of packaged human pharmaceuticals are shown as $107 million and down below you will see they say R, D is $7 million and royalties are $3 million, odd—they are of the same kind and character—and that is $10.5 million, and then over here on page E-6 you will see they refer to $5 million that various people in the industry have estimated they ought to be paying to their parent or related companies but for which they have not been charged. So that altogether, you see, in the P.M.A.C. brief there is an indication

that the total cost of these kind of things ought to be, even if it is not, about $15 million and that altogether—not what they do pay, but what they should pay—is about 15 per cent.

Mr. MACKASEY: I am glad that you pointed it out to me, but it does not say too much for the brief of the P.M.A.C., because none of the witnesses bothered to point that out to us when we were discussing the prescription dollar, which is on page 3 of section 2, and which states—and we can only assume it is accurate—"Research and Development—7%".

Mr. HUNTER: Yes, but I am saying this with some knowledge, that the figures of the industry are quite high and this is a reflection of that fact.

Mr. MACKASEY: I am not taking issue with you, but I am taking issue with somebody. Either you are right and they are wrong, or vice versa.

Mr. HUNTER: Well, I am not saying I am right. I am saying that is what this statement says.

Mr. MACKASEY: Research and development is 12 per cent, as against the industry's 7 per cent. Marketing is only 18 per cent. I was wondering about the relationship between research and development. Is it based on the actual cost of research done in the central office or in your three research centres, or is it strictly on a percentage of your sales in Canada?

Mr. HUNTER: No, it is much the same as is spelled out in the Lederle brief. You will remember when they gave evidence about it they said, "We actually pay royalties which really amount to 5 per cent on sales." They also said, "We ought to be paying, on the basis of the spread of the cost of research over the total sales in the world, about eight point something percent." Then you will remember—I think it was you who was questioning them—you said, "What is this local research you talk about?" I think it was clear from the answers to your questions that this is what we call clinical trials here, and that amounted to about 3 per cent, and in the Roche case they amount to about the same thing, about 3 per cent. Therefore, the world figure of Roche that is in there is about 9 per cent, which is very near to Lederle's. You can say in general that these figures in all the drug industry tend to be about the same.

Mr. MACKASEY: Mr. Hunter, you have been very honest in your evidence today and I appreciate it. In other words, what Lederle calls research should really be considered clinical trials and should have been introduced that way?

Mr. HUNTER: Well, I am not trying to criticize Lederle, I am saying that there really are two things about research. There is the research done at some large centre with perhaps about thirty different disciplines and with all kinds of technicians who must be brought into it—thirty, maybe forty today—all kinds of people whose names I cannot even remember. There, of course, the drug is first found and proved. However, in practice, even if it is proved in such a central place and in order that doctors in any local place may be satisfied, there almost invariably has to be clinical trials on top of that locally. The doctors who have never heard of "Mr. Ush-Kush" in some faroff European country say, "However there is 'Professor Whatsit' in the university and so and so that I know very well and he says it is alright." This is the kind of thing that I think happens, but the doctors will know this better than I.

Mr. MACKASEY: They need a safety factor.

Mr. HUNTER: This is a form of detailing. They are convincing doctors like Dr. Isabelle by people that they know—

Mr. MACKASEY: But the point is, Mr. Hunter, you would have to stretch your imagination to call it research.

Mr. HUNTER: Well, it is a form of research but nobody has ever been able to define research; that is the point.

Mr. MACKASEY: I am going to do it right now. On page 29 of your brief there is something which intrigued me. It really does not have any relationship to anything but it comes back to patents, which we were talking about earlier. There I think you are discussing the Denver chemical firm, and by "It" I presume you mean the Denver chemical manufacturing firm, and this is in connection with the request for licence, I presume:

> It said it would withdraw if Roche could give it some lesser drug, coming out of Roche research, which would be potentially too small for Roche to introduce, but which would be interesting for a smaller concern like Denver to introduce.

That smacks of blackmail to me. I do not know what impression you get.

Mr. HUNTER: I do not know. I had some part in this. I personally thought it was recognition by the new owners of the facts of life of this industry. If you are a copier—they bought a copying firm, in effect—you may slaughter the price, but who is going to get any money out of it? As Mr. Fralich said this morning—or somebody did—in the end they quit, and it is only a short ride for so long as the market holds up at this price. Now, Denver clearly realized this. They said there is no ultimate future in this. The Canadian Drug Manufacturers' brief more or less says the same thing; sooner or later we have got to get into research. As I said this morning, how do they do it with the scale as it is? Then, of course, Denver said, "But you must have a lot of products in your research which you do not bother with." Mr. Fralich said just recently that probably this is hardly true. This was looked at by Roche but finally it was decided, for the reasons that Mr. Fralich gave, that there really was no such drug that Roche would not put out if they were determined that it was useful, however small it was. So this is a very difficult thing. What Denver were saying, in effect, was that if they had a small drug which would not interest such a large house, they could put it out and would then become the innovator.

Mr. MACKASEY: But in return they would cease trying to get a compulsory licence?

Mr. HUNTER: Yes. Since Roche was unable to meet this request they went on with the case.

Mr. MACKASEY: Perhaps the accountant could answer this. I believe—and I might be wrong—that under Canadian law you are entitled to 150 per cent of the money spent on research. Am I right? Do you take advantage of this in any way?

Mr. HUNTER: We do not do it here.

Mr. MACKASEY: You do not do any research in connection with the money spent on clinical trials, do you consider research for tax purposes?

Mr. HUNTER: No.

Mr. MACKASEY: Thank you. Now I have one question that I have not asked for a long time. Federal Sales Tax. I see it has been anticipated.

Mr. NOWOTNY: Federal sales tax. The percent to taxable sales is roughly 9.7 per cent. Percent on total sales is roughly 7.5 per cent.

Mr. MACKASEY: Based on your sales to—

Mr. NOWOTNY: On all sales. In other words, on taxable sales where we have to collect and remit the sales tax it is about 9.7 per cent. If you take all our sales, including the hospitals and the government, where no sales tax is paid, it drops down to about 7.5 per cent.

Mr. MACKASEY: Talking about the ultimate consumer, the little fellow again, and rounding if off to 10 per cent, would you like to comment on its real effect on a person buying a prescription at a drug store?

Mr. NOWOTNY: Yes, I do not mind. I think I can do it in the following way. Assume the net price, without the sales tax, to be about $4.50. Add your sales tax to it, which is fifty cents. That would make it $5, which would be what is called the wholesale price. If you take the usual mark-up which the retailer would put on under the mark-up system, that would be double, so it would make it $10. Now, if you remove the sales tax on the same example, as I have done, $4.50 then becomes the wholesale price and doubling it on the usual mark up it would become $9, therefore the difference would be a dollar. The dollar, of course, would be ten per cent, if you want it on the consumer level. On our level of course, it would be 20 per cent, on the level on which we add the sales tax to our prices, as we must.

• (6.15 p.m.)

Mr. MACKASEY: It would be 20 per cent on your price.

Mr. NOWOTNY: That is right, on the wholesale price.

Mr. MACKASEY: That is all, Mr. Chairman.

The CHAIRMAN: Are there any other questions?

I wonder if I could ask one brief question that I meant to ask some of the other witnesses. I noticed in the breakdown of your figures you quote a figure of costs under your marketing of some samples, 3.6 per cent. I think the figure for Lederle on Tuesday was 5 per cent. I wanted to ask you if the change in the legislation, Bill No. C-3, that went through about two years ago on sampling, discouraged sampling in any way and did this save you money in any way, or did it increase your costs?

Mr. NOWOTNY: I think I am right, but I do not know whether I am the right person to answer it. I do not think that Roche has ever been a very heavy sampling firm. As you realize, we are of course mostly in prescription drugs, so that samples would not be passed out as much as when you deal, let us say, in over the counter products. I do not think that this legislation has in our case affected the cost of samples to sales to any great extent now. Maybe Mr. Fralich can add something to it.

Mr. FRALICH: No. This is correct. There has been no change in the general relationship of sample costs to sales.

Mr. MACKASEY: Mr. Chairman, might I ask one supplementary question on my federal sales tax. On $4.50 item, the federal treasury gets fifty cents.

Mr. NOWOTNY: Yes, normally.

Mr. MACKASEY: Now under the normal mark-up the druggist is charging $10 and the cost is a dollar. The federal treasury is still getting only fifty cents.

Mr. NOWOTNY: That is correct.

Mr. MACKASEY: And who is getting the other fifty cents? I know the answer but I would like it on the record.

Mr. FRALICH: Everybody in the channel of distribution.

Mr. NOWOTNY: Thank you, Mr. Fralich.

Mr. MACKASEY: And who is paying for it? In other words, the public is paying the druggist profit on federal sales tax. He is not only meeting the fifty cents for the federal government but he is adding fifty cents to the gross profit of the drugs.

Mr. FRALICH: That is correct, but I think the same analogy applies to anything on which sales tax is collected.

Mr. MACKASEY: It applies to the suits we are wearing and the shoes, but we are not discussing those.

Mr. FRALICH: No.

Mr. MACKASEY: What I am trying to get at, Mr. Fralich, is that we are beating our brains out to save money to the consumer and the federal government has the power on the morrow to reduce the cost of drugs in this country ten per cent. For some unaccountable reason, they seem reluctant to do so.

The CHAIRMAN: No. This statement is not corroborated by our own accountant. As you know there is nothing to stop—

Mr. MACKASEY: Regardless of the effect, Mr. Chairman, the federal sales tax had on it, is it not a fact, that you, in your report to the parliament of Canada two years ago recommended the abolition of the federal sales tax on drugs.

The CHAIRMAN: No. No such report was made.

Mr. MACKASEY: Well, we should have made one.

The CHAIRMAN: My only point was that you have no assurance that if you take off the federal sales tax that somewhere along the line somebody will not put that price in under some other title. But this is not the problem of the manufacturer, it is the problem of—

Mr. MACKASEY: I appreciate the witness answering the question.

The CHAIRMAN: Are there any other questions? If there are not, I think we could thank Hoffman-LaRoche, as represented by these gentlemen, for coming before this Committee and giving us a very excellent brief and a very frank discussion of its contents. Thank you.

Mr. FRALICH: We would like to thank you also.

APPENDIX "A"

BRIEF

TO THE

SPECIAL COMMITTEE OF THE HOUSE OF COMMONS

ON DRUG COSTS AND PRICES

BY

HOFFMANN-LA ROCHE LIMITED

October 1966

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TO THE
SPECIAL COMMITTEE OF THE HOUSE OF COMMONS
ON
DRUG COSTS AND PRICES
BY
HOFFMANN-LA ROCHE LIMITED

Introduction

(1) This brief is written to comply with the requests made in the Committee's letter to the Company (hereafter referred to as Roche) dated May 20, 1966. Roche is a wholly-owned subsidiary of the Hoffman-La Roche group of companies.

(2) The Hoffmann-La Roche group was founded in Switzerland before the turn of the century. It made and sold drugs. The business gradually expanded outside Switzerland, and some plants were constructed abroad to prepare the dosage forms of drug substances which, until the outbreak of war in 1939, were largely manufactured in Switzerland. Shortly before the war, Roche took a leading, and in some respects, a pioneering part in the development and sale of vitamins. This proved a considerable success and it was this that transformed Roche into a widely organized international business. (For a more detailed history, see Appendix VIII)

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(3) Roche wishes to state at the outset that, in its opinion, the misconceptions and misunderstandings as to why drug prices must largely be what they are, can only be dispelled by thorough and painstaking enquiry into the costs and their causes, and that any such enquiry must necessarily be as much in the particular interest of Roche as in the general public interest.

(4) In order to save needless repetition to the Committee and to economize on its time, Roche has endeavoured in this brief not to discuss the general questions which have already been discussed by the Pharmaceutical Manufacturers Association of Canada, and the Canadian Medical Association. Roche largely shares the views put forward by both Associations, and accordingly this brief is, in many respects, the application and extension of these views to the particular case of Roche, and in other respects support of these views derived from the facts of the Roche case.

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Contents of Brief

(5) The brief will

(a) summarize and comment on the Earnings and Capitals Employed of Roche for the 12 year period, 1954 to 1965 inclusive

(b) discuss the information provided to the Commissionner of Patents for the purposes of the application made by Bell-Craig (Appendix II, Case No. 1) under Section 41 (3) for a compulsory licence for the drug chlordiazepoxide patented by Roche

(c) comment upon the conflict between the refusal of the Commissioner and the Courts to consider or enquire into this information and into Roche's costs and prices, and the enquiries now being made by the Committee into those same costs and prices

(d) comment upon the reluctance of Bell-Craig and other applicants for licences to disclose, discuss or compare their own practices, costs and prices, and the refusal of the Commissioner and the Courts to compel them to do so

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(e) explain and comment on how drug prices are determined

(f) explain and comment upon the evident and fundamental differences in the interpretation of the purposes and requirements of Section 41(3) in Canadian Courts, with the interpretation of the similar statute in the United Kingdom

(g) comment on and dissent from many of the views expressed by the Commissioner, and the Canadian Courts in the course of the Bell-Craig case

(h) make comments and recommendations in respect of patent protection and Section 41(3)

(i) include various appendices containing a short resume as to
(i) the History of Roche
(ii) the activities of Roche in the field of Research

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THE ACCOUNTS OF ROCHE CANADA
FOR THE 12 YEARS 1954 TO 1965 INCLUSIVE

(6) As the Hinchliffe Commission (a copy of which report is marked Appendix IV hereto) in the United Kingdom perceived, a cause of great difficulty for the drug industry in regard to its pricing and economic planning generally, is that "really outstanding drugs are still very few in number and if a firm makes one major advance in 10-20 years, it is doing very well".

(7) A clear example of this problem is provided by the case of world-wide Roche, which, after many years of great expense in research, achieved a "major advance" in chlordiazepoxide. This drug was first marketed in Canada in 1960 and a related compound, diazepam, was marketed in Canada in late 1963.

(8) But, notwithstanding the achievement of a "major advance", Roche's total financial performance in Canada judged over the whole period 1954-1965 has not been particularly remarkable. This is shown by the attached Appendix I which briefly summarizes the Profit & Loss Statements of Roche for the 12-year period from 1954 to 1965 inclusive.

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(9) It should be self-evident that the long-term and costly hazard of drug research, continually poses serious problems for the owners and management of every corporation engaged in it.

Unless, within a reasonable time, adequate financial success is achieved, the hazard is unlikely to be continued.

(10) The business must also eventually generate enough earnings to finance its growth. Rapid growth, of course, has been common in the drug industry during the past two decades. This enhances the strain of providing all the required finance.

(11) The attached Schedule I (Appendix I) is a cumulative Summary of Profit and Loss of Roche for the 12-year period 1954-1965, inclusive. Schedule II (Appendix I) shows the cost elements as a percentage of cumulative sales and other income. Schedule III (Appendix I) shows the same cost elements as a percentage of sales and other income for each year within the period 1954-1965, inclusive.

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(12) Schedules I and II (Appendix I) show that the net earnings averaged 4.7% of the sales and other income.

(13) Schedule IV (Appendix I) shows that an additional $8,900,000 was needed by the business to support the level of operations achieved by the end of 1965.

(14) Schedule VI (Appendix I) shows that $7,524,000 of these funds were provided by the Roche group from sources outside Canada. The after-tax earnings of Roche were therefore inadequate to provide the funds necessary for the natural growth of the business in such a rapidly growing country as Canada. Not even the greater earnings of 1964 and 1965 were able to provide the finance required for the continuing growth of those particular years.

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(15) Schedule VII (Appendix I) shows that the sum of the net assets employed in Roche during the 12-year period was $38,057,000. The net earnings of $3,389,000 shown in Schedule I represent 8.9% of those assets. Moreover, the prospective future earnings will be reduced as a result of compulsory licenses.

(16) It should be apparent that without a considerable act of faith both in the emergence of an eventual "major advance", such as chlordiazepoxide, and in the prospects of reasonable earnings in Canada from the "advance" if it came, the organization necessary to make the drug rapidly available to the public in Canada would not have existed in 1960 because the required investment in prior years would not have been made.

(17) In practice, therefore, however much the industry and the public interest might wish it to be otherwise, the maintenance of research and of the means to convey the results rapidly to the medical profession, depends upon the willingness of

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(a) the industry patiently to endure lean years of none or only partial success and yet to maintain and expand its organization of research and dissemination against the day when success may come.

(b) the public interest to recognize the need for and to permit a reasonable period of profit to compensate for the lean years and to enable the search for newer and better drugs to continue.

(18) It is believed that the 12-year Earnings of Roche expressed as percentages of both their Sales and Capital Employed would be broadly comparable to those of the average of the other like companies in the pharmaceutical business in Canada. As already explained, and as doubtless the Committee will see from its examinations of individual companies other than Roche, the periods of relative success vary greatly from company to company. Not all can be at the same time within their years of comparative prosperity; not all will have a "major advance" even in 10-20 years, whereas some may achieve them more often.

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(19) As already stated, Roche largely agrees with and accepts the comments and views of the Canadian Medical Association, upon the industry's costs and their causes and necessities. The C.M.A. seems generally satisfied about most of them but apparently has some reservations about the cost and character of certain aspects of Direct Mail. It would hardly be practical in this brief to explain and justify in detail the character of the Direct Mailings of Roche but the total cost relevance of Direct Mail to the net sales dollar of ethnical drugs is only 3 per cent. Also, Roche is willing to submit to the Committee examples of its Direct Mail programme with appropriate comments.

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THE INFORMATION AS TO COST AND PRICES OF ROCHE CANADA SUPPLIED TO THE COMMISSIONER OF PATENTS AND THE COURTS IN THE COURSE OF THE BELL-CRAIG CASE

(20) It will be evident to the Committee that while it is concerned with the costs and prices of ethical drugs in Canada as a whole, and therefore also with those costs and prices of Roche, a compulsory license application by its nature relates to one drug only, selected by the applicant in his private interest. Such applications have been in respect of the few large selling drugs only, and not for the many smaller selling drugs. There have been no applications for compulsory licenses in Canada for Roche drugs except those referred to in paragraph 21 herein.

(21) The Committee will doubtless understand that Roche believes that returns similar to those earned recently are unlikely to continue because—

(a) two compulsory licenses have already been granted in respect of chlordiazepoxide, the largest selling drug of Roche, at identical rates of compensation amounting to less than 2 per cent of the patentee's selling price, which will thus afford no protection whatever to that price.

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(b) a third license application for that drug is currently before the Commissioner.

(c) a license application has been made for the second largest selling drug of Roche, namely, diazepam.

(22) If a patentee is to try to explain and justify its price for a particular drug selected for a compulsory license application, it must try to separate, as

best it can, the cost relating to that particular drug from the costs of the remainder of its business. Roche made that separation in opposing each of the aforesaid applications. Nevertheless, as the greater part of the costs is fixed and not variable, and cannot be specifically attributed to a particular drug, much of it must be attributed only upon a turnover or other broad basis. Furthermore, as chlordiazepoxide is by far the largest selling drug, it follows that the cost attributed most inevitably be not very different from the total cost applicable to all.

(23) What will vary therefore, will necessarily be the ostensible profit level of a particular drug, dependent largely upon its price in relation to the variable and specific costs. In general, the newer drugs show a larger profit than the older by this test. But the necessary attribution of so much of the cost on a turnover basis inevitably means that the margin of profit so determined for a particular drug can necessarily be challenged. This difficulty does not arise in a consideration of the total cost and profit for all the drugs.

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(24) It seems appropriate at this point to explain that the inherent differences between and the resulting difficulties in reconciling an enquiry in the public interest into the costs of all the drugs of such a concern as Roche and the restricted enquiry into the facts relating to one drug arising in the private interest of an applicant are not unique to Canada. As the Committee knows, the Ministry of Health in the United Kingdom is responsible for the public interest in the price of drugs. It has now a well defined system for enquiry into them known as the Voluntary Price Regulation Scheme. In the course of its negotiations, it makes an enquiry into the total costs, earnings and capital employed for all drugs of Roche in the U.K. similar to that which the Committee is now making in Canada. The Parliamentary Committee may also know that the Sainsbury Committee in the United Kingdom is currently enquiring into the costs, profits and prices of drugs, and in so doing, is asking

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for financial information to be supplied relating to the whole business of each concern in drugs without involving itself in the difficulties of determining the costs etc., relating to a particular drug. The U.K. Comptroller in a compulsory license case, on the other hand, restricts his enquiry, in form at any rate, into the facts relating to the one drug selected by the applicant in its private interest.

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The Conflict Between the Present Enquiry by the Committee and the Refusal of the Commissioner of Patents and the Courts to Make a Similar Enquiry for the Purposes of an Application for Compulsory License

(25) Roche is unable to reconcile the attitude of the Committee towards the problem of the costs of and profits on Roche drugs with the attitude of the Commissioner of Patents and the Courts in regard to the costs of and profit on chlordiazepoxide. If the questions put by the Committee and the answers provided by Roche about those costs and profits are relevant to the question of

what the prices of all Roche drugs should be, as Roche believes they are, it seems impossible to conclude that they are or should be irrelevant to a compulsory license application under Section 41(3) which Roche believes is legislation clearly related to and intended to influence the price of drugs.

(26) However, the Supreme Court evidently believes the contrary and particularly, that the legislature did not intend that Section 41(3) should invoke an enquiry into the costs and profits and consequently, into the prices either of the patentee or of an applicant for a license. As, moreover, in the Bell-Craig case, the Court has restored the Commissioner's usual award of compensation which he has described as a "pittance" and which, as already stated, affords no

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protection of the patentee's necessary selling price, it follows that the practical effect of the Court's interpretation is virtually to abolish patent protection in Canada in relation to drugs. Indeed, that seems to have been the Court's intention.

(27) In the Roche vs Bell-Craig case referred to in the P.M.A.C. brief, the Supreme Court stated that Parliament intended that "there should be competition in the marketing of such products produced by a patented process". This is really concluding that although the legislature provides that a patent may be obtained for a drug, it also intends that the patent shall not thereby confer any reliable degree of monopoly upon the patentee, that the monopoly may readily be broken, and that when it is broken the compensation shall be related to and restricted by these preceding intentions. Indeed it is not very difficult to construe the above quotation of the Supreme Court judgment as necessarily implying that Parliament did not really intend to grant a patent on a drug at all.

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(28) The P.M.A.C. has referred to the competition that exists in and is the whole basis of this industry, to the substantial competition that drugs have with each other, and that new and better drugs come only from that competition. These facts are stated in the Restrictive Trade Practices Commission (R.T.P.C.) Report at page 356. Evidently, the Supreme Court nevertheless considers that the legislature has assumed that the competition between drugs would not contain a sufficient element of price competition, and that, accordingly, price competition must be created and encouraged within a particular drug regardless of whether the price could or could not by other standards or tests be regarded as fair and reasonable. It seems that the Court believes that this will enable the patentee and perhaps a number of licensees to race in healthy competition in the public interest. But it completely overlooks that the patentee in that race would be carrying burdens immeasurably greater than the licensees, although quite unable to discard them and would also be carrying the licensee on his back. Unless the awarded compensation fully allows for this, the resulting price competition must necessarily tend to impair or destroy in the long run the competition in research to find new and better drugs in the public interest.

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(29) Canada has accordingly chosen to adopt and follow the pattern of the drug industry in Italy rather than that of either the United States or the United Kingdom.

(30) The purpose of Roche in drawing attention to this is not so much to challenge the Court's interpretation, which cannot now be changed without legislative action, but to point out that

(a) the various recommendations and remedies of the Restrictive Trade Practices Commission or of the Hall Commission such as to

(i) limit or restrict the patent protection of drugs

(ii) limit or restrict the use of trade marks on drugs

(iii) grant compulsory licenses under Section 41(3) of the Patent Act for the import of drugs; or

(b) an enquiry of the Parliamentary Committee into those recommendations and remedies seem now unnecessary and have little practical

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meaning and purpose so long as this interpretation stands. None of the remedies proposed can have, in the opinion of Roche, any greater effect on drug prices than the Supreme Court's decision will have.

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THE RELUCTANCE OR REFUSAL OF APPLICANTS FOR COMPULSORY LICENCES TO DISCUSS THEIR OWN ACTIVITIES, COSTS, PROFITS AND PRICES

(31) Representatives of Roche attended the hearing of the Committee in July at which the representatives of the Canadian Drug Manufacturers were examined on their brief. Roche assumes, from these proceedings, that the Committee has an understanding of the great differences which exist between the functions and services performed by such copiers of drugs, and those of such researchers and introducers as Roche. These differences are fundamental. They go to the heart of the problem of the price of drugs, and of the reconciliation of the two potentially conflicting aspects of the public interest, namely, the "lowest possible price", on the one hand and the maintenance of research and of medical information, on the other.

(32) A simple illustration of this conflict may suffice. In many cases the copiers do not have "field representatives" as the C.M.A. brief describes them. Where they do, they apparently find it impossible to survive if they cut the price of their copies drastically. Those copiers that do not have or cannot afford "field representatives" at all tend to claim, perhaps inevitably, that neither field

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representatives nor any other method of conveying medical information to doctors are necessary. The C.M.A., on the other hand, in paragraph 39 of its brief makes it quite clear that a "field representative" is not only necessary but that he ought to be not only highly qualified but highly and expensively trained

by such houses as Roche to "make him still more useful" to doctors. Here then lies the essence of the dilemma for Roche and other similar houses, namely how to reconcile the ever increasing need for greater and more expensive training of representatives, and for improving the general quality and standard of their information about their drugs and yet to keep the costs of drugs, and consequently their prices, at "the lowest possible" level.

(33) In order to draw attention to this fundamental difference and problem and to the importance of the costs incurred, Roche in each of the above mentioned compulsory licence cases, has

(a) provided complete evidence of what it does, what its costs are, what its price covers and what capital it employs, and

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(b) endeavoured, without success, to induce the applicants to be equally forthcoming and frank so that proper comparison could be made in the public interest.

Bell-Craig Application

(34) The Committee will doubtless understand that as chlordiazepoxide is a successful new and patented drug the margins earned on it and thus the return on the capital employed in it, will inevitably tend to be and should be greater than those of older and smaller selling drugs. That is among the reasons why such a drug is selected by small copiers for compulsory licence applications. What matters in the long run, both for such concerns as Roche and the public interest, is the overall return from and viability of the total business in drugs, the stronger more successful drugs partly carrying the smaller weaker as is the case in human life itself.

(35) The following comments upon some of the disputes in these cases may assist the Committee. The applicant Craig frankly said he could not estimate his probable cost of manufacturing the substance very accurately, but maintained that any such accuracy was largely irrelevant to the selling price of the drug to the public. Roche agrees with this.

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(36) As to the other costs of manufacture, capsuling, bottling and packaging, the applicant was more explicit. This Roche understands because the applicant's main experience is in that and not in making chemical substances.

(37) The applicant could not state his own Distribution costs. He did not contend that they would be lower than those of Roche. Roche believes they could not be lower because in small scale distribution the costs mount greatly both actually, that is per kilo and relatively, that is percent of the selling price.

(38) As already stated despite its efforts in all its compulsory licence cases, Roche has been unable to elicite enough information from the applicants to throw light on the margins they require, for what activities they precisely require them and how their profits relate to their capital employed. It is apparently the intention of the Parliamentary Committee to examine some of these applicants on their costs and profits, just as the Sainsbury Committee is

doing in the U.K. It may be possible, therefore, after these examinations to see more clearly what is really involved. In the meantime Roche makes general comment which may help the Committee.

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(39) As already indicated, the crucial factor for everyone in the drug industry, whether patentee or copier, is the scale of the turnover. The main variable costs are in the manufacturing, and to some extent in the distribution. The remainder are mainly shares or allocations of fixed costs. The President of Bell-Craig made much of this to explain his difficulties in estimating his own costs and his price. He said however that he would be fortunate to obtain a turnover of as much as 60 kilos a year. He had also stated in his application his proposed prices and these, he agreed, should result in a selling price of about $3500 per kilo for the main dosage form which he expected to sell. If he sold other dosage forms in the proportion of the Roche sales, his average price would be about $3000 per kilo.

(40) It should be apparent to the Committee from the Bell-Craig case that for a compulsory licence an irreducible minimum price could be as low as $1300 per kilo. Roche believes that a licencee would abandon its licence, as it may do for it has no obligation to use it as Roche has to use its patent, if the price fell to anywhere near as low as $1300 per kilo.

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(41) At any rate this means that if the applicant could sell at its expected prices in the face of competition from other licencees, it apparently has a margin of $1700 per kilo to cover its promotion (if any) or advertising, its possibly greater distribution, etc., costs, and its profit. The difficulty which Roche has encountered is to get any applicant to account for the items in this gap of $1700 even broadly.

(42) In Roche experience there is usually greater difficulty in obtaining information from such an applicant as to the capital it can and will employ in the business which will result from its compulsory licence. In the Bell-Craig case, the applicant's President merely said that he would be constructing a new plant and would borrow money for that purpose. Roche is unable, therefore, to comment upon the rate of return on the capital employed that such applicants enjoy in general or expect from successful applications for compulsory licences. The Committee will have seen from the brief of the "Canadian-owned" drug companies that applicants of this kind are prone to suggest that return on investment is "a very effective way to measure the earning capacity of any

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industry", and further that the return in the drug industry is too high. But as far as Roche is aware none of them have stated or disclosed their capital circumstances or the returns they expect to earn.

(43) During the hearing of the Bell-Craig case before the Commissioner, the applicant agreed that

(a) the substance (active materials) has no commercial value before its therapeutic qualities are accepted by doctors

(b) the introducer of any drug must make a great effort and incur a great cost to get the drug accepted by the medical profession.

(c) the inventor and introducer of chlordiazepoxide was Roche and Roche had incurred great effort and expense in getting the drug accepted

(d) the patentee, in this case Roche, must continue to support the drug with costly medical information services in order that the drug should be maintained in face of therapeutic competition from other drugs

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(e) the applicant's criteria, therefore, in applying for a licence would be that the demand for the drug should be large, created by thorough, detailed and costly information to doctors, that the demand should be sustained continuously by the patentee, and that the selling price should reflect all these costs.

(44) These facts are stated by Roche in order to bring out the following points:

First, that applicants generally cannot afford and do not really intend to provide serious and reliable medical information, though they may say they will provide it; which in practice seems to be confined merely to repeating what the patentee or originator says. (See Appendix V for an extract of the cross-examination of Mr. L. C. Marion, President of Elliott-Marion Company Limited in an action instituted in the Exchequer Court of Canada, wherein Roche was plaintiff and Elliott-Marion defendant. The cross-examination relates to Mr. Marion's affidavit filed in the action and took place on April 21st, 1966).

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Second, even if the applicant's margin was entirely profit, bearing no cost either of medical information or otherwise, then after taxes it would be so small that their prospects of building up enough capital to make the drug generally available in Canada should be largely if not wholly discounted.

Third, that the effect of the price-cutting and of loss of volume to licencees would be to reduce the ability of patentees such as Roche to develop new drugs through research and service the drug by medical information and otherwise.

Fourth, that the competition between patentees and such licencees is so unequal that it should not really be described as competition, which is meaningless if it is not equal.

(45) This should also explain to the Committee why so many of these applicants find it difficult to survive, and why they so often sell their businesses to larger drug concerns. At any rate between the hearings by the Commissioner and the Supreme Court the Bell-Craig business was sold to a somewhat larger

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American drug house, The Denver Chemical Manufacturing Company Inc., of Stamford, Connecticut. This concern obviously realized that a hard, difficult and

probably unrewarding road lay before it even if the licence was upheld by the Supreme Court on the awarded minimal terms. It said it would withdraw if Roche could give it some lesser drug, coming out of Roche research, which would be potentially too small for Roche to introduce, but which would be interesting for a smaller concern like Denver to introduce. In point of fact, even potentially small selling drugs are usually marketed by the larger research houses if they represent a therapeutic advance, and other difficulties are inherent in such a transfer. So Roche concluded that no useful purpose would be served in accepting this offer. This may, however, serve to illustrate to the Committee that few, if any, concerns of experience in the drug industry believe that a viable and permanently satisfactory business can be derived from mere copying as distinct from finding and introducing a new drug, even if it is small selling. Among the reasons for this is that the market for all drugs is largely inelastic, and accordingly a copier does not create new business in it but has to fight to take away part of the entrenched originator's business, and in doing so to persuade doctors to switch to the copy.

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(46) The problem of the capital locked up in the discovery, proof, information upon, and general and immediate availability of drugs, lies behind the representations made to the Committee by the "Canadian-owned" drug manufacturers that the State should subsidize their specific research projects and also create some king of information centre presumably to disseminate the results of research. In Roche's opinion research and the dissemination of knowledge obtained therefrom are inseverable. There are, of course, many other practical aspects of these suggestions which evidently have not been considered by the aforesaid manufacturers. The political question involved for Canada is, of course, a matter for the Committee rather than Roche. But it is perhaps proper for Roche to say that these ideas are not new and have in some respects been partly tried elsewhere. It might for example assist the Committee to look at the experience of the National Research and Development Corporation of the United Kingdom in this regard.

(47) The "Canadian-owned" drug manufacturers made no suggestions as to how the costs of this inevitably long term investment of the State in research should be recovered. The U.K. experience shows that the only practicable way

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of recovery is to patent discoveries and market them through a limited number of exclusive licencees wherever possible in the world, though even that has not apparently resulted in financial success. Otherwise, the price cannot be held up to a level sufficient to recover the costs of discovery and proof. The "Canadian-owned" drug manufacturers say their combined turnover is about $4 millions. If they contributed to the State research equally, ignoring whether they would all be beneficiaries by licence, at 20 per cent of their turnover this would provide $800,000 per annum.

(48) If research were always inevitably successful then the incentive for it would perhaps not be needed or so important, nor, as the "Hinchliffe Report" points out in paragraph 228, would it then be so costly. The "Hinchliffe Report" also stresses in paragraph 256-258 (ii) that it is necessary to encourage such

patentees as Roche to continue to endure, in the public interest, the frustrations and costs of the innumerable failures at all stages of its research before it achieves an "occasional success"—"Hinchliffe Report" paragraph 228.

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Delmar Application

(49) In March 1962, that is before the Bell-Craig application, an application had been made by Delmar Chemicals Limited for a compulsory licence for chlordiazepoxide. This was granted in February 1963 by the Commissioner of Patents and the usual rate of minimal compensation of 12½% of the selling price of the substance. Roche Canada appealed both against the grant and the royalty. The appeal against the grant failed, though taken to the Supreme Court of Canada. The appeal against the fixing of the compensation without evidence was upheld by the Exchequer Court of Canada and the question of royalty was referred back to the Commissioner of Patents for further consideration. On June 21st, 1966, the Commissioner issued a revised compulsory licence in which he changed the royalty to 15% of the selling price of the bulk substance, thereby raising the royalty from $56.25 per kilo to $67.50 per kilo.

(50) Before the appeals on the grant were concluded, Delmar was acquired by Labatt Breweries, which in turn was associated with a European firm. The Committee has seen from the evidence of the "Canadian-owned" drug manufacturers that the European interest has now been acquired by Labatt, so that Delmar may now also be considered as wholly "Canadian-owned".

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(51) Soon after this acquisition, Delmar and its new owners opened negotiations with Roche for a voluntary license in place of the compulsory grant. Roche believes and said to Delmar that voluntary licenses of this kind are not necessarily in the public interest because, among other reasons, they tend to impair the present intense competition in research, and thus restrict progress.

(52) Delmar stated that its new owners would not want it to apply for further compulsory licenses, but said that it was unable to withdraw from pursuit of the existing license because of a commitment, prior to its being acquired, to the Elliott-Marion Company Limited, then also a "Canadian-owned" concern. Roche replied that as Delmar and its new owners understood very well, Roche must have proper compensation for the contributions to fixed overheads which it would lose in consequence of such a license. Roche's view of the scale of the necessary compensation was quite clear from the Bell-Craig hearing and known to Delmar.

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(53) Delmar did not disguise that in its opinion the awards of compensation made by the Commissioner were quite unrealistic and inappropriate. In the end it advanced its offer of compensation to $1200 per kilo. This should be compared with the Commissioner's original award of $56.25 per kilo and his revised award of $67.50 per kilo. Delmar said that it could not afford to pay more. As it was not itself marketing the drug but simply sold the substance to Elliott-Marion at $450 per kilo plus whatever compensation would be payable to Roche, and as Elliott-Marion in turn has prescription prices ranging from $2800 to $7700 per kilo, it was implicit in this offer and statement that it was Elliott-Marion which was willing to pay $1200 per kilo but that it could not afford to pay more.

(54) As the Elliott-Marion prescription prices were carefully posed, as such copiers tend to pose them, at about 90% of the patentee's price, this meant that, on its face, it would have an average price of about $4000 per kilo. This would provide it with a margin for its profit and promotion of $1500 per kilo if it voluntarily paid $1200 per kilo, and approximately $2700 per kilo if it paid the minimal compulsory licence rate.

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(55) The Committee may very well ask, at this stage, why Roche refused to grant the voluntary licence. Among the reasons were

(a) the Bell-Craig appeals had not been heard, and Roche still believed that the Courts would take a realistic attitude to this problem (in fact, as will be seen later the Exchequer Court intended to award $525 per kilo)

(b) other applicants might appear, and they did appear

(c) the Roche price would still be liable to drastic cut, as it now is in the hospitals, in respect of which Elliott-Marion would incur minimal medical information costs and no research costs

(d) as a matter of principle, because granting a voluntary licence under the duress of a compulsory licence application, would be tantamount to accepting that reasonable patent protection for drugs does not really exist, and ought not to exist.

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(56) According to sworn testimony of the President of Elliott-Marion, American Home, a firm which has a large international business in drugs, acquired, about January 1966, a majority interest in Elliott-Marion which would eventually lead to its total acquisition.

(57) It has been emphasized in this brief that the economics of scale play a dominant role in this business. Roche has been quite unable to understand why Delmar and subsequently Labatt should have begun and continued in an affair such as this, which cannot possibly be rewarding to them and which is mainly, at least on its face, for the benefit of Elliott-Marion. The returns of manufacture so far by Delmar to Roche for the purposes of compensation have been

1.9 kilos in 1963
2.85 kilos in 1964
119.08 kilos in 1965

If the drug cost nothing to manufacture, Delmar would have a profit at its selling price to Elliott-Marion of $450 per kilo and this would amount only to

$ 860.00 in 1963
$ 1,292.50 in 1964
$53,563.50 in 1965

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(58) Delmar informed Roche in the course of its approaches to Roche that Craig had approached it to buy the substance from it saying that if he could do so that would avoid his continuing with his own (Bell-Craig's) application and

avoid the investment in a chemical plant for an unpredictable but inevitably small output; Delmar refused to sell to Craig, saying that it had an exclusive commitment to Elliott-Marion. This may indicate to the Committee that such copiers do not really want equal competition from their own kind, but a ride on the back of such patentees as Roche in the most exclusive conditions possible.

Micro Application

(59) The third application for a compulsory licence for chlordiazepoxide was made by Micro Chemicals Ltd. in August 1965. This was between the dates of the Exchequer Court decision of March 1965 and the Supreme Court of Canada hearing of December 1965 in the Bell-Craig case. At or about the same time Micro applied for compulsory licences in respect of other large selling drugs patented and marketed by Smith, Kline & French, Merck, Sharp & Dohme, and Poulenc.

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(60) Notwithstanding that one of the bases of the Exchequer Court's judgement in the Bell-Craig case was that Section 41 (3) neither required nor called for an enquiry into either the patentee's or the applicant's price, and that the Section merely required the creation of price competition within the drug, the Micro application, somewhat to Roche's surprise, in large part followed the line most applicants had taken before that judgement. It

(a) stated its own expected prices which were 75 per cent of the patentee's price,

(b) alleged that the patentee's (Roche) price was too high

(c) nevertheless contained no information to support either its own price per (a) or its condemnation of Roche's price per (b)

(d) said the compensation to Roche should be 5 per cent of the selling price of the bulk material (substance) plus the cost of converting into a dosage form (this was to conform with the rejection by the Exchequer Court of the Commissioner's theory that the compensation should be restricted to the substance only).

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(61) As has been explained, the total inequality of conditions of the competition between Roche Canada and the licensees would have meant that no cut in price to reduce the margins or returns to a supposedly reasonable level, could be relied upon either to prevent the price from falling to a sub-marginal level or effectively to oppose the competition. Moreover during this period 1964 and 1965, Roche Canada was still hoping that a realistic view of this problem and the necessary compensation would be taken by the Canadian Courts.

(62) It may perhaps be worth stating that there is a similar situation and dilemma in the United Kingdom at the present time. The Ministry of Health has recently said to Roche that it feels that the returns on its capital employed are now high enough to suggest that "there is room for reductions in some prices". However, there are two applications for compulsory licences for chlordiazepoxide which should be heard by the U.K. Comptroller of Patents within the next few months. The Ministry have accordingly agreed that any question of

reductions in prices must be deferred until it is known whether the licences will be granted and what their terms would be. The Ministry has agreed with Roche

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that agreement as to reasonable prices is meaningless if others may come into the market for chlordiazepoxide on unknown terms and upset its price. The situation in the United Kingdom is however, such that the licences may be refused on the grounds that a "reasonable price" must be presumed to result from the negotiations with the Ministry, and, furthermore, the terms of compensation would, in any event, be much greater than those currently awarded in Canada.

(63) In view of Micro's contentions about its prices and those of Roche respectively, Roche suggested that Micro should state how its prices were calculated, what costs it incurred and what profit it would earn upon its selling price and on the capital employed.

(64) Roche also pointed out that two compulsory licences had already been granted to Delmar Chemicals and Bell-Craig respectively so that the grant of yet another licence would not be in the public interest.

(65) In response, Micro

(a) repeated and extended its assertions that Roche's price was too high

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(b) contended that its own price was fair, but gave no information whatever either as to its costs or how it had calculated its price, nor its capital employed

(c) nevertheless contended that its estimate of its profit on its average selling price of $3400 per kilo would be close to 17.08% of that price

(d) contended that Elliott-Marion's "policy was to maintain prices as high as possible because it expects through its large detail force to obtain prescriptions from doctors who are well disposed to it", and that Elliott-Marion's prices were "not as low as they could be"

(e) contended that "it is seriously open to doubt whether Bell-Craig could sell chlordiazepoxide at the prices it proposed"

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(f) contended that "its superior experience to Bell-Craig in manufacturing drugs" and the fact that "the competition from Delmar is not so great as it could be" were grounds for the Commissioner granting a further licence to Micro.

(66) The Committee from its experience in questioning the late Mr. L. Winter of Empire will not be surprised to see this repetition of the kind of claim made by him, namely that his own methods of business, and his prices were exactly right, and that those not only of such patentees as Roche but of other copiers were neither right nor what they should be. In sum, all virtue lies, according to each copier, in what he himself does and not in what anyone else does.

(67) The inherent absurdities of and contradictions in these claims do not seem to worry or concern such copiers. So that such as Micro will contend that

their own average prices of $3400 per kilo is exactly right, that Bell-Craig could not really sell at $3000 and that Elliott-Marion's price of $4000 per kilo, contains an obnoxious element of detailing, which, presumably, accounts for the $600 per kilo by which that price is superior to Micro's. Each one in turn attacks the

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prices of and the activities of all the others, and thereby expects to avoid being asked about its own activities, costs, prices and capital. So far, of course, this expectation has been realized in Canada by the refusal of the Commissioner and the Courts to examine these matters. Bell-Craig, following the lead given to it by the Exchequer Court, contended in the Supreme Court that it did not have to explain or account for its price, and did not in fact do so. Delmar by postponing any discussion of compensation until after the Supreme Court upheld the Commissioner's decision in the Bell-Craig case has effectively avoided discussion on behalf of Elliott-Marion, of the costs and price structure.

(68) In order to stress the contradictions, Roche pointed out, in a further submission to the Commissioner, that

(a) Micro was apparently admitting that its manufacturing costs would be around $460 per kilo

(b) Micro was now proposing compensation to Roche of $69 per kilo

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(c) Micro was claiming that its profits would be about 17.08% of its average selling price of $3400, or $578 per kilo

(d) the sum of (a), (b) and (c) was $1107 per kilo

(e) there was thus a completely unexplained gap of no less than $2293 in its selling price, though it must cover distribution among other costs

(f) this total failure to explain should be contrasted with Micro's tendentious and continuing attacks on both the necessity and scale of Roche's costs especially of research and medical information

(g) that such indications as Roche had of the limited capital which would be employed by Micro would indicate that its return, even only the $578 per kilo per (c), quite apart from the unexplained gap, would represent a much larger return than Roche itself obtained.

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(69) Specifically, both in the applications for chlordiazepoxide and in those for the drugs of Merck, Micro attacked and denigrated all the customary forms of informing doctors, including in particular detailmen. So evidently similar costs do not account for the unexplained gap in the Micro price. In the Merck case Micro also chose to assert that Mowatt & Moore and Neo Drug who were selling that drug were too small to make inroads into the market. This, of course, was a continuance of the theme that the best servant of the public interest would be Micro and none other.

(70) In consequence of the Supreme Court upholding the Commissioner in the Bell-Craig case, Roche will be deprived of any further opportunity to pursue these contradictions. The Commissioner will not enquire into them and has since awarded without an oral hearing or other cross-examination on the submissions made a further compulsory licence under Section 41(3) of the

Patent Act to Micro Chemicals Ltd. in respect of the latter's application against Smith, Kline & French.

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(71) At the end of May 1966 a compulsory licence in respect of diazepam was applied for by Empire Laboratories Ltd., hereafter referred to as "Empire". The application states

(a) Empire's total turnover and before-tax profits for the years 1960 to 1964 inclusive were

Turnover	*Profit*
$3,114,000	$501,000

(b) Empire's proposed prices, which will be about 60% of Roche's prices for all dosage forms

(c) Empire calculates its cost of manufacturing diazepam will be about $68 per kilo, and after "the addition of overhead and profit", it will sell diazepam in bulk to others at about $170 per kilo, "not including any royalty payable to the patentee"

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(d) Empire considers the "due reward for the research leading to the invention" would suggest that "a reasonable royalty would be 15 percent of the net selling price of diazepam in bulk". This is obviously contemplated to be about $30 per kilo namely $170 plus $30=$200 of which 15% is $30

(e) Empire has a "consistent policy to make available drugs to the Canadian public at essentially lower prices than those by foreign companies" as, for example,

100 Chloramphenicol 250 mg capsules Parke Davis $39.40	Empire $15.70
500 Tolbutamide 5 gm tablets Horner $59.40	Empire $23.00
100 Dexamethasone 0.75 mg tablets Merck $29.80	Empire $12.50
500 Meprobamate 400 mg tablets Wyeth $43.75	Empire $6.25.

(72) The comparison of the prices of "foreign companies" with those of Empire is clearly intended to suggest that it is comparing likes and that

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Empire's competition with those "foreign companies", and with Roche if it obtains its license on the terms it offers, is fair competition between equals. Empire does not seen to realize that within its own statements is an obvious refutation of the equality of the competition. If the "foreign companies' " prices are more than twice those of Empire, on which Empire claims it makes a satisfactory margin of profit, then the "foreign companies" are either

(a) earning quite fantastic margins on their total sales, or

(b) incurring very heavy costs which Empire does not incur.

The first alternative obviously conflicts with the PMAC brief. It conflicts with the attached Schedules relating to Roche's business, and will doubtless conflict with the evidence submitted by the other "foreign companies" asked to appear before the Committee.

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(73) The total before-tax profits of Empire as a percent of sales for the years 1960 to 1964 inclusive represent about 14%. They are comparable with those of Roche for its total business. The Empire price list contains many drugs, more items than Roche itself sells. It is to be assumed, as the evidence of the "Canadian-owned" drug manufacturers tends to confirm, that Empire has a few items which earn quite a high profit, carrying others which perhaps earn very little. This is, of course, the experience of Roche and doubtless others.

(74) The indications from this are that quite high rates of return on the capital employed have been earned by Empire in these years. Thus, if the starting capital were $50,000 and if by the end of 1964 there were another $300,000 of retained earnings, the 1964 before-tax profit of $191,000 would have represented a return on capital employed at the end of the year of over 60%. Roche refers to this not to disparage such an excellent achievement but to emphasize that the capital employed by such concerns as Empire is structually

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quite different from that of concerns such as Roche, and further that even after such a period it is probably very small in relation to the capital which it requires for future growth and certainly to make its drugs available throughout Canada.

(75) This dearth of capital seems to be the explicit cause of many of the complaints and suggestions made to the Committee by the "Canadian-owned" drug manufacturers. Appendix E-1 of the P.M.A.C. brief shows that the members thereof employed nearly $78 millions at the end of 1964. It would be surprising if the capital employed by the "Canadian-owned" drug firms turned out to be more than $1 million. This illustrates how and with what means drugs must be made generally available to the public in Canada.

(76) Roche thinks that when Empire in its compulsory licence application states that it has an "analytical and research laboratory", the inclusion of the words "and research" conveys an impression, though that may not be intended, that Empire is conducting research comparable in kind to that of such concerns as Roche. That cannot be the case, as the evidence of the "Canadian-owned" drug manufacturers shows. The problems of organization and of finding capital

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to conduct any worthwhile research today are clearly quite beyond the resources either actual or likely for such concerns as Empire, and that explains their request for government sponsorship.

(77) Roche believes that in general a Canadian concern which is not organized and established worldwide could not now hope to have a wide enough

base on which to recover its research costs. The "Canadian-owned" drug manufacturers, as their evidence tends to show, only do business in limited areas of Canada.

(78) What is perhaps not so evident is that the even heavier cost of the organization to disseminate the results of research, which is described in this brief as medical information, must also be world-wide if it is to be viable in today's conditions. As the doctors on the Committee will know, the vital clinical test of a drug is its actual performance in widespread use by patients. This cannot be evaluated by anyone so reliably as those who have discovered it and know already a little of what it will or will not do. Medical information,

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therefore, is really inseverable from and an extension of research. Research may perhaps be likened to the roots of a tree, and medical information the trunk, branches and leaves visible above ground. Neither can exist without the other.

(79) Canadian national interests must naturally be regarded in relation to drugs as to anything else. But Roche considers that in the controversy about drug prices far too little regard has been paid to the facts. The breakdown of costs given by the PMAC should show the Committee what is really involved. Every concern in the drug business in Canada, whether an international house such as Roche or a "Canadian-owned" drug manufacturer incurs the major part of its manufacturing costs in Canada itself. Though such international houses as Roche may consider it more practical and sensible to make substances in larger quantities elsewhere to serve many countries including Canada, the cost involved is smaller than the cost of the remainder of the manufacturing

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which takes place in Canada itself. Therefore, the emphasis which applicants for compulsory licences often put upon there being a "Canadian-owned" drug manufacturer of the particular drug substance is an appeal to emotion.

(80) The main other cost which is normally incurred outside Canada is that for research. Some international concerns have begun to perform a part of their total research operations in Canada. But it is usually only an integrated part of a wider programme of that international house. The Committee will, of course, understand that the principle or theory that every sovereign country should be self-sufficient in such a comparatively minor aspect of its economy, can easily be carried to absurd conclusions. Roche at any rate believes that the already great and growing burden of research costs in drug prices would tend to get completely out of hand if the question of where to conduct research were too much regarded from the standpoint of national or patriotic emotion rather than of business economics.

(81) In the Empire case discussed above, there is the usual unexplained gap between the substance cost and the proposed Empire selling price. Thus, the

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application merely states the cost of the bulk substance of $170 per kilo, apparently in order to suggest a royalty of only $30 per kilo. At the prices stated in the application, the applicant's average selling price should be somewhere around $6,000 per kilo.

(82) The unexplained gap in the Empire price is, therefore, somewhere around $5,800 per kilo. Having regard to the Bell-Craig case, Empire is refusing to volunteer what its other costs are. In the case of Roche this gap must cover its contribution to research and its share of medical information.

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(83) Roche, like similar patentees, is unable to compete with the prices of concerns like Empire if its compensation in respect of a compulsory licence is something so totally irrelevant as $30 per kilo. The mischief for Roche lies not so much in what business would actually be lost to copiers but what happens to the price level as a result of their entry. If, for example, the average Roche prices had throughout been

for chlordiazepoxide, the $3000 average per kilo of the Bell-Craig prices

for diazepam, the $6000 average per kilo of the prices proposed by Empire

then the effect on the total before-tax profits of Roche Canada would have been to reduce them by:

$1400 per kilo on 3424 kilos of chlordiazepoxide sold up to the end of 1965	$4,794,000	
$4000 per kilo on 357 kilos of diazepam sold up to the end of 1965	1,428,000	$6,222,000

(84) But, Craig's Counsel said in the Bell-Craig case, when under pressure from the Supreme Court, much lower prices than those stated in its application, would result from the licence.

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(85) In either case, therefore, it is apparent that Roche's prospects of continuing a viable business in Canada would be gravely impaired if not destroyed by price reductions of this character.

(86) Empire has recently filed its Reply to the Roche Counterstatement in respect of the compulsory license application discussed above. Empire's Reply confirms and focuses the situation now existing in respect of compulsory licenses, as Roche has seen it and explained it in the brief. A short summary of the Reply may, therefore, help the Committee.

(87) The Reply relies upon the Supreme Court's view that the legislature did not intend to permit absolute monopoly by patent in respect of drugs, whatever the circumstances and facts in relation to the drug may be. It contends that, in addition to some limit in time, which all patents universally have, the Canadian legislature intended, by its use of the words "lowest possible price", that the patentee should be granted only a token royalty as compensation for a token monopoly. Empire seems in no doubt that patents on drugs have been effectively abolished in Canada.

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(88) The Reply, nevertheless, specifically and contradictorily refutes that the question of the prices of ethical drugs is relevant to Section 41(3).

Consequentially, it contends that—

(a) The enquiries of the Committee in general and the questions it may ask as to the costs either of Roche or Empire, are irrelevant to Section 41(3).

(b) The reasonableness of the Roche price is equally irrelevant to Section 41(3).

(c) Empire does not have to and does not intend to explain to the Commissioner of Patents why it can sell at a lower price.

(89) The Reply contends that Empire is "merely exercising its statutory rights under the Patent Act which it is entitled to do". All this seems to exclude the "public interest" with which the Committee is clearly concerned. At any rate, the Reply contends that neither Dr. Wright nor any other officer of Empire should be asked to submit to cross-examination by Roche before the Commissioner of Patents. It also contends that none of them can be "required" to appear before the Committee for the like purpose.

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(90) The Reply contains no information whatever as to the scale and character of the cost of Empire and refuses to disclose its capital employed. It nevertheless contends that it will not make an exorbitant profit at the prices it has stated in its application. To support this denial, it significantly admits that, having regard to the relative size and turnover of Empire and Roche, the Empire costs will be substantially higher per unit than those of Roche.

(91) As further support of this denial, and in contradiction of the letter written by Empire to doctors in Canada following the appearance of Dr. Wright before the Committee on July 7th, 1966, the Reply of Empire now denies that it regards as unnecessary the efforts of such researchers as Roche, to inform doctors about their discovered drugs. It also makes a vague general assertion that Empire's policy is "to make such information fully available to doctors on a regular basis".

(92) While refuting the Roche contention that the said prices of Empire are not "the lowest possible", it nevertheless contends that these words in Section 41(3) do not mean the lowest possible price "in vacuo" but "the lowest possible price at which the drug can be sold commercially". This seems to be

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directly in conflict with the views of both the Exchequer Court and the Supreme Court of Canada. Roche has consistently contended that what is "commercially possible" is a question which can only be determined by an enquiry into the necessary costs, such as that which the Committee is now making, and which the Courts have said is irrelevant.

(93) Actually as has already been stated above, the copier does not really want competition with his own kind. That may explain, for example, the choice by Empire of diazepam instead of chlordiazepoxide for compulsory licence, notwithstanding that the market in chlordiazepoxide is more than twice as large as that for diazepam. And it may explain the refusal of Delmar to supply the substance to Bell-Craig. A compulsory licencee's expectations, therefore, rest, in Roche's opinion, upon the following factors

(a) the drug must have a large demand, which must be world-wide, created and sustained by a concern such as Roche

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(b) the price must be high enough to reflect the ever-increasing load of research and medical information cost

(c) a prospect of a long enough run of benefit from this situation, aided by minimal compensation rates, until the run is terminated by competition from other copier licencees.

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HOW ARE DRUG PRICES DETERMINED

(94) The Committee will have seen from the figures which Roche has supplied and from the foregoing discussion, that the problem of pricing any drug is very difficult indeed. In general like the price of an automobile, a "new model" drug has normally to be in line with those of other drugs already on the market, though not so closely competitive in price as general commodities must be. But unlike an automobile or commodity into whose price known variable costs largely enter, they neither play nor ever can play a major role in the price of a drug, simply because of the overwhelming content of fixed charges, such as research and to a large extent medical information, and because the shares of them that should be attributed to a particular drug are so difficult to predict, ascertain or control. The demand itself is, in practice, largely unpredictable, and full of surprises. Rarely has anyone ever been able to predict either whether a new drug will succeed or especially what degree of success it will achieve. If its success exceeds expectations, as that of chlordiazepoxide and diazepam have done, then the effect on cost calculations will be very great and certainly unpredictable. These difficulties undoubtedly explain why in the

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United Kingdom after many years of discussion and negotiation between the Ministry and the drug industry, the Ministry places most stress and reliance on ex-post-facto examination of the profits in relation to the capital employed.

(95) The price of an international drug in any particular country will also be affected by the situation existing elsewhere, particularly in adjacent or adjoining countries having comparable standards of living. So that the costs and competitive situation in these other countries may influence the price at which a new drug starts.

(96) Experience shows that once a drug price has been established, it would rarely be increased. Therefore, inflation and rising costs have gradually tended to erode it. So have special factors such as the absence of patent protection, whether from compulsory licence or otherwise. Whether the current mounting rate of inflation everywhere will now tend to create situations in which some drug prices may have to be increased in future, especially for those concerns with no recent "major advances", is obviously a speculative matter.

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(97) There has been some discussion before the Committee as to the relationship between hospital and prescription prices, and whether either

supports or subsidizes the other. Roche believes this can be a somewhat sterile discussion unless it is faced that the dominant factor and problem in all drug prices is the high content of fixed charges and the very low content of variable cost. Almost an infinite number of permutations are consequently possible as to the contribution that any particular sale may make towards the fixed costs, and thus an infinite number of prices. No one can really say which is the right price or what the right relationship should be between various prices either of the same drug or of different drugs. Probably the only realistic test of prices is to take all drugs together and to consider the profits therefrom over a long period and their ability to self-finance the considerable capital required to make them "available to the public" and the rapid expansion there has been in the demand for drugs in recent times.

(98) Roche believes that if the Committee should question such a compulsory licence applicant as Empire and the others referred to in this brief, it will find, as Roche has indicated, that they simply establish their price at a certain percentage of the originator's price. They make no calculation whatever of cost

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certainly not of what is the "lowest possible" in relation to the cost of manufacturing with a reasonable markup on their capital employed. If questioned, as Roche questioned Craig, they will usually contend that they are unable to make a reliable cost calculation, because their overhead or fixed charges content is unpredictable, and the variable manufacturing cost has so little significance. Moreover, on the vital cost of medical information they may vaguely say they will provide it, without seriously attempting to show that they can do it or what it would cost them.

(99) As explained in this brief, compulsory licence applicants tend to think that in order to get a compulsory license, they must say that they are shocked by the height of the patentee's price, which either is expressly or by implication "too high". Since the words "too high" invoke a comparison, and since the applicants are never prepared to make a cost calculation to demonstrate why and where it is too high and what either a reasonable price or the lowest possible price could be, this means that the whole problem is left completely in the air. That, of course, is what the applicant wants. It really wants the

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originator's price to be high containing a large loading for research and medical information, as a prerequisite of it existing in the market at all. It will ride on the patentees for as long as the ride is profitable, and will switch to ride on others whenever the ride becomes unprofitable. The compulsory licensee has no real stake in the drug, and can abandon it when it suits it, as the originator cannot.

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The Differences between the Interpretation of the Purposes and Requirements of Section 41 [3] in the Canadian Courts, and the Interpretation of the Similar Statute in the United Kingdom

(100) The P.M.A.C. brief states at page 11.11 that Section 41(3) was modelled on a similar section in the United Kingdom. Neither statute was much

used until recently. It might be thought that the headlines arising out of the Kefauver hearings have been responsible for encouraging applicants for compulsory licenses both in Canada and the U.K. Alternatively, and perhaps more plausibly, it may be thought that the Kefauver hearings were themselves provoked by the continuous growth, in the cost content of drug prices, of the mounting costs of research and of its accompanying medical information.

(101) Before the recent wave of compulsory license cases there were apparently no great differences between Canada and the United Kingdom in the interpretation and application of the respective legislations. Now there are serious and growing differences. These are apparent to Roche in consequence of the compulsory license cases for the same drug, chlordiazepoxide, in both countries. A brief recital of the differences may assist the understanding of the Committee.

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(102) The legislation's basic purpose was described by the Assistant Comptroller in the United Kingdom in his unreported decision of August 2nd, 1965, in the case of The Irish Sugar Co. Ltd., vs The Farmers Marketing & Supply Co. Ltd., (see Appendix VI). After enquiring into the costs and the patentee's price, and what the applicant's costs and price might reasonably be, the Assistant Comptroller apparently concluded that the patentee's price was reasonable, and refused the grant on that and other grounds. The Comptroller stated there: "The whole purpose of the section is to keep the price down to a reasonable level". Roche believes that this interpretation is sound and correct.

(103) A little later in February 1966, the U.K. Assistant Comptroller refused to grant a compulsory license in respect of Pfizer's drug tetracycline (see Appendix VII for a copy of this unreported decision). Again, among his grounds for refusal, was the ground that Pfizer's price either was reasonable or that it would become so as a result of the negotiations Pfizer would necessarily have with the Ministry under the Voluntary Price Regulation Scheme.

(104) Those negotiations, like those of Roche with the Ministry, as ex-

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plained earlier in this brief, would be based on a consideration of the total results of the patentee's business in drug in relation to the capital employed over a long period. In other words, the Ministry would have regard to the costs, profits and capital employed by tests similar to those shown in the Schedules attached to this brief, in determining whether the patentee's prices in the United Kingdom are reasonable or not.

(105) All this really means that the U.K. Assistant Comptroller has concluded that—

(a) the legislation should not be used against a patentee withoug regard to whether the price is reasonable or not, and that the legislation does not intend to enforce or achieve a "lowest possible price" regardless of all other considerations such as the maintenance of research incentive

(b) "reasonable price" can be determined just as much for a drug as for potato flakes (The Irish Sugar case)

(c) the Ministry of Health is capable of determining and does arrive at the "reasonable price".

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(106) The situation in Canada, as it results from the Bell-Craig case and as explained earlier in this brief, is quite otherwise. "Reasonable price" is not regarded by the Courts as relevant to the legislation's purpose, which the Courts believe is to create competition by licensing others to use the patent regardless of whether or not the patentee's price can be shown to be reasonable.

(107) Nor can it apparently matter or prevent the grant of a compulsory license in Canada if the price should be shown clearly to be the "lowest possible". Thus, for exampleple, even if chlordiazepoxide could be and were sold by Roche in Canada at only the manufacturing cost, without the addition of distribution or any other cost, or of profit, which on its face is the "lowest possible price" then nevertheless, a compulsory license apparently not only could but should be granted to any person who applied for it, and with minimal compensation to Roche, whether or not that person claimed that he would sell the drug at an even lower price.

(108) The only difference between this interpretation and that which would result if patents on drugs had been abolished entirely in Canada, is that some

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minimal compensation is awarded to the patentee. The scale and relevance of the compensation currently awarded has been fully explained earlier. Again, there is a great difference from that awarded in the United Kingdom. In both the Geigy* and Pfizer cases the Assistant Comptroller has awarded compensation which contains—

(a) a research attribution calculated in the same manner as that claimed by Roche in the Bell-Craig case

(b) a part of the medical information cost, and

(c) returns on the capital employed in (a) and (b).

(109) Therefore, not only is the compensation awarded in the United Kingdom very much larger than is awarded in Canada, but specifically it relates to what is "made available to the public" (Section 41 (3)) and to the costs of making it so available. Whereas in Canada, the Commissioner of Patents has been upheld in his conclusion that all such costs are irrelevant.

(110) In sum, if the Ministry of Health is capable of determining a reasonable price for a drug in the United Kingdom by some reliable and

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objective tests or standards, then some similar authority or tribunal acting for the public interest in Canada should be equally capable of determining a reasonable price in Canada. Further, if such a proof of the existence of a reasonable price is regarded in the United Kingdom when considering whether a compulsory license should be granted, it ought to be so regarded in Canada.

* (See Appendix II, Case No. 4).

(111) Roche, therefore, believes that there will be both continuing controversy and public harm until it is recognized that the compensation, if a compulsory license is granted, must be sufficient to protect a determined reasonable price.

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COMMENT ON CERTAIN OF THE VIEWS EXPRESSED BY THE COMMISSIONER AND THE CANADIAN COURTS IN THE BELL-CRAIG CASE

(112) The following comments are not made in order to disparage the efforts of the Commissioner and the Courts in trying to understand this complex question of drug prices.

(113) The Commissioner's statements to the Restrictive Trade Practices Commission quoted at page 11.16 of the P.M.A.C. brief as well as the questions put to the Roche witnesses during the bearing to the Bell-Craig case, cannot, in Roche's view, be reconciled with his decision. When he commented to the aforesaid Commission that "the price of drugs has been so high" in Canada, he can only have meant the price of that which is made available to the public, namely, the dosage form. And when he asked the Roche witnesses to compare at par rates of exchange the Roche prices for chlordiazepoxide in the United Kingdom and in Italy, quite clearly he was also asking for the selling prices of the dosage form. Yet the whole basis of this decision is that none of the costs, which relate to and completely dominate what the selling price should be, have any relevance to the grant of a compulsory license.

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(114) As the P.M.A.C. brief at page 11.17 states, it was quite clear that the President of the Exchequer Court found this view erroneous, both as to the principle and the quantum. He, therefore, said that the compensation should be based on the selling price of the dosage form, not of that of the bulk substance. He also said that he was awarding compensation which was about 20 times per kilo that awarded by the Commissioner. There is accordingly no possibility of doubt as to the degree of his differing from the Commissioner.

(115) Nevertheless, although the President had a reasonable understanding of the complexities of drug costs and prices, as they were explained to him and are contained in this brief, he himself made mistakes of fact. He said that Roche was contributing to research at a rate much lower than that which his award covered. In fact his award was much less than that contribution. The evidence before the Commissioner of Patents was plain enough, but unfortunately, the President asked no questions on the point during the course of the appeal.

(116) The President had said that he "cannot conceive of any other class or type of evidence that might have been placed before the Commissioner" by Roche in order "to give a balanced picture—of the costs—and necessary

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overhead expenses and a modest profit". But, he said that Section 41(3) did not require an enquiry into price. He said that if any enquiry were needed it would be into the "lowest possible price" and not into the "fair and reasonable price"; and added, that the "lowest possible price" should have regard to the prices

which the patentee obtains in other parts of the world and not merely those in Canada.

(117 These are, in Roche's opinion, rather extraordinary propositions. The evidence before the Commissioner of Patents clearly showed that the greater part of the cost of any drug and therefore its price, would be incurred in Canada at Canadian levels of salary and other cost. The fallacy that par rates of exchange could be applied to test the "lowest possible price" anywhere in the world, was clearly implicit in this part of the judgment.

(118) Implicit also was the illusion that the "lowest possible" price must necessarily be, and could remain permanently at a level considerably less than the "reasonable price". The inherent fallacy in both these propositions could quite simply be tested by asking any of the compulsory licensees whether they would be prepared to make the drug available at the "lowest possible price"

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which could be shown to be obtained anywhere in the world. Roche, in consequence of the absolute discretion now vested in the Commissioner as to whether he shall enquire into any such matters, will undoubtedly be deprived of any opportunity to put this question to the licensees. But it is self-evident that none of the prices put forward by the applicants in any of the compulsory licence cases of Roche is anywhere near as low as the "lowest possible price" obtained in other parts of the world if assessed at par rates of exchange.

(119) The President also said that he did not believe that a reasonable price could be determined by arithmetical (which presumably include accounting) means, and that Section 41(3) could not have contemplated that. Yet that is in fact what the Ministry of Health is doing under the V.P.R.S., in the United Kingdom. It is also apparently accepted by the U.K. Assistant Comptroller as both necessary and decisive.

(120) The President further said that "competition regulates prices". Roche agrees with this and asserts that there is ample competition between the drugs put out by competing research-based firms to achieve this. The Court also stated that competition "brings about greater efficiency, better service and

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further research". Roche agrees that these results come from that competition between drugs. But there is no evidence whatever, nor could there be that those results could come from competition between a patentee or research-based firm and compulsory licensees. They are totally unlike and if the compensation were adequate to put them upon equality, the licensee would be unlikely to continue in the competition.

(121) Nevertheless, certain rather difficult passages in the judgment indicate that the President himself was uncertain about the consequences of all this. At any rate he made a clear attempt to justify the level of the compensation he awarded. It seems to be necessarily implicit in this that he was attempting to recognize, redress or balance, in part at least, the basic and inescapable inequality which must and does exist between a patentee and a compulsory licensee.

(122) As explained in the P.M.A.C. brief, the Supreme Court of Canada in effect wholly restored the Commissioner's decision, and did so in such terms as to

make it very difficult to contest any future decision which he may make or his reasons for it. In restoring the Commissioner's decision, the Supreme Court of

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Canada contradicted what it had already said in another recent case because:

(a) the Commissioner of Patents in his decision in the Bell-Craig case said that he was dealing with a process only and that the dosage form of the product was outside the scope of the patent whereas

(b) in Hoechst Pharmaceuticals of Canada Limited et al vs Gilbert & Company et al (Appendix II, Case No. 3), the Supreme Court of Canada held that the inventive merit in a case involving an important drug resides in the discovery of the useful properties of the product rather than in any particular method of producing it.

(123) In the course of the hearing of the Bell-Craig case before the Supreme Court of Canada, various observations were made by the members of the Court, which are not reflected in the judgment, and from which it seems necessary now for Roche to repeat its dissent. It was suggested to Roche that—

(a) research by houses such as Roche was unnecessary because the research that really mattered was in any event done by the universities

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(b) medical information services of Roche and others were also largely unnecessary because what mattered in that respect was being and would be done by the Food & Drug Directorate

(c) the award of 15% of the selling price of the bulk substance should be quite enough to satisfy foreign "inventors" like Roche and the market should be abandoned to generic distributors—in the light of the subsequent decisions of the Commissioner this award would probably be no more than $50 or $60 per kilo.

(124) Though, of course, Roche must accept the Judgment, in its view, the Judgment merely adds confusion to an inherently difficult problem, and gives no help towards a reasonable solution of it. From the Supreme Court's general attitude, Roche thinks it must be inferred that, despite the evidence to the contrary which Roche had produced, the Court believes that most drug prices in Canada are scandalously high and should be reduced drastically. Apparently, the Commissioner of Patents and the Supreme Court believe that drug prices should be reduced to a "lowest possible" of something slightly higher than the manufacturing cost.

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(125) The President of the Exchequer Court did not apparently share these beliefs, for his Judgment states clearly that Bell-Craig would sell at $3500 per kilo, and that accordingly Roche would get compensation of $525 per kilo at his awarded 15% of that price.

(126) Roche hopes that the rather detailed information it has given earlier about its dealings with various applicants for compulsory licenses, and the underlying economics, will help the Committee to understand why Roche believes the expectations of the President of the Exchequer Court may be much

nearer to reality than those of the Commissioner of Patents and the Supreme Court. There is also no factual ground, in Roche's opinion, to suppose that any applicant would like the prospect of being obliged to make drugs available to the Canadian public at the "lowest possible" prices apparently contemplated by the Commissioner and the Supreme Court.

(127) The fact is that such a drug as chlordiazepoxide competing as it does with similar drugs, depends for its existence not only upon the original introduction to doctors, but also upon the constant support by medical informa-

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tion upon the drug to doctors. If that support were withdrawn because the number of licensees had reduced the price to a level which would not permit its costs to be borne by the patentee so that the patentee or introducer were obliged to leave the field to the licensees, then the drug would quite quickly disappear from the market altogether. In this sense, licensees who merely sell the active material or the dosage form as commodities without any of the servicing, are like parasites in nature whose means of life disappears when the host dies. Even if one of the licensees should have the considerable means and enough experience in drugs to attempt to provide the support for the drug which the patentee had formerly provided, it would be obliged to have a level of price much like the patentee to pay for that support. In this sense, the licensee would become another host for the parasites.

(128) The Committee should have seen from Appendix I that large reductions in price could not occur without growing and serious erosions of the present services to doctors and to the public. As these levels of service are broadly the same as in other advanced countries, such as the United States, it is

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not reasonable to suppose that either the doctors or the public will tolerate lower standards of service in Canada.

(129) It was explained earlier in this brief that in the Bell-Craig case, Craig himself freely acknowledged the height and scale of the costs involved. He did not attempt to assert either that drug prices in general could and should be drastically reduced, nor even that the Roche price for chlordiazepoxide was much too high. For this reason, in the hearings before the Commissioner of Patents, the Exchequer Court, and the Supreme Court of Canada, Roche had not really to defend its costs, prices and practices, against attacks by the applicant, as to try to explain and convince the Courts as to the inescapable facts which, when pressed, most copiers will not deny.

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Comments and Recommendations in Respect of Patent Protection and Section 41 (3)

(130) Roche shares the opinion of all the major concerns in the industry, and of impartial enquiries such as the Hinchliffe Commission that patent protection is necessary for the continuance of drug research, and for its future increase or expansion.

(131) Roche hopes that the practical consequences and mischief of the extreme interpretation of the phrase "lowest possible price" contained in

Section 41 (3), to which the P.M.A.C. refers at page 11.16 of its brief, are illustrated by the cases recited in this brief. As that interpretation cannot now otherwise be changed, Section 41 (3) ought to be repealed.

(132) Roche, therefore, supports the P.M.A.C. in its recommendation No. 5 on page 11.25, that an early revision of the Patent Act is required. No license should be granted if the price of that drug is adjudged to be reasonable by objective standards.

(133) Roche also suggests in line with the proposals being made by the Patent and Trade Mark Institute of Canada that—

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(a) a compulsory license for a drug ought not to be granted merely to serve the private interest of a particular person, but only in the public interest at the instance in the first place of the Attorney General of Canada or the Minister of National Health and Welfare;

(b) such a license should not be granted unless there is a finding by the tribunal of the first instance that, having regard to all the circumstances, the drug is not being made available in Canada in such forms and to an extent both territorially and in volume and at such a price as is reasonable;

(c) the license should be revocable at the instance of the Minister of National Health and Welfare or the patentee if the licensee fails in respect of any one of the conditions stated in (b);

(d) no license for a drug shall be granted under Section 67 (2) (c) of the Patent Act.

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(134) Roche thinks that the proposals made by either the P.M.A.C. or the Patent and Trademark Institute of Canada ought also to stipulate that regard should be paid to calculating the compensation to the patentee so as to protect what is determined to be the reasonable price. And further, in determining reasonable price, regard should be paid to—

(a) the patentee's total business and not in that drug in isolation, and to

(b) Hinchliffe's recognition of a major advance in only 10 to 20 years; the patentee's business should, accordingly, be considered over a similar period.

Appendix I to Brief

SCHEDULE I

HOFFMANN-LA ROCHE LIMITED

Cumulative Summary 1954-1965 Statements of Profit and Loss

(Thousands of Dollars)

Revenues	
Sales (FST & Excise not incl.)	$56,317
Other Income	206
Total Revenue	$56,523
Expenses	
Cost of Sales	39,668
Research & Development	4,963
Administration	5,874
Royalties & Interest Charges	750
Total Expenses (Before Income Taxes)	51,255
Earnings	
Earnings (Before Taxes)	5,268
Less: Income Taxes	2,602
Net Earnings (After Income Taxes)	2,666
Add Back Interest Paid to Roche— Sources Outside Canada	723
Net Earnings After Taxes Plus Interest	$ 3,389

SCHEDULE II

HOFFMANN-LA ROCHE LIMITED

Cumulative Summary 1954-1965 Statements of Profit and Loss
(As % of Revenue)

Revenues	
Sales (FST & Excise not incl.)	99.6%
Other Income	.4
Total Revenue	100.0
Expenses	
Cost of Sales	70.2
Research & Development	8.8
Administration	10.4
Royalties & Interest Charges	1.3
Total Expenses (Before Income Taxes)	90.7
Earnings	
Total Revenue	100.0
Less: Total Expenses (Before Income Taxes)	90.7
Earnings (Before Income Taxes)	9.3
Net Earnings	
Earnings Before Income Taxes	9.3
Less: Income Taxes	4.6
Net Earnings (After Income Taxes)	4.7%

SCHEDULE III

HOFFMANN-LA ROCHE LIMITED

1954–1965 STATEMENT OF PROFIT AND LOSS
(As % of Total Revenue)

	1954	1955	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
	%	%	%	%	%	%	%	%	%	%	%	%
REVENUES												
Sales (FST and Excise not incl.)	98.6	98.4	99.4	99.6	99.5	99.7	99.8	99.9	99.1	99.8	99.7	99.5
Other Income	1.4	1.6	.6	.4	.5	.3	.2	.1	.9	.2	.3	.5
Total Revenue	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
EXPENSES												
Cost of Sales	82.6	86.3	82.0	82.2	82.3	79.1	75.0	75.2	71.4	65.7	63.0	61.7
Research and Development	2.8	2.8	3.2	3.4	4.3	4.5	5.0	9.7	11.0	10.8	10.9	11.1
Administration	8.8	9.8	10.8	12.3	11.0	11.2	11.6	10.7	12.4	11.7	9.5	8.3
Royalties and Interest Charges	—	.1	.3	.7	.7	1.1	1.3	1.4	2.3	1.8	1.6	1.2
Total Expenses (Before Income Taxes)	94.2	99.0	96.3	98.6	98.3	95.9	92.9	97.0	97.1	90.0	85.0	82.3
NET EARNINGS												
Earnings Before Income Taxes	5.8	1.0	3.7	1.4	1.7	4.1	7.1	3.0	2.9	10.0	15.0	17.7
Less: Income Taxes	2.4	.2	1.7	.4	.7	2.0	3.6	1.0	1.3	4.7	7.6	9.3
Net Earnings (After Income Taxes)	3.4	.8	2.0	1.0	1.0	2.1	3.5	2.0	1.6	5.3	7.4	8.4

SCHEDULE IV

HOFFMANN-LA ROCHE LIMITED

1954-1965 *Comparison of Total Assets Employed in Business*
(Thousands of Dollars)

	1954	1965	1954-1965 Increment
Current Assets			
Cash	$ 97	$1,551	$1,454
Accounts & Notes Receivable	213	2,012	1,799
Inventory	256	4,100	3,844
Total Current Assets	566	7,663	7,097
Property			
Land, Plant & Equipment	49	2,213	2,164
Less: Accumulated Depreciation	(34)	(642)	(608)
Total Property-Net	15	1,571	1,556
Other Assets			
All Other Assets	22	269	247
Total All Other Assets	22	269	247
Total Assets Employed	$603	$9,503	$8,900

SCHEDULE V

HOFFMANN-LA ROCHE LIMITED

1954-1965 *Comparison of Total Assets Employed in Business*

(% Distribution)

	1954	1965
Current Assets		
Cash	16.1%	16.3%
Accounts & Notes Receivable	35.3	21.2
Inventory	42.4	43.1
Total Current Assets	93.8	80.6
Property		
Land, Plant, & Equipment	8.2	23.2
Less: Accumulated Depreciation	(5.7)	(6.7)
Total Property-Net	2.5	16.5
Other Assets		
All Other Assets	3.7	2.9
Total All Other Assets	3.7	2.9
Total Assets Employed	100.0%	100.0%

SCHEDULE VI

HOFFMANN-LA ROCHE LIMITED

Cumulative Summary 1954-1965 Sources & Applications of Funds

(Thousands of dollars)

Sources of funds:		
Increase in Liabilities		$ 1,376
After Tax Profit	$ 2,666	
Less: Dividends	180	
	2,486	
Additional Roche Sources From Outside Canada	5,038	7,524
Total Sources		$ 8,900
Application of Funds to Financial Requirements:		
Cash		$ 1,454
Accounts & Notes Receivable		1,799
Inventories		3,844
Plant Property & Equipment		1,556
Other Assets		247
Total Applications		$ 8,900

SCHEDULE VII

HOFFMANN-LA ROCHE LIMITED

Cumulative Summary 1954-1965 Total Assets Employed in Business
(Thousands of dollars)

	1954-1965 Cumulative Total
Cumulative Current Assets	
Cash	$ 3,936
Accounts & Notes Receivable	8,965
Inventory	17,326
Total Current Assets	30,227
Cumulative Property	
Land, Plant & Equipment	13,364
Less: Accumulated Depreciation	(3,055)
Total Property-Net	10,309
Cumulative Other Assets	
All Other Assets	1,145
Cumulative Total Assets Employed	41,681
Less: Liabilities to Outside Creditors	3,624
Cumulative Net Assets Employed	$ 38,057

APPENDIX II

CITATIONS FOR CASES REFERRED TO IN BRIEF

1. Bell-Craig Pharmaceuticals vs. Hoffmann-La Roche Ltd.
(Commissioner of Patents)—1965 43 CPR 117
(Exchequer Court of Canada)—1965 2 ExCR 266
(Supreme Court of Canada)—1966 32 Fox's P.C. 106

2. Delmar Chemicals Limited vs. Hoffmann-La Roche Ltd.
(Commissioner of Patents)—1964 41 CPR 196
(Exchequer Court of Canada)—1964 1 ExCR 611
(Supreme Court of Canada)—1965 SCR 575
(For unreported decision of Commissioner dated June 21 1966, revising royalty, see Appendix III)

3. Hoechst Pharmaceuticals of Canada Limited et al vs. Gilbert & Company et al.—1966 SCR 189

4. Re J. R. Geigy S.A.'s Patent (Assistant Comptroller)—1964 RPC 391
(Patent Appeal Tribunal)—1964 RPC 407

Appendix III

UNREPORTED DECISION OF THE COMMISSIONER OF PATENTS DATED JUNE 21st, 1966 REVISING ROYALTY IN THE CASE OF DELMAR CHEMICALS LIMITED vs HOFFMANN-LA ROCHE LIMITED

OTTAWA, June 21, 1966.

Gentlemen,

Re: Licence granted to Delmar Chemicals Limited to use Canadian Patent No. 612,497—Hoffmann-La Roche Limited Number 94

Please find enclosed a formal document amending the above licence recorded in the Patent Office under No. 586,306 as a consequence of the ruling of the Exchequer Court, (1965) 1 Ex. C.R. 611.

This document now forms part of the original licence and has been attached to it in the records of the Patent Office.

Yours very truly,

J. W. T. Michel,
Commissioner of Patents.

MM. Gowling, MacTavish, Osborne & Henderson,
116 Albert Street,
OTTAWA 4, Canada.

Copy of the Original Amendment

OFFICE OF THE COMMISSIONER OF PATENTS

OTTAWA, June 20, 1966.

AMENDMENT to licence recorded under No. 586,306 in the Patent Office.

IN THE MATTER of a licence granted to Delmar Chemicals Limited dated March 26, 1963, recorded in the Patent Office under No. 586,306, to manufacture under Canadian Patent No. 612,497—Hoffmann-La Roche Limited for "1,4-Benzodiazepine 4-Oxides and Process for the manufacture thereof"

WHEREAS the Commissioner of Patents did set a royalty of twelve and one-half per cent (12½%) in the said licence,

AND WHEREAS on appeal to the Exchequer Court the decision of the Commissioner to grant a licence was affirmed, but the question of royalty was referred back to him for reconsideration (1965, 1 Ex. C.R. 611),

AND WHEREAS in the appeal to the Supreme Court from the decision of the Exchequer Court, no appeal was made on the ruling of the Exchequer Court on the question of royalty, (1965, S.C.R. 575),

NOW THEREFORE, pursuant to the ruling of the Exchequer Court, the Commissioner, having reviewed the submission of Hoffmann-La Roche Limited on the question of royalty, hereby declares the following by way of amendment to the said licence:

1. Clause 1 to be amended to read in the first paragraph "a royalty of fifteen per cent (15 percent)" instead of
"a royalty of twelve and one-half per cent (12½ percent)" the second paragraph to stand as is.
2. This amendment and the new rate of royalty to take effect with the half-yearly report due thirty days after June 30, 1966 as set out in clauses 3 and 4.
3. All the other clauses to remain as they are.

SCHEDULE

In the Licence granted to Delmar Chemicals Limited under Canadian Patent No. 612,497 and recorded in the Patent Office under number 586,306 the amended clauses should now read as follows:

Clause 1. Delmar Chemicals Limited shall pay to Hoffmann-La Roche Limited a royalty of fifteen per cent (15 percent) on its net selling price to others of the active product in its crude form, prepared or produced pursuant to this licence and sold by it.

The term "net selling price" employed herein shall mean the price actually received by Delmar Chemicals Limited from the sale of the product prepared or produced by it pursuant to this licence, less any allowances for returns and any sales tax or other tax forming part of the sale of such product and required to be remitted by Delmar Chemicals Limited to any taxation authority.

Clause 3. Delmar Chemicals Limited shall keep an accurate record of all matters pertaining to this licence and shall furnish Hoffmann-La Roche Limited with a half-yearly statement within thirty days after the end of each one-half calendar year during the continuance of this licence, showing the quantity and selling price of the product sold under this licence during the preceding half-year and also the royalty computation from the operation.

The royalty computation on the basis of amended clause 1 should be made with the half-yearly report due thirty days after June 30, 1966 and previous half-yearly computations shall not be affected.

Clause 4. On presentation of the statement referred to in clause 3 as amended, Delmar Chemicals Limited shall pay in full the royalty as computed from the statement.

The first statement and royalty payment are to be made within thirty days from June 30, 1963 and from then on continue as set out in clause 3 above.

The royalty computed according to clause 3 and payable according to paragraph 1 of this clause shall be subject to the new royalty applicable to the payment due thirty days after the 30th day of June 1966 and thereafter and previous payments shall not be affected.

DATED at Ottawa, Ontario, Canada
this twentieth day of June, 1966.

J. W. T. Michel,
Commissioner of Patents.

Appendix IV

THE HINCHLIFFE REPORT

(Submitted separately)

FINAL REPORT OF THE COMMITTEE

on

COST OF PRESCRIBING

MINISTRY OF HEALTH

London, England

APPENDIX V

EXTRACT FROM CROSS-EXAMINATION OF PRESIDENT OF ELLIOTT-MARION COMPANY LTD.

Q.—Now, in reference to Paragraph No. 19, it is correct is it not that the defendant company has no research costs to recover in the sales of Chlordiazepoxide?

Mr. GOLDSMITH: Would you please define what you mean by "search costs"?

Mr. MCCLENAHAN: These would be the chemical research costs.

A.—Our research costs on the chemical itself does not exist, as far as we are concerned, on the chemicals.

By Mr. MCCLENAHAN:

Q.—That is right, so you have no chemical research costs to recover in your price?

A.—No.

Mr. GOLDSMITH: He said he had not any.

By Mr. MCCLENAHAN:

Q.—As a matter of fact is it not correct that the defendant company does not do any chemical research?

A.—That is correct.

Q.—And in the defendant's price it does not have to recover any costs for explaining the nature and usefulness of Chlordiazepoxide to the medical profession?

A.—I beg your pardon.

Mr. MCCLENAHAN: Would you please repeat the question?

REPORTER: "And in the defendant's price it does not have to recover any costs for explaining the nature and usefulness of Chlordiazepoxide to the medical profession?"

A.—I believe that we do, Mr. McClenahan.

By Mr. MCCLENAHAN:

Q.—Well, Chlordiazepoxide was a well-known drug when you started into the market, was it not?

A.—It was known, definitely.

Q.—And it was well accepted, was it not, by the medical profession?

A.—Yes.

Q.—And it was well familiar with its nature and usefulness?

A.—Yes.

Q.—So you certainly would not have to explain anything of that to the medical profession?

A.—We have had to produce a review of the literature to physicians.

Q.—Could I have a copy of that, please?

A.—Yes.

Mr. GOLDSMITH: What do you want now?

WITNESS: A review of the literature on Chlordiazepoxide.

A.—(Continued). I might add to that that this is being translated right now so we can supply it in both French and English; and it is a long job to translate it.

By Mr. McCLENAHAN:

Q.—You have handed me a booklet, Mr. Marion, and is this the booklet that you are referring to? Is this a copy of it?

A.—We have two (2) copies of this because there has been a corrected copy particularly in the reference or in the biographical section.

Q.—Yes?

A.—Whereby the Food and Drug had asked us to state, close to the title of the publication, "Dr. Bikadoroff had in no instances used the word "Chlordiazepoxide H.C.L." where it might have been published under the name of Librium; and the Food and Drug asked us that we check our biography list and we sent Dr. Pugsley a list. I think that you might have got it there before because the correction is right on the front page stating the correction as far as the various reverences, 1 and 2—and I forget the other numbers that were supposed to be corrected.

Mr. McCLEHAHAN: Could we save Exhibit No. 4 for the corrected booklet; Oh, no, save Exhibit No. 5 for the corrected booklet and we shall mark this one as Exhibit 4. (Exhibit so marked).

By Mr. McCLENAHAN:

Q.—Would you confirm then that what you have is a copy of the booklet in its uncorrected form?

A.—I would believe that is correct. This is the original supplied, I believe, to Ottawa; and when they reviewed it, Dr. Pugsley asked us to make the changes.

Mr. McCLENAHAN: It will be so marked as Exhibit 4. And are we agreed, Mr. Goldsmith, that on the receipt of the corrected booklet it can be marked as Exhibit 5 in these proceedings by ourselves?

Mr. GOLDSMITH: Yes, I agreed with that.

By Mr. McCLENAHAN:

Q.—Is it not correct, Mr. Marion, that the booklet which has been market as Exhibit 4 consists of a summary of some of the information that is contained in a great number of publications relating to Chlordiazepoxide?

A.—It is a review of all—of a great deal of literature.

Q.—Which is also referred to in the biography that appears at the end of the booklet?

A.—Yes, that is right.

Q.—Is it not correct that all of this literature related to the plaintiff's Chlordiazepoxide and not the defendant's?

A.—I would say so.

Q.—And is it not also a fact that Chlordiazepoxide was a well-known and a well-established drug and that was the principal reason why the defendant company wished to sell it?

A.—Partly so.

Q.—Would that not be the main reason, that it was well-established, that there was a good market for it and that was the reason why?

A.—I would say that the main reason was to extend our own markets, our own activities.

Q.—And in order to do that you selected a drug which had a large market which had already been established?

A.—Yes.

APPENDIX VI

UNREPORTED DECISION OF ASSISTANT COMPTROLLER DATED AUGUST 2nd 1965, IN THE CASE OF THE IRISH SUGAR CO. LTD., VS. THE FARMERS MARKETING & SUPPLY CO. LTD.

THE PATENT OFFICE,
25 SOUTHAMPTON BUILDINGS,
LONDON.

I, the undersigned, being an officer authorised by the Board of Trade in accordance with Section 62(3) of the Patents and Designs Act, 1907, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that in the matter of an application by The Irish Sugar Company Limited and Erin Foods Limited under Section 41 of the Patents Act, 1949, for Licences under Patents numbered 767,903, 773,361, 791,193 and 884,267, and in the matter of oppositions thereto by The Farmers' Marketing and Supply Company Limited, the annexed is a true copy of the Decision of the Assistant Comptroller, acting for the Comptroller, dated 2nd August, 1965.

WITNESS my hand this
day of September 1965
(Signature illegible)

Copy of the Original Decision

PATENTS ACT, 1949

IN THE MATTER OF an Application by The Irish Sugar Company Limited and Erin Foods Limited under Section 41 for Licences under Patents Nos. 767903, 773361, 791193 and 884267

— and —

IN THE MATTER OF Oppositions thereto by The Farmers' Marketing and Supply Company Limited.

DECISION

The application is opposed on the following grounds:—

(1) that the grant of a Licence to a Company whose only intention is to import the product is contrary to the public interest;

(2) that the grant of a Compulsory Licence to a Company which is controlled by a foreign government is likely to operate unfairly to the interests of existing manufacturing companies in the United Kingdom; and

(3) that the available market in the United Kingdom for the product of the process is fully supplied at fair and proper prices and the grant

of a Compulsory Licence is unlikely to lead to any reduction in the price of the product to the public, unless the applicants follow unfair and damaging trade practices.

At a Hearing on the 21st June, 1965, the Hon. T. G. Roche, Q.C. and Mr. Goeffrey Tomkin appeared as Counsel for the applicants and Mr. Guy Aldous, Q.C. and Mr. T.A. Blanco White as Counsel for the opponents.

The four patents in respect of which applications have been made for Licences under Section 41 relate to the manufacture of dehydrated potato flake which can be reconstituted into mashed potato by the addition of milk or water. All the specifications have claims for processes for making the flake, and each of specifications 767903, 773361 and 791193 also has a claim for dehydrated mashed potato prepared by the process.

Section 41 reads as follows:—

"(1) Without prejudice to the foregoing provisions of this Act, where a patent is in force in respect of—

(a) a substance capable of being used as food or medicine or in the production of food or medicine; or

(b) a process for producing such a substance as aforesaid; or

(c) any invention capable of being used as or as part of a surgical or curative device, the comptroller shall, on application made to him by any person interested, order the grant to the applicant of a licence under the patent on such terms as he thinks fit, unless it appears to him that there are good reasons for refusing the application.

(2) In settling the terms of licences under this section the comptroller shall endeavour to secure that food, medicine, and surgical and curative devices shall be available to the public at the lowest prices consistent with the patentees' deriving a reasonable advantage from their patent rights.

(3) A licence granted under this section shall entitle the licensee to make, use, exercise and vend the invention as a food or medicine, or for the purposes of the production of food or medicine or as or as part of a surgical or curative device, but for no other purposes."

It is apparent that patents for food and medicine have been selected by the legislature for special treatment which may deny to the patentee the sole right enjoyed by patentees in all other fields to make, use, exercise and vend his invention. The purpose, as I understand it, is to encourage competition in order to ensure, as far as possible, that these essential commodities shall be available to the public at reasonable prices. Although the patentee is protected to the extent that he must derive a reasonable advantage from his rights, nevertheless, because he may be deprived of the sole right normally given under a patent it seems to me that the Comptroller must be careful to ensure that the provisions of the Section are strictly applied.

As a first consideration, he must be satisfied that the patent is in respect of a substance or process within the meaning of the Section. In Mr. Roche's submission, the product of the patented process, i.e., dehydrated potato flake, is a substance within the meaning of the Section. On the other hand, Mr. Aldous submitted that, although the patents contained claims to substances resulting from the processes the inventions were concerned primarily with processes and,

while the applications might, therefore, be held to fall within subsection (1)(b) of Section 41, subsection (1)(a) did not apply.

The patents all relate to processes for treating a naturally occurring food substance, namely potato, to convert it into dried flake from which the well-known dish of mashed potato may be more readily prepared. Apart from dehydration, the potato is not altered in any way and the process does not result in the production of a new or different food substance. The product is no more than a preparation (which, as I understand, is not new in itself) of a food substance which is normally in plentiful supply in its natural form at reasonable prices. The process, therefore, creates no new sources of food supply nor does it add to the existing supply.

It seems to me to be extremely doubtful whether the legislature intended the Section to be applied to processes and their products of this kind. However, after careful consideration, I have reached the conclusion that, while the processes are such as to fall within the terms of subsection 41(1)(b), the nature of the process and its product are part of the circumstances of the case which must be considered in deciding whether good reasons exist for refusing the grant of a licence, and I shall refer to this later.

The applicants, the Irish Sugar Company Limited, produce dehydrated potato flake by the patented processes, but they produce it in Eire where no such patents are in force. They admit that if the Licences were granted they would continue to manufacture the flake only in Eire and would import and market it in this country through a wholly owned subsidiary company, Erin Foods Limited. At the Hearing, application was made to join Erin Foods in the application for the Licences.

By an agreement with the inventors, the opponents' subsidiary company, F.M.S. (Farm Products) Limited, became the exclusive licences under Patents Nos. 767903, 773361 and 791193, with the right to grant sub-licences for the manufacture and sale of dehydrated potato flakes made in accordance with the processes covered by the patents. Subsequently, Patent No. 884267 was granted to F.M.S. (Farm Products) Limited, and this patent together with the rights in the other three were assigned by F.M.S. (Farm Products) Limited to the holding company, The Farmers' Marketing and Supply Company Limited, who are the opponents in this action. A sub-licence was later granted to J. Bibby and Sons Limited.

According to the evidence of Mr. Templeton, the Chairman of the opponent company, given in March, 1960, the opponents control production equipment with a capacity more than sufficient to produce the whole current United Kingdom demand for dehydrated potato flake and also considerable reserve manufacturing capacity. In the winters of 1962/63 and 1961/62, however, the United Kingdom potato crop was adversely affected by weather conditions and the price of potatoes rose to a level at which it became uneconomic to buy them, and potato flake was then purchased from The Irish Sugar Company Limited and imported. Mr. Templeton, who was cross-examined by Mr. Roche, impressed me as a truthful and reliable witness.

Copies of correspondence filed with a declaration by Mr. Bradley, the General Manager of Erin Foods division of the Irish Sugar Company Limited, show that the applicants made enquiries of the opponents in February, 1962, as to the terms and conditions for a voluntary licence and that the opponents have

consistently refused to grant one. Later, the present application for compulsory licences under Section 41 was filed.

Mr. Roche, for the applicants, dealt in turn with the three grounds of opposition. He argued that importation was not something which should be prohibited, it was one aspect of international trade which was generally recognised as desirable. Suppression might bring about retaliation and, in any event, this was a matter of government policy and not a matter for the Patent Office. Secondly he argued that it was absurd to assume unfair trading methods dictated by the government of Eire and denied that the applicant company was subsidised. Thirdly, he said that if the applicants obtained a licence they would embark on a vigorous advertising campaign to expand the sales of dehydrated potato flake for which, on the basis of sales in the U.S.A., there was a large potential market. This would in turn lead to a reduction in costs and lower prices to the public. He suggested that it was the threat of active competition which had induced the opponents to announce a price reduction at about the time of the licence application.

In support of the first ground of opposition, Mr. Aldous submitted, as I understand it, that the patents in suit are essentially patents for processes, although all but one have claims to the product of the process, and the words "the grant to the applicant of a licence under the patent" in Section 41 do not contemplate a licence in which the patented process is to be exercised outside the Realm. The Comptroller has power to grant a licence to make, use, exercise and vend only within the Realm. Monopolies for importation have always been invalid, and the sole reason why monopolies can continue is to increase manufacture within the Realm. This is borne out by the terms of the patent itself.

Mr. Aldous also directed my attention to the case of *Van Heydon v. Neustadt* (14 Chancery Division, page 230) confirming *Elmslie v. Boursier* (9 Equity cases, page 217) that "the sole right to make, use, exercise and vend the invention and to enjoy the whole profit, benefit, commodity and advantage accruing and arising by reason of the said invention includes a monopoly of the sale in this country of products made according to the patented process whether made in the Realm or elsewhere". It is, therefore, an infringement for a person to carry out the patented process abroad and import the product of the process into this country. Under Section 41 the Comptroller has power to grant a licence to do that which is preserved by the Statute of Monopolies: but he has no right to grant a licence to do that which is prohibited by the Letters Patent, namely, to make use indirectly of the patent by carrying out the process abroad.

The sole rights of a patentee are of course effective only within the Realm, and I accept that the Comptroller has no power to order the grant of a licence which is effective outside the Realm. But the prohibition of the Letters Patent on use by third parties specifically exempts use with consent or licence of the patentee. No distinction is made in the Letters Patent between a licence granted voluntarily and a licence granted by order under the provisions of the Patent Act. Nothing in the Letters Patent overrides the power of the Comptroller under Section 41 to grant a licence to make, use, exercise and vend the invention. Within these limits the licensee may lawfully do anything otherwise prohibited to him and reserved as the patentees' sole right. The right does not extend outside the Realm but it is clear (see Van Heydon above) that it does include the right to vend in the United Kingdom no matter where manufacture takes place.

The Comptroller, therefore, has power to order the grant of a licence in the present case. But importation for sale by the patentee is considered to be an abuse of the monopoly because it avoids one of the primary objects of the patents system, i.e., to encourage the establishment of new industry in the United Kingdom. For this reason, provision is made in Section 37 of the 1949 Act to encourage manufacture in the United Kingdom by the grant of a compulsory licence to any interested person where abuse is established. Because abuse of monopoly is contrary to public interest intention to exploit a licence in such a manner would, I think, of itself constitute a good reason for refusing to order the grant of the licence under Section 41 unless it could be shown that the benefit to be derived by the public from the grant is such as to override the contrary public interest.

In determining in which direction the balance of public interest lies, all the circumstances of the case must be considered, and I shall return to this later.

Mr. Aldous argued further that Section 41 is stated to be without prejudice to the earlier Sections of the Act, and these include Section 37 which lists the grounds generally regarded as abuses of monopoly, including working by importation. If a licence were granted under Section 41 and exercised only by importation, the following absurd position could arise; An application for a compulsory licence could be made under Section 37(2)(c) on the ground that the working of the invention in the United Kingdom was being hindered by the importation. Such a licence under section 37 would not, however, prevent the continued importation, and so later an application for revocation under Section 42 could be sought on the ground of that importation. Thus the grant of the licence under Section 41 might result in the revocation of the patent.

Both Section 37 and Section 42 are designed to protect the public against abuse of patent rights, and it seems to me, assuming that Mr. Aldous is right in his submission on the possible sequence of events leading to an application under Section 42, that it is in the highest degree unlikely that such an application could succeed when the patent was being worked by order of the Comptroller for the benefit of the public in a manner deemed to override contrary public interest.

Mr. Aldous's next submission was that if the Comptroller did grant a licence under Section 41 he should impose the condition that the substance must be manufactured in the United Kingdom. Such a condition might well be contrary to the spirit of subsection (2) which makes it clear that the lowest price to the public is the Comptroller's main consideration in settling the terms of the licence, and although the Comptroller has power to make such a condition by reason of the words "on such terms as he thinks fit" in Section 41(1), I think he should exercise it only if the circumstances demand it as a matter of public interest.

Mr. Aldous's third point was that there are good reasons for refusing the licence. There was a real threat of unfair trading because the financial backing given to the applicant company by the government of Eire would enable the company to sell at a loss in order to break into the market and, furthermore, a licence would enable the applicants to circumvent the statutory marketing provisions which apply to new potatoes. Mr. Bradley, who was cross-examined on these matters, was an evasive and unconvincing witness; nevertheless, I do not think that the evidence before me establishes beyond doubt that the opponents would derive an unfair advantage by reason of financial backing of

the Eire government. On the question of marketing, I prefer Mr. Roche's view that if the legislature wanted the importation controls which exist for raw potatoes to apply also to dehydrated flake, they would introduce provisions to this end. It would, no doubt, be a good reason for refusing a licence if in exercising it the applicants would break the law, but that is not the position in the present case.

I return now to the question of balance of public interest and the main question for consideration under Section 41 in this respect is the selling price to the public.

Mr. Lawler, the Chief Accountant of The Irish Sugar Company Limited, has given an analysis of the estimated selling price of two shillings per pound for their flake. These figures have been criticised by Mr. Trist, the Chief Accountant of The Farmers' Marketing and Supply Company Limited, in a declaration made on the 12th April, 1965. According to the experience of the opponents the figure of one penny per pound for the distribution cost is far too low—a figure of 3½d would be more realistic, the figure of two pence per pound for packing is inadequate, and in addition no figure is given for the cost of additives, which would probably be another ½d per pound. The cost of royalties has also been omitted. Mr. Trist goes on to compare the opponents prices with those given in a price list for Erin Foods Limited for July, 1964, and says that the applicants' selling price in Eire is greater than the opponents' selling price in this country.

From these figures, Mr. Aldous argued that in suggesting a selling price of two shillings per pound, the applicants were preparing to sell in this country at a price lower than the fair market price in the country of origin. This, he submitted, would constitute "dumping" within the meaning of Section 1(2) of The Customs Duties (Dumping and Subsidies) Act, 1957. This is not, however, a matter for enquiry by the Comptroller.

It seems to me to be clear from the evidence that the applicants' selling price is unlikely to be substantially less than that of the patentees, who are now selling at two shillings. Moreover, there is no evidence before me of the comparative cost of a portion of mashed potato obtained by reconstituting the dehydrated flake and by cooking the raw potato and then mashing it. Having regard to the cost of manufacturing and packaging, however, it seems unlikely that the public could obtain mashed potato more cheaply from the dehydrated flake unless the retail price of potatoes rose to an exceptionally high level by reason of shortage in supply.

Finally, it appears from the opponents' evidence that at the present time there is a very small market for dehydrated potato flake in this country, and that they have more than sufficient manufacturing capacity to meet present requirements. The applicants admit that the present demand is small, but submit that on the basis of consumption in the U.S.A. there is a large potential market. If the licence were granted they would begin an advertising campaign to increase the demand. A licence is not, therefore, required in order to meet an existing demand, but to supply a future demand which they hope to be able to create.

To summarise, the Comptroller has, I think, power to grant a licence under Section 41 which may be exercised solely by importation and sale in the United Kingdon, but working of this kind by a patentee is contrary to the public interest and constitutes an abuse of monopoly, which is a ground for the grant of a compulsory licence under Section 37 to any interested party. Any intention

to work under licence in a manner constituting grounds for a licence under Section 37 would, in my view, be a good reason for refusing to grant a compulsory licence under Section 41 unless it were established that what would otherwise be an abuse of monopoly should be permitted as a matter of overriding public interest.

The relevant circumstances to be considered in the present case for the purpose of determining whether such an overriding public interest exists, are as follows:—

(1) On evidence before me there is unlikely to be any substantial difference in the selling prices of the licensee and patentee unless the market expands considerably.

(2) The patentees are manufacturing in the United Kingdom and although they are satisfying the present relatively small demand, their plant is not working full time. Unless the market expands this home industry will be adversely affected with no real immediate advantage or certain future advantage to the public if a licence is granted.

(3) Dehydrated potato flake does not provide a new food source nor does it augment an existing food supply. It is merely a convenient preparation of a well-known food which is normally readily available to the public at a reasonable price.

(4) There is no widespread demand for the flake, which cannot be regarded as a basic essential food, and the public will have to be persuaded as to the advantages of its use in preparing mashed potato over the conventional means.

Of the above points, (1) fails to achieve the main purpose of Section 41; (2) may lead to a further abuse of monopoly of the kind which constitutes a ground for a compulsory licence under Section 37, subsection (c) and (3) and (4) show no compelling public demand for the substance as an essential food.

In the result, I am not satisfied that there is any overriding reason in the public interest to justify an order for the grant of compulsory licences under the patents for the purpose of importation for sale and, accordingly, I refuse to make the order sought.

Dated this 2nd day of August 1965.

A. E. Tollerfield,
Acting for the Comptroller.

APPENDIX VII

UNREPORTED DECISION OF U.K. ASSISTANT COMPTROLLER DATED FEBRUARY 24th, 1966, IN THE CASE OF D.D.S.A. PHARMACEUTICALS VS CHAS. PFIZER CO. INC.

IN THE PATENT OFFICE

Before: *Mr. A. E. Tollerfield*

24th, 25th, 26th, 27th, 28th January and
24th February 1966

PFIZER CO. INC'S PATENTS.

Application for compulsory licence under Patents Nos. 684,417 and 747,779 by D.D.S.A. Pharmaceuticals Ltd.

DECISION

Mr. Tollerfield—Applications for compulsory licences under section 41 are made in respect of two patents, namely patents Nos. 684417 and 747779. The specifications describe methods of manufacturing oxytetracycline and tetracycline respectively and claim in each case both the method and the product. Both substances may be used as drugs or in supplement for animal feed. The first-mentioned patent expires at the end of its full term on 27th February 1966.

The applicants intend to exploit the licences solely by way of importation of the patented substances and the sale thereof to hospitals and chemists under the provisions of the National Health Service.

The opponents' main ground of opposition is that the Comptroller has no power to grant a licence which is required for the sole purpose of importation of the patented drugs and sale in the United Kingdom.

On the question of importation for sale, I have already decided (see *Farmers' Marketing and Supply Company Limited's Patents* (1965) F.S.R. 316) that the Comptroller has power to order the grant of a licence under section 41 for the sole purpose of importation for sale. I also decided, however, that since the working of a patent in this way by the patentee would constitute an abuse of monopoly for which any interested party might request the grant of a compulsory licence under section 37 of the Act, the Comptroller ought not in these circumstances to exercise the power which he has under section 41 unless he is satisfied that the balance of public interest demands it.

Mr. Johnston, while submitting that the Comptroller has no power to order the grant of a licence for importation for the reasons given by Mr. Aldous and set out in my said decision, recognised that in the light of that decision, the only question to be argued before me was that of balance of public interest. In his submission, since working by importation is, *prima facie*, a good reason for refusing a licence under section 41, the onus of proof in the circumstances must be upon the applicants to establish that the balance of public interest lies in the grant of a licence.

I cannot accept this argument. It is well-established that the onus is upon the opponent in proceedings under section 41 to establish that there is a good reason for refusing to order the grant of a licence. As I understand it, the onus of proof is not discharged by the opponent until all the relevant matters have been taken into consideration and a final conclusion reached. The fact that the applicants intend to exercise the licence by importation is not conclusive but only one of the factors to be considered in this connection for, as I said in the *Farmers' Marketing decision*, there still remains for consideration the question of balance of public interest before a final conclusion can be reached.

Accordingly, in my view, the onus of proof is upon the patentee to establish that the balance of public interest supports refusal of the licence.

The balance of public interest must I think be determined by considering all the circumstances of the case, and the relevant factors were presented by Mr. Johnston under various heads, as follows:—

(1) The patentees have sufficient manufacturing capacity to satisfy all demands for the patented drugs in the United Kingdom.

This is a matter which, it has been held, would not of itself be a good reason for refusing a licence since it is a purpose of the section to encourage competition, but it is, nevertheless, one of the circumstances which may, in my view, be taken into consideration to determine balance of public interest when, if a licence is granted, manufacture is to take place abroad. Mr. Graham conceded that the patentees and their licensees could satisfy public demand but only, in his submission, at prices which were higher than those of the applicants' imported product. Since, as I have said, one subject of section 41 is to encourage competition with the ultimate aim of reducing prices to the public, I think that this factor can only carry weight in the patentees' favour if there is no substantial advantage to the public in price reduction.

(2) The patentees have a large export trade.

This amounts to 42 per cent of the total output and is backed by a thriving home market which is certain to be adversely affected by importation. In Mr. Graham's submission, the patentees' export price would either be higher than the applicants' import prices with advantages to this country in foreign exchange, or else exports would be at prices at, or lower than, the applicants' price in the United Kingdom. In either event, he submitted it was clear that importation would have a beneficial effect from the public point of view.

It seems to me, however, to be highly undesirable to upset a thriving home industry by permitting importation unless there are substantial overriding advantages to the public. This depends to a large extent on the question of price, and I shall return to this later.

(3) It is necessary to ensure that the drugs are pure and may be used with safety, especially in the present climate of public opinion. It is more difficult to exercise control for this purpose in the case of imported drugs than for those manufactured in the United Kingdom, because it is not possible for a United Kingdom organization satisfactorily to control foreign manufacturing processes. However, control during manufacture, i.e., in-process control so called, is essential for new drugs and remains necessary even after the drug has become established, because it is possible during manufacture to find

and eliminate impurities. The British Pharmacopoeia lays down standards for the final product, but is not exhaustive for all impurities, and it is accordingly essential that there should be close co-operation between the analyst and the manufacturer.

There is in fact reason to be critical of D.D.S.A. products, since the evidence of Mr. Forder, for the opponents, established that some of these products, i.e. meprobamate tablets and hydrocortisone skin lotion, were either below British Pharmacopoeia standards or of poor formulation. The evidence of Mr. McLachlan established that samples of a feed supplement sold under the name of "Terrafac" contained from 40 to 84 per cent more oxytetracycline hydrochloride than the standard laid down by the British Pharmacopoeia.

I understood Dr. Solomon who was, in my view, an honest and straightforward witness under cross-examination, to accept the need for in-process control, but he said that although the applicants' relations with their suppliers permitted them to exercise in-process control, in practice they found it sufficient to leave this to the manufacturer and that in any event the standards laid down in the British Pharmacopoeia were a sufficient safeguard. No drugs were sold by D.D.S.A. or its subsidiary—Chelsea Drug and Chemical Company—until they had been passed as conforming to British Pharmacopoeia standards by a qualified analyst. The Ministry of Health had in fact inspected some foreign plants engaged in the manufacture and supply of drugs under section 46, including in particular the plants from which the applicants were importing the patented drugs.

In Mr. Graham's submission, the Food and Drugs Act, which was read, provides ample safeguards to ensure that drugs comply with British Pharmacopoeia standards, and there was in fact no evidence of any complaint about the quality of the applicants' tetracycline and oxytetracycline.

In my view, the Comptroller is not the proper authority for ensuring that the relevant regulations are complied with and, in the absence of any evidence of any proceeding under the Food and Drugs Act establishing that the applicants for a licence have contravened the provisions of the Act, the Comptroller must assume that the prospective licensees will obey the law in this respect.

(4) Research.

Mr. Johnston submitted that the need for research in the drug field has been established as a matter of public interest, and pointed to the evidence of Messrs. Wilkins (of Beechams) and Howard (of I.C.) as showing the disastrous effect which the grant of compulsory licences could have upon the research programmes of drug manufacturers. Manufacturers who spend considerable sums of money in the public interest are entitled to more consideration, in Mr. Johnston's submission, than those who do not. Dr. Solomon said that D.D.S.A. themselves do research on a small scale and also rely upon the assistance of commercially available research organisations when the need arises.

I have some doubts about the weight to be given to the evidence of Messrs Wilkins and Howard since, to the best of my knowledge and belief, no compulsory licence has been ordered under section 41 against either of their respective firms, and their protests seem to be somewhat premature. However,

it is plain, in my view, that ability to continue research in face of compulsory licences is primarily a matter of the reasonableness of the compensation provided for by section 41. Whether or not there is any substance in the arguments put forward by these declarants, the complaint is clearly against the section itself, and the remedy lies with the legislature.

(5) Provision of an information service for the patented drugs.

It is clear from the evidence that there are certain basic sources of information available to all doctors. These are the British Pharmacopeia, the British Pharmaceutical Codex, certain Medical journals and the Prescribers' Journal, in addition to the circulars prepared by manufacturers. The Prescribers' Journal gives the most up-to-date information, but even this is not up-to-date for new drugs and, while information about these may appear in the Prescribers' Journal within a year or so of introduction (e.g. "Aldomet", a drug which was introduced in June 1962, appeared in the Prescribers' Journal in August, 1963 and in the British Pharmacopoeia in 1964) five years normally elapse before new drugs are listed in the British Pharmaceutical Codex. There is, therefore, a need for information about new drugs, and, in the patentees' submission, a continuing need to keep doctors informed of new developments even after a drug is established. For this purpose the patentees provide an advisory service to deal with queries from doctors on the basis of information derived from sources all over the world. Against this, D.D.S.A. rely for information on the basic sources listed above, and Dr. Solomon answers any queries from these sources or, if these are insufficient, he may ask consultants for assistance.

In Mr. Johnston's submission, D.D.S.A. cannot provide anything comparable with the service provided by the patentees in respect of their drugs. On the other hand, Mr. Graham, while conceding the need for an information service for new drugs, submitted that when a drug is well-established, there is no further need for an elaborate service.

There can be no doubt on the evidence before me that D.D.S.A. do not provide an information service equal to that of the patentees; nevertheless, this is not of itself a sufficient reason for refusing a licence, though it may carry some weight against D.D.S.A. when considering the question of balance of public interest.

(6) Price to the public.

In Mr. Johnston's submission, there is no evidence that the applicants' price for branded goods will be substantially less than that of the patentees when due allowance is made for a suitable royalty payment. Moreover, the patentees' branded price is now under negotiation with the Ministry of Health under the Voluntary Price Regulation Scheme.

The price of unbranded drugs for supply to hospitals is also at present the subject of negotiations with the Ministry of Health.

Mr. Graham did not dispute that there was unlikely to be any large saving in price, but submitted that the applicants' competition with the patentees has already had the effect of bringing prices down.

Whatever may have been the result of the applicants' activities in the past, the evidence before me does not enable me to anticipate the price position in

the future. As I understand it, the prices of the patentees' patented drugs, both branded and unbranded, are the subject of negotiations with the Ministry of Health. I must, therefore, I think, assume that the prices finally determined will be reasonable having regard to the public interest. There is no reasonable certainty that the applicants will be able to under-cut those prices to any appreciable extent, and the most that can be said is that if a licence is granted an element of competition will be introduced.

Since one purpose of section 41 is to encourage competition, even if prices are stabilised, the balance of interest in this aspect of the matter favours the applicants.

(7) Discretion

Finally, Mr. Johnston argued that the Comptroller should, in the exercise of his discretion, take into consideration the trading methods employed by the applicants in resorting to two bonus schemes. Under one of these the chemist received a supply of three different drugs at a cost some 20 per cent below the published price at which he would be able to claim from the National Health Service.

Under the other scheme, a chemist who ordered 1,000 tablets received 1,500 tablets of which only 1,000 were invoiced. He was, therefore, able to claim from the National Health Service at the invoiced price whilst paying only two-thirds of that price.

As I understood Dr. Solomon, both schemes were introduced because his advertisements were rejected by all the usual medical advertising journals, and this was the only method he could use to bring his goods to the attention of chemists. In any event, he said, the schemes were of short duration and did not represent D.D.S.A. normal practice.

I do not think that the Comptroller has any discretion under section 41. Unless there are good reasons for refusing a licence he "shall" order the licence to be granted. These are matters for the authorities administering the National Health Service, and it is not for the Comptroller to question them, much less to refuse to order a licence to be granted, unless the appropriate authority condemns the practices in terms which fully support such an action.

In the result, the answer to the question of the balance of public interest to be weighed against abuse of monopoly in the circumstances of the present case appears to me to lie between the ultimate effect on prices and the damage likely to be caused to a thriving home industry which is exporting some 40 per cent of its products. After careful consideration of the evidence before me and bearing in mind the Voluntary Price Regulation Scheme of the Ministry of Health, I am not satisfied that any advantage in price reduction would be sufficiently large or certain in the future as to outweigh the adverse effect on a home industry by such as extent as to override the contrary public interest against abuse of the monopoly.

Accordingly, I refuse to order the grant of a licence solely for the purpose of importation and sale.

Since I may be held to be wrong in this conclusion by a higher authority, it would no doubt be convenient if my conclusions were available on the questions of royalty and the terms of the licence, which were fully argued before me.

The discussion on the question of royalty included some reference to compulsory licences ordered in the U.S.A. at a royalty rate of 2½ per cent but, in view of the circumstances in which the order was made, I do not think that it was seriously contended that this would be of any assistance to me in assessing a royalty rate in the present case.

As I understood Mr. Johnston and Mr. Whitford, however, voluntary licences have been granted in the United Kingdom by the patentees at rates of 3½ per cent of the licensees' selling prices. Similar royalty rates granted in the U.S.A. to voluntary licensees are alleged to be due to settlement of interference proceedings, and to be affected by cross-licensing and know-how agreements.

There is, however, no direct evidence before me as to the terms of the United Kingdom licences. But if it be accepted that somewhat similar conditions apply as in the U.S.A. it would be clear that 3½ per cent could service only as a starting point from which, with suitable adjustment to take account of the different circumstances, the rate in the present case could be determined.

However, in the absence of any relevant evidence, I see no alternative to adopting the general approach to the determination of royalty rates laid down in *Geigy v. Biorex* (1964) R.P.C. 391.

That is to say the royalties to be paid should be made up of three elements to take account of the patentees' expenditure in—

1. Research and development.
2. Promotion of the patented drug.
3. Profit on capital investment in research, development and promotion.

On this basis, it is not disputed that the patentees are entitled to the proportion of world sales turnover which they spend in research, and this amounts to 4.6 per cent.

On the question of the licensees' liability for promotion expenses incurred by the patentees, Mr. Johnston submitted that one advantage derived by the patentees under the patent is their ability to allot a proportion of their annual turnover to research and also to promotion of new drugs. In both cases, in his submission, the patentees are entitled to recoup similar proportions from the licensees. This principle was accepted in *Geigy v. Biorex* as regards research because it is in the public interest that research should continue; further, because it is virtually impossible to ascertain the precise cost of research in producing any particular drug and, finally, because it is a convenient method of accountancy for abortive research.

As regards promotion, the *Geigy* approach was to ascertain the cost of establishing the drug as a lump sum and spread this over the remaining sales life of the drug. For reasons expressed in that case, the sales life was taken to be the remaining life of the patent after establishment. To this was added allowances to account for continuing promotion expenditure on the medical side after the drug was established, and for profit on capital expenditure.

It will be apparent that the proportion of the total turnover allotted to promotion annually should be roughly equivalent to the sum for all drugs of the individual amounts assessed for each drug by the *Geigy* method. Since details of promotion expenditure and total sales for each drug are not in evidence before me, I think it reasonable to assume for present purposes that the proportion of

promotion to sales is the same for each drug and corresponds to the proportion of total expenditure to total sales. But the actual amount contributed to promotion by each drug from its sales turnover is of course only a fraction of the total expenditure on all the drugs; and the fraction is determined by the number of drugs concerned. It would seem to me to be unreasonable to expect a licensee who benefits from a patent for one drug only to pay more than a proper share of the promotion charges attributable to that drug. He should not be called upon, in my view, to contribute also to the promotion charges of all other drugs.

Accordingly, the promotion figure for all drugs given at viii in the Appendix to Mr. Hobson's declaration must be divided by the number of patented drugs on sale by the patentees in order to find the amount to be allocated to each of the drugs now under consideration. Again, I have no evidence as to this, but I think it would be generous to the patentees if I abated Mr. Hobson's figure by four-fifths. Moreover, although in my view it would be reasonable to assess the proportion to be allowed for promotion on the basis of world turnover, I am prepared for present purposes to accept the figure of 9.8 per cent, based on United Kingdom sales, put forward at the hearing by Mr. Johnston after allowing something for costs not chargeable to the licensees. On this basis the percentage to be added in respect of market development or promotion of the patented drug is approximately 1.9.

It is necessary also to add a percentage in respect of administration, and Mr. Johnston's figure of 22 per cent of the above total was not seriously challenged. Thus, we need to add a further 1.43 per cent.

Finally, there is the question of the allowance for profit. Whereas in Geigy profit was assessed on capital expenditure on research, development and promotion, the patentees' figure of 10 per cent is based on total turnover. Some adjustment is, therefore, necessary; and by applying *Geigy* principles I assess the allowance for profit at 1.8 per cent.

On the most generous estimate in the Patentees' favour I assess the royalty payable as the sum of these various percentages, or 9.7 per cent in all. It is abundantly clear that the evidence is not sufficient to enable the royalty to be assessed with any degree of accuracy, but I am satisfied that a figure of 10 per cent would, on the assumptions I have made, be more than generous to the patentees.

In the *Geigy* case the royalty was adjusted to make it applicable to the licensees' selling price. In Mr. Johnston's submission, the royalty should in any event be payable on the patentees' price to avoid difficulties in determining to which of the licensees' prices it should apply. On the other hand, Mr. Graham saw possibilities in this for unfair charges on the licensees. In my view, it would be reasonable to charge royalty against the Ministry of Health price for the patentees' drug as suggested by Mr. Graham. The matter is further complicated by the fact that any future price of the patentees' branded drug may differ considerably from their price for the equivalent unbranded drug.

Accordingly, taking all the circumstances into consideration, I assess the royalty at 10 per cent of the price accepted by the Ministry of Health for the patentees' branded and unbranded drug respectively, the branded price being

used to calculate royalties payable on the licensees' sale of the branded drug, and the unbranded price being used for sales of the unbranded drug.

I append hereto a full statement of the terms of a licence I should have thought necessary, after taking into consideration the arguments addressed to me, had I decided to grant it. The licence is drawn in terms relating to Letters Patent No. 747779, but similar terms would be applicable in the case of Letters Patent No. 684417.

APPENDIX VIII

The History of Roche

Pharmaceutical "Specialties" of consistent high quality were the products envisaged by Swiss businessman Fritz Hoffman when, on October 1st 1898, he founded a pharmaceutical factory on the banks of the Rhine in Basle. For this purpose he had bought an ink factory and engaged the services of a young chemist, Dr. Emil Barell, and 23 employees. As his wife's name was La Roche, he followed an old Swiss custom of attaching her name to his and called the company F. Hoffman-La Roche & Co.

The young enterprise achieved its first major development with the cough syrup 'Thiocol' developed in 1898 and still used today. The Company's next major development occurred in 1904 when production of 'Digalen' was started. This product contained all the active substance from the leaf of Digitalis purpurea in purified standardized form. For the first time doctors were able to prescribe exact quantities of the drug and expect a uniform effect in their cardiac patients. These developments were followed five years later by 'Pantopon', the first injectable whole opium product for relief of severe pain.

With greater refinement of chemical methods and techniques during the latter part of the 19th century, scientists had begun to probe into the secrets of organic structure and to venture on the syntheses in the laboratory of organic compounds for practical uses.

Hoffman-La Roche was in the forefront of this activity. The acceptance by the medical profession of Roche products brought industrial expansion; new installations were built in Basle, new factories set up on five continents and a network of agencies sprang up all over the world. Roche celebrated the half century jubilee in 1946. During the first 50 years the staff of the Swiss company rose from 24 to 1,276; the real estate in Basle increased forty-fold to about 30 acres and the area covered by the factory installations was nearly 45 times as large as the original building. Today, the Hoffman-La Roche group of companies employs almost 10,000 people. The organization now comprises 25 associate companies and 120 agencies to ensure that in countries throughout the world Roche products can be prescribed by doctors in accordance with prevailing national conditions. Of the 25 companies—7 manufacture chemicals and pharmaceuticals, one produces chemicals only, and the remaining 17 produce pharmaceuticals only.

Roche—Canada

Hoffman-La Roche Limited, Montreal, founded in 1931, is one of the 25 associate companies. Starting modestly in dowtown Montreal, the Company moved in 1957 to a modern plant in suburban St. Laurent, which houses the most advanced production and quality control facilities. Pharmaceutical manufacturing facilities include tableting, encapsulation, as well as liquid and ointment production. Chemical manufacturing includes the production of vitamin C, sodium ascorbate, vitamin B_6 and diazepam.

24878—8½

The control laboratories are staffed by competent chemists and equipped with modern apparatus to permit such quality control procedures as Photofluorometry, Thin-layer Chromatography, Hydrogen Flame Ionization and Thermal Conductivity Gas Chromatography and Recording Spectrophotometry. A well qualified force of 40 representatives. as well as the ...personnel of the Medical and Professional Service Departments, enable Roche Canada to maintain a close personal contact with the Medical and Pharmacy profession from coast to coast. Warehouses in Toronto, Winnipeg, Calgary and Vancouver assure the availability at all times of Roche products in metropolitan as well as remote areas of the country.

Roche Canada employs a total of 225 people and its activities favourably affect a host of auxiliary industries. The growth of Roche Canada since 1957 necessitated the company to plan and complete three new building projects raising the total floor space from 30,000 sq. feet to 100,000 sq. feet in 1966.

APPENDIX IX

RESEARCH

Roche—in the universal fight against illness

Roche is proud to be accounted among the small group of pharmaceutical houses which have been able to accept a considerable share in the responsibility for basic scientific research. Roche holds that its responsibilities go beyond the preparation of quality medicines, beyond the provision of sound data on their proper use. The company's responsibilities demand active, continuing participation in biologic research, in experimental and clinical pharmacology and in the task of relating these to the solution of problems in clinical practice.

The Roche Research Record

The pioneer work of Roche in a number of medical fields has ensured for certain products a lasting reputation in the international world of medicine.

Sulfisoxazole ('Gantrisin' Roche)

For centuries, trachoma was one of the most widespread and devastating of all eye diseases. The World Health Organization has estimated that it numbers among its victims some 15-20% of the world population. Trachoma not only causes physical suffering and incapacity to those afflicted, but may also consign them to permanent poverty as a result of blindness. In countries where trachoma is endemic, sulfisoxazole has provided doctors with an effective weapon, the extensive use of which has done much to stem the ravages of this disease. In western countries, sulfisoxazole has become one of the most widely prescribed sulfonamides for the treatment of urinary tract infections. Moreover, in its injectable form it has saved many lives from meningococcal meningitis.

Neostigmine ('Prostigmin' Roche)

Neostigmine has become a "household" world in pharmaology and medicine. By activating smooth muscle and stimulating the vagus nerve, neostigmine relieves postoperative intestinal atony, once such a frequent and dreaded complication of abdominal surgery. Neostigmine also has the property of restoring muscle function after use of curare alkaloids during anesthesia. The preparation made headline news when in 1935 Dr. Mary Walker discovered its dramatic effect in myastheni a gravis. In this disease, the characteristic weakness of voluntary muscle responds almost instantaneously to neostigmine and normal motor activity is restored at least for a time. Neostigmine and the analogous preparation pyridostigmine bromide ('Mestinon' Roche) have since enabled many previously helpless patients to lead a tolerably normal life.

Isoniazid ('Rimifon' Roche)

In the summer of 1950 a member of a Roche research team in the United States discovered that the substance known as isonicotinic acid hydrazide was active against tubercle bacilli. Clinical trials proved this and subsequently the new antituberculous drug isoniazid was introduced for general use. Isoniazid

was recognized to possess antituberculous properties of the highest order and has proved a significant aid in the fight against tuberculosis. Roche was proud to receive the Albert Lasker Award of the American Public Health Association for this development, but the greatest reward resided in the photographs of empty beds and the statistics of closed TB Sanatoria. Though widely imitated in its oral form 'Rimifon' Roche remains the only injectable presentation which has also taken the sting out of tubercular meningitis, once a certain death warrant.

Psychopharmaceuticals

With the synthesis of the first monoamine oxidase inhibitor in 1951, Roche entered the field of drugs 'that influence the mind'. With this class of compounds, culminating in isocarboxazide ('Marplan' Roche) drug treatment of mental depression became, for the first time, a real possibility. This was followed by chlorprothixene ('Tarasan' Roche), an antipsychotic tranquilizer.

A major advance in psychochemotherapy occurred in 1960 with the introduction of chlordiazepoxide ('Librium' Roche) a drug acting specifically on anxiety and tension states without dulling the patient. In 1963 another important contribution was made with the introduction of diazepam ('Valium' Roche), which in addition to its psychopharmaceutical properties was described as "a muscle relaxant of unusual potency". It is rewarding to see the beneficial effect of diazepam on children afflicted with cerebral palsy in whom it favourably reduces heretofore uncontrollable movements in addition to its favourable action on the emotional component of this entity.

The new science of psychopharmacology has drastically changed the treatment of mental and emotional disturbances. Many a patient, who would once have occupied a hospital bed and claimed the attention of a highly specialized staff, can now be treated far more conveniently and economically in his own home.

The intensive research carried out by Roche has made available a broad-spectrum of preparations and has placed the company among the pioneers in this fascinating field.

Success and Failure

Among the list of Roche scientific breakthroughs a number of products, such as anticoagulants, sulfonamides, antitussives, anticancer compounds, hypnotics and pain-relieving drugs, could be enumerated. But even a company such as Roche, which can look back over 65 years of uninterrupted chemical and pharmaceutical research, must reckon with a relatively small "harvest". Of roughly 2,500 chemical compounds synthesized each year in Roche laboratories, approximately 1,000 are tested pharmacologically and only about twenty move on to the next stage, the clinical trial. On the average, only one out of these may develop into a drug of use to physicians. But even among the "marketable" drugs there are failures in the commercial sense because there is no large need for these drugs. Although not of commercial significance enough is produced to supply the modest demand because some people need them.

Vitamins—Another field of Roche research

No name is more intimately associated with vitamin research than Roche. Isolation and synthesis of many pure vitamins were effected by Roche chemists in close cooperation with research workers in universities. Roche was first in the

commercial syntheses and large scale industrial production of vitamins A, B_1, B_2, B_3, C, E, K and the carotenoids. Panthenol and Biotin are produced by Roche only. Today the company is the largest producer of synthetic bulk vitamins in the world. Roche constantly endeavours to develop new forms of vitamins for application in pharmaceutical preparations as well as for the special purposes of the food and feed industries, and strives to perfect the knowledge of . . . the vitamins and to contribute to their scientific investigation to the largest extent possible.

The Scope of Research

Roche and the people that work there: People with ideas and inspiration, grounded in good scientific training, are the heart of research. Thousands of men and women make up this indispensible element in the world of Roche research. At Roche in Basle, Switzerland, more than 600 men and women with advanced scientific training are actively engaged in a wide range of clinical, pharmacologic and medical investigations. In Nutley, N.J., more than 100 scientists with postgraduate degrees (M.D. and Ph. D.) work with about 250 graduate assistants. A third major group of Roche investigators, at Roche in Welwyn Garden City, England, also direct their efforts to the basic work of developing new therapeutic agents. In addition to their investigative work, many of the members of the Roche research staff are constantly in attendance at scientific meetings and in further special training at the postgraduate level.

Recent Research Programmes: Roche research programmes bear directly on the major basic problems confronting medicine. Some of the areas of recent research were:—

Psychotropics: Roche scientists have been probing the biochemistry of anxiety, the mechanisms of tension, the pharmacology of antidepressants. They have studied behaviour, memory and learning as influenced by various agents. Much work was done in brain physiology. Implanted electrodes in experimental animals afforded new, promising leads in cerebral localization of drug activity.

Infectious diseases: New antibacterials were studied and research was pressed in the field of virus infections.

Cardiovascular disease: Activities in this area have been directed toward a better basic understanding of the mechanisms of cardiovascular disorders. Efforts in experimental medicine in this area have involved the intensive study of cardiac anoxia and myocardial necrosis. Investigations of hypertension have involved not only the classic approaches but also the study of states induced by central, that is hypothalamic stimulation. In this field a promising antihypertensive compound is already in an advanced stage of clinical evaluation.

Cancer research: Roche expanded those activities which had previously yielded Fluorouracil. New Roche antitumor compounds, such as ibenzmethyzin ('Natulan' Roche) for Hodgkin's disease, are now under investigation in leading cancer centers throughout the world. Basic effects on RNA and DNA synthesis of potential antitumor agents have been the subject of intensive study.

Gastrointestinal disorders: Roche experimental medicine has advanced new methods for measurement of bile flow and has developed studies on the experimental production of gallstones in the hope of eventually eliminating or controlling this condition.

Metabolic medicine: In biochemical studies Roche scientists have sought to define more precisely the effects of insulin on adipose tissue; the influence of new substances on cholesterol biosynthesis;. . .the storage and release of amines in heart and brain; the effects of fatty acids and heparin on thrombocytes; the mechanisms of muscular spasm and the regulation of appetite. These metabolic studies have utilized not only the traditional biochemical and pharmacologic approaches, but have also been pursued to the challenging and promising enzymatic level. One of the chemical accomplishments by Roche chemists was the synthesis of pure arachidonic acid.

Tropical disease: A major scourge in many countries and a world threat in the jet age, has been another area of Roche research which has yielded encouraging results. Roche has developed a new synthetic drug related to emetine, showing the promise of therapeutic advantages in amoebic infections. A new antimony derivative has been prepared which appears helpful in the treatment of schistosomiasis.

Veterinary medicine: This field bears interesting relationships to human medicine not only in experimental but in clinical areas as well. Roche research is elucidating the effects of a special water-dispersible parenteral vitamin A which appears valuable in improving feed utilization, breeding performance and growth in cattle, pigs and other animals. New drugs have also been developed for the treatment of animal disease. The implications of such advances in terms both of food supply for and better understanding of disease in man are obvious.

Advanced procedures: The rate of development of modern research relates to progress in technology and methodology. Accordingly, Roche research has placed heavy emphasis on pioneering new methodologies . . . whether they be in the area of radioactive tracer studies, thinlayer chromatography, gas-liquid chromatography or in the development of sophisticated techniques of biometrics. One example of Roche pioneering in improved planning and evaluation of clinical research with modern statistics was the utilization of "single case experimental design" in the study of psychotropic agents. The experimental pattern was developed in order to have patients serve as their own controls in an effort to eliminate such variabilities as differences in personalities, culture, education and physical structure. The disease process, reacting to a drug, becomes the major variable which we seek to isolate for statistical study.

Roche . . . and its role in society

Patient benefits are the ultimate goal of all medical research. Roche research policies reflect this belief; Roche policies are likewise based on the conviction that no matter how good research is or drugs are, they are of no help unless their benefits can be brought to a patient by his physician.

Government, as representative of both patients and physicians, has been engaged to an increasing degree in the area of drug regulation. In this area

Roche honours its obligations by going beyond complete fulfillment of both the letter and the spirit of law and regulation. Here again, it is the Roche policy to seek to advance medicine, not simply by meeting existing standards, but by raising these and setting new and more advanced standards both for responsibility and for research...To Roche today, toxicity studies, particularly chronic long-term ones, are developed in new dimensions as it tests for years and through generations of experimental animals, as it increases its efforts in the study of the metabolic pathways of drugs, their halflife and their excretion and their mechanisms of action.

Patients and Clinical Pharmacology: Roche is pioneering new affiliations, relationships and techniques to assure simultaneously the best possible care for patients as well as the production of valuable, objective scientific data. Roche is continually developing affiliations specially staffed and equipped for as thorough and as safe as possible evaluation of new drugs. Roche laboratories are engaged in extensive programmes adapting electronic computer techniques for the management of the rapidly amassing world scientific data in fields of medical interest.

The future

The very fact that many areas of therapeutic endeavour still remain unexplored serves as incentive for Roche to increase its efforts towards maintaining and improving the health of people everywhere and its aim will continue to be to search for the new, to create the trustworthy and to preserve what has stood the test of time.

APPENDIX X

HOFFMANN-LA ROCHE LIMITED

Income Statement—Packaged Human Pharmaceuticals for the Years 1954–1965 inclusive

	Percentage
1. Net Sales	100
Expenses and Taxes (Except Sales & Excise Tax)	
2. Cost of Goods Sold	29
3. Distribution (Include Warehousing)	4
4. Marketing	24
5. Research & Development	11
6. Royalties	—
7. Administration	14
8. Interest	2
9. Income Taxes	8
10. TOTAL EXPENSES & TAXES	92
11. Net Earnings	8
	100%

HOFFMANN-LA ROCHE LIMITED

Income Statement—Packaged Human Pharmaceuticals for the Year 1965

	Percentage
1. Net Sales	100
Expenses and Taxes (Except Sales & Excise Tax)	
2. Cost of Goods Sold	29
3. Distribution (Include Warehousing)	3
4. Marketing	18
5. Research & Development	12
6. Royalties	—
7. Administration	9
8. Interest	2
9. Income Taxes	14
10. TOTAL EXPENSES & TAXES	87
11. Net Earnings	13
	100%

HOFFMANN-LA ROCHE LIMITED

Breakdown of Marketing Expenses of Packages Human Pharmaceuticals for the Year 1965

		Percentage
Field Sales Expenses		7.5
Administration		1.6
ADVERTISING & PROMOTION:		
Journal Advertising	1.7	
Samples	3.6	
Direct Mail	3.0	
Others	0.6	8.9
		18.0

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 12

TUESDAY, OCTOBER 25, 1966

WITNESSES:

Representing Ayerst, McKenna & Harrison Limited: Mr. E. Glyde Gregory, President; Mr. John A. Walker, Executive Vice-President; Dr. H. L. Smith, Vice-President; Dr. Donald A. Buyske, Director of Research; Mr. James Robb, Legal Adviser, all of Montreal.

ROGER DUHAMEL, F.R.S.C.
QUEEN'S PRINTER AND CONTROLLER OF STATIONERY
OTTAWA, 1966

24880—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

Vice-Chairman: Mr. Patrick T. Asselin (*Richmond-Wolfe*)

and

Mr. Brand,	Mr. Hymmen,	Mr. Pascoe,
Mr. Clancy,	Mr. Isabelle,	Mr. Prud'homme,
Mr. Côté (*Dorchester*),	Mr. Johnston,	Mrs. Rideout,
Mr. Enns,	Mr. MacDonald (*Prince*),	Mr. Roxburgh,
Mr. Howe (*Hamilton South*),	Mr. Mackasey,	Mr. Rynard,
Mr. Howe (*Wellington-Huron*),	Mr. MacLean (*Queens*),	Mr. Tardif,
	Mr. O'Keefe,	Mr. Whelan,
	Mr. Orlikow,	Mr. Yanakis—(24).

(Quorum 10)

Gabrielle Savard,
Clerk of the Committee.

MINUTES OF PROCEEDINGS

TUESDAY, October 25, 1966.
(20)

The Special Committee on Drug Costs and Prices met this day at 9.45 a.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout and Messrs. Brand, Enns, Harley, Howe (*Hamilton South*), Isabelle, Johnston, MacDonald (*Prince*), MacLean (*Queens*), Pascoe (10).

Other Member present: Mr. Goyer.

In attedance: *Representing Ayerst, McKenna & Harrison Limited*: Mr. E. Glyde Gregory, President; Mr. John A. Walker, Executive Vice-President; Dr. H. L. Smith, Vice-President; Dr. Donald A. Buyske, Director of Research; Mr. James Robb, Legal Adviser, all of Montreal.

Also in attendance: Mr. A. M. Laidlaw, Legal Counsel for the Committee.

The Chairman introduced Mr. Gregory who, in turn, introduced his associates.

Mr. Gregory read a prepared statement, copies of which were distributed to the Members.

On motion of Mr. MacDonald (*Prince*), seconded by Mrs. Rideout,

Resolved,—That travelling expenses by paid to Mr. W. J. Blakely of Kingston, Ontario, Accountant for the Committee, when such expenses are incurred in relation to his work with the Committee.

The Committee proceeded to the consideration of the submission of Ayerst, McKenna & Harrison Limited.

Agreed,—That the said submission be printed as part of today's record. (*See Appendix "A"*).

Mr. Gregory was questioned. He was assisted by Dr. Smith, Mr. Walker, Dr. Buyske, and Mr. Robb.

Mr. Goyer also asked questions of the witnesses.

It was agreed that Mr. Laidlaw write the President of Ayerst, McKenna & Harrison Limited for supplementary information with reference to patents and compulsory licensing; this information to be tabled at a later date.

The Chairman thanked Ayerst, McKenna & Harrison Limited for their brief and the officials of the Company for their presentation, and at 12.35 p.m. the Committee adjourned to 9.30 a.m., Thursday, October 27.

Gabrielle Savard,
Clerk of the Committee.

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EVIDENCE

(Recorded by Electronic Apparatus)

TUESDAY, October 25, 1966.

The CHAIRMAN: Ladies and gentlemen, I see a quorum. We might start this morning's meeting. I would like to welcome the representatives of Ayerst, McKenna & Harrison Limited from Montreal. I will now introduce Mr. Gregory who, in turn, will introduce his delegation.

Mr. E. GLYDE GREGORY (*President, Ayerst, McKenna & Harrison Limited*): Thank you very much, Dr. Harley.

Ladies and gentlemen on my immediate right is Mr. John A. Walker who is our executive vice president, a graduate from McGill University with a bachelor of science degree in 1938. He has been with our company since that time. Next to Mr. Walker is Dr. H. L. Smith, vice president of our company. He is a physician, a graduate of McGill University in 1943, with post graduate work and private practice. Next to Dr. Smith is Dr. Donald A. Buyske, a Ph.D. in organic chemistry and biochemistry from the University of Wisconsin. He is past assistant professor of chemistry from Duke University and now our research director. Next to Dr. Buyske is Mr. James Robb, our legal consultant or adviser.

This is the team representing Ayerst for this hearing and it is our wish to be helpful to you in any way that we can. In order to give you some indication of our feelings, I would like to make this statement.

Mr. Chairman and Members of this Committee, my name is Edmund Glyde Gregory and I am President of Ayerst, McKenna & Harrison Limited. I am personally, and in my capacity as President of Ayerst, McKenna & Harrison Limited, deeply concerned with the subject before this Special Committee. Ayerst recognizes that its business activities are closely related to the public health and for that reason welcomes and wishes to help an inquiry seeking to advance the public health and the broad availability of drugs at fair prices. My personal concern that drugs be available to the public at reasonable prices predates my association with Ayerst and began when I first apprenticed as a pharmacist in Brockville, Ontario in 1930. (My choice of pharmacy as a career was no doubt influenced by the fact that my grandfather established one of the early pharmacies in Upper Canada at Lindsay, Ontario in 1858 and this continues to be owned and operated by the Gregory family to this day.)

Incidentally, we are running out of Gregory men, we all have daughters. I have thus been made aware of the importance of prescription medicines in the lives of our Canadian citizens, both as a pharmacist and as an executive of a pharmaceutical company, and I share your desire that safe, effective prescription drugs be available to Canadians at fair and reasonable prices.

My many years of association with pharmacy have convinced me that prescription drug prices in general and prices of Ayerst products in particular are, in fact, fair and reasonable. Certainly we would all like the cost of drugs to

be lower, just as we would be happier with lower food costs and lower rent, but the facts are that the costs of manufacturing, of the quality control measures necessary to produce safe and effective drugs, and of conducting research in Canada are all high and rising sharply. For example, Ayerst research expenses in 1963 barely exceeded $2,000,000 while in 1966 they are estimated at close to $3,500,000. Indeed, it is surprising that drug prices, unlike the prices of other goods and services, have not risen but have declined slightly and for this, I believe, pharmaceutical manufacturers should be commended.

Without a doubt there are Canadians who are indigent and for whom the cost of drugs in the case of prolonged sickness seems high, and I would agree that these people are entitled to receive their necessary medications. (I might add that for these people the price of food and shelter also might appear burdensome.) But for most Canadians the prices of the safe, effective drugs now available are not excessive or burdensome. This is most clearly shown by the testimony previously submitted to this Committee by the Pharmaceutical Manufacturers Association of Canada which indicates that when one considers the real cost of drugs—the hours of labour required to earn the money for their purchase—one finds that Canadians have to work fewer hours to earn the money to purchase their necessary prescription drugs than do the citizens of all other countries with the possible exception of the United States.

Most certainly, relief should be afforded those Canadians for whom the cost of prescription drugs required by prolonged illness exceeds their means. In framing a solution to this problem however, I think it essential that the Committee recognize the following:

1. It is important for the technological and industrial development of Canada that the scientific research now being conducted in Canada be nurtured and encouraged. The experience of industrialized countries has been that this is best done through a patent system designed to reward the inventor for his efforts. The fact is that scientific research is being conducted in Canada by the drug industry on an expanding scale. Ayerst is proud that it conducts, *in Canada*, research for the entire worldwide Ayerst organization. During the past five years Ayerst has expended over $2,500,000 in plant and equipment for research and over $10,600,000 in operating our research laboratories.

Ayerst is not alone among the drug manufacturers doing research in Canada. Nine PMAC members have research laboratories in Canada, including Pharma-Research Canada Limited, Bristol Laboratories of Canada Limited, Smith Kline & French and Warner-Chilcott Laboratories Company Limited, and all have recently constructed modern research facilities in Canada to complement the research being conducted by their parent firms outside our country.

Five other companies have had established research laboratories here previous to the others just starting up. If these expenditures are to continue to be made in Canada, this Committee must recognize that it is necessary that patent protection be provided so as to foster the incentive which justifies incurring these large expenditures. Any proposal which would further reduce the already limited and discriminatory patent protection now available to drug discoveries in Canada would *discourage* drug manufacturers from conducting

research in Canada and would be inconsistent with the rationale of the federal tax laws which attempt to *encourage* the prosecution of research in Canada through tax incentives.

2. Proposals for encouraging the importation of foreign-produced drugs by extending the compulsory licensing provisions to include the licensing of imports, or by abolishing patent protection for drugs as recommended by the Restrictive Trade Practices Commission, would inhibit the development and growth of new research-oriented companies in our country. Such companies, I believe, can best develop under the protective umbrella of a patent system which serves to encourage the discovery and introduction of new products by rewarding inventors with a temporary monopoly. This is so because young Canadian pharmaceutical companies are not likely to embark on research programmes which might lead to important pharmaceutical discoveries if they know that their discoveries can be pirated with impunity by their larger competitors with extensive sales forces and financial resources.

Thus a patent system, affording a reasonable degree of protection, is of prime importance, not only to the large, international, research-oriented company, but to an even greater extent to the young, developing Canadian pharmaceutical firm.

3. It is important to the public health of all Canadians that safe, effective medicines be quickly available when needed. Any legislation which would result in Canadians being made dependent upon foreign sources for a commodity so important to their well-being as pharmaceuticals is clearly unsound. Such legislation creates the possibility that essential drugs would be denied Canadians as a result of war, strikes or other emergencies including a change in a foreign government's policies. The objective of having safe, effective drugs readily available to Canadians, when needed, can best be accomplished by maintaining a sound and vital drug industry in Canada.

4. The free choice of the physician to prescribe those medicines which in his judgment he deems to be in the best interests of his patient must be retained. Should the physician prescribe a so-called generic drug, so be it. If, on the other hand, the physician considers it advisable to prescribe a trademark drug, this decision must also be respected. Nor should this vital principle be violated with respect to indigent patients, for it would be highly illogical to develop programmes to insure that indigent patients receive all the physician's services they need and then limit the means of treatment the physician may prescribe. I would urge that, in this highly specialized and difficult area where there is compelling evidence that no two drugs are truly equivalent, this Committee not interfere with the right of the physician to prescribe the drug of his choice or the right of the patient to receive the drug prescribed by his physician.

5. The proposal of the Royal Commission on Health Services that a ceiling of 15 per cent of sales be established as the maximum allowable tax-deductible expense for advertising, sales promotion, etc., is clearly unsound and would result in higher rather than lower drug prices. This

would be so because drug manufacturers would be compelled by the competitive situation to incur these expenses even if they were non-deductible for tax purposes, and therefore prices would rise in order to achieve a reasonable profit level.

In summary, I know you will consider the question of drug prices in Canada fairly and objectively. I believe the Canadian drug industry, and especially Ayerst, McKenna & Harrison, have contributed much to the public health and economic well-being of Canada and I am seriously concerned that the restrictive and discriminatory recommendations of the Restrictive Trade Practices Commission and the Royal Commission on Health Service will cripple and may destroy this essential industry. I ask, therefore, that you weigh carefully the evidence and recommendations which have been placed before you by the Pharmaceutical Manufacturers Association of Canada. I believe you will find that these recommendations offer a constructive, realistic approach to dealing with the health needs of our fellow Canadians.

Wih these thoughts, the brief of Ayerst, McKenna & Harrison Limited is respectfully submitted.

The CHAIRMAN: Thank you very much, Mr. Gregory. Copies of Mr. Gregory's statement will be distributed to members as it was not included in the brief.

Before we proceed with the questioning, there is one motion that I would like to have from the Committee. At the time the Commitee hired our accountant, Mr. Blakely, it was understood that the travelling expenses he would have, would be paid. However, in our terms of reference that we had for hiring him, this was omitted; therefore, I would need a motion from the Committee that the travelling expenses be paid to Mr. W.J. Blakely, accountant for the Committee, when such expenses are incurred, in relation to his work with the Committee.

Mr. MACDONALD (*Prince*): I so move.

Mrs. RIDEOUT: I second the motion.

The CHAIRMAN: All in favour. Against?

Motion agreed to.

The CHAIRMAN: The meeting is now open for questioning. Is it agreed that the brief be printed as part of today's proceedings?

Agreed.

Mr. BRAND: I must say I enjoyed reading the brief; it is a very well written one. I notice you carefully stayed away from figures.

Mr. GREGORY: I have some figures here, Dr. Brand.

Mr. BRAND: Good, I was hoping you had. I get the impression, and I am sure this is true, that Ayerst is the one company that does more research than any of the others. Is this correct?

Mr. GREGORY: I might be biased but I think probably that is so, certainly in Canada.

Mr. BRAND: I meant in Canada.

Mr. GREGORY: Yes.

Mr. BRAND: What percentage of the manufacturers' dollar would your research represent?

Mr. GREGORY: I think I can give you that figure. It is 9.6 per cent.

Mr. BRAND: On the regular operations?

Mr. GREGORY: On the regular operations.

The CHAIRMAN: I was just wondering, for the benefit of the Committee, would you have a breakdown of your dollar that you could give the Committee. You mentioned a 15 per cent figure for marketing costs, etc. Could you give us the breakdown of your whole dollar?

Mr. GREGORY: Yes, of course.

Mr. BRAND: I think this would be very useful, Mr. Chairman, in view of the fact that this 9.6 figure is higher than the composite one presented in the P.M.A.C. brief.

Mr. GREGORY: Yes, theirs is 7 per cent, I think. Our manufacturing dollar is 33.3.

Mr. HOWE (*Hamilton South*): May I ask a question here just for clarification? Do you mean that this 9.6 per cent represents the $2 million to $3.5 million of which you spoke of in 1963 to 1966?

Mr. GREGORY: The figures I am giving you, gentlemen, are based on 1965.

Mr. HOWE (*Hamilton South*): Is this the prescription dollar or the manufacturer's dollar?

Mr. GREGORY: This is Ayerst's regular operations' dollar which is the amount of money we receive at the end of the year.

Mr. HOWE (*Hamilton South*): So this is the manufacturer's dollar not the prescription dollar. The figure of 9.6 would be smaller in the prescription dollar?

Mr. GREGORY: Presumably, yes.

Materials, 25.1; labour, 5.4; plant costs, 2.8, all of which adds up to 33.3; distributing warehousing costs, 4.6; professional service representation, marketing and medical information, 21.3, and that is broken down into field sales expense, 12.2; administration of marketing, selling and advertising functions, 3.2 and advertising and promotion, 5.9. I think you will find that adds up to 21.3.

Mr. BRAND: That also is lower than the one in the P.M.A.C. brief.

Mr. GREGORY: Yes, I think their figure was 15. I am running two columns here.

Medical and pharmaceutical journal advertising is 1.1; direct mail advertising, .5; samples, 2.8; medical exhibits face another 1.5; research and development, 9.6, as I said earlier; royalties, 4.4; administration in general, 8.6; income taxes, 9.4; earnings, 8.8.

Mr. ISABELLE: Does the figure of 9.6 per cent include medical research?

Mr. GREGORY: Yes. Let me see if I can give you the figure for medical research. In 1965, I think—Dr. Smith, would you agree with me—it was about $100,000.

Dr. H. L. SMITH (*Vice President, Ayerst, McKenna and Harrison Limited*): Yes, that is correct.

The CHAIRMAN: Could I ask a question to clairfy a point raised in Dr. Brand's question? I think you have broken down into several headings the items which were lumped together by previous witnesses as part of their marketing costs. I think you have marketing separately and then I think you have direct mail separately.

Mr. GREGORY: That is correct.

The CHAIRMAN: And advertising separately. What would be the total of all your, shall we say, marketing, advertising and promotion costs? I think the P.M.A.C. brief gave a figure of about 30 per cent.

Mr. SMITH: It was 29.9 per cent.

Mr. GREGORY: Our figure is 21.3 per cent.

Mr. HOWE (*Hamilton South*): In your brief, Mr. Gregory, I believe you have 29.9 per cent. That figure must include something else.

Mr. GREGORY: Yes. Was that the industry average?

Mr. HOWE (*Hamilton South*): No, it was your figure. I just remembered the figure without remembering the page. It is on page 18.

Mr. GREGORY: The P.M.A.C.'s Annual Statistical Survey for 1964 submitted previously to this Committee indicates the total marketing expense including the cost of providing some important information to physicians accounts for 29.5 per cent of the manufacturer's dollar.

Mr. HOWE (*Hamilton South*): I am sorry, I just remembered the figure, not the circumstances.

Mr. GREGORY: That is the P.M.A.C. figure.

Mr. HOWE (*Hamilton South*): So yours is about 8 per cent less than P.M.A.C.'s.

Mr. GREGORY: Yes.

The CHAIRMAN: That is quite so because I think you did add in several things after that that would have normally been included in this element here. Would that not have been included?

Mr. GREGORY: That is the breakdown there.

The CHAIRMAN: The chairman apologizes. The figure for total marketing costs is 21.3 per cent.

Mr. BRAND: This is considerably lower, I think, percentagewise than in the P.M.A.C. brief. Do you feel you do just as good a job of marketing, etc., as the other firms?

The CHAIRMAN: With earnings of 8.8 per cent? That figure is about the same.

Mr. BRAND: The earnings are also a little lower.

The CHAIRMAN: I beg your pardon?

Mr. BRAND: The earnings are a little lower as well.

Mr. GREGORY: I think, Dr. Brand, that we at Ayerst try to do an effective job and discharge our responsibilities to the medical and pharmaceutical professions. One of the things we try to do in our company is not to have too much fat.

Mr. BRAND: Could I ask one more question? If the government removed the sales tax what difference do you think this would make on the prescription dollar? We have had about 29 other views and I wonder what yours is.

Mr. GREGORY: First of all, I know some of those various views and I would prefer not to become involved in the mathematics or machinations of those figures. However, let us say this that Ayerst has been a tax collector over the years and if the government removes the sales tax, Ayerst will, by whatever means is necessary, make sure that our cost to the druggist is reduced by the amount of the tax involved.

Mr. BRAND: You mean 11 per cent?

Mr. GREGORY: Yes, indeed.

Mr. BRAND: With better patent protection would this mean more research in your firm?

Mr. GREGORY: We are probably going as full out as we can at the present moment. It would certainly not discourage more research, Dr. Brand.

Mr. BRAND: I believe in your brief you made a statement or wandered around that point. It is in here somewhere that it would be a little better and it might encourage more to come in and do more.

Mr. GREGORY: It would probably encourage other worldwide companies to do something in Canada as Warner-Chilcott, as you know, have just recently opened up a new laboratory in Toronto in Research Park up there for just one phase of medical research. I think it would certainly do no harm and probably do a great deal of good.

Mr. BRAND: So you do not really know if you would do any more research or not. You think you are doing as much as you can?

Mr. GREGORY: Our company is now, I think, 42 years of age and if I remember our statement here in the brief, if I can find it for you, on page 3: "Our company was founded in 1925 under Dominion charter. The company's original founders were all Canadians. At its inception in 1925, Ayerst commenced an imaginative and progressive research program unusual for that time." I was not with the company in 1925 but when I joined in 1935 it was the beginning of the endocrine era, the era of nutrition, and since that time I have passed through the era of chemotherapeutics, antibiotics, and so on. Therefore, I can only answer your question, Dr. Brand, by saying that any company in the pharmaceutical manufacturing industry, unless it devotes a great part of its energies and vigour to research, is only going to go in one direction, as I see it.

Mr. BRAND: That does not quite answer the question. There has been a lot of evidence that the patent laws are not too beneficial for the drug manufacturing companies. If they were improved would this make any real difference, or would you just continue as under the present patent laws?

Mr. GREGORY: I would believe—and this is all that I can say—that members of our industry would be much more inclined to give serious consideration to doing more, or starting up new research if they have not already done so. This would, to me, be the obvious approach.

Mr. BRAND: I must be satisfied with that. Will you, then, give me another opinion. Do you think—

Mr. GREGORY: My executive vice president wishes to speak on this, Dr. Brand, if you will let him take over from me.

Mr. WALKER: Dr. Brand, I feel that the question is a little difficult for Mr. Gregory to answer because it is almost like saying to the engineer of the Rapido between Montreal and Toronto; "If we give you green signals will you go faster?" He is going about as fast as he can go, and I think that with Ayerst, as far as our research is concerned, we are at full throttle right now.

I think the figures pretty well speak for themselves in this connection. Any company which is doing $3.5 million of research in Canada must, I think, be considered a real leader in this field.

You say; If the patent act were tightened up would we do more? This is a very difficult question to answer, because I feel that we are doing an all-out job now. But if you were to say: If the patent act were relaxed would we do as much, I think the answer would be No, we would not.

Mr. BRAND: If you are doing $3.3 million of the total of $6 million for the whole industry in Canada, you are doing a very substantial amount.

Mr. WALKER: I do not have the industry figure. We will do about $3.5 million this year.

Mr. BRAND: That is a very creditable amount, Then my next question would not be apropos: Would increased research increase the cost of the product? In your case, obviously this would not be true.

While you are talking about research, and just to give you an opportunity to say something about it, since there has been a lot of talk about pregnant mare's urine in the press lately, is there anything you would like to say about this in your own defence against some of these rather wild charges that have been made lately?

Mr. GREGORY: It so happens that Mr. Walker is our project officer in this area and I know is well informed on the subject. If you would like Mr. Walker to discuss it with you I am sure he would be very pleased to.

Mr. WALKER: Every time this subject comes up I get a little gun-shy. I find my name in Maclean's magazine, in the popular press, and when I come home at night my wife and children sneer at me and say, "You are cruel to animals." there is really quite a witch-hunt going on at the present time.

However, I would say in connection with this product, that I feel personally—and I know this feeling is shared by the other members of our company—that this is probably one of the most creditable pieces of research and pharmaceutical development that has ever been done in any country, and it happens to have been done in Canada in a Canadian laboratory by Canadian scientists.

This whole development of Premarin is a Canadian invention. It was invented about 1939, placed on the market about 1943, and it has become one of the largest pharmaceutical specialty items in modern day drugs.

I think that it is worth while to point out that all the raw material for this product for the entire world, with very few exceptions, is produced right here in Canada. This gives a very realistic economic assistance to the Canadian farmer. I think that our purchases of raw material from Canadian farmers this year will run somewhere around $7 million. As I say, this is a real "shot" for the Canadian farm enterprise.

The other thing, too, is that it is a very large dollar earner. Our export sales were very, very considerable, inasmuch as we do ship this all over the world.

This is the product. I do not know whether you have any other questions about it. I would say that we have licensed this product very broadly. People are manufacturing it in most of the major countries of the world. We have our own companies in ten foreign countries. We ship them bulk and they fabricate it. We are also sending the finished product from Canada to about 35 different countries through distributorships.

Mr. BRAND: This is exactly what I wanted you to say.

The CHAIRMAN: I think, also, Dr. Brand was giving you an opportunity to defend the practices of collecting the specimens.

Mr. BRAND: Yes; I just wanted to place on the record the fact that it was the result of Canadian research by a Canadian company with Canadian horses.

Mr. WALKER: I do not know whether some of these horses are actually nationalized, because we had to go very far afield this year. We have under contract to us at the present time about 30,000 mares. The entire horse population of the Dominion of Canada is under 400,000. Half of those are no good—they are male horses—so that you have to cut that down to about 200,000. Some are too old, and some are too young, and perhaps some are disinclined; therefore, when you actually figure out the number of mares which are on contract to us we probably have one out of every five in the country.

To get this number, we have had to go as far south as Texas, into Montana and North Dakota. If you say "30,000 horses" quickly it does not sound like much; but I am sure if you lined them up on the Manitoba border and started them across the prairies you would have the biggest horse race the world has ever seen.

The CHAIRMAN: This is one example where the Department of National Revenue allows you to have horses on your payroll.

Mr. WALKER: There is one very important feature of this, though, that I think should also be brought out, and that is that at the time Premarin was elaborated in our laboratories Ayerst was a relatively small Canadian company. This one product, through patent protection, allowed us not only to work our own domestic market, which was the only market we were in at that time, and to prevent larger companies from pirating the fruits of our Canadian invention from us, but it also allowed us to move into the international field through international patents. I am very certain that if we had not had this product, and not had patent protection abroad, Ayerst would not be the company that it is today. This was our springboard into the international field.

Mr. HOWE (*Hamilton South*): May I ask a question at this point to allow you further opportunity to elaborate. What is the difference between Premarin and the regular stilboestrol which was ordinarily used? You have used the word "Premarin" but I do not think that people would just understand what the significance is in the discovery.

Mr. GREGORY: I know that Mr. Walker can probably answer this question, but we have two medical experts with us here. Dr. Buyske or Dr. Smith, which one of you would like to answer the question?

Dr. H. L. SMITH, (*Vice-President, Ayerst, McKenna and Harrison, Ltd.*): Premarin is a combination of natural estrogens, and actually was the first really orally active combination of estrogens that was marketed. Prior to that time there were other estrogens being sold; most of them injectables. With Premarin we had a natural source of estrogenic substances and these, over the years, have proved to be probably the best oral estrogen today.

Stilboestrol is a synthetic. It is in no way related to the steroid hormones that you obtain from a natural source. It will do many of the same things that Premarin and Ethinyl Estradiol and other estrogens will do, but from all the publications that have appeared since 1943—and we have a tremendous bibliography to date—certainly I would say that Premarin is really the standard for all other estrogens today. In the human, as you know, it is probably used mainly for the treatment of the menopause, and it is certainly the estrogen of choice.

Mr. HOWE (*Hamilton South*): In other words the secret of its being better is in the fact it is of natural origin rather than synthetically derived?

Mr. SMITH: This is correct.

Mr. MACDONALD (*Prince*): Mr. Chairman, may I ask a supplementary while we are on this? Mr. Gregory, in your listing of the areas where you obtained the raw product I wondered why, there were no Maritime mares indicated? Is there not a sufficient supply of horses in eastern Canada?

Mr. GREGORY: May I ask Mr. Walker to answer that one?

Mr. WALKER: I take it that you are a Maritimer.

Mr. MACDONALD (*Prince*): That is right. I am becoming parochial.

Mr. WALKER: This is correct. There are 6,000 mares in Nova Scotia. As a matter of fact, about a year and a half ago we tried to start an operation down there. We were going to centre it on Truro. We sent field staff down—a veterinarian and some field men—and they covered Nova Scotia from one end to the other and found that the mares are in twos and threes and ones—somebody will have two mares in a barn—and this is absolutely of no use to us; we have got to have them in large numbers otherwise the economics do not work for the farmer or for us. Therefore, while we did try in the Maritimes we had to forego that. We moved instead to the west, where we have just completed a million dollar plant in Brandon, Manitoba.

Mr. MACDONALD (*Prince*): I was thinking of the considerable concentration of race horses, in particular, throughout eastern Canada, and I wondered if you had explored that possibility?

Mr. WALKER: Yes; these are not the best type. They are a little high strung and a little light. The best type of horse for this is a quieter horse, the farm or draft type horse.

Mr. ENNS: I am interested in the subject under discussion, but my question is not necessarily related to it. I may tell Mr. Gregory that in my own home town there was an auction sale of some 500 horses, and they came all the way from Texas and wherever else. It is quite a flourishing business. It is, as you say, an excellent supplement to the Prairie farmer so far as income is concerned.

My question comes back to Mr. Gregory's statement regarding promotional and advertising costs. I was very interested in your telling us that your firm

was able to do this with 21 cents out of the prescription dollar. Is that your figure, Mr. Gregory?

Mr. GREGORY: I said that our advertising and promotional cost was 5.9 out of this 21.3 of our Ayerst operation.

Mr. ENNS: Yes. We have heard from other witnesses, other manufacturers, who quoted us figures ranging from 29, which is the industry average, to 31 cents on the prescription dollar. If your firm can do what I consider, in my limited experience to be quite an excellent promotion with 21 cents, is it not conceivable that a further reduction, as recommended by the Hall Commission, to 15 per cent is not all that unrealistic?

I realize that you stated that this would probably add to the cost, and I would like more elaboration on this.

I am simply saying that if one firm can make a difference of some 10 points, is it not conceivable that the whole industry could narrow this down and still do effective and constructive promotion?

Mr. GREGORY: First of all, I would hate to think that any discriminatory act would be undertaken by any government in Canada which would limit our ability to provide good and useful employment to the 860 people who work for us. If our advertising marketing areas were affected I can only believe that the growth of our company would be retarded.

Mr. ENNS: There would not be 800 people involved with the direct promotion of the company?

Mr. GREGORY: No, no; but we have a payroll to meet every week, and that is how many people have their hand out at our place. Anything we would do to endanger our ability to meet this payroll would not, in my judgment, be good.

I think that what anyone spends on promotion or advertising is predicated on the nature and type of their business. For some of the old products that we have on our list we find new areas of usefulness. You just do not give up when you get some sensational drug that is useful and so on. You have to keep supporting it.

I think that because ours is perhaps a little lower than the national industry average, it may be good or it may be bad for us. I do not know. I can only speak as a person who believes that, to be successful in any area you must communicate with the people. Any restriction placed upon our ability, or our right, to communicate as we see fit, to the best of our ability, would work quite a hardship, and I do not know that it would reduce the price of drugs. I do not think it would.

We have always tried to bring about reasonable price reductions, and the only way you can do this is when you get an adequate sale going. Of course, if you realize that our advertising effort is pro-rated over a larger volume, perhaps, than some other companies, this is probably why ours is lower.

I hope it is effective but I would hate to see it go down to 15 per cent. And, I believe this is the viewpoint of the industry too.

Mr. MACLEAN (*Queens*): Mr. Chairman, I would like to ask a supplementary question. Is there not a danger of misinterpreting these percentages? It would seem to me that probably companies do not estimate their sales ahead and then decide to use a certain percentage of their total sales on advertising. Is it not rather the other way about, that they have a budget for advertising, and that

their sales resulting from that marketing effort are dependent upon the acceptability of the product they are selling? It may produce "X" or "2X" in the amount of value of sales, and if the resulting sales are high the percentage of your costs of merchandising, as a percentage of sales, will be low?

Mr. GREGORY: Right.

Mr. MACLEAN (*Queens*): I would think probably the reason that this percentage is low in your case is that you have this product, premarin, which is asily sold, so to speak.

Mr. GREGORY: It is just what I said latterly, Mr. MacLean, it is pro-rated over a larger base, if you would, and this is exactly what you have said.

Mr. HOWE (*Hamilton South*): I think that we are dwelling on this 30 per cent because it seems to be the one flexible point in the prescription dollar that is a large bite out of that dollar. We have to accept labour charges and material charges as more or less fixed. That percentage will vary as the others vary. I think we dwell on this large amount because it seems to be, possibly, the one realm that we can conceivably work on to lower the price of drugs if this is at all possible.

I think we have to remember that any drug price is excessive so far as people are concerned, because people do not want to be sick. Other commodities they buy willingly because they have chosen to buy them. The doctor, so far as drugs are concerned, prescribes something for a patient who does not really want to buy it, because it is not something tangible that he has any use for, and from which he does not receive the benefit of the advertising, gimmicks and so on that the doctor receives. Therefore, the doctor is the go-between between the drug manufacturing company and the ultimate consumer.

If you are able to keep your drug promotion percentage at about 21 per cent, instead of the industry average of about 30 per cent, you could almost assume that, relatively, your selling price should be this much less to the consumer if there is any way of relating any of your drugs to any other company who was selling or promoting at around this 30 per cent that we speak of. Would you say that this was so in any comparable drug that you manufacture?

Mr. GREGORY: I would say because this figure is somewhat less than the industry average it reflects somewhat on the efficiency of our organization. It reflects also on the mix of our product range and this figure could matrially change—not at a moment's notice, obviously—but it could change if we were called upon to inform the medical community and the pharmaceutical community about a new lifesaving drug which may come out of our laboratories at any time. So this figure, while it is very clear for 1965, it may not be true in 1966 or 1967.

Mr. HOWE (*Hamilton South*): That evades the question. Would you say that any of your comparable drugs at this time, based on this 21 per cent, are lower in ultimate sales price to the consumer than a comparable drug from another company which is running around 30 per cent promotion? I am trying to establish a point, if you see what I mean. Is there any allowable flexibility in this average of 30 per cent which is going to produce a lower cost to the ultimate consumer?

Mr. GREGORY: Well, competition usually takes care of that, Dr. Howe.

Mr. HOWE (*Hamilton South*): This 10 per cent or 9 per cent difference has got to show up either in the consumer price or in the net profit to the company, does it not?

Mr. GREGORY: This is true, yes.

Mr. HOWE (*Hamilton South*): Well, where does it show up?

Mr. GREGORY: Well, it shows up in our earnings.

Mr. HOWE (*Hamilton South*): It merely producs an increase in your earnings rather than a decrease in the price to the patient.

Mr. GREGORY: No, not necessarily. It gives us more money to spend in developing new products in research, Dr. Howe.

Mr. HOWE (*Hamilton South*): In other words, this 8.8 per cent you call earnings, does this include money which is put back into the company for development or is this the amount which is actually taken out of the company?

Mr. GREGORY: No, this is the money which we earn by our efforts and, incidentally, since 1963 we have plowed these earnings all back into the company.

Mr. HOWE (*Hamilton South*): All earnings?

Mr. GREGORY: All earnings.

Mr. HOWE (*Hamilton South*): There were no dividends paid to shareholders?

Mr. GREGORY: No, sir, not since 1963?

Mr. HOWE (*Hamilton South*): In other words, the shares all privately owned rather than on the public market?

Mr. GREGORY: No, we do not pay dividends to share holders, we pay them to our holding company. We do not pay dividends.

Mr. HOWE (*Hamilton South*): What is your holding company?

Mr. GREGORY: American Home Products Corporation.

Mr. HOWE (*Hamilton South*): You are part of American Home Products, which owns some of the other large drug manufacturers, too?

Mr. GREGORY: That is right.

Mr. HOWE (*Hamilton South*): Is Wyeth's one of them?

Mr. GREGORY: Yes, sir.

Mr. HOWE (*Hamilton South*): Is Wyeth's promotion per cent comparable to yours?

Mr. GREGORY: I have no idea, sir.

Mr. HOWE (*Hamilton South*): They do make identical products sold under a different trade name. Is this not so?

Mr. GREGORY: It might be true; it is not necessarily true.

Mr. HOWE (*Hamilton South*): No, I say there are some.

Mr. GREGORY: Well, you give me one, for instance. I cannot think of one at the moment.

Mr. HOWE (*Hamilton South*): You are testing me.

Mr. GREGORY: No, no. Well, we both sell penicillin.

Mr. HOWE (*Hamilton South*): Yes.

Mr. GREGORY: Well, there you are. We both sell antacids but they are different antacids.

Mr. HOWE (*HamiltonSouth*): Yes.

Mr. GREGORY: Now, I cannot think of another one. Can you, Dr. Smith?

Mr. SMITH: No, I think dibenzyl penicillin is the main one.

Mr. GREGORY: Dibenzyl.

Mr. SMITH: Dibenzyl penicillin is the main one which we both sell.

Mr. HOWE (*Hamilton South*): Does your penicillin and their penicillin sell for same price to the consumer?

Mr. GREGORY: I cannot answer that; I do not know.

Mr. HOWE (*Hamilton South*): Then you do not know their promotional sales per cent?

Mr. GREGORY: Dr. Howe, as far as I am concerned they are another pharmaceutical company.

Mr. HOWE (*Hamilton South*): You coincidentally do make identical things under different trade names in some instances.

Mr. GREGORY: Well, we have discovered a few areas there, yes. This could also be true of other products, too, could it not?

The CHAIRMAN: I just wanted to interrupt to get a better pronunciation of this penicillin for purposes of the tape.

Mr. SMITH: Dibenzyl penicillin.

The CHAIRMAN: Dibenzyl penicillin. We are having a little trouble with the taping in that the people who are transcribing the tapes are not familiar with medical terminology. This causes a great deal of 'phoning around trying to get the proper spelling of various names.

Mr. HOWE (*Hamilton South*): I would like to say one more thing. It is really more a statement than it is a question. You commented on indigency; people who are indigent with regard to being able to buy drugs. I think this is a much wider field than we like to think because I do not believe a person who is indigent in the ordinary sense of the word is the only person who is indigent with regard to buying drugs. I think this is mainly true because people do not make allowance for the purchase of drugs in, shall we say, their over-all budgeting of their income. Many times they go into a drug store with their prescription—this has happened many times to me because of prescriptions I have given—and they will ask the druggist how much is it and he will say "$10.00", and they will walk out of the store. Yet this may be a person with an income which you would not consider indigent but he, with his income, cannot afford this amount for drugs. I think you have to extend your definition of indigency when you are speaking of illness and drugs. Do you not agree that this is so? It is not in the ordinary context of the word because I think indigent people are well looked after. They are able to get these drugs for nothing. The ordinary people who are considered indigent can go to hospital clinics and have drugs prescribed which they can get for nothing. It is this in between group who have not enough money to spend that amount on drugs although they are certainly not within the category of people who would be considered indigent and allowed free drugs. Do you not agree with that as sort of a general

statement? This is not being critical of the drug manufacturing companies but rather just a statement of fact as to who buys drugs.

Mr. GREGORY: Well, Dr. Howe, I think that probably you are making a fair statement but could not this same statement apply to anything else that anybody buys any place? It could apply to an expert fee in any area. It could apply to an automobile, it could apply to a television set, it could apply to anything. I do not think that you should necessarily discriminate either against the services of a pharmacist, or a pharmaceutical industry, or a physician, or an expert in anything.

Mr. HOWE (*Hamilton South*): I do not feel my statement was discriminatory. It was not intended to be. There is a certain compulsion for the need for drugs that there is not for a television set or a refrigerator. You cannot use last year's tablets, which have already been used up, like you can use last year's refrigerator or do with a black and white television instead of buying a coloured one. I think there is a realm of difference there. It falls in the same category as food, which has to be put first.

Mr. GREGORY: Yes, indeed it does.

Mr. HOWE (*Hamilton South*): One has to live and get sick in order to need the drugs.

Mr. GREGORY: Right.

Mr. MACDONALD (*Prince*): Mr. Gregory, am I right in assuming that the Canadian company of Ayerst is really a subsidiary of an American company?

Mr. GREGORY: That is right, sir.

Mr. MACDONALD (*Prince*): Could I have some idea of the comparative size of the two companies; the Canadian one as compared to the American one.

Mr. GREGORY: I think you had better rephrase that question because I do not think I understand it.

Mr. MACDONALD (*Prince*): Well, I am just trying to get an idea of the relative size of the two companies in terms of their operation. In other words, we are told that some 800 people are being employed by Ayerst in Canada, and you have indicated the amount which you spend on research, this kind of thing. Could you give us an idea of the number of people employed in the United States and also the amount of money that is spent in the United States on research.

Mr. GREGORY: Do you mean the Ayerst organization in the United States? I will have to ask my confreres to help me on this one if you will permit me. Do you know roughly, Mr. Walker, how many people we have in the employ of our American company?

Mr. WALKER: I think possibly there is a little misunderstanding here. Ayerst of Canada is not a subsidiary of Ayerst, (U.S.) Is that what you meant?

Mr. MACDONALD (*Prince*): Yes.

Mr. WALKER: No, we are not. We are both subsidiaries of a holding company called American Home Products. American Home Products sells nothing, they are strictly a holding company. They own companies which sell such products as Chef Boy-ar-dee foods. Old English floor wax, Kolynos toothpaste, Three-in-One oil, pharmaceuticals, Wyeth and Ecko pots and pans, this type of thing. It is strictly a stock holding company.

We are a subsidiary of that holding company. Our company in the United States, Ayerst Laboratories, is also a subsidiary of that holding company.

Mr. HOWE (*Wellington-Huron*): Are there other drug companies than the two mentioned?

Mr. SMITH: Yes, there is Ives-Cameron. Also of course, there is Whitehall, which is classed among the non-ethical pharmaceutical companies.

Mr. WALKER: On the other question you asked about research, I think it might be emphasized that all the research for Ayerst (Canada), and Ayerst (U.S.) is done in Canada. Ayerst (U.S.) does no basic research in the United States.

Mr. HOWE (*Wellington-Huron*): That is the information I was looking for.

Mr. GREGORY: By the way, we have Dr. Buyske here, who is the director of that research operation. If this interests you at all, ask him some questions.

Mr. MACDONALD (*Prince*): Might I ask a question following another line. You emphasized, in terms of discussing patent regulations, protection for the inventor of various pharmaceuticals. I wonder if you could tell us what percentage of the drugs that you market would be drugs that you yourselves have developed, as compared to other drugs that you may do some testing on but essentially have been developed by the Connaught Laboratories or the National Research Council, or some other agency. Have you any percentage breakdown on that?

Mr. GREGORY: I do not have a percentage breakdown for you here, Mr. MacDonald, but I can tell you that there is a trade and Patent Office record of patents. I think it starts in 1920, I am not sure of the date. We have 113 issued Canadian patents and 25 pending applications. This will give you some idea of the amount of research that has gone on at Ayerst in order to have this number of patents.

Mr. MACDONALD (*Prince*): You have indicated that a great amount of money is spent on research by your firm. I am trying to gain some idea of the number of products your firm has been marketing that you have researched from the beginning, and those that you have basically acquired through the research efforts of other establishments?

Mr. GREGORY: Well, Premarin is the greatest example. This is patented.

Mr. MACDONALD (*Prince*): You have not really answered my question. What I am looking for is a relationship between the products that you market and which you research yourselves and the products which you are marketing that you did not research, because it gives us some idea of the importance of this question and particularly in relationship to your own company as well as to other companies.

Mr. GREGORY: I cannot give you that figure offhand. I would have to study the situation a little.

Mr. MACDONALD (*Prince*): Would you have an idea of the relationship?

Mr. GREGORY: It is not a high figure.

Mr. MACDONALD (*Prince*): No.

Mr. SMITH: There are certainly a few products here which are probably worth mentioning. Premarin is the main one. This is certain. We also have an anti-tussive, or a preparation for coughs, Cothera, which came out of our own

labs. During the war Ayerst was the first company in Canada to develop penicillin, and all the penicillins, and we supplied all the penicillin to the Canadian armed forces throughout the war. This came out of our own plant through our own development. There is streptomycin as well. I think these are the principal ones that I can think of at the present time.

Mr. MACDONALD (*Prince*): You have documented this very well in your brief.

Mr. SMITH: We have about three or four of our own drugs presently under clinical investigation out of our own research labs. These are drugs that probably came out of our labs three, four and five years ago that are still under clinical investigation. However, we have three or four which should come to market which are good, valuable drugs.

Mr. MACDONALD (*Prince*): The reason I am asking these questions is that it brings to mind two or three things. First of all, you urge very strongly a tightening up of patent regulations so that those who do invent a new drug may benefit from the invention.

Mr. SMITH: That is right.

Mr. MACDONALD (*Prince*): I am wondering what effect this would have, in fact, if the regulations were tightened up. Would it not increase, perhaps, the cost of certain drugs that you will be marketing that you yourselves would not have invented. In other words, you would gain somewhat on the product that you have invented but would you not lose a comparative, or perhaps greater amount, in terms of having to pay royalties on certain drugs, resulting in an increased cost which you normally would not be paying now because of the somewhat relaxed restrictions that exist. Have you considered it from that side as well as from the other?

Mr. GREGORY: No, I have not, but you were talking about the percentage of patented drugs versus the ones that were not patented. You might be interested to know that in the laboratory it is usual that about one out of every 3,000 discoveries turns out to be a useful, commercially acceptable drug. So, this is why the numbers are not high and this is why we need patent protection, when we get that one in 3,000 or 4,000, to protect us until we can recover the expenses which have been incurred.

Mr. MACDONALD (*Prince*): May I ask a question related to that. I would gather from all the testimony we have heard in this committee that in spite of the fact that Ayerst does all its research in Canada, and comparing the relative amount of research that is done in Canada as against the United States, that more restrictive patent regulations than at present in Canada which would offer increased protection for products being marketed which have been invested elsewhere in Canada would increase the over-all cost of drugs, would it not? I am speaking of drugs, for instance, which were invented somewhere else and were able to gain Canadian patents. Through this kind of protection they would be afforded the advantage of charging increased prices, knowing that other companies who normally might be able to manufacture larger amounts, or for other reasons with relaxed restriction, would no longer be able to market at the cheaper price. So, in effect, the impetus would be an increase in the actual price to the patient consumer.

Mr. GREGORY: I do not believe so.

Mr. MACDONALD (*Prince*): But you have not given any great consideration to this possible effect?

Mr. GREGORY: I think you have to start a long way back to answer your question. If you do not have investigation and research going on, you do not have new drugs. If you do not have new drugs, you do not have production of new drugs. If you do not have production of new drugs, you do not get rolling in mass quantities and producing them to the point where you can sell them at a lower price. In other words, when you know more about these drugs the yields become greater and you can lower prices.

The other thing that I think has been forgotten in this discussion of patents —and I think Mr. Laidlaw will help me out on this one if I get into trouble—is that the patent system was established not only to protect the patent holder but also to disseminate information throughout the patent system all over the world so that scientists here and there could become more knowledgeable faster. That is one other reason for patients, I believe. Is that not so, Mr. Laidlaw?

Mr. LAIDLAW: That is correct.

Mr. MACDONALD (*Prince*): You are probably right but I do not know whether that really affects the question I am raising as to the possible increase.

Mr. GREGORY: This is my belief, sir.

Mr. MACDONALD (*Prince*): I have one or two other questions here, Mr. Chairman. One of the things, too, that seems to be brushed aside or not indicated is that while you mention the great cost of research and advertising which, if the company is going to operate realistically, of course has to be regained from sales, but would it not be fair to say that some of the products being marketed now which involve a major amount of research and even advertising cost in terms of getting a new product before the doctors particularly, and even the public, should have been retired many years ago. Often it is difficult to see a realistic decline in the cost of a drug in spite of the fact that under normal circumstances and in terms of research costs and advertising costs, I would think it would have been paid for at an earlier date. A drug, for instance, that is marketed today and which was researched and advertised in the first instance in the late thirties or early forties, one would expect the possibility of a fairly good decrease in the actual cost of manufacturing that drug today. Is that fair?

Mr. GREGORY: Yes, I think that is a fair statement, Mr. MacDonald.

Mr. MACDONALD (*Prince*): I have another question I would like to ask. In the latter part of your brief it is suggested that these 80 medical sales representatives, the detail men, normally have a bachelor's degree in pharmacy or related medical experience. Is this true of all the 80 sales representatives?

Mr. GREGORY: No, not 100 per cent, obviously not. Generally we try to engage people who are medically oriented: students in one of the medical sciences, bacteriology, biology, or something of that sort. We do have on our staff, although I cannot tell you the exact distribution of them, 42 pharmacists.

Mr. MACDONALD (*Prince*): In other words, about half of them would not have a bachelor's degree in pharmacy?

Mr. GREGORY: It would be a mix.

Mr. MACDONALD (*Prince*): Would it fair to ask what is the least amount of formal education represented by the men who carry on this service?

Mr. GREGORY: I cannot answer that question but I know our marketing people are very careful about it. These people are very carefully interviewed. Obviously we cannot send out people representing us to the medical or pharmaceutical profession that will not represent us well and capably. I cannot tell you about their degree of formal education.

Mr. MACDONALD (*Prince*): I am not a doctor and I have never had any direct experience with detail men, but your brief suggests these men are competent nough to talk at the doctors' level about the products and make their case, I think, on the basis of that ability.

Mr. GREGORY: I would say they were quite well informed, Mr. MacDonald. I think, perhaps, you should ask some of your medical confreres if this is true or not.

Mr. MACDONALD (*Prince*): Just let me pursue this a little further. Would you say their main *raison d'être*, as far as your industry is concerned, is to advertise the product, promote the product, or to be able to carry on a conversation with a doctor in some detail on the various effects, side effects, liabilities, and what have you, that a drug may have to offer?

Mr. GREGORY: That is basically what they do. They endeavour to acquaint the physician with the availability of X drug for Y disease and introduce the physician to its usefulness with printed literature which we have him distribute, or by referring him to publications in medical journals or wherever else the drug might be discussed.

Mr. MACDONALD (*Prince*): So you would put the emphasis on their ability to talk intelligently about the drug with the doctor rather than just to promote the fact of its existence?

Mr. GREGORY: I think they probably go hand in hand. During an intelligent discussion the physician might see a need for it in his practice.

Mr. SMITH: I might add here that all our representatives have at least a B. Sc. degree as far as I am aware. They all have a college degree. There may be one or two exceptions here, I am not 100 per cent certain. Nearly all of them have a college degree and we try to take people who, as Mr. Gregory has said have had some training in chemistry or pharmacology or physiology or biology. Certainly in our company our main idea is to get men who can take the information that is given to them and present it to the doctor in an intelligent way. This is the thing we look for most. They are also promoting and selling, there is no doubt about that, but I think we emphasize the former. Dissemination of Medical Information. All our new men, after they have had initial training in the field, are brought into Montreal for at least a month where most of their training consists of medical lectures, lectures in our laboratories with all our scientific people, and we do our utmost not to make these people doctors, obviously, or not make them pharmacists if they are not pharmacists, but if they are given an opportunity with a new drug, to at least give the basic information without going any further and without trying to teach physicians.

Mr. ISABELLE: Mr. Chairman, first of all I want to congratulate Mr. Gregory because he is representing a very good firm. It has been a good firm since the very beginning.

I have three questions. Could you tell me first if you are undertaking more research since you became an American subsidiary than you were when you were strictly a Canadian-owned company?

Mr. GREGORY: Dr. Isabelle, it so happens that during Mr. Walker's early years with us he was the administrator of our research laboratories. I think I would like Mr. Walker to answer that question.

Mr. WALKER: Are we doing more research today because we are a subsidiary of an American company? We are certainly doing more research, yes. It is probably due to the fact that we are a subsidiary of an American company because they have put large sums of money at our disposal, more than was available out of current earnings in our own company. This enabled us to take a quantum jump in the research field that we probably could not have done when the company was smaller. Now, the fact that we are a subsidiary of an American company also permits us to do research for a world-wide operation, which has had the benefit of some pushing from the holding company. Does this answer your question?

Mr. ISABELLE: Yes, thank you very much. Now, my second question. In your brief you mention somewhere that Canada and Italy are the only two countries that give practically no protection at all for pharmaceutical discoveries. Mr. Gregory also said that many companies were trying to come to Canada. Are they copiers or will important companies who are going to come to this country to undertake research do so if there is no protection at all?

Mr. WALKER: Well, today there is protection of a sort. It is not good protection because you cannot have a restricted field and people can force licences. However, there is a Patent Act and there is patent protection. The companies that are coming in here to do research are mainly important companies. There has been an incentive from the government to encourage research. It always seems paradoxical to me that one branch of the government would say, "We want all you people to do lots of research and we will give you incentives", and then another branch says, "I think we should cut out all the protection that you have on your research". The two things are diametrically opposed, I think. Yes, I think the companies doing the research are solid, good, serious companies.

Mr. ISABELLE: I have another question and, I think it is a good one. In 1964, the drug firms spent about $280 million for research, compared with $282 million in 1963. The figures for research in 1966 are expected to reach $370 million. The main products concerned have been psychotrophic drugs. You prepare preparations to combat cancer and indigenous diseases and compounds especially used in aging patients. Could you tell me, without revealing any secrets, what kind of research you are doing in your laboratory. Are you coping with the threat that is existing throughout the world today?

Mr. GREGORY: Dr. Isabelle, may I turn this over to Dr. Buyske, who is our director of research.

Dr. DONALD A. BUYSKE *(Director of Research)*: Thank you Mr. Gregory. I can answer that directly and say that Ayerst laboratories are certainly doing research in the fields which you mentioned. All large pharmaceutical companies are trying hard to make a contribution to find new drugs to combat these diseases. Specifically at Ayerst, we have some agents in the laboratory under

investigation in these fields to measure their activities on animals. The next step would be to go into toxicology studies to measure their toxicity in animals and, if they pass these tests, we would then propose that it be tried clinically. You must understand though that this is a very long drawn out investigation program that involves easily three to five years. Ayerst has had a research group, as Mr. Gregory has pointed out, from the very beginning of the company. The research group in the last three or four years, has grown up into almost what might be called a critical size. You have to have a certain large cadre of people to be able to carry on this complex research effectively. Therefore, three to five years from now we might be able to say that we do have these agents. Have I answered your question, sir.

Mr. ISABELLE: Yes.

Mr. HOWE *(Hamilton South)*: May I interject a question having to do with this. Are your findings in this field given to other research laboratories so there will not be duplication of effort as well as expense? For example, in the search for a cure for cancer, is this being secretly guarded by you, as far as your work is concerned, as in all other laboratories, or is there some cross reference of findings so there will not be this duplication?

Mr. BUYSKE: There really is no duplication. I think the scientists in pharmaceutical companies are members of a greater scientific community and it is to our benefit to communicate what new knowledge we uncover in our laboratories, because we get new knowledge from government laboratories and academic laboratories. The Ayerst laboratories publish their information in the scientific journals and in the patent literature. In 1966, we published some 30 odd papers in the scientific literature. We are proud of our accomplishments and we encourage our scientific staff to publish things quickly. There is this that we must say about the understanding and degree of protection we have. We file patent applications on items which are patentable not all the work we do is patentable, nor is it intended to be patentable. I would like to come back to that in a moment.

We file patent applications and, once the application is filed, we are quite prompt in letting this be known by publishing papers, giving talks at sientific meetings, communicating with our colleagues in the universities and government laboratories. The other feature of what we do at Ayerst, which is quite typical of pharmaceutical research laboratories, is it is difficult to develop drugs against diseases of which the cause is not known. We do not know the cause of arthritis, therefore, how are we going to find a drug in a laboratory to treat arthritis, when we do not know the basic cause. We must set up models in which we try, as closely as possible, to mimic the natural spontaneous disease as it occurs in man. The developing of the models is a very complex and serious problem. We communicate with each other in trying to improve the model so the pharmaceutical company, the scientific medical community as a whole, has a proper model in laboratory animals that has some relationship to human disease. This is a very important type of work we do and, it is communicated as quickly as possible.

Mr. HOWE *(Hamilton South)*: But unpatentable information is not passed along.

Mr. BUYSKE: Patentable?

Mr. HOWE *(Hamilton South):* Unpatentable information that you may have learned is not necessarily then passed along. This is kept secret until it reaches a condition or a state which you could put a patent on before it is passed on, shall we say for the benefit of mankind, as far as the cure of some of our incurable diseases at the moment is concerned?

Mr. BUYSKE: As a rule, unpatentable information—except if it is involved in a commercial manufacturing, so-called trade secrets—is not passed along, but in terms of methodology of finding drugs, these are very important things and they are passed along. We may hold them in the laboratory for a period of time to assure ourselves that we have made a real contribution, but we are quite quick to pass them along. By passing them along, we maintain our good status with our scientific colleagues outside of industry and we trade information. There is very little that is held in scientific laboratories of major pharmaceutical houses in the way of true contributions to science or true contributions to methodology.

Mr. HOWE *(Hamilton South)*: I am thinking specifically of the treatment of an incurable disease, let us say cancer. If any advances were made in your information, whether it was patentable information or not, this would be passed on to other laboratories who are doing similar work for the benefit of the treatment of a disease that is the scourge and fear of everyone living, I suppose.

Mr. BUYSKE: Yes, indeed. We would be the first to knock on the doors of other laboratories to tell them of such an invention if, for no other reason, than to have it confirmed. Other people have different ways and different models of looking at drugs. So-called cancer cures are fairly common in the laboratories. You may appreciate that we can cure so-called cancer in rats and mice, but these are not the kind of spontaneous cancers which occur in man; therefore, it is a question of the model we are talking about. I think a pharmaceutical company would just hold this information long enough to assure themselves that they know what they are doing and have something solid, then they would be quick to communicate it.

Mrs. RIDEOUT: Mr. Gregory, I cannot help but take advantage of this opportunity of congratulating you and your associates on your foresight in locating one of your warehouses in Moncton. We have heard a lot about innovators and copiers in this Committee, and you are an innovator in that you are located in Moncton. I have no objection to any copiers following your example. This is an open invitation.

Yesterday I had an opportunity to attend the opening of the Ontario Hospital Association. Many medical suppliers had their booths and were displaying the latest in equipment, and what have you. I was really very interested and spent some time looking over the various pieces of equipment and how they have changed in only a short time, but one thing that really startled me and surprised me was the display of disposable syringes for giving penicillin, which the doctor may use and then throw away. I inquired about the price of them and, much to my amazement, they cost the doctors 6 cents, and equipped with penicillin 13 cents. Naturally this was amazing to me. I chatted a bit only to find out that these people are experiencing what they call a price war. It is so serious that some of them are concerned that they are going to be out of business. Do you have a price war in the drug business? If penicillin can

be sold for 13 cents in a syringe that is disposable, who is getting the benefit of this so-called price war, the consumer?

Mr. GREGORY: I should think the consumer must be.

Mrs. RIDEOUT: I hope so.

Mr. GREGORY: Mrs. Rideout, let me see if I can find an example for you. Here is a vial of penicillin and I have a price in 1950 of $9.85. In October, 1959, I have it at $1.50. That is the list price.

Mrs. RIDEOUT: I think probably what I was interested in knowing is, is there serious competition between drug companies on prices of drugs that they both manufacture?

Mr. GREGORY: I do not hink there is any doubt that the pharmaceutical industry is a competitive one.

Mrs. RIDEOUT: It is competitive?

Mr. GREGORY: Oh, yes.

Mrs. RIDEOUT: I wondered about that, because just listening to the different companies who have been here it seems to me that one of their great concerns is the research and discovery of a new drug which is one that is very important in so far as the health of Canadians is concerned, and so there is really no competition in that. When they find a drug they have an advantage, provided it is not copied.

Mr. GREGORY: Here I think Dr. Buyske could elaborate on this more, but the desire of one or another pharmaceutical company to develop a new life saving drug, or a cancer cure or something of that nature, is a inherent, basic, scientific desire or goal to reach. That is the sole purpose that medical scientists were born and created for. So there is probably not only competition in the price field, but there is also a burning desire to save mankind with a new life saving drug. You could call this competition, too, if you wished. Obviously, the drug has to excel and be superior to the existing ones for medical people to leave the existing drug and move to the new one.

Mrs. RIDEOUT: Do you have any worry about a price war on drugs affecting companies who are starting out in Canada?

Mr. GREGORY: I am sorry, I missed the first part.

Mrs. RIDEOUT: Do you have any problem or any concern about this so-called price war, if there is one, on drugs, I have not been aware of any.

Mr. GREGORY: I do not know that there is one. There may be one. We all tend, perhaps, to devote our energies to our own business, and unless something affects us we do not really know what is going on in other areas.

Mrs. RIDEOUT: I just bring this up because I noticed in an earlier part of your brief your concern is that of lowering the price of drugs lower, and you think possibly one way is through the elimination of the federal sales tax.

Mr. GREGORY: Yes, and I so stated my case quite clearly, I think, Mrs. Rideout.

Mrs. RIDEOUT: Just one other question relating to the one David MacDonald asked about your representatives. I just gathered from your brief that you really feel it is important to your company to make sure that your representatives are qualified, well-educated, knowledgable, up-to-date and informed on

what is going on. Am I correct in assuming that you feel this is more important than your direct mailing?

Mr. GREGORY: They are both extremely important. One complements the other, I think, but certainly an effective representative professional service staff—medical communications, if you wish—I do not think there is any doubt about their importance, not only to Ayerst but to the medical and pharmaceutical community.

Mrs. RIDEOUT: Thank you, Mr. Gregory.

Mr. JOHNSTON: Mr. Gregory, with regard to the hormone preparations particularly, does your company sell directly to the cosmetics industry at all?

Mr. GREGORY: Not to my knowledge, sir.

Mr. JOHNSTON: One thing your brief does that I do not believe the others did—and perhaps it is because of its all-Canadian nature—is to mention or complain slightly about the cost of bilingualism. Does this seriously affect the cost of the product? With respect to a drug that you manufacture in Canada, and that your subsidiary manufactures in the United States and packages there, would there be a difference because the promotional literature in the United States would be in one language and the literature here in two languages?

Mr. GREGORY: It might interest you to know, Mr. Johnston, that our business started in 1925. Since 1934, we have produced a French language catalogue. Earlier than that—I do not know the facts because I was not with the Company at that time—we produced most of our literature in two languages. At the present time we have two translation departments in our company; one a French scientific translation organization and the other a commercial French translation organization. These are permanently on our staff.

Dr. Smith has with him a French speaking medical director, Dr. Maurice Dufresne. We publish everything in two languages. We have a Division Francais under the direction of Andre Marier, who has a team of French speaking medical representatives.

What else might I say, gentlemen? I do not know how much extra it costs us, but I am sure that you can see from what I have said that it must contribute something to our marketing costs. We are not disturbed about it because we are Canadians. It so happens that in our laboratory we have equal joy for both our French speaking members of our staff and our English speaking members. As a matter of fact, I think I am correct, Dr. Buyske will you help me out on this? I think in your laboratory we speak 32 different languages. So we are not narrow as to whether a person speaks English or French. It comes quite naturally to us, sir. But I do think it would be better if we had a larger run in English or a larger run in French, as the case may be, but we have to have two runs of everything.

Mr. MACLEAN (*Queens*): If I understood your brief properly, when your company started out it was started out by Canadian enterprise, Canadian research and Canadian capital. It was an entirely Canadian effort. Is that correct?

Mr. GREGORY: That is absolutely true, Mr. MacLean.

Mr. MACLEAN (*Queens*): And then at some point in time you became a wholly-owned subsidiary of an American holding company.

Mr. GREGORY: That is right.

Mr. MACLEAN (*Queens*): I do not know whether this has much direct bearing on the cost of drugs, but I think it is of general interest as far as national development is concerned. Could you say a word as to what the circumstances were which caused your company, or the original owners, to sell out to a holding company? Was it lack of risk capital in Canada that would come forward to allow you to expand as you thought your efforts were worthy of, or was it just an attractive offer that was made by someone and the Canadian owners wanted to liquidate their assets and cash in on what they had achieved up to then, rather than wait for dubious, and rather long-term benefits from investment which might accrue in the future, if they had been willing to plow their profits back into the firm? I think this is something that might be of interest to the Committee.

Mr. GREGORY: Mr. MacLean, first of all, let me tell you when the company was sold to American Home Produce Corporation I was resident in Vancouver, so I actually was not on the location. Anything I might tell you is subject to correction, but I believe that I know some of the facts. This company was founded by four gentlemen, the Messrs. Ayerst, McKenna, Harrison and McPherson, and as we so stated in our brief they had some very forward-thinking ideas on the future of the company based on research. I believe about 1943, or 1942, they found that their families were not particularly interested in the carrying on of the business. Mr. McKenna had a son who is an outstanding physician in Montreal; Mr. McPherson had a daughter who I think, at that time was an assistant professor in physics at McGill; Mr. Ayerst's son was not interested in the business for some reason or other. These gentlemen were getting down the road a bit. They were not young any more and I presume they did just what any normal businessman would do if his family was not there to take it on and carry it on, they did the obvious thing. That, Mr. MacLean, to my knowledge, is what happened.

Mr. MACLEAN (*Queens*): This I understand perfectly, and I have absolutely no objection to it but the thing that concerns me is that presumably when the firm was put on the market there was no market in Canada for it or, at least, there was presumably no holding company in Canada that was willing or able to compete with investors in the United States.

Mr. GREGORY: I would have to agree with you, Mr. MacLean, yes.

Mr. MACLEAN (*Queens*): So, basically the problem is the availability of risk capital in large quantities in Canada to retain the ownership in Canada of businesses that have been started and developed in Canada?

Mr. GREGORY: Or Canadians who are devoted and willing to take on a big load. That is the way you put it and this is the way I put it.

Mr. MACLEAN (*Queens*): That is all I wanted to say on that particular line but, now, I wanted to ask a few questions with regard to the general field of patent protection as it affects your company. I take it that you license companies in other countries to manufacture or to sell some of your products, some of the drugs you have developed?

Mr. GREGORY: I am going to ask Mr. Walker to answer this one.

Mr. MACLEAN (*Queens*): Presumably, also, you pay licences to other companies for the ability to produce or market their drugs. Now what is the

balance? Is your income greater than your expenditures in this general field or is it near balance or what?

Mr. WALKER: That is a little difficult to say. I would say it would be very closely in balance. We are licensed by Imperial Chemical Industries, as you know, for some of their preparations. We are also licensed by Beecham Laboratories. On the other hand, we have licensed at least two and probably three products quite broadly, in possibly eight to ten countries. So I would say in balance if you are thinking just of royalties, we break out about the same. Now royalties, of course, are not the entire story.

Mr. MACLEAN (*Queens*): In this connection, have you had much expenditure in protecting yourselves against copiers of your products?

Mr. WALKER: No, fortunately we have not. But, each company differs. Our big product, Premarin, has not been attacked by copiers because in order to get in and force a licence on this product they have to go out and find 30,000 pregnant horses and nobody really is very interested in this. Now, if we had another drug, for instance Hoffmann-LaRoche last week were mentionning their product Librium. This is a relatively simple thing for people to come in and pirate. I think there has been no one coming in to force a license on the tetracyclines. There is too much capital involved. The people that will copy and force licences are, you might say, jackals that are following the camp. And, when the camp leaves a few things scattered around they pick up the easy ones. This is the big problem in this forced licence problem. The copiers contribute nothing. They only pick off the easy ones but if there were a life saving drug that required a lot of capital to manufacture, they would have nothing to do with it. This is too complicated, too difficult; they do not want this. They want the quick, easy profit.

Mr. MACLEAN (*Queens*): Now, somewhere in your brief you say that you have a considerable business in veterinary supplies. I take it you do not class them as pharmaceuticals, but I suppose there are a lot of pharmaceuticals that have applications in the treatment of animals as well as humans. How is the bookkeeping done with regard to pharmaceuticals on one hand and veterinary supplies on the other which are, in effect, the same product or basically the same product. I am thinking now of the cost of research. Is any of the cost of research chalked up against the cost of the veterinary supply product or is it considered as a fall out from your research for drugs for human use?

Mr. WALKER: It is done on percentage on sales. We run three profit and loss statements, one for export, one for veterinary and one for humans. A lot of the general administration expense is prorated on the basis of sales over these departments.

Mr. MACLEAN (*Queens*): I see. Generally speaking, I suppose the veterinary supplies would not have to be kept up to such strict standards as pharmaceuticals. They would be a little cheaper to produce?

Mr. WALKER: Well, the regulations controlling veterinary medicaments are becoming very exact and you cannot, just because it is for an animal, say, "we will not worry too much about sterility". All our injectable antibiotics, for instance, go through exactly the same sterility tests and the same potency testing as do our human pharmaceuticals.

Mr. MACLEAN (*Queens*): So there would not be cases where one was much cheaper than the other, for instance, a fraction of the cost. The veterinary article would be only a fraction of the cost of the pharmaceutical. What I am approaching is you do not think there are cases where veterinary supplies are being used as pharmaceuticals because they are a lot cheaper. Perhaps, being used by humans although they are manufactured and intended to be used only for animals?

Mr. WALKER: I would not think so. Anything can happen in this world but I would not think that would be a common thing.

Mr. MACLEAN (*Queens*): I have a special reason for asking this which I will not go into now. I have other question. Have you produced or innovated drugs which are very useful for some diseases but for which there is not a wide market and you produce them at a loss, or, you could never hope to recover the research costs involved but you market them for ethical reasons?

Mr. SMITH: Yes, we certainly do. We have one product I can just think of quickly, known as APL which is anterior pituitary like hormone, chorionic gonadotropin and this is a preparation which we have had on the market for a long, long time, along with another one called Equanex and these are products that I am sure we give away more each year than we sell. I think really we keep these on the market only because there is a demand and a real use in special cases and even though we might like to take it off the market I do not think we would. We do have some of this type of product where there is very little demand but there are very specific uses for it in places where it is really indicated, and we feel that we should not take it off the market.

Mr. MACLEAN (*Queens*): What about the supplying free, or at low cost, of drugs or pharmaceuticals which you have developed up to a certain stage, making them available for research in universities and this sort of thing? You do this as well, I suppose?

Mr. SMITH: Yes. All our drugs for clinical investigation naturally are supplied to the investigator free of charge, and in nearly all instances, even after some of these drugs have been marketed, we have continued to supply the investigators and the patients, who were maybe first put on these drugs, free of charge for a long time afterwards.

For instance, we have at the present time two drugs which have come to us from another company and which are actually marketed in another country now, which we have had under clinical investigation for three to four years. Due to the Food and Drug regulations which are presently in force in Canada, it takes a tremendous amount of time, effort, money and clinical and pharmacologic studies to get these on the market. We have been supplying these free of charge now for three to four years, and it looks as though it maybe longer. We will certainly continue to supply some of these investigators on a complimentary basis for some time after.

Mr. MacDonald made the point about whether patents, in so far as they concern outside companies who provide us with drugs which we may sell, may affect the price of the drug, and increase the cost of the drug in Canada. The point, I think, which, perhaps, a lot of people do not realize is that you can have a drug on the market today, say, in England, which is being freely marketed and used by the medical profession, which is not still on the market in Canada because we have to repeat just about all the pharmacology, all the toxicology,

all the clinical investigations and generally a lot more before we can market that here. Therefore, even though it is on the market in England today, it may be three to four years before we get it on the market in Canada; and we bear all of these costs.

Mr. MacLEAN (*Queens*): In this connection, there is a question which comes to my mind right now as a result of your reply. Are there any agreements between Canada and countries where the standards that the food and drug department have set up are acceptable in the other country, so that if a drug is approved in one country it is automatically accepted in the other?

Mr. SMITH: The answer is a big No.

Mr. MacLEAN (*Queens*): Perhaps I had better not pursue that further but, it seems to me that here is a field where there might be some reduction in cost.

Mr. SMITH: Yes, very definitely. I have to be a little careful here, I guess, but it would seem that the Canadian Food and Drug Directorate, on the whole, want to have a certain amount of work done on Canadians, because it is not the same if you do it on Americans, or on people from overseas and so on. The same applies to the United States food and drug department. They insist that the majority of their clinical work be done in the United States with United States investigators on citizens of the United States. Therefore, there is a great deal of repetition.

Mr. MacLEAN (*Queens*): It seems to me that they are considerably behind the times in their thinking. Surely there are some fields where this is not the case, like the recognition of medical standards of various kinds in one country and another. I think a certain amount of this is accepted, is it not?

Mr. SMITH: Yes, that is true.

The CHAIRMAN: As a doctor, that also is limited.

Mr. MacLEAN (*Queens*): I realize there are limitations, but on the other hand I think there is some acceptance.

I wanted to ask a few other questions having to do with research generally.

I have the impression—and correct me if I am wrong—that you have developed most of the better known drugs by the use of natural products rather than synthesized drugs, if I can make that distinction. There are vitamins and Premarin and items of this sort. I suppose this involves some fairly complicated chemical research to discover the active radical in very complicated natural compounds, with the possibility of developing a compound that would still retain this effective radical and eliminate side effects. I suppose you do a good deal of research in this field? Am I correct in assuming that?

Mr. GREGORY: Dr. Buyske could perhaps discuss this intelligently with you.

Mr. BUYSKE: That is right, Mr. MacLean. The major source of new knowledge of drugs certainly does come from natural products in our sophisticated science. It is now possible to look to a natural source, chemically characterize the compound and then proceed on to its synthesis. There is a story Mr. Gregory likes about penicillin as an example of how we have grown up and increased our sophistication. Penicillin, as you know, was discovered in Britain, and there was a vast army of people—scientific talent—associated with the development of penicillin to elucidate the chemical structure. When you see it on a piece of paper it looks fairly simple, but to actually arrive at what the chemical structure of penicillin is, and a three-dimensional model of what

penicillin looks like, required well over a thousand scientists working full blast for a number of years.

If penicillin were to come into any large laboratory today, we could very likely tell you the structure accurately, with scientific equipment, in perhaps two to three weeks just by putting it into the kind of equipment which is available. Therefore, to follow on, it is not likely that important drugs will come from natural sources, or be supplied from natural products, plants, or animal origins in the future. What will happen, and what is happening, is that we will indentify what the active component is in a natural source and proceed into a laboratory to synthesize it.

Mr. MacLEAN (*Queens*): To synthesize, I suppose, the identical compound, or a substitute that has the desired characteristics?

Mr. BUYSKE: The identical compound first, and then make the chemical modifications to improve the compound in terms of toxicology, or in terms of better pharmacology.

Mr. MacLEAN (*Queens*): In this connection, what is the state of affairs with regard to the production of vitamins? Are they generally produced from natural sources, or are some of them synthesized?

Mr. BUYSKE: Some are synthesized and some are of natural sources.

Mr. MacLEAN (*Queens*): My reason for asking this question is that I am thinking of markets for fish oils and items of this sort. Is the development that has taken place recently liable to change the marketable value of some of these raw products, or has it done so already?

Mr. BUYSKE: It is hard to predict. I could take an example, of which I am presently aware, such as insulin. This is a Canadian discovery. It comes from a natural source. It is quite cheap. In the last two months there has been an announcement by Chinese scientists that insulin can be totally synthesized. However, this is a 97-step synthesis. It would take years of development to be able to reduce this chemical possibility into a practical reality, to be able to compete with the natural supply of insulin.

How the economics would work out in things like vitamin A from fish sources, I would not know. There is always the danger that chemical technology will eventually catch up with natural supplies.

Mr. MacLEAN *(Queens):* I have one other general question. Mention has been made of the fact that there maybe research of a thousand, or two or three thousand—I have forgotten the figure—chemical compounds and only one of them turns out to be a satisfactory, marketable pharmaceutical in the end.

Could you say something about recent developments in the field of research in this regard? The statement makes it sound as if you operate completely by guess and by God—trial and error. I do not accept this.

I presume that you know, to begin with, that you are looking for a certain pharmaceutical for possible use against some disease and that you start with a given group of chemicals. You can eliminate some immediately. This is difficult for a layman to express, but what progress has been made in general research with regard to the problem of being able, as it were, to tailor-make a pharmaceutical for a given purpose? Has science developed to the stage yet where you know beforehand what type of drug is probably needed, and, where to find it, or how to synthesize it?

Mr. BUYSKE: The short answer to that is No; science has not developed to that point.

To go back to your 3,000 compounds, it is true that, on the international scale, roughly one out of every 3,000 compounds synthesized by organic chemists results in a product. In a research laboratory, 600 man years is required to produce a single product today; that is, six hundred people working for a year, or 600 man years. The chemist starts from two points from an understanding of natural products, on the chemistry of materials found in nature, and from synthesizing and making derivates. Penicillin is an example. We know what the original penicillin molecule looks like. Penicillin as a product—as the original molecule—has some disadvantages. It is destroyed too rapidly in the stomach, perhaps, or there are enzymes which destroy its activity. It is not stable under certain conditions. The original penicillin is not as well absorbed as we would like it to be.

The chemist has taken the original penicillin molecule and modified it to eliminate some of these difficulties.

This has been true with the steroids, the anti-inflammatory steroids, starting with hydrocortisons and originally understanding the structure of hydrocortisone, and then modifying the molecule. Very important modifications of the molecule were performed, and today the steroids of the hydrocortisone class are, of course, used very little as compared to the more potent, the more desirable, less side-effect types of steroids which have come out of the original hydrocortisone discovery.

Therefore, the chemist starts with knowledge of natural products, and he builds on that, but he also starts, in making new chemical structure that man has never seen, by putting together atoms in a different way and then submitting this entirely new moleculre, which does not resemble anything know in nature, to a pharmacology laborator for a battery of tests, to see if it has any useful pharmacological activity.

These are fairly simple tests. You simply inject the compound into an animal and observe it. Trained people observe it. If it rolls over and falls asleep then it might be potentially a sedative. If it runs around a cage it might be a stimulator. If you can prick the tail and it does not turn around and try to bite you, it might have analgesic properties. This is the type of thing that is done. They are entirely new structures.

I have forgotten the second part of your question, sir.

Mr. MACLEAN (*Queens*): You have answered it pretty well, I think. The second part of my question was—

Mr. BUYSKE: Whether or not we can tailor-make things directly?

Mr. MACLEAN (*Queens*): Yes.

Mr. BUYSKE: No, we cannot. Actually even with the existing drugs that we have today we do not have a detailed knowledge of their true mechanism of action; or even the old drugs such as, digitalis which dates back 200 or more years. We do not honestly know from the physiologist's point of view, the biochemits's point of view, on the pharmacologist's point of view just how digitalis works. There is controversy. There is disagreement. If we knew a little more about how this molecule fits, what the receptive sites are in the heart tissue, we could perhaps then sit down and make something a little bit different

from digitalis without the undesirable side effects of digitalis. We are approaching that very rapidly, but we are not there yet.

Mr. MacLEAN (*Queens*): That is what I was going to say. There is a great deal of research being done to try to discover some of these basic things with radioactive tracers, and this sort of thing.

Therefore, it is fair to say that the money that is being used in research by pharmaceutical companies, as well as other research organizations, such as publicly supported ones and so on, is not completely determined by the possible economic benefits which may result to the company by the discovery of some new pharmaceutical. There is a great deal of pure research, or basic research, being done by pharmaceutical companies. Is that a correct assumption?

Mr. BUYSKE: That certainly is a correct assumption.

Mr. MacLEAN (*Queens*): And, therefore, it is fair to state that the fraction of the cost of a drug which may go to support research, not only pays for the cost of researching the drugs already in use, but some of it at least is an investment in the future for the possible development of new drugs which may be of tremendous benefit to mankind in the future. The investment may pay off magnificently in terms of benefit to mankind in the control of diseases. Is that a valid assumption?

Mr. BUYSKE: That is right. Actually many compounds that were developed hopefully as drugs, which never made the grades as drugs, because they are too toxic, have become extremely important tools to medical scientists in unravelling the complications of disease process, or biochemical pathways, or mechanisms of life itself. There is the example of some antibiotics which were developed, which never were sold as antibiotics. They killed microorganisms but they were far too toxic ever to be considered clinically. These have become very important in unravelling the biochemical intimacy, if you will, of protein biosynthesis. It is a big field now.

We want to understand how proteins are put together from the building blocks of amino acids and the sequence of events that is involved. These compounds are used as tools in laboratories, and the pharmaceutical companies which develop these tools supply them gratis in kilogram quantities around the world for this type of thing.

By using these tools, eventually we will be able to learn how proteins are put together. Undoubtedly it will be important knowledge, in cancer, if we could stop protein growth. After all that is what cancer is—undifferentiated cellular growth. We could make specific blocks. This, in the end, will pay off through the use of these tools.

There are 600 men working for a year and developing 3,000 compounds, only one of which ever becomes a product, but these 3,000 compounds are reported. The labours of these 600 man years are reported in the literature Ayerst, in four years now, has published well over 200 papers in the scientific literature on the results of our misses. We have one compound now which was developed, hopefully, to lower cholesterol. It did not make the grade, but we have given it as a result of something over 3,000 requests for this compound around the world, because if is used as a tool in medical laboratories in understanding how cholesterol is made biochemically. This is the type of thing that is quite common.

Mr. MACLEAN (*Queens*): I was trying to establish the fact, and I think you have done it in a very fine way, that research of any kind is bound to have beneficial "fall out", as it were, in other fields, apart from its primary purpose, and you would agree with this?

Mr. BUYSKE: That is right. There is a beautiful example of this of Isoniazid. It is a compound that is used to cure tuberculosis, really. This is one of the miracle drugs of our day. This compound was a research problem in a chemistry laboratory, where someone just tried to make this unusual structure, and from that day it stood on the chemical shelves for years until it was dicovered to have antituberculosis activity. This is the final pay-off.

Mr. MACLEAN (*Queens*): I have just one other question in an entirely different field. With regard to the contracts for the raw material for the production of Premarin, who controls the conditions under which these farms are operated? There have been some statements in the press that so far as these farms are concerned, pregnant mares naturally produce foals that are unwanted, as it were, and that these are maltreated and, in some cases, slaughtered, and are an economic loss to the farmer. Who controls this? Does your company lay down requirements or does the department of agriculture of the province concerned, or someone else take any interest in this?

Mr. WALKER: There are several bodies that do take an interest in this. There is, of course, our own company. We are most concerned that there is no inhumane treatment of any animal which directly or indirectly we have anything to do with. I must say this, that Ayerst as a company owns not one single horse. These are all on contract, and they all belong to the individual farmer. If they decide they want to take their horse out behind the barn on Monday morning and shoot it, this is their horse and it is their right to do so.

However, we as a company are spending over $200,000 this year on research directed towards the health and well-being of animals—not just horses, but animals in general, and I do not think there are very many other organizations in Canada that can make the same boast, so that obviously we are not in the business to be mean to horses.

In our contract with the farmer we have a clause. I do not have the exact wording, but in essence it is this: If, in the reasonable opinion of Ayerst, we feel that anyone is ill-treating or being inhumane to their animals, we can immediately cancel that contract. We have, at the present time, fieldmen who operate throughout the country. The cost of maintaining this group is over $100,000 a year. The purpose of these fieldmen is to visit every indivual farm, help the farmer with any problems which he might have in feeding, watering, animal husbandry, and also to make sure that the barn conditions are proper and that the animals are well-cared for. In addition to that, the S.P.C.A. and humane societies can visit any farm if there has been a complaint.

There has been a great deal of talk in the lay press about inhumane treatment of these mares. Believe me, there is nothing inherently inhumane in this operation. If there were we would have nothing to do with it. There need be nothing cruel about it, but if you have a sufficient number of people looking after animals, obviously somebody will neglect them. This is the same as if you take a sufficient number of people, somebody will neglect his wife and children, and this is a basic fact of life. But there should be no inhumanity. If there is, it is the responsibility of the individual farmer and we will cancel his contract.

Now, when they talk about the treatment of the foals, again they say they are being trucked from market to market, from the stock sales in Kitchener to the stock sales in Guelph and the stock sales in Toronto, but in each one of these stock barns there is a government inspector, a government veterinarian. These inspectors are at every one of these sales. These are government men, and if the foals are too young or undernourished or in ill-health, they are not to be sold. The humane societies also have their inspectors at these places.

To the best of my knowledge there have been very, very few cases where these farmers have been taken into court, and I do not think that one of our people, to my knowledge, has ever had a case stick against him where they took him into court and he was either fined or jailed, or anything of this nature. So while you read a lot, it cannot be this bad or there would be people that have been prosecuted successfully under the laws of the land. The laws are there, and they are very clear.

As far as the foals are concerned, people say, where did they all go? They must be being cruel to them because we cannot find them. But this is not a real good argument. The fact that they cannot find them does not necessarily mean that somebody was cruel to them. I get letters from people which say, where are all these little unwanted foals? Where can we buy one? I do not know. I do not know where there are any unwanted foals. The people I know who have them are getting $120 each for them, and if they have 100 bred mares they are going to get roughly 100 foals, and if they get 100 foals and they sell them for $120 each, this is $12,000 to a farmer and this, believe me, to most farmers is a very fine economic asset.

Mr. MacLean (*Queens*): What about the charge that the farmers follow the practice of prematurely weaning these foals, to keep the mares on the production line, so to speak? I do not see anything very wrong with this myself, unless it is done at a very young age, because there are synthetic feeds that are almost as good as milk for young animals. Have you anything to say about this?

Mr. Walker: It all depends, as you say, on when you personally consider a colt should be taken away from its mother. They do this with other animals, of course, and even humans are not breast-fed to any great extent today. I do not think this is cruelty if somebody brings that foal up properly.

Mr. MacLean (*Queens*): I agree. Please understand that I am not trying to attack you on this. I was trying to give you an opportunity to defend yourself.

Mr. Walker: Well, I hope that we are doing it successfully, because I have had a lot of fall out on this one.

Mr. MacLean (*Queens*): Thank you very much.

(*Translation*)

Mr. Goyer: I will try to be brief. I see that the Company devotes a large amount of money to the welfare of animals. It is a good thing. I should like, first of all, to congratulate the delegate who has presented his brief in both official languages. Now, I would like to know if it is the policy of the Company to publish its literature in the two official languages; if it is for good business purposes, or just to be courteous?

(*English*)

Mr. Gregory: Mr. Chairman and Mr. Goyer, I am delighted that you should have addressed me in French. I hope you will forgive me if I do not reply in

Mr. GOYER: Yes, of course.

Mr. GREGORY: My French ear is good, but my French tongue is not so good. I might say ladies and gentlemen, that Mr. Goyer is the elected representative from our constituency. He has visited our laboratories and I think he knows what we have been speaking about. He asked, as you heard, whether we were publishing our literature in French for business reasons or just to be courteous. Is this true, Mr. Goyer?

Mr. GOYER: That is correct.

Mr. GREGORY: We have long recognized the importance of the two languages in our company. I think if you visit us, you will find that we answer our telephone in both languages, signs in our various offices are in both languages and the labels on our bottles are in both languages. Some of the heads of our departments are of French origin and probably one of our most illustrious French speaking Canadians was Dr. Roger Gaudry, now the rector of the University of Montreal, who for 11 years, was director of our research laboratories. We have a very outstanding woman on our board, Marie-Thérèse Bourgeois, who is a director of the company, and a director of our personnel organization. Dr. Smith has with him a French-speaking physician, Dr. Maurice Dufresne. I should think that Dr. Buyske has a great number of French-speaking scientists with him. Dr. Rochefort, Dr. Langis, Dr. Papineau-Couture, Dr. Claude Vézina, who is an associate director of research. He is in charge of the microbiological activity in our laboratory. We do not use French in our company because it is good business or because it is courteous, but because of the fact that both languages are official in Canada. I hope I have made myself quite clear.

I believe this is true in most of the industries, Mr. Goyer.

(Translation)

Mr. GOYER: Now, you said that in the United States there was another affiliated company. Apart from the one in Canada and the one in the States, is there any other agency?

(English)

Mr. ROBB: Doctor, Mr. Goyer asked if there was any other plant of Ayerst other than in the United States?

Mr. GREGORY: We at Ayerst think of Ayerst as one company. To us there is really no border down there except for income tax purposes and so on. Mr. Walker, you will have to help me with this, we do have a plant in Italy.

Mr. WALKER: We have manufacturing plants in 10 foreing countries, including Italy, Venezuela, Colombia, Brazil, Argentina, Australia, the Philippines and South Africa.

(Translation)

Mr. GOYER: Can we know what are the business figures of those agencies of Ayerst?

(English)

Mr. GREGORY: I do not have them with me, Mr. Goyer. These could be provided, if you wish, through the Chairman, at a later date.

(*Translation*)

Mr. GOYER: If I understood well, all the research activity—contrary to other companies who decentralize it—all your research activity is centralized in Canada, if I understood it well?

(*English*)

Mr. GREGORY: That is true.

(*Translation*)

Mr. GOYER: One of the reasons, apart from scientific reasons, is the fiscal advantages you find in Canada, fiscal aid from the Federal Government to companies making research in Canada?

(*English*)

Mr. GREGORY: There are two good reasons. Ayerst was founded here in 1924, and almost our total scientific community has been centralized in Montreal, and also because of the tax incentives in recent years that you have suggested. Unfortunately for us and, fortunately for the government, we had done a good deal of our major expansion before these tax exemptions became available, but we are very glad to share them.

(*Translation*)

Mr. GOYER: About the taxes as indicated now being applied, do you think that Canada compares favourably with other companies in other countries doing research in the same field?

(*English*)

Mr. GREGORY: I regret that I cannot answer that, Mr. Goyer. I am not well enough informed on that subject.

(*Translation*)

Mr. GOYER: Now with regard to patent rights you have noted in your brief that Canada does not appear to provide proper patent protection and, in consequence, the originality of research. On the other hand you have mentioned problems caused by the import of pharmaceutical products from other countries. Would your suggestion be that patent protection be reinforced, in other words that we have more stringent patent regulations, or rather that we deal with the matter through tariff regulations?

(*English*)

Mr. WALKER: I would say yes, we should definitely strengthen the Patent Act. We, as a company, are doing very considerable research in Canada today, but I am sure that this would lessen if the Patent Act was softened. On the other hand, I think that we must be very careful to clearly define the problem when we are talking about patents. If we are thinking only of Canada, this is one thing, but if we are thinking of patents internationally, this is something else. If we intend, as a nation, to simply pirate on the ideas and achievements of other nationalities, this is one thing, but I think we would be held up to international scorn in this area, the same as Italy is to a certain extent. Italy has roughly 1,100 pharmaceutical companies and there are about 10 doing any research, because they have no patents there and they are allowed to capitalize on the ideas and the industry of others.

I think it is quite significant when you look at the Italian drug industry that very, very few significant achievements have come out of Italy. Very few advances have come out in the form of new useful drugs. This is not true of Great Britain, France, Germany or Japan and, it certainly is not ture of the United States, where there is a strong patent system. Italy, of course as you all know, is getting ready, I think, to bring in patent regulations. I think again it is significant that they are reversing their field and they are now moving back towards patents. If Canada wants to sit back and just say: "Well, we will patent Canadian inventions," which Ayerst did, "in Argentina and then Brazil and in France and then in 30 or 40 countries of the world. We would like you all to pay attention to our patents and observe our patent rights but if any of you people, of course, invent anything do not expect us to look after your patent rights in Canada." Now, I do not see how we can say this and still hold our heads up. We cannot say: "You protect Canadian inventions in your country; we will not protect your inventions in our country."

Now, if you cut out all patents on an international basis you have certainly sounded the death knell of big research as we know it today. The costs are too big, the amounts involved are too high. People will not risk this kind of money without having some idea that they are going to get a just reward for the fruits of their effort. They will not do this.

If you cut out research on an international basis it is possible that you might reduce the price of existing drugs because you will have so many people with only a letterhead and a sales staff peddling these things; they have no overhead. But, they contribute nothing. You have put the kiss of death on any possibility on a new potent drug for heart disease; of a new drug for mental illness; of any possibility of a cancer cure.

(*Translation*)

Mr. GOYER: Admitting that patent rights would be stricter than they are now in Canada, would you consider a just as strict control on imports or would you be for abolishing tariff penalties so that there would be open competition when the product being discovered is put to the market? On condition of course that within a country the actual discoverer of the product be afforded proper protection when it comes to putting it on the market.

(*English*)

Mr. WALKER: If I understood your question correctly, you wish to know whether I felt that if the Patent Act was strengthened we would be willing to see imports from other countries coming in here without duties.

(*Translation*)

Mr. GOYER: I see three advantages here, as far as the actual marketing development of pharmaceutical products is concerned, and also as far as research is involved. The government provides fiscal incentives. Then we have patent protection and also imports. These are the three tools at the disposal of the government which it may use to protect the industry if it so wishes. Is that a fact?

(*English*)

Mr. WALKER: Yes, I would say that is correct. The two tools the federal government have would be first patents and the other protective tarrifs. Was that your point?

(*Translation*)

Mr. GOYER: On page 4 of your brief Mr. Gregory—at (2) in the English text, we find:

(*English*)

> 2. Proposals for encouraging the importation of foreign-produced drugs by extending the compulsory licensing provisions to include the licensing of imports, or by abolishing patent protection for drugs, as recommended by the Restrictive Trade Practices Commission, would inhibit the development and growth of new research-oriented companies in our country.

Mr. WALKER: I think there is a very important statement in here to the effect that the young Canadian companies can best progress under the umbrella of patent protection. If there is no patent protection there is very little chance that a small company can ever become anything but a small company because as soon as they invent something the giants move in with their bigger sales forces and their greater reserves and take the market away from them. If there is patent protection then, the same as Ayerst did, a small company can come up with a good compound and can exploit its home market in Canada.

(*Translation*)

Mr. GOYER: I will give you an example to make myself clear. If an English company develops a new compound and wants to export it to Canada, does the company buy the exclusive licence rights for sale in Canada or can the company simply sell its rights to several companies or go to an agency in the other country, that agency being willing to produce that compound in Canada?

(*English*)

Mr. GREGORY: I am afraid I do not understand Mr. Goyer's question.

Mr. WALKER: I am afraid the translation is not working out very well—

(*Translation*)

Mr. GOYER: Say we have a product being developed in England which we want distributed in Canada, at that time must the company sell its rights or can it distribute that product in Canada to producing companies?

(*English*)

Mr. SMITH: I think I understood the question.

An English company that discovers a new drug can either come into Canada and sell that drug themselves or give the rights to Ayerst? Correct?

Mr. GOYER: Yes.

Mr. SMITH: It can be done either way except that the company who has discovered the drug in England must generally have an adequate sales and distribution force in this country, which they may or may not have, so this would probably be the only reason why they would give the rights to somebody else. Now in either case, whether they give the rights to Ayerst or whether they sell it direct themselves, they still have to go through all our Food and Drug regulations in the same way that we would. What has happened with our agreements with, for instance, Imperial Chemical Industries is that we are representing them over here and we have the sales and marketing force, and so

on. We have the laboratories and, as I mentioned before, we have to repeat not only most of the clinical studies but we have to go back right to the animal stage and go through all the pharmacology, toxicology and everything else. So either they have to do it or we have to do it.

(Translation)

Mr. GOYER: Would your company object to submit to the same type of thing that we have in the United States, i.e. that is its profits and its expenses as well as the profits of the parent company and the other subsidiaries be made public?

(English)

Mr. WALKER: Yes.

The CHAIRMAN: For those who do not know, we have lost the interpreter.

Mr. JAMES ROBB (*Legal Adviser to Ayerst, McKenna and Harrison Limited*): Mr. Chairman, I do not know if that is relevant to this inquiry.

(Translation)

Mr. GOYER: Yes, it is very relevant, it is certainly relevant. Take for instance the C.P.R. Up to about a year and a half ago, it was impossible in Canada to know from C.P.R. Investments what was its portfolio—the complete portfolio—and to know whether we could obtain financial reports from all companies where it had majority holdings. And over the last five years, in the United States, according to this legislation, C.P.R. Investments which have far more funds in fact in Canada than in the United States, was obliged, in the United States at least, to divulge exactly what its portfolio was, what its financial operations were. In this way it was brought before us; we know how it is operated because of American legislation. Now, this being the case, are you ready, as a subsidiary, and since your main investment is in the United States, are you ready to be subjected to similar Canadian legislation?

(English)

Mr. ROBB: I think the answer to that is that Ayerst, McKenna is a Canadian corporation and would submit to Canadian laws under present Canadian corporate law which is the example you mentioned—

(Translation)

Mr. GOYER: I understand that C.P.R. Investments have funds in strictly American companies but because C.P.R. Investments have its main funds here in Canada, it had to submit to the law of the United States. I will simply ask this, I do not want an explanation at any great length, but I am just asking whether you would have any objections to that?

(English)

Mr. ROBB: Needless to say I do not think that the company has any objection to submitting to the laws of Canada. It always has. It is a Canadian company and is, in fact, proud of being a Canadian company.

(Translation)

Mr. GOYER: I understand very well that Ayerst-McKenna have always respected Canadian laws, but would your company object to such legislation?

(English)

Mr. WALKER: I think the two things are not really parallel because Ayerst, McKenna and Harrison have no holdings in the United States which the

Canadian Pacific did. But, we do not. As far as the holding company you mentioned, publishing figures, they do publish their figures and anybody who wants to find out where American Homes Products are doing business, in what parts of the world, what companies they have and so on can do so as it is all published in their annual report.

(*Translation*)

Mr. GOYER: Yes, I can see the importance of that implication. This comes from the fact that we are conscious of the fact that we have to invest a great deal of money in research, that we should assist industrial research in this country. However, we should also realize that we must render an accounting of those sum we put into research. Since we want to encourage research by tax deductions I think we should have to return something to the people. The only way we can do so is having, not control over the management of the company but having a certain control on the actual use of the profits of the company, especially if the original firm is foreign based.

(*English*)

Mr. WALKER: Our profits have all been used in Canada; that is, the Ayerst profits. We have, as Mr. Gregory mentioned previously, not sent any dividends out of this country since 1963. All the profits we have made have been used and employed in Canada. I do not know whether it was mentioned earlier but we have just completed a million dollar plant in Brandon. We are in the process of completing a $2 million pharmaceutical manufacturing plant in Montreal. We have just finished a $1.4 million research building in Montreal. Not only have we used up all our profits, but we have had to go to the bank and borrow money to do this. If I understood you correctly I think you were worried about the fact that we would not have any profits or you wondered where they had gone or some such thing.

(*Translation*)

Mr. GOYER: But it is not simply in the form of profits. Of course we appreciate the fact that you do invest a great deal of money in Canada and that your research is concentrated in Canada; the fact does remain, however, that there may be a movement of funds which can be carried outside the actual profit structure. For instance, you mentioned that you had sales of patent rights to your subsidiary companies outside Canada. These sales of course could have financial implications, that should be readily understood according to the fact that you pay taxes in one country or the other. I do not think I will teach you anything when I say that, but in that spirit, would you have any objection to the Canadian Government having a right to look at your books, not directly to look at "American Home Products", but looking at your books in respect of all the pharmaceutical activities.

(*English*)

Mr. WALKER: Not a bit, this is done every year. The tax department come in and look at our books and they find out exactly what we are doing.

(*Translation*)

Mr. GOYER: I do not mean only Ayerst-McKenna of Canada, but subsidiary firms as well. Would you have any objection to providing the same information.

This does not mean that you would be paying Canadian income tax to another country, of course, but since these tax incentives are used, in part, for the financing of your research, and since, too, you are asking us for more assistance in this regard, to you not realize that this involves, on your part, some rendering of accounts? We are not involved here in the management process; we are simply asking to have the right to look into the way in which you administer these funds which Canadian citizens are putting into research more particularly the pharmaceutical industry.

(*English*)

Mr. WALKER: I think the answer to your question is yes. We would be quite willing to have anybody look at our books.

(*Translation*)

Mr. GOYER: One last general question. How much,—let us speak here of the last year for which we have statistics,—how many Canadian patents have been exported, how many foreign patents have been imported into this country? I am not dealing here exactly with Ayerst-McKenna, but you might have some idea of that question?

(*English*)

Mr. GREGORY: I think Mr. MacLean asked this question a moment ago, did you not, Mr. MacLean?

Mr. MacLEAN *(Queens)*: The question I asked was not the number of patents each way but the royalties.

Mr. GREGORY: Royalties, yes.

Mr. MacLEAN *(Queens)*: And they were about in balance, you said.

(*Translation*)

Mr. GOYER: But as far as the number of patents in concerned do you know?

(*English*)

Mr. GREGORY: I do not have that information. I have this information which was placed on the record before, if you were not here, that we have 113 issued Canadian patents and 25 patents pending.

Mr. GOYER: Yes, I heard that.

(*Translation*)

Would you be in favour of the establishment of international standards for the export of pharmaceutical products, that is for the manufacture also of pharmaceutical products in various countries? Would it be of economic advantage to you to any degree?

(*English*)

Mr. GREGORY: Yes, I think so.

It could conceivably be so and also not so. It works both ways.

(*Translation*)

Mr. GOYER: In which way?

(*English*)

Mr. GREGORY: If, for instance, we were allowed to forgo some of this great clinical testing and pharmacological and technicological testing that has to go on in Canada, because it has been done in some other country, that would work to our advantage and to Canada's advantage. But, on the other hand, if in the course of these international standards and so on there was more work piled on to do, then it would act to our disadvantage, the way I see it. Does that answer your question?

Mr. LAIDLAW *(Counsel):* I think, Mr. Chairman, that time is going along pretty fast and I have a few matters which I would like to have clarified mainly for the record. I wondered, with the agreement of the committee and possibly after hearing the other briefs from the other companies whether I could write a letter to Mr. Gregory and ask him to answer these questions and then I would table them for the committee. I think it would be rather purposeless right now, if you would like to adjourn for this afternoon, if I made an issue of any number of technical points.

The CHAIRMAN: These are particularly probably in relation to patents.

Mr. LAIDLAW: That is right. It will deal with patents.

The CHAIRMAN: In patents.

Mr. LAIDLAW: Compulsory licensing and so on.

The CHAIRMAN: Is this agreeable to the company?

Are there any other questions?

There are many, many committees sitting this afternoon and it will probably be impossible to meet, but I was hoping we could conclude the questioning of the witnesses this norning. I have already spoken to the members of the committee and I think they are in agreeement with this. The meeting is adjourned until Thursday.

APPENDIX "A"

SUBMISSION

TO THE

HOUSE OF COMMONS SPECIAL COMMITTEE

ON

DRUGS COSTS AND PRICES

BY

Ayerst, McKenna & Harrison Limited

CONTENTS

I - INTRODUCTION

Ayerst, McKenna & Harrison Limited ("Ayerst") is deeply concerned with the subject before the Special Committee—the cost of drugs to Canadians. We recognize that our business activities are closely related to the public health and we wish to help an inquiry which seeks to ensure the availability of drugs to Canadians at fair prices.

We will describe in our brief those factors which we believe are responsible for the present level of drug prices in Canada—the cost of discovering new medicines, the cost of producing and building into our products the quality which Canadians deserve, and the costs of distributing these medicines in a vast country with a bilingual population. We believe that it is not only a necessary prerequisite to survival in the pharmaceutical industry that these costs be incurred but, indeed, we urge that it is in the best interest of all Canadians that research for safe and effective new medicines be continued—that efforts to ensure better quality and safer products go on—and that the present method of distribution be maintained.

Furthermore, when one compares the real costs of drugs to Canadians—the hours of labour necessary to earn the money for their purchase—one finds that Canadians need work fewer hours to purchase their medicines than do the citizens of most other countries.

We have, therefore, concluded that the present level of drug prices is fair and reasonable. This conclusion is particularly justified when one considers figures published by the Price Division of the Dominion Bureau of Statistics, which show that prescription drug prices have declined somewhat from their

1949 level as compared with a rise of almost 50 per cent for those commodities included in the "all items" classification (food, housing, clothing, etc.).

Ayerst is proud that it has developed into the largest pharmaceutical company in Canada, distributing its products throughout the country and employing over 840 people. Ayerst accepts willingly its special responsibility to make available to Canadians safe and effective drugs at fair and reasonable prices. We believe that we have met this responsibility in the past and look forward to meeting it in the future. We ask only that this industry not be subjected to discriminatory or unreasonable legislation which will prevent it from fulfilling its special responsibilities to Canadians.

II - RESEARCH

Ayerst is now in its forty-second year of continuous operation, having commenced the business of pharmaceutical manufacturing in Montreal, Canada in 1925 under a Dominion charter. The company's original founders were all Canadians with years of executive experience in the pharmaceutical industry and they well recognized the importance of research in the development of a pharmaceutical company.

At its inception in 1925, Ayerst commenced an imaginative and progressive research programme unusual for that time. Its initial undertaking was the establishment of the first commercially operated biological laboratory in Canada which produced biologically tested and standardized cod liver oil products, and in 1929 produced the first concentrated cod liver oil in North America. In addition, considerable research was conducted by the Ayerst laboratories on the natural vitamin B complex as obtained from wheat germ and brewer's yeast resulting in the Ayerst line of Beminal products (vitamin B factors alone and together with other therapeutic agents) which continue to be marketed to this day.

In 1930 Dr. J. G. Collip of McGill University, a co-discoverer of insulin, reported on human placental hormone preparations. Ayerst recognized the importance of Dr. Collip's work and a joint research programme with Dr. Collip and his associates at McGill University was started. This programme led to the development of "Emmenin", the first orally active female sex hormone available to the medical profession. "Emmenin" was well received by both the Canadian and American physician, and in response to increased sales Ayerst expanded its laboratories in order to properly perform the complex biological and chemical assays on the increased production runs. Additional hormone products were soon added to the Ayerst line, (A.P.L., an equeous solution of chorionic gonadotropin, and other pituitary hormone products) which required considerable investigation to ensure clinically acceptable products and the development and standardization of suitable assay methods to assure uniform potency.

In the year 1939 a new synthetic estrogen, "diethylstilbestrol" was developed which appeared to threaten the future of "Emmenin". In searching for a more effective and less expensive oral estrogen to meet the challenge posed by "diethylstilbestrol", our scientists chose to investigate the merits of estrogen derived from pregnant mares' urine in spite of the then prevalent belief that conjugated estrogens equine were unstable, with low biological activity. In January 1939 a gallon of pregnant mares' urine was collected and processed.

Potency studies of the concentrate containing the estrogens confirmed our belief that an active preparation of estrogenic conjugates could be made from pregnant mares' urine. Thus was developed "Premarin", an outstanding therapeutic agent for the treatment of estrogen deficiency, a condition most frequently found in menopausal women. Later research established its usefulness in intravenous form as a hemostatic agent and, recently, strong evidence has been developed which tends to establish its usefulness in the treatment of atherosclerosis. Extensive research continues even today in our laboratories in Montreal to more fully understand how this important drug brings about its beneficial action.

The success of Ayerst is due, in large part, to the enthusiasm with which "Premarin" has been, and continues to be, received by physicians throughout the world. If the development of insulin therapy by the Connaught Laboratories ranks as the foremost medical achievement by Canadian scientists, surely the development of "Premarin" by Ayerst is close behind. Export sales from Canada of this one product are expected to exceed $7,000,000 in 1967.

Furthermore, Canadian farmers now have a new source of income from the collection and sale of pregnant mares' urine—an activity that takes place during the winter months when other farm income-producing activities are at a low level. During the next 12 months it is estimated that payments by Ayerst to Canadian farmers producing pregnant mares' urine will amount to over $6,-250,000. The Ayerst system for collecting pregnant mares' urine extends from Southern Quebec through Ontario and into Manitoba, Saskatchewan and Alberta. Just recently a $1,000,000 plant was constructed in Brandon, Manitoba so that urine collected from pregnant mares in that area can be processed before shipment. The effect that the construction of the Brandon plant will have on the economy of that area is illustrated by an article in the recent "Brandon Reports" published by the Brandon Industrial Commission stating that as a result of the Ayerst programme "an economic boost of some magnitude will result and the impact will be felt throughout the retail trading area of Western Manitoba and Eastern Saskatchewan".

But hormones (such as "Premarin") and vitamins (such as concentrated cod liver oil and the "Beminal" line) were not the only accomplishments of Ayerst research in the 1930's. A bacteriological laboratory was established in 1937 and soon thereafter staphylococcus toxoid for the treatment of boils and other staphylococci infections was prepared and standardized in conjunction with Professor E. G. D. Murray and his associates at McGill University. This was followed by Ayerst production of antipneumococcal sera(rabbit), a new treatment for pneumonia developed by Dr. Horsfall of the Rockefeller Institute in New York and found more effective and less toxic than the older serum from horses. Although the invention was conceived by Dr. Horsfall, Ayerst played a vital role in making the serum available to the patient. This process involved elaborate laboratory investigations including growth of virulent organisms, standardization of the sera, courses of hyperimmunization of the rabbits, bleeding of the animals to supply the antisera, preparation of immune globulins from the sera, assay for potency, tests for aerobic and anaerobic sterility, pyrogen tests, and safety of the final packaged vial. Specific antisera for all thirty-two types of pneumococcal infections were made available for clinical use and proved effective in human therapy. But within months after the Ayerst

antipneumococcal sera were made commercially available, they were replaced by the newly-discovered sulfa drugs and the entire Ayerst investment in this project was, in effect, lost. Ayerst's research group thus turned to the synthesis of sulfa drugs and produced the first Canadian-made sulfonamide.

In 1938 Ayerst began the study, production and assay of purified concentrates of the "blood clotting" vitamin K, discovered by the Danish scientist Dr. Henrik Dam. This led to the development of a synthetic compound with vitamin K activity which was made available to the medical profession and supplanted the original natural K concentrates. This compound is still marketed by Ayerst under the trademark "Kavitan".

In the early 1940's, a great deal of research effort was being directed towards devising methods of producing penicillin. In 1942 Ayerst had obtained cultures of several mold species which had been reported to have antibiotic activity, including cultures of "penicillium notatum" produced from Professor Fleming's original strain. These were grown experimentally in our laboratories in Canada and several methods of producing a satisfactory product were developed.

Consequently, in July 1943, when Ayerst offered its facilities to the Canadian Government for the production of penicillin for the Armed Forces, a qualified research team was available. This team had experience in penicillin research and, most important, had access to valuable technical information and know-how from affiliated firms which at that time had made considerable progress in penicillin production.

Late in September 1943 Ayerst was requested by the Canadian Government to construct facilities to produce penicillin for the Armed Services. A temporary plant was constructed for penicillin fermentation within six weeks where penicillin mold was grown in thousands of large milk bottles in a continuous operation. Within six months the first Canadian-produced penicillin was delivered by Ayerst to the Armed Services.

Early in 1944, the permanent Government penicillin plant was finished and in operation at Ayerst's location in St. Laurent. The milk bottle method of preparation was shortly thereafter replaced by deep culture fermentation in large tanks, permitting more rapid production of greater quantities of this life-saving drug at lower cost.

Again, in 1951, penicillin was in short supply in the United States, Great Britain and Canada as a result of the Korean War. The Canadian Government was concerned about the availability of sufficient supplies of penicillin in Canada in case of an emergency and Ayerst enlarged its prodiction facilities to ensure an adequate supply of the drug in Canada for National and Civil Defence. However, by the time the new facilities were in operation, the worldwide shortage had been overcome. Excess production from the United States and foreign markets found its way into Canada at distress prices making it almost impossible for Ayerst to compete, particularly in sales to the Government. As a result, the company incurred very substantial losses and the entire penicillin fermentation facilities were eventually sold in 1953.

But Ayerst's interest in antibiotics was not restricted to penicillins. In 1946, shortly after Professor Wakeman's discovery of streptomycin, Ayerst produced

for clinical investigation the first streptomycin in Canada by arrangement with the National Research Council. Sixty per cent of Ayerst's production was shipped free of charge to physicians throughout the country and the remaining forty per cent was sold to the Department of Veterans Affairs at cost.

Ayerst continued to pursue its research programme intensively and, by 1944, had outgrown its facilities in downtown Montreal. In that year a completely new and fully-equipped research laboratory, pilot plant and quality control laboratory were constructed at St. Laurent to house the increased staff required for its expanded research activities. While in the infancy of Ayerst the main research emphasis was in the fields of vitamins, hormones and bacteriologicals, the emphasis following World War II shifted to natural products, antihypertensives, analgesics, anesthetics, antihistamines, bronchodilators, central nervous system drugs, enzymes, anorexiants, antitussives, oral progestins, antifungal agents, antibacterial agents and anticancer agents.

Since World War II the Ayerst research laboratories have also conducted pharmacological and toxicological investigations of a great many compounds brought to Ayerst through arrangements with well known European pharmaceutical companies. As a result, Ayerst has made available to Canadians such important and useful drugs as "Penbritin", the first synthetic penicillin with broad spectrum activity, "Thiosulfil" (sulfamethizole) for urinary tract infections, "Fluothane", the leading hospital anesthetic and "Mysoline", an anticonvulsant for the treatment of epilepsy. "Penbritin", "Thiosulfil", "Fluothane" and "Mysoline" all required extensive pharmacological and toxicological investigations by Ayerst to determine proper dosage levels and their effect in animals before their release for clinical evaluation. This required acute and chronic tests on laboratory animals and gross and microscopic pathological examinations of the various organs and tissues of these animals.

At present the Ayerst research staff numbers 270 people of whom 42 per cent have university degrees. On the staff are 54 scientists with Doctorate degrees, 16 with a Master of Science degree and 37 with a Bachelor of Science degree. The laboratories are housed in a building complex covering 100,000 square feet and costing somewhat more than $3,000,000 to construct and half again as much to equip with modern scientific apparatus.

The Research Laboratories are subdivided into departments of chemistry, biology, microbiology and biochemistry. In addition, the Ayerst Research Laboratories maintain a library containing over 12,000 technical volumes on various aspects of chemistry, pharmacology and other medical sciences. To keep the staff abreast of the latest findings in these fields, the library subscribes to over 400 scientific journals.

The major function of the Chemistry Department is to synthesize or isolate new chemical substances from plant or animal sources for subsequent screening by various biological test procedures for useful activity. The department has over 40 people, including 17 Ph.D. chemists who are assigned to the following 4 groups:— steroid chemistry, medicinal chemistry, the chemistry of naturally-occurring materials and chemotherapy directed against microorganisms and parasites.

The Biology Department consists of 80 people with 15 having Doctorate degrees. Its function is to test new and novel chemical compounds for biological

activity as potential agents for treatment of human disease, to determine the mechanism of action of drugs and to conduct basic research on the effects of drugs on normal and diseased organisms. Its efforts are concentrated in eight major areas:— autonomic nervous system, circulatory pharmacology, reproductive endocrinology, non-steroidal anti-inflammatory mechanisms, parasitology, central nervous system, neuropharmacology and veterinary research. Teams of scientists work exclusively in specific fields with the purpose of providing improved or entirely new agents for treatment of diseases. The basic research done in these areas provides a better understanding of the benefits and possible dangers of therapy with a new drug. This work also provides a better understanding of the causes and allied systemic disturbances in disease states.

The Microbiology Department consists of 25 people, including 6 Doctorate level scientists. One of its functions is to develop and utilize procedures to test compounds that are active against harmful bacteria and fungi. Another is to discover microorganisms that will produce useful chemicals such as antibiotics or that will interact with a complex molecule such as a steroid to bring about a desirable chemical change of a type that is impossible or very difficult to accomplish by straight synthetic chemical methods.

The Biochemistry Department has 35 people, 9 of whom have Ph.D. degrees. The primary responsibilities of this department are to make biochemical measurements on the tissues of animals receiving drugs to assess the safety of new compounds; to study the absorption, excretion and chemical changes that take place during the sojourn of a drug in the human body; to attempt to define the beneficial action of a drug in terms of a biochemical mechanism; and to conduct testing programmes to find new drugs designed to control biochemical reactions that have gone astray and have resulted in producing a state of disease.

Ayerst has also constructed a modern pilot plant capable of making the substantial quantities of the compounds needed for the laboratory and clinical evaluation of a new drug. In a rural area near St. Justine de Newton, 50 miles from Montreal, Ayerst maintains a 100 acre farm which includes a very special and extensive facility for the housing of dogs used as test animals. This kennel accommodates over 400 pure bred beagles. In addition, research and evaluation of new drugs for potential use in farm animals and domestic pets are conducted at this farm.

Today several classes of drugs are under study including progestational agents, anabolic agents, anti-inflammatory sterols, psychic energizers and antidepressant drugs, new cardiovascular drugs for the treatment of atherosclerosis, new antibiotic agents and new anticonvulsant drugs for the treatment of epilepsy. Indeed, every phase of medicine is under constant review and Ayerst is continually searching for new drugs that will benefit mankind. Just recently, for example, Ayerst research scientists achieve the total synthesis of a hormone-like compound called "prostaglandin" found in many places in nature and in man. These substances, which were first discovered in the early 1930's, are extremely active biologically, lowering blood pressure and causing smooth muscles (such as intestines, stomach or uterus) to contract. The short supply of the natural form of these very interesting compounds has hampered investigations into their ultimate usefulness in medicine. However, their synthesis promises to relieve this shortage and there is high hope that the "prostaglandin"

compounds will be developed as were the hydrocortisone-like steroids 20 years ago.

Conducting research in Canada, as elsewhere, is slow, laborious, costly and uncertain. Ayerst has literally spent millions of dollars on specific projects which have had to be abandoned, either because the agent under study failed to exhibit the anticipated activity or because the toxicity was such that the product could not be safely marketed. The Ayerst experience in the development of antipneumococcal sera (rabbit) which was subsequently replaced by sulfa and antibiotic therapy has been previously detailed. Again, in the early 1950's, a project in cancer research was started which required the growth of a special mold, the isolation and purification of the resultant antibiotic and its screening in mice. A special method of producing the antibiotic in large-scale submerged "tank fermenters" was developed and in fact the antibiotic was produced and sent for clinical appraisal. But because the product in tolerated doses did not prove effective, the entire project was abandoned.

The experiences described above are not atypical. It has been estimated that only one in every 3,000 compounds tested will yield a drug of sufficient value to justify its commercial introduction. Nevertheless, research—slow, laborious, all too often unrewarding—continues to expand in Canada. But the continued growth of research in Canada is dependent not only on the availability of competent scientific and technical people and a stable political climate, but also depends on the economic incentive afforded by Canada for research in this country. The fact of the matter is that Canada provides less protection to pharmaceutical discoveries than does any other industrial country except Italy, and the situation in that country is presently under review by the Italian parliament. Indeed, this discrimination against the pharmaceutical inventor is difficult to rationalize for can it not be argued that if there is to be any distinction at all between one kind of inventor and another, the medical inventor is worthy of a higher reward than most? Is not the public more greatly benefited by the inventor who alleviates disease than by the inventor who improves the rate of fire of a machine gun or the capacity of a juke box? Should not, therefore, the public give a greater reward to the inventor from whom it secures the more desirable benefit?

Should the limited and discriminatory patent protection now afforded pharmaceutical discoveries in Canada be further emasculated, it would be unreasonable to expect that the expansion of pharmaceutical research facilities in this country will continue. It is quite unrealistic to expect international pharmaceutical firms to make substantial investments in research facilities in any country when the economic system of that country permits the fruits of that research to be appropriated by others for what is in effect a pittance. If, on the other hand, pharmaceutical inventions were to be rewarded in the same manner as are other discoveries, there is every reason to believe that many companies will be encouraged to emulate the Ayerst experience and conduct an increasing share of their international research in Canada. With this kind of encouragement, there is good reason to believe that a medical scientific technology can be developed in our country that will rival that of any in the world.

III -MARKETING

Ayerst is today the largest drug manufacturer in Canada. The pharmaceuticals it markets range from antibiotics to vitamins and include antitussives, ataractics, hormones, geriatrics, antispasmodics, sulfonamides, anticonvulsants, anesthetics and a complete line of veterinary products. Its products are distributed to retail pharmacists, wholesalers, hospitals and government departments throughout Canada. Six warehouses in Moncton, Toronto, Winnipeg, Calgary, Vancouver and Montreal are maintained as shipping depots to facilitate quick delivery to our customers in all parts of Canada. Thus a patient in desperate need of an Ayerst medicine can be assured that it is not too far distant from his bedside.

As this Committee will appreciate, the acceptance of a prescription pharmaceutical depends entirely on the degree of support it receives from the medical community. To ensure that physicians are aware of our products and receive all the information which they must have in order to make an intelligent decision concerning the use of a particular Ayerst drug for a particular patient, Ayerst maintains a force of 80 medical sales representatives. To be sure, the job of the representative is promotional, but it cannot be emphasized too strongly that he performs a most valuable service for the physician and pharmacist (both hospital and retail) in disseminating up-to-date and complete information concerning drugs which he may not otherwise receive. Recently, for example, Ayerst received a communication from Professor Douglas Stewart of the Faculty of Pharmacy, University of Toronto, and Director of Pharmaceutical Services of the Toronto General Hospital in which he wrote—

> "I want to congratulate the Ayerst Company on the fine Product Data Bulletin issued on "Penbritin". This Data Bulletin, in my estimation, meets in a unique way almost all the requirements of a Drug Information Centre. I especially like the format you have used, as it will save considerable time for our Pharmacists to obtain information on any specific point, for example the rate of excretion."

In addition, the medical sales representative relays back to the Ayerst Medical Department any side effects the doctor may report or unusual reactions to Ayerst products.

The Ayerst representative is particularly well equipped to perform this function for he is typically a university graduate with a bachelors' degree in pharmacy or a related medical science. On first joining Ayerst, he receives a four-week training course dealing with the pharmacological application of Ayerst drugs, their contra indications and precautions. Once in the field he receives continuous field supervision from experienced supervisory personnel to ensure that he supplies physicians with correct and accurate information. Every two months each of the nine sales districts holds a two-day seminar in which the sciences relating to Ayerst drugs are reviewed, and every two years each of the representatives attends a formal one-week refresher course in Montreal. Every effort is made to ensure that the Ayerst representative is kept abreast of new medical developments applicable to Ayerst drugs, including newly-encountered side effects which he can pass on to the physician.

Thus the Ayerst medical representative functions as a professional, performing an important service to the physician. Because the only contact most physicians have with Ayerst is through our sales representatives, it is of extreme importance to us our representatives perform in a professional manner lest our standing with the medical profession be jeopardized. Misrepresentation, exaggeration and the normal fulsome praise permissible when selling the usual commodity are not allowed. There is just too much at stake for the physician, his patient and for Ayerst.

In addition to employing medical service representatives to inform the physician of Ayerst products, a number of other techniques are used, including direct mailings, advertisements in professional journals and sampling. With regard to direct mailings, we attempt to limit this material only to physicians who have a practicing interest in the product it involves.

All our advertising and promotional literature must be reviewed and approved by our Medical Department so that the only therapeutic claims permitted are those which are medically correct and, in the case of "new drugs", those which have been approved by the Food and Drug Directorate.

Sampling is yet another way of acquainting physicians with our products. Many physicians use these samples as starter dosages to determine whether the drug will cause a side effect in a particular patient before putting the patient to the expense of purchasing the medicine from a retail pharmacist, other phsicians use samples to supply indigent patients. But in any event, samples are only supplied to physicians who request them, either directly from a sales representative or by written request to our head office in Montreal.

Finally, Ayerst underwrites the cost of a number of activities which do not relate directly to any of our products, but which we hope will reflect favourably on our company. Just recently, for instance, Ayerst published a glossary of medical terms for the French-speaking medical community entitled, "Glossaire des termes médico-hospitaliers." In addition, Ayerst has distributed to physicians and hospital personnel handbooks on epilepsy (for use by the physician and the parent of the epileptic), anesthesiology, and cystic fibrosis, charts describing the different antibiotics available, and sensitivity testing materials.

Critics of the industry have noted what appears to them to be the high cost of marketing and have asked why pharmaceutical companies spend so much on the marketing of their drugs. The P.M.A.C.'s Annual Statistical Survey for 1964, previously submitted to this Committee, indicates that total marketing expense, including the cost of providing of important information to the physician, accounts for 29.9 per cent of the manufacturer's sales dollar, but only 11 per cent of the prescription dollar.

Ayerst would be most happy to spend less money in the marketing of its products, but it is a prerequisite to survival in the pharmaceutical industry, in Canada as in other industrial countries, that a manufacturer actively, vigorously and fairly promote its products to physicians. Also, certain factors peculiar to Canada result in a somewhat higher cost of marketing than might otherwise be the case. For one, Canada is a vast country with a scattered population, with the result that detailmen servicing large rural territories do not operate as efficiently as do detailmen in large cities. Secondly, the cost of providing promotional services in two languages is substantial. Lastly, the market for any one drug

(unlike other consumer product in Canada) is not a mass one, with the result that fixed cost must be spread over a relatively small number of sales.

IV—SAFETY

Every effort is made by Ayerst to ensure that its products are safe and will perform in accordance with label claims. These efforts, which are discussed below, include a system of checks and safeguards in drug manufacturing and distribution to achieve and maintain the highest quality of our products and maintenance of a competent Medical Department to ensure that the Canadian physician receives up-to-date, reliable information on Ayerst products.

Quality Control

The Ayerst Quality Control Department is directed by Arthur D. Grieve, Ph.D., considered to be one of Canada's foremost authorities on pharmaceutical quality control. Dr. Grieve graduated with a B.A. in chemistry from the University of Western Ontario in 1929 and received his Ph.D. from McGill University in 1932. Dr. Grieve has been Director of Quality Control for Ayerst since 1947 and presently directs a staff of 84 which includes 2 Ph.D.'s and 32 Bachelors of Pharmacy. The building housing the Quality Control Department and the equipment contained therein is valued at nearly ½ million dollars.

In 1965 Ayerst spent over $840,000 on quality control to ensure that the products it distributes are of the highest possible quality. The Ayerst Quality Control Department has two functions:

1. To develop analytical methods and specifications for a new drug substance and its dosage forms, so that each batch of the new drug substance and its dosage forms has the established identity, potency, purity and safety.

2. To ensure that the final manufactured durg has the claimed identity, potency, purity and safety. Thus, before proceeding with the manufacture of any batch, the raw materials required, including active and inactive ingredients, are sampled and tested to ensure their conformity with specifications. After the batch is manufactured, samples are again submitted to the Quality Control Department for testing for conformity to the established specifications, using methods developed by the Analytical Department.

Additional studies continue even after the product is released for sale. Samples of representative batches are selected and stored under the normal conditions prescribed on the label to study stability so as to make sure that the products retain their potency and purity during their normal shelf life. These samples are re-examined and re-tested at appropriate intervals to ascertain whether any change in potency or purity has occurred. If the product is found to undergo slow deterioration, an expiration date is established and stamped on the package, indicating the date beyond which the product should not be used.

Therefore the user of an Ayerst drug can be sure that it is true to its label identity and conforms to the potency claims on the label at the time of use. To place the matter in statistical terms, every one of our major products is subjected to 131 different testing procedures before it is ready for the market.

Manufacturing

The procedures employed by the Ayerst Manufacturing Department are designed to ensure the potency, purity and stability of Ayerst pharmaceuticals. Each of the manufacturing departments—Tablet, Injectable, Liquid and Packaging—is supervised by a trained pharmacist who personally checks each step in the manufacture of each batch. An apprentice system of training personnel is employed whereby a new employee must pass through seven different levels of instruction before achieving a top grade Process Operator ranking. For those able to assume such responsibility, several years are usually required for the progression. The training programme, which is personally supervised by the Department Supervisors, places maximum emphasis on meticulous adherence to written procedures.

A new production facility is now under construction and will be ready for occupancy January 1, 1967. This 70,000 square foot building which will cost approximately $2,000,000 is designed to conform to the highest standards of the pharmaceutical industry and will undoubtedly be a model for other pharmaceutical manufacturing facilities throughout the world. For example, all air entering the building will be filtered and conditioned for the special temperature and humidity needs of each manufacturing operation. In the case of the Injectable Department, the air will again be filtered prior to passing into each separate work area. The exhaust air leaving the building will be washed free of dust to avoid contaminating the air entering the building.

Separate rooms are provided for all manufacturing procedures in the Tablet Department, each with individual air systems, so that only one-in-process product is in any one room at one time. There are no overhead pipes or other dust-catching obstructions and the walls, floors and ceilings are of materials chosen to allow easy cleaning. Both wet and dry vacuum pickup systems are installed in each room for area cleaning and the various machines are vacuumed while being operated to eliminate the accumulation of dust.

Similar provisions are made for the particular needs of all manufacturing departments. In certain work rooms a positive air pressure is maintained to avoid the possibility of contamination from air coming from other parts of the building. In other work rooms where dust cannot be avoided, a negative air pressure is maintained to prevent dust from migrating to other parts of the plant.

Access to the Injectable Department is through dressing rooms where the personnel change clothes to sterile gowns, caps, masks, gloves and over-stockings, after having performed a scrub-up procedure similar to that employed by a surgeon prior to an operation. Precautionary procedures take place in other areas in the plant to avoid carrying dust from one area to another on regular work uniforms.

Finally, "air showers" consisting of 60 mile per hour blasts of filtered air will be used in different locations to remove dust from clothing.

Medical Department

The Ayerst Medical Department consists of three qualified physicians under the direction of one of our Vice-Presidents, Dr. Leighton Smith, who received his medical degree from McGill University in 1943. The Department organizes,

plans and supervises clinical investigations on all new compounds, and provides a complete information service on all marketed compounds to physicians throughout Canada. If a physician wishes to learn whether it may be advisable to use one of our products for a particular patient, he may, if he chooses, request the advice of the Ayerst Medical Department. The Medical Department also reviews the validity and acceptability of all company literature and the claims made for all Ayerst drugs. Finally, the Ayerst Medical Department is responsible for the basic medical training of all new Ayerst representatives and their continuing or refresher training in medical subjects relating to Ayerst products.

V - SUMMARY

The price paid by Canadians for our drugs is fair and reasonable when one considers their real cost - the hours of labour required to earn the money for their purchase. The data presented in the submission of the P.M.A.C. to this Committee clearly shows that a Canadian is required to work fewer hours than his foreign counterpart to purchase his needed prescription drugs.

No doubt we would all be happier if the price of drugs to Canadians was lower. But the fact of the matter is that the costs of manufacturing and distributing safe, effective drugs, of ensuring that the physician receives up-to-date, scientific information on their use, and of engaging in research in Canada so that new, more potent and safer drugs will be available to Canadians in the future, are high and rapidly rising. Even if the entire profit earned by the manufacturers was to be eliminated, the average price of a prescription to the patient of $3.47 would be reduced only to $3.36 (See P.M.A.C. Submission, Page 2.1).

The cost of marketing pharmaceuticals tends to be higher in Canada than in other countries because of our geography, the cost of providing promotional materials in two languages and the limited market for individual products. It is a condition of business survival, however, that a pharmaceutical company engage in promotional activities and for this reason the recommendation of the Royal Commission on Health Services that a maximum of 15 per cent of total sales be allowed as a deduction for income tax purposes for promotional expenses is unworkable. If enacted, it would result in higher rather than lower drug prices since drug manufacturers would nevertheless be compelled to incur these expenses and would pass the after-tax effects on to the consumer in the form of higher prices. Finally, it cannot be emphasized too strongly that in promoting the use of its products to physicians through medical service representatives, advertising and direct mailings, Ayerst makes available to physicians complete information concerning its products which they might not otherwise receive.

Production costs in the pharmaceutical industry also tend to be higher than in other industries because of the necessity of building quality into every pharmaceutical product during every stage of the manufacturing process. The brief of the Canadian Medical Association recognizes the importance of insuring that pharmaceuticals are of the highest quality and concludes that—

> "—if reduction in price in any way impairs the ability of Canadian drug manufacturers to maintain the highest quality of their products, and

curtails the easy availability of these products, which we as doctors have come to expect, it is our feeling that such a reduction must be resisted, and that in any such consideration, these current standards be maintained as a first principle. Drugs form the basis of much modern therapy and we feel that the good health of Canadians must not be sacrificed to the admittedly important but secondary factor of costs." (Page 1)

Finally, the costs of doing research in Canada are appreciable and rising rapidly. These costs are certainly necessary if new, more effective and less toxic drugs are to be developed. Ayerst is proud of its role as a leader in conducting research in Canada as documented in Section II of this Submission.

Indeed, the reasonableness and fairness of drug prices seems to have been conceded by the Royal Commission on Health Services which stated that—

> "We conclude on the basis of the evidence presented to us that it is the unequal and generally unpredictable incidence of heavy drug costs that have given rise to the greatest concern on the part of the public, rather than what has been described as the 'high costs' of drugs as such." (Report, Page 355)

Most certainly a solution should be found to help those Canadians for whom the price of prescription medicines required by prolonged illness seems high or excessive. Clearly, the first step in this direction should be the abolishment of the Federal sales tax on prescription drugs, a course recommended by the Royal Commission on Health Services and concurred in by the Canadian Medical Association. Programmes of drug prepayment or insurance may be indicated, provided, however, that the discretion of the physician to prescribe those medicines he believes in the best interest of his patient is not restricted. Should the physician prescribe a so-called generic drug, so be it. If, on the other hand, the physician deems it in the best interest of his patient to prescribe a trademark drug or to indicate a preference for a drug manufactured by a specific company, this desire must similarly be respected. It would be inconsistent and illogical to devise a programme to ensure all citizens the medical services they need and then limit the means of treatment physicians may prescribe.

Also, it is essential that the present level of patent protection now afforded to drug discoveries not be further reduced. Indeed, the limited patent protection now afforded drug discoveries in Canada is illogical since it results in the inventor of a pharmaceutical which may cure a dreaded disease receiving a more limited reward than an inventor of a gadget which may be of little benefit to mankind. Furthermore, the enactment of laws designed to reward the pharmaceutical inventor fairly will benefit not only the pharmaceutical manufacturer now doing research in Canada but will also foster the industrial and technological development of Canada. As Mr. C. M. Drury, Minister of Industry, has stated in an address to the Second Ministerial Meeting of Science of the Organization of Economic Co-Operation and Development excerpted in the submission of the P.M.A.C.—

> "The task facing governments then is to stimulate the innovation process so as to ensure the rapid and effective exploitation of new scientific and technological advances. The solution involves the creation

of a favourable climate for innovation and the devising of techniques to promote research and development in industry, where it can be applied for economic purposes..."

No better vehicle to stimulate innovation has yet been found than the patent system which provides the incentive to invest in research. Pharmaceutical companies are in fact investing in research in Canada on an ever-increasing scale and Ayerst is proud to be the leader in this development. If expenditures for research are to continue to be made in Canada by Ayerst and others, a reasonable and fair degree of patent protection must be provided so as to foster the incentive which justifies these large expenditures.

There is yet another, perhaps even more cogent, reason to afford a more reasonable degree of patent protection to pharmaceutical discoveries made in Canada than is now the case. Much has been made of the fact that most of the important pharmaceutical companies in Canada are subsidiaries of foreign companies. But if Canadian-owned companies are to develop, they can do so only under the umbrella of a patent system which would encourage them to conduct research by protecting the fruits of their research with a temporary monopoly. If the discoveries of a young research-oriented company can be pirated with impunity by its competitors, there is no reason to expect it to incur the large expenditures which research demands. An effective patent system is therefore of prime importance, not only to the large international research-oriented company but to the smaller Canadian company hoping to become a more potent force in the market. The importance of patent protection to a small research-oriented firm was perhaps best expressed by Dr. Chester A. Cavallito, then Director of Research of Irwin, Neisler & Company, a small U.S. drug firm, in testimony before the Sub-committee on Antitrust & Monopoly of the Committee on the Judiciary United States Senate, in December 1961. In explaining his company's decision to increase its research commitment, Dr. Cavallito stated:

"It must be emphasized, Mr. Chairman, that this decision to invest in research was predicated upon the ability of Irwin, Neisler & Co. to market exclusively the results of its research. So long as this would be possible, the company could proceed to sell with assurance that the merits of the product would lead to sales and to the manufacturing profit constituting the principal form of remuneration for the efforts. If the company did not receive exclusive rights, however, the larger concerns could step in, capitalize on their greater advertising and sales resources and displace Irwin, Neisler & Co."

In summary, we believe that the present level of drug prices is a reflection of the costs of discovering, producing and distributing safe and effective medicines to Canadians. We at Ayerst, together with our competitors, recognize that we are engaged in an industry unlike any other industry and that we have a special obligation to make available to the public safe and effective drugs at fair and reasonable prices. We believe that in the past we have fulfilled this obligation and can assure this Committee of our determination to do so in the future.

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 13

THURSDAY, OCTOBER 27, 1966

WITNESSES:

Representing Smith Kline & French/Montréal: Mr. Robert F. Daily, Vice-President and General Manager; Mr. Ross F. Bethel, Technical Manager; Mr. Alan J. Dalby, Director of Marketing; Mr. John C. Martin, Director of Administration and Finance; Dr. Andrew J. Moriarity, M.D., Director of Research and Development; Mr. Michael Sheldon, Assistant to the General Manager, all of Montreal; and Mr. Russell A. Fraser, Senior Hospital Representative, of Toronto.

ROGER DUHAMEL, F.R.S.C.
QUEEN'S PRINTER AND CONTROLLER OF STATIONERY
OTTAWA, 1966

25071—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

Vice-Chairman: Mr. Patrick T. Asselin (*Richmond-Wolfe*)

and

Mr. Brand,	Mr. Hymmen,	Mr. Orlikow,
Mr. Clancy,	Mr. Isabelle,	Mrs. Rideout,
Mr. Côté (*Dorchester*),	Mr. Johnston,	Mr. Roxburgh,
Mr. Enns,	Mr. MacDonald	Mr. Rynard,
Mr. Goyer,	(*Prince*),	Mr. Tardif,
Mr. Howe (*Hamilton*	Mr. Mackasey,	Mr. Whelan,
South),	Mr. MacLean (*Queens*),	Mr. Yanakis—24.
Mr. Howe (*Wellington-*	[2]Mr. Noble,	
Huron),	Mr. O'Keefe,	

(Quorum 10)

Gabrielle Savard,
Clerk of the Committee.

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[1] Replaced Mr. Prud'homme on October 25.
[2] Replaced Mr. Pascoe on October 26.

ORDERS OF REFERENCE

TUESDAY, October 25, 1966.

Ordered,—That the name of Mr. Goyer be substituted for that of Mr. Prud'homme on the Special Committee on Drug Costs and Prices.

WEDNESDAY, October 26, 1966.

Ordered,—That the name of Mr. Noble be substituted for that of Mr. Pascoe, on the Special Committee on Drug Costs and Prices.

Attest.

LÉON-J. RAYMOND,
The Clerk of the House of Commons.

25071—1½

MINUTES OF PROCEEDINGS

THURSDAY, October 27, 1966.
(21)

The Special Committee on Drug Costs and Prices met this day at 9.45 a.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout and Messrs. Brand, Goyer, Enns, Harley, Howe (*Wellington-Huron*), Hymmen, Johnston, MacDonald (*Prince*), Mackasey, MacLean (*Queens*), Orlikow (12).

In attendance: Representing Smith Kline & French, Montreal: Mr. Robert F. Daily, Vice-President and General Manager; Mr. Ross F. Bethel, Technical Manager; Mr. Alan J. Dalby, Director of Marketing; Mr. John C. Martin, Director of Administration and Finance; Dr. Andrew J. Moriarity, M.D., Director of Research and Development; Mr. Michael Sheldon, Assistant to the General Manager, all of Montreal; and Mr. Russell A. Fraser, Senior Hospital Representative of Toronto.

Also in attendance: Mr. A. M. Laidlaw of Ottawa, Legal Counsel for the Committee.

The Chairman referred to correspondence received from Dr. Marvin Darrach, Professor and Head of the Department of Biochemistry, Faculy of Medicine of the University of British Columbia, including a statement on "Medical Research and the Drug Industry".

Agreed,—That a copy of Dr. Darrach's letter and the statement be sent to each member of the Committee.

The Chairman introduced Mr. Daily, who, in turn, introduced his associates.

Mr. Daily read a prepared statement.

Agreed,—That the submission by Smith Kline & French of Montreal be printed as part of today's record. (*See Appendix I*).

Mr. Daily was examined on the brief. He was assisted by Messrs. Dalby, Fraser, Bethel, Martin, Sheldon and Dr. Moriarity.

At 10.10 a.m. the Chairman having to leave, Mrs. Rideout took the Chair.

During the course of questioning, samples of Smith Kline & French Products and Look alikes were circulated among the Members.

Agreed,—That a paper tabled by Mr. Bethel with reference to Trifluoperazine be included in today's record. (*See Appendix II*)

Also agreed,—That the generic firms mentioned as copiers be invited to submit evidence in rebuttal to the charges made in Smith, Kline & French's brief as appearing at page 40.

Mr. Martin was requested to supply further information of a confidential nature to the Accountant of the Committee.

Mr. Mackasey acted as Chairman *pro tempore* during the proceedings.

Mr. Laidlaw asked some questions, more particularly with reference to compulsory licensing and royalty agreements.

The Committee agreed that Mr. Laidlaw write to Smith Kline & French for further information of a technical nature.

At 1.10 p.m. the Committee adjourned to 9.30 a.m. Tuesday, November 1st.

Gabrielle Savard,
Clerk of the Committee.

EVIDENCE

(Recorded by Electronic Apparatus)

THURSDAY, October 27, 1966.

The CHAIRMAN: Gentlemen, I think we might start the meeting.

First of all, we have received some communications from Dr. Darrach, professor and head of the faculty of medicine, University of Britsh Columbia. We have a four page brief on medical research in the drug industry. I think we will just send it around to the members and, if anyone thinks that it will contribute a great deal, then we can probably have it printed as an appendix at a later date.

I must apologize to the Committee, but I will have to leave the meeting at approximately 10.10. I am hoping Mrs. Rideout will take over the chair, but I have not been able to get in touch with her to ask her to do so.

Mr. MACKASEY: Do you mean just for the day or for all time?

The CHAIRMAN: Just for this morning. If the Committee sits this afternoon, I would expect to be back.

We have with us this morning Smith Kline & French, a drug company from Montreal. I will ask Mr. Daily, the vice president and general manger to introduce his colleagues.

Mr. ROBERT F. DAILY (*Vice President and General Manager, Smith Kline & French*): Thank you, Dr. Harley. I am very pleased to be here with you this morning and, I would like to start the introductions with a gentleman on my right who is Dr. Andrew Moriarity, director our of research and development division, based in our new research laboratory in Senneville, Quebec, who has over-all responsiblity also for our medical department activities; Mr. Alan Dalby our director of marketing: Michael Sheldon, executive assistant; John Martin, director of administration and finance; Ross Bethel, our technical department manager and, last but not least, when the P.M.A.C. was appearing before your Committee, some attention was devoted to the activities of professional service representatives, known in the vernacular as detailmen and, we have with us today our Toronto-based senior representative, Russel Fraser.

With your permission, Mr. Chairman, before getting into our brief, which I believe has been distributed to all Committee members, in both French and English, I would like to read a prepared statement. Our presentation is designed to provide an insight into the workings of Smith Kline & French as the Canadian member of an international pharmaceutical enterprise. It deals in particular with those activities and requirements which most influence our operating costs, and therefore the prices of our products.

I do not propose to summarize the various sections, but I would like to describe in a few words what I believe to be the true function of a company

such as Smith Kline & French. Ours is a research-based operation; we could not exist as a pharmaceutical company without that base. Our task is to develop the findings of research into safe and useful medication, and make this available throughout Canada. At the same time, we must keep physicians fully informed about our products—in the interest both of better medical treatment and of our own business success; you cannot disentangle these two purposes. The prices of our products must compare reasonably with the prices of competitive means of therapy. By this I mean the pharmaceuticals of other research-based houses, not the products of imitating companies with no research commitment and at best only a scanty information commitment. If we are successful in our discovery and choice of products, in our pricing, and in our information and promotion programs, we will be able to earn a fair profit.

The record of company growth during the past 16 years demonstrates, I believe, that we have both fulfilled a useful purpose in Canda and have made a worthwhile contribution to the national economy. In 1950, the year we began business here, sales amounted to $645,000; in 1965 they reached $7,326,000. Investment in fixed assets at cost was valued at the end of 1965 at $3,297,000. We have twice extended our plant and head office building in St. Laurent, a suburb of Montreal and have built a research centre at Senneville also on the Island of Montreal at the cost of $1,700,000. We are about to undertake a further major building program requiring an expenditure of approximately $4,000,000. More than 80 per cent of our revenues have been expended on Canadian goods and services or have been reinvested in this country. Payments to employees account for 35 per cent of our operating expenditures, and of the 300 people we employ 20 per cent are university graduates. I would like to make a few general comments here on our submission. Most of the figures relate to the overall company operation in Canada. Some 75 per cent of our sales come from what are known as ethical pharmaceuticals, that is drugs which are not advertised to the general public. The growth of our other business is a comparatively recent trend, but we expect it to account for an increasing share of total sales. Like many pharmaceutical companies, we see the need for a broader and more diversified base of activity. We believe that the stability this provides will assist us to maintain a long-term pharmaceutical research operation. As quite a large corporation, Smith Kline & French must plan for the long-term.

Our figures deal with the total Canadian operation because this is the only sound way to present the company to you. Efficiency requires the integrated utilization of all human material and financial resources. In many areas of operations it is not possible to provide a reliable breakdown of costs between our various activities. In an operation the size of Smith Kline & French in Canada people can wear several hats, equipment can serve several purposes. For instance, my own time and that of our senior personnel is shared among our various concerns. The market research group will make sales forecasts for both tranquilizers and suntan lotions. The same installations produce both "Dexedrine Spansule" capsules, available only on prescription, and "Contac. C" capsules, a proprietary product advertised to the general public. Our research laboratory fills assignments in the ethical and the proprietary areas. The need to ensure the most efficient utilization of resources has other implications. My

company believes in international investment. We have constructed a substantial manufacturing plant in Canada and also a research laboratory. In both of these we are increasingly engaged in work for our associates in other countries. Last year 7 per cent of our sales revenue came from exports; we manufacture products notably for the Latin American, Japanese and Philippine markets. We are much concerned about the way pharmaceuticals are treated under Canadian patent law. This is partly a question of the legislation, itself, partly of the way it is being interpreted and administered. The P.M.A.C. reviewed this question at some length in its presentation to you, and made certain recommendations. These recommendations we strongly support. We believe that the entire question of compulsory licensing under Section 41 should be reviewed in the light of the safety hazards it can give rise to and also the way it discourages development of a strong, research-based pharmaceutical industry in this country. We would suggest that in contrast Section 67 of the Patent Act can be employed both to check any abuse of pharmaceutical patents, including unreasonable pricing, and to encourage manufacturing in Canada. We believe you will find that Section 41 no longer serves the national interest, if indeed it ever did, and that it should be replaced by a more thoughtful treatment of drug patents.

Direct experience has engendered particularly strong feelings in this regard as far as our company is concerned. Earlier this year the Commissioner of Patents granted, through an order now under appeal, a compulsory licence for trifluoperazine, an important and potent tranquilizer which we market under the name of 'Stelazine'. The licence was granted even though we synthesize trifluoperazine in this country, and even though the applicant, whose published prices are roughly 20 per cent lower than ours, is clearly unable to provide the continuing research and medical information services the public safety would seem to require. Implementation of the Hilliard Committee recommendations would obviate to a very large degree the health hazards which can result from compulsory licensing. However, in one crucial regard—the classification of a product as a "New Drug" if significant new side effects have become associated with it, the Food and Drug Directorate doubts that it has the legal power to take the necessary action. However, the matter is still under study at the directorate I understand, and we hope that some means will be found to implement this most important recommendation of the Hilliard Committee.

We have presented the facts and figures of this situation on page 43 of our brief, and would draw these particularly to your attention.

The figures in our brief were generally based on definitions comparable to those used by P.M.A.C. Naturally enough they did differ in various ways, however, from the average. We discussed in the brief some of the reasons for this. I would like, however, to make one additional comment if I may. The P.M.A.C. brief was a composite picture of the activities of over 40 companies with different product lines and methods of operation and different accounting techniques. Ways of allocating similar expenses may vary considerably from company to company. We would caution against using any particular company's methods or any average picture as an absolute yardstick, particularly in view of the international nature of industry ownership.

Your Committee has been "empowered to consider and recommend, as it may deem expedient, respecting a comprehensive and effective program to reduce the price of drugs". The P.M.A.C. stated its belief that the prices charged for prescription drugs sold by its members are fair and reasonable in view of the quality of the products and the services provided, as well as the general costs of conducting our business in Canada. The P.M.A.C. also made several recommendations bearing on the price of prescription drugs in Canada. We endorse both the association's position and its recommendations.

In common with other organizations, P.M.A.C. recommended the abolition of the Federal sales tax on prescription drugs. I would like to give you my company's assurance that if this tax is removed, we will immediately reduce our prices for the products affected by the related amount.

We strongly support the P.M.A.C. recommendation that some means be developed to provide physicians with more extensive information about the cost of therapy to their patients. However, it is essential that any such information deal with the safety and reliability of the products concerned as well as with their dollar cost. Your own investigations into drug safety, the report of the Hilliard Committee and numerous scientific papers have shown conclusively that the safety and reliability of the drugs he prescribes must be the dominant concern of the physician.

In this connection, we suggest that legislation should be enacted against counterfeit products, a matter which roused your interest and concern earlier in these hearings, and we endorse your previous recommendaton for the publication of Food and Drug Directorate seizures and prosecutions. We would also suggest you study the advantages of having the label of the package received by the patient carry the name of the actual drug product which has been prescribed in such a way that both product and source are clearly defined. In recent years this has been recommended officially by both the British Committee on the Safety of Drugs, known as the Dunlop Committee, and the Council on Drugs of the American Medical Association. I believe just recently the Alberta Medical Association passed a similar resolution.

Finally, I would mention the desire of my company to be able to develop our business as a responsible research-based organization, making a strong contribution to both the health of Canadians and the Canadian economy. We would hope that the recommendations that your Committee makes will foster this kind of growth, which we truly believe best serves the Canadian national interest.

We would also draw your attention to the hazards which can arise from policies or regulations that might hobble the proper development of the pharmaceutical industry. Canadians at present have available medication of the highest quality, and have access to the latest products of international research. A comparatively young industry is continually expanding its investment in both manufacturing and research in Canada. But ours is, and it must be, an international industry, and international companies have to weigh carefully the value of their commitment in Canada against the advantages offered by many other countries. For instance: Should we invest in research in Canada or

Australia? What are the comparative long-term benefits of expansion in Canada or the European Common Market? Is Canada the most suitable base from which to supply certain underdeveloped countries? Economic considerations, scientific manpower, patent and other legislation are all assessed not only for their specific merits and disabilities but also in country-to-country comparisons. Measures that dissuaded the research-based companies from investing in the future in Canada would, we believe, only serve the interests of a handful of copiers and importers, not those of the people of this country.

The CHAIRMAN: Thank you very much, Mr. Daily.

Is it agreed that we will print today's brief as part of today's proceedings?

Some hon. MEMBERS: Agreed.

The CHAIRMAN: We are pleased to have Smith Kline French here. I think there have been many questions of the Committee at times relating to detailmen. We thank you particularly for bringing along Mr. Fraser who is thoroughly competent to answer questions about detailmen in the drug field. The meeting is open for questioning.

Mr. MACLEAN (*Queens*): Mr. Chairman, I would like to take advantage of this opportunity to ask some questions which may seem a bit naive perhaps to professional men but, for the record and for the Committee generally, could you tell us in some detail exactly what are the responsibilities of the detailmen; what are their duties when they call on professional men in the hospitals and so on, and what does the company expect them to do? What are their chief responsibilities?

Mr. DAILY: We seize with alacrity this opportunity to develop our own company's views on this, and I think they coincide with the views that the P.M.A.C. developed for this Committee and made available to it in its submission. I think in one of the appendices—in Appendix "D" as a matter of fact—there is quite a bit on this matter. I think it would be useful to give the Committee our own company's attitudes, you might say, in support of what the association has have already developed for the Committee.

I am wondering if I can ask Mr. Dalby, our Director of Marketing, to commence this discussion. Perhaps he can also draw our senior representative from Toronto into the discussion.

Mr. ALAN J. DALBY (*Director of Marketing, Smith Kline & French*): On page 30 of our brief there is a capsule form of what the representatives do perform with Smith Kline & French. At the bottom it says:

> Representatives perform a dual function: they bring doctors information about our products, and also report back to the company any reactions, favourable or unfavourable, that they hear.

The detail force in Smith Kline French consists of about 28 representatives calling on physicians in private practice; and other representatives, totalling six, call on hospitals—call on physicians in hospitals.

Generally in the morning the detailman calls on pharmacists in a pharmacy and reports to them what they are speaking to the doctors about at that particular time, because during the course of our 12-month year our marketing

through detailmen is divided into eight periods with a six-week cycle in each period.

In the afternoon they call on physicians. Naturally these can number anywhere from three physicians to eight or nine physicians, depending on how busy the physicians are on that particular day and the territory in which the detailman is calling. But, I think to give you an idea of exactly what a detailman does, perhaps, Mr. Fraser could tell you—if there is such a thing as an average day—I do not think there really is—what he would do, from personal experience in one day in his activities.

Mr. RUSSELL A. FRASER (*Senior Hospital Representative, Smith Kline & French*): As Mr. Dalby pointed out there is no average day. But, as I am concerned primarily with the hospital division as against the general office program, my work would primarily consist initially of calling on the chief pharmacist of a hospital; then discussions with the assistant pharmacists associated with this man. I would also be involved with the nursing department relevant to our special services which are available in service education programs for staff. Then, my calls would be on the psychiatric personnel—the medical personnel attached to the treatment program. This would be a fairly average day, although during the course of this day you may be called upon to discuss in detail with auxiliary personnel in the hospital some of our special services. You may be called upon to speak to the nursing group on the role of drug therapy to explain particular problems relative to the administration of our particular drugs. In general, it is a very comprehensive approach to the hospital, both from the medical standpoint and the non-medical standpoint, bringing relevant information about our medications, at a highly technical level with the medical staff and a less technical level with the auxiliary staff.

Mr. MACLEAN (*Queens*): A related question, who actually takes orders from pharmacists for your products, the actual merchandising of your products? Is there a detailman or is this done by mail or have you another set of salesmen?

Mr. DAILY: Mr. MacLean, this question necessarily involves an examination of our distribution methods and I would like Mr. Dalby, again, to handle this one.

Mr. DALBY: Our distribution in Smith Kline and French is handled 100 per cent through wholesalers. This leaves the detailman more time for speaking with physicians. The actual orders are not taken, or very few are taken, by our own detailman when he calls on the pharmacy. However, he can take an order but it is immediately sent to the wholesaler and not to Smith Kline and French in Montreal. It is therefore the wholesale salesman who will call on the pharmacy and write out the order for any S.K.F. stock or the pharmacist in turn can call the wholesaler, which happens a great deal of the time. Of course, each wholesaler in the country has what they call telephone order clerks who are responsible for calling the pharmacist. Usually at a set time each morning, the wholesaler will call the pharmacist and take his order for products.

Mr. MACLEAN (*Queens*): So to your company's merchandising cost there is another cost of distribution which is borne by the wholesale distributor. He too has a sales organization of some sort?

Mr. DALBY: Very definitely. We actually give a discount to the wholesaler to perform this service. This discount is quoted at 16⅔.

Mr. MACLEAN (*Queens*): I would like to ask one more question. The physicians on the committee may be fully aware of this but I am not. When a detailman calls on a physician, generally speaking, are there appointments made ahead, and so on, and how much time is the average physician able to give to a detailman, especially when a new drug—not new in the technical sense of this five year business—is being introduced? Is much effort spent on detailing to physicians the properties of the drug, its side effects and all this sort of thing?

Mr. DALBY: Yes, our detailmen are trained—and again this is spelled out very well in our brief I think—to give a balanced picture. The time taken in the doctor's office, depends on how busy the doctor is on that particular day, how many patients are in the waiting room, and the number of questions he would like to ask. As an example, we have just recently introduced a new product. In fact, it has only been on the market for two weeks. We give the detailman detailing instructions on how he should present this to the doctor, but it never does take exactly that form of presentation because there is, I think, a two-way street between the physician and the detailman and this can last anywhere from three minutes to seven or eight minutes, a one product detail. But again, it depends on the doctor and it depends on his day.

Mr. MACLEAN (*Queens*): Just one more supplementary question; in general terms, what are the qualifications of your detailmen, their formal training and so on?

Mr. DALBY: Again, this is spelled out in our brief. It is a decided advantage for the detailman to have a university education. We do not demand this as being absolutely essential because we do have a training program as shown on page 31 in the last paragraph, which reads: "Training is a continuing activity..." In relation to the representative, I go back to the preceding paragraph, his education is obviously important, "...experience, personality and character must all be considered". But the training is a continuing activity. We have a full-time lecturer on our staff, and the new representative receives three weeks of training before he calls on the physician and he works for at least one week under direct supervision. Also, during his first six months he must complete a special course of home studies. These deal with the medical and scientific background to our products as well as the products themselves. So training and education are continuing month by month.

Mr. DAILY: I think it might be important at this point to indicate that the role of a professional service representative is not by any means just a one-way street. As Dr. Moriarity who is the physician responsible for our research program and also medical department activities, will testify, much valuable information is received from physicians via the professional service representative regarding treatment of patients with our products, which aids him in assessing and co-ordinating the on-going clinical program concerning our drugs.

Dr. ANDREW J. MORIARITY (*Director of Research and Development, Smith Kline & French*): I do not want to get into the details of clinical testing at the moment except perhaps as it relates to our marketing division. But, as Mr.

Daily said, detailing is a two-way street, and the most important single aspect of this from the point of view of the medical department is the feed back that we get, especially from the negative report form. This check with side effects and problems with drugs in the field. Perhaps we could get into it later but Mr. Fraser knows this form very well. When a physician calls to the attention of our professional service representative a problem with the drug, a side effect or a toxicity, we have a very detailed self-addressed form. But first of all the representative gives as much immediate information as he can; if it is urgent the two of them get on the telephone together and call us in Montreal. We have a 24 hour telephone service by our Montreal office for problems with drugs. The thing that we really like, though, when it is not urgent, is to get essentially a complete medical history so we have a large comprehensive form that is filled out and signed by the doctor with as much detail as possible in it. This is a self-addressed form that comes back to our medical department in Montreal.

In turn, as you are all aware, when a new drug is involved this helps us comply with the food and drug requirements on side effect reporting. Within I believe it is 10 or 15 days we process this, get additional information and forward it on to the Food and Drug Directorate in Ottawa.

Mr. MACDONALD (*Prince*): Mr. Chairman, may I ask a supplementary with regard to that form. How many forms will you receive related, perhaps, to the new drug you mentioned you had put on the market? What I am trying to find out is if there are many doctors that would take the time and trouble to get out that form.

Dr. MORIARITY: By far most of the comments are related to conditions of usage. "Would you clarify this for me? Can the drug really be used in this indication? Why do you not allow it to be used in another indication?" By and large these are handled, we hope not exclusively but largely, by the professional service representative, who is aware of all these things. We have a series of lectures and a comprehensive detail training program for the professional service people, prior to the introduction of any major new product. This type of form which is detailed and is difficult, and takes the physicians time to fill out, is largely reserved for a specific side effect or toxicity problem.

Mr. MACDONALD (*Prince*): Do you get many of these forms being returned?

Dr. MORIARITY: I honestly do not know the figure at the moment but they certainly are in the hundreds every year. The answer is yes. In our particular case, according to the law, only where it is a new drug do we have to forward these—essentially it is a copy of this same form—to the Food and Drug Directorate. In the case of old drugs this is not required by law but we forward them anyhow to the Food and Drug Directorate.

Mr. MACLEAN (*Queens*): With regard to your detailmen, I had already seen in the brief where most of them are university graduates, but are they men who specialized in chemistry or pharmacy or a mixture of both, or what is their university training, in general terms?

Mr. DAILY: I think we would like, Mr. MacLean, the ideal situation to prevail whereby all of our professional service representatives were college graduates who had scientific degrees. Of course, this does not necessarily mean

that such an individual is going to be the best representative for Smith Kline and French. In actual practice, because of the limitations of skilled people of this kind, we do have a mixture. Maybe Mr. Dalby would care to comment further on that.

Mr. DALBY: I was just going to say that this would be ideal but the training program, we think, helps to take care of this.

Mr. MACLEAN (*Queens*): I have one other question which does not relate to prescription drugs. In your presentation I think you said the company was expanding its efforts with regard to non-prescription preparations of various kinds. In regard to the advertising of such preparations—I am not thinking of your company in particular, at all—is a contract given to an advertising agency and are they turned loose to sell as much of the product as possible; what are the ethics of the advertising? I am thinking of television advertising, particularly for so-called patent medicines. It seems to me that most of it is geared to such a low intelligence of audience, or it is so generally ridiculous and repulsive in some cases that my only reaction when I see the commercial, if I make a mental note of it at all, is to never buy the stuff consciously. Is there a general practice in this field of the producing company specifying the type of advertising they want or do they control it in any way?

Mr. DAILY: I guess with your permission, Mr. Chairman, we had better put our proprietary hat on. You were correct in saying we have expanded into a related but different field of drugs. The consumer product division of Smith Kline and French is called Menley & James. To answer your question, I think we have stated objectives ourselves which were pretty clearly outlined when we entered this field because of our concern about public well-being and about the quality of our product, both in terms of the product quality as well as the quality of the message that we present to physicians as well as to the consumer. We quite naturally were pretty zealous, you might say, when we entered this field, about how we were going to conduct this business. I think Mr. Dalby who was instrumental in organizing our consumer division is perhaps better qualified to speak on these stated objectives.

Mr. DALBY: First of all, we have absolute control over all advertising. Second, all broadcast advertising is approved by the Department of National Health and Welfare, the Board of Broadcast Governors and in fact, the C.B.C. Furthermore, the marketing manager of our proprietary area is an eight-year employee with Smith Kline & French, speaking of the ethical side, and has only recently been moved into the proprietary side of our business. The sales manager of our proprietary division, which we call Menley & James, was eight years a detailman with Smith Kline & French. The brand manager responsible for contact worked for two and a half years detailing our ethical products in Saskatchewan. I think this perhaps answers the question, does it?

Mr. MACLEAN (*Queens*): What you are saying is that you are concerned with having your advertising of an ethical nature?

Mr. DALBY: Very much so.

Mr. MACLEAN (*Queens*): I will pass, I have taken enough time.

Mr. JOHNSTON: In your preliminary remarks, you make a suggestion on page 7 that we study the advantages of having the label of the package received by the patient carry the name of the actual drug product so that both products and source are clearly defined. Would there not be a safety factor involved here, not only for the convenience of the user but for the guidance of the doctor in case of an accidental overdose. Is this part of your concern?

Mr. DALBY: That is certainly part of the concern. I should not suggest this is an uncontroversial question because, and I am sure our doctor friends will agree, in many cases it is possibly better for the patient not to be aware of the medication he is taking. However, because there has been an increasing emphasis in recent years, brought about by the introduction of newer and more potent drug therapy, I think that these medical groups I mentioned in England, the United States and more recently in Canada, have felt that the advantages of having clearly stated on the label what the product name is and the source of the product outweigh the other advantages of, perhaps, preserving product anonimity in so far as the patient is concerned.

Mr. JOHNSTON: Do you see it as part of the manufacturer's task then to do this, and could it be done through the manufacturer packaging the drugs in the size of normal prescription as I believe is done in some European countries? Would this not be one way of reducing the cost of drugs, by having the manufacturer take over this area and send drugs out in those sizes?

Mr. DAILY: An answer to that would be purely speculative. It is true that in some European countries, and I think this has been brought before the Committee in previous presentations, it has either been by custom or by law the practice for prescription drugs to be made available in their original containers, and, as I understand it, the pharmacist is obliged to dispense the medication without interfering with the label or the seal of the container. Whether or not this would have an effect on the cost of drugs, I think there are pros and cons on this question. Certainly, it could help standardize the production runs but, on the other hand, because of the availability of the product in a smaller container, it might tend to increase the unit cost also as opposed to having the product available in bulk sizes for dispensing purposes.

Mr. JOHNSTON: Somebody has to pay for the bottle and the changeover from bulk to small size eventually anyway.

Dr. MORIARITY: From the point of view of emergency identification of products, I think, as perhaps all of us are aware, there have been a number of attempts made. I think other companies do the same, but, for instance, all our products are colour-coded and identified. An S.K.&F. monogram is on it and, where there are a number of dosage sizes, the actual amount of the drug in the tablet is monogrammed on as well. For instance the 2 milligram Stelazine tablet is a particular shade of blue that is readily identified except perhaps where counterfeit drugs are involved, but it is readily identified as S.K.&F with number 2 standing for two milligrams. The Eli Lilly Company has recently come out with another procedure whereby each individual dosage unit would be coded and, therefore, the poison control centre and other agencies that become involved in such things could very readily identify, in the case of an overdosage, what the patient had taken.

Mr. JOHNSTON: Provided some were left, I suppose.

Dr. MORIARITY: Provided some were left, yes.

Mr. JOHNSTON: Would you prefer to do this naming rather than that it be done after the product had left your hands or your control?

Mr. DAILY: I think that from our point of view this could be easily done, and we would certainly not be against a move in this direction. However, it is something that is going to take time to evolve because I think that we have to admit that there is physician, as well as pharmacy, resistance in some quarters to this type of program. From a practical point of view, I think it would be easier to institute by having, first of all, the prescription label itself identified with the name and source of the product.

The ACTING CHAIRMAN (*Mrs. Rideout*): Have you finished, Mr. Johnston?

Mr. JOHNSTON: Yes.

The ACTING CHAIRMAN: You are next, Dr. Brand.

Mr. BRAND: Thank you, Madame Chairman. There are several areas you went into here, but before I go into these, I have a couple of questions. You were talking with Mr. Johnston about prepackaging and whether it was cheaper or not. Is it not a fact that many companies already have prepackaging.

I can think particularly of such things as ointments and cream—certainly eye ointments with which I am concerned today; also certain antibiotics such as the Frosst company puts out in their 60cc bottles, which are prepackaged in the factory. Referring to some of the ointments, would it not be cheaper to put them out in bulk and re-dispense them at the pharmacy rather than pre-packaging them at the factory?

Mr. DAILY: I do not think we have had any real direct experience in this area.

Mr. DALBY: Yes, this is correct. Here we are not really talking about prepackaging but rather pre-labelling.

Mr. BRAND: No. Prepackaging is what I am talking about. I am referring to where you package at the factory, at the manufacturing level. It is put in a bottle and this bottle is sent out and the same bottle is used to give to the person who buys the prescription. That is prepackaging in the way I understand it.

Mr. DALBY: That is correct. This is carried out, in the case of most of the ointments, and many of the antibiotic preparations for children, particularly the liquids. It is all prepackaged. But I do know that in the case of cortisone or hydrocortisone ointments, particularly the druggist buys it in bulk in certain instances and dispenses in his own little jars as the person wishes. It is actually cheaper that way, for the pharmacist to buy in bulk rather than the other way around, as Mr. Johnston was suggesting.

Mr. BRAND: I know your company does not deal in these.

Mr. DAILY: I think this is the point, that our experience is confined to producing a standard line of package sizes and, generally speaking, when we introduce a new product. We try to assess the average prescription size by

market research investigations. We try to confine our package size so far as possible to that size for a number of reasons, including the fact that it would perhaps enable the pharmacist in turn, to dispense it to the consumer which perhaps would have a salutory effect on the end prescription price of a product.

Mr. BRAND: The point I was trying to make, of course was that it depends entirely on the type of product, whether this is feasible or desirable. However, you did mention, Mr. Daily, I believe in your presentation to us today, that you were concerned about the counterfeiting, and that was brought up before. Counterfeiting is quite a strong term. Are you referring to the "look alike" capsules or pills which have been produced by some of the generic manufacturers?

Mr. DAILY: By counterfeiting, I would describe the concern we have by saying yes, definitely, the products that have been bothering us in recent years are the "look alike" products—not only the products that are designed to a popular formula, you might say, since after all this is a competitive society we are living in, and even though we as the originating manufacturer, may not like it, in time, any invention becomes copied. We would hope that the copying, however, takes place in a way which helps to protect the research investment of the manufacturer. Unfortunately, under the present administration, there is section 41(3), and these considerations seem to be gravely undermined. But what is referred to as counterfeiting or "look alikes" goes beyond just copying the formula. This is I think, where the question of deception arises, because the manufacturer or the copier or the imitator goes to the extent of not only copying the formula but also imitating the distinctive characteristics of the product so that when you put the two products side by side—perhaps later on we can show you what I have in mind through a visual display—it is difficult for the unsuspecting consumer or even the unsuspecting pharmacist to differentiate between the two.

Mr. BRAND: To save a little time and to make it a little easier for you, your reference to counterfeiting then in Appendix "B" of your brief is the same idea as in the Public Law 89-74 of the 89th Congress.

Mr. DAILY: That is correct. We, as well as the government of the United States, have considered, after studying the situation, that this is a practice which is dangerous to the public health and safety. In Appendix "B" the Congressional Act which, I believe, was instituted in 1965, does specifically fit this practice and establishes control over it so that the government can take appropriate action. Unfortunately, as I understand it, our Food and Drug Directorate in Canada does not have responsibility which extends to this area. It is primarily concerned with the labelling of a product, and when it comes to a question of dealing with a product which may copy the physical characteristics of an original product and be used in trade in such a way that it is substituted on prescription for the original product, this is something that so far as I can determine our Food and Drug Act does not have strong enough control over.

Mr. BRAND: What you are suggesting then, I presume, is that you would like to see a similar type of provision enacted in our laws to take care of this type of circumstance.

Mr. DAILY: Yes, Dr. Brand, this was put forward as an example of something that could be done.

Mr. BRAND: You mentioned that later on you might have a display. What did you mean by later on?

Mr. DAILY: Perhaps this is an appropriate time for Mr. Bethel, our technical department manager, to show the display.

Mr. BRAND: Well, if you could pass it around, members could look at it while I ask a few questions. I do not want to take up too much time of the committee.

You seem to spend quite a bit of time—and in your brief certainly some very strong statements were made—concerning this matter of compulsory licensing, particularly on pages 42, 43 and 44. I get the impression, correct me if I am wrong, from this brief that you feel that the one company, Mowatt and Moore, has done a fairly good job of reproducing trifluoperazine whereas Paul Maney does not seem to. Is this correct?

Mr. DAILY: Dr. Brand, let me give you a little background on this.

We have established certain terms and standards in a licensed agreement that we approved with the Mowatt and Moore Company which we feel enables the Mowatt and Moore brand of trifluoperazine to meet these high standards which we have established and which, you might say parallel our own product standard. However, in the case of the other company you have mentioned, we have no control over the terms or the standards of manufacture as well as the distribution of this drug because as you say, it was a compulsory licence. We were not able to come to agreement with this other company, and, as a result, this was what lead to the Hilliard committee's investigation of the whole area of compulsory licensing as it applies to the standards of quality of a product issued under the licence.

Mr. BRAND: You make some rather serious charges here. You say, for example, on page 44 "a patient taking Paul Maney trifluoperazine tablets may thus suddenly receive a 20 per cent increase or decrease in dosage, besides receiving an average 16 per cent less of the drug than if he were taking 'stelazine' ", which is your brand name for the same product. Can you back up these statements by assays—this is the point—and not just make a statement?

Mr. DAILY: Obviously, any statement such as this was an outgrowth of chemical assays in our own laboratories, and I would like to ask Mr. Bethel who has had intimate experience in this whole area of dealing with counterfeiting, compulsory licensed products and so on from a chemical assay point of view, to give us some insight into this matter.

Mr. BETHEL: Yes, I believe I can give you examples, Dr. Brand, of the type of thing to which you refer.

Mr. BRAND: Could you tell us first where these assays were done?

Mr. BETHEL: We have done assays, in our own control laboratories in Montreal. We have also had assays performed by an independent testing laboratory in Montreal.

Mr. BRAND: Can you mention this particular laboratory? I am used to watching television where there is always a sign which says an independent laboratory has done such and such, but I do not know who they are.

Mr. BETHEL: I doubt that you have seen this particular laboratory on television. They are certainly a nationally known laboratory. It is the Warnock Hersey Company. I can perhaps give you a a few examples of why we feel as we do.

First of all, there is a difference in our product, stelazine and in trifluoperazine tablets as they have appeared in the British Pharmacopoeia. Trifluoperazine was introduced by Smith Kline & French about 1958, and since then we believe we have established a market standard for this drug. A drug may be used in different dosage forms and the nature of the basic chemical of a basic drug may vary depending on the dosage form. The basic drug is referred to simply as that, the base form. You may have salt forms, which—I am sure you are well aware of this, change the physical characteristics of the drug so that you may prepare it in different dosage forms.

In the case of trifluoperazine, we state our dosage, our potency in terms of the base. In other words, a 5 milligram stelazine tablet contains 5 milligrams of trifluoperazine base. The British Pharmacopoeia, perhaps unfortunately, uses the hydrochloride salt as the term of reference so that a 5 milligram trifluoperazine tablet, according to the British Pharmacopoeia is going to contain approximately 15 per cent less active drug because the hydrochloride salt contains roughly 85 per cent of the base form.

Mr. BRAND: Do you have any comparisons of the clinical efficacy of the trifluoperazine and the trifluoperazine hydrochloric salt.

Mr. BETHEL: My role is strictly in the quality control laboratory. May I defer this question to Dr. Moriarity?

Dr. MORIARITY: I am sorry but I do not get the full significance of your question.

Mr. BRAND: Let us put it this way. Is there any difference in the effect on the patient of either of these drugs?

Dr. MORIARITY: You mean the two brand names?

Mr. BRAND: Yes.

Dr. MORIARITY: Again, we have not run a control comparison, and I do not know of anybody who has. To our knowledge, clinical data of this type has not been presented to the Food and Drug Directorate and, of course, one of the really disconcerting things is that information of this sort is not required to be reported to the Food and Drug Directorate before the drug can be marketed. I do not want to repeat much of what you have heard already from other sources with regard to the Hilliard Committee recommendations and differences between new drugs and old drugs, but from the point of view of a professional medical man in the pharmaceutical industry, the really disconcerting part about the compulsory licensing procedure is the fact that the patent commissioner is concerned solely with the chemical synthesis part of it and not concerned about safety or efficacy. The Food and Drug Directorate, of course, is charged with the safety and efficacy of all drugs but the really tight controls relate only to new drugs or so-called new drugs.

Again, our good friends at the Food and Drug Directorate are as concerned as we are about many of these points, but the key to the thing is that their

hands are largely tied. When a drug—there are other criteria but I believe it is fair to say that this is the chief one—is finally recognized by an official pharmacopoeia—and we should at this stage of the game acknowledge the fact that there is no Canadian pharmacopoeia that is official in Canada—when it is so recognized perhaps under different clinical or market circumstances in other countries, say by the British Pharmacopoeia or the U.S. Pharmacopoeia it—by and large, becomes an old drug in Canada. What this means, again, from the medical safety point of view is very disconcerting.

I will very briefly summarize the question for you—you have heard it before—and I will use the example, trifluoperazine. When trifluoperazine was a new drug we, of course, did all of the initial clinical testing and had market experience on millions of patients, but we were made, by regulation, to satisfy the Food and Drug Directorate that we knew how to synthesize it, and that the drug was, in fact, effective and safe in human beings, in Canadian patients as well as elsewhere; that we then knew how to make it and to make it consistently, that our tablets from batch to batch, from day to day, and from year to year were, in fact, the same drug.

Any changes that we made in manufacturing procedure or in labelling; any changes in clinical experience—if a serious side effect was brought to our attention—we were forced by regulation, and would in fact want, to report to the Food and Drug Directorate. Any labelling errors—God forbid that —somehow a wrong label got on a bottle, are reportable, if it is a new drug, to the Food and Drug Directorate immediately—not just 10 days or 15 days hence, but immediately.

Any failure to meet our new drug standards, namely the standards by which we arrived on the market, the standards with which we initially satisfied the Food and Drug Directorate with regard to manufacturing or clinical, is reportable. If a drug fails to work in the clinic it means that we have failed to meet our new drug standards, because our new drug standards show that at that time the drug did work and was, in fact, effective. Any failure to meet these new drug standards or any unexpected toxicity or any new thing we find in the laboratory with regard to animal work, we have to report to the Food and Drug Directorate within 15 days, so long as the drug is a new drug. This is essentially how it works in Canada as of the moment.

If the drug is published in a pharmacopoeia—as I said, it cannot be a Canadian pharmacopoeia because we do not have one—it essentially becomes and has to be declared no longer a new drug, and this means that it is subject only to the general manufacturing controls of the new drug regulations. This means that the company has to have adequate standards of housekeeping and sanitation—he has to keep his place clean. He has to have a control laboratory, although the definition of this is not really very clear. He has to do stability tests and he has to keep information in his records relating to the quality of the hazards of his drug for five years. There is absolutely no requirement for reporting to the Food and Drug Directorate if he sticks the wrong label on the package or if he makes a mistake. There is no requirement for side effect reporting. If he has a death reported to him from his particular product, under the regulations as they stand now with regard to a drug which is no longer a new drug, he does not have to report this to the Food and Drug Directorate.

The only control on him—and this is in a somewhat round-about fashion; time it is not contained in the general manufacturing directions but in the Food and Drug Act itself—is that where a pharmaceutical standard has been established—and with regard to trifluoperazine, the example we are using today, this happens to be the monogram in the British pharmacopoeia—the product which the manufacturer puts out has to meet these standards. The obvious point is that these standards are nowhere near as restrictive or demanding as the standards that, in this case, the company itself helped define with the Food and Drug Directorate when the drug was a new drug.

Our problem, with regard to compulsory licensing, is that the patent commissioner reviews a drug largely only from the point of view of the legal aspects, and the Food and Drug Directorate, if it is no longer a new drug, cannot use the new drug regulations in order to control the distribution of that particular drug product. As you heard from our marketing division earlier, in addition to just supplying good drugs, we feel that it is our responsibility to at least get the basic directions in the hands of the physicians as to how to use these drugs. Here again, there is a tremendous difference discernible because in the case of a drug that is no longer new there is no requirement for a physician's brochure.

In this particular case, the example of the other company which is now manufacturing trifluoperazine, there is a small brochure which is distributed with the package now, but by our standards this is completely inadequate. If trifluoperazine were still a new drug, this would be completely inadequate. As an example—and I have some copies of this which I would like to show the physicians later—you can see this Smith Kline & French description of stelazine in the *Vademecum International*; all the underlined portions of the description are not contained in the circular of the competitive product.

I believe, Dr. Brand, much of this came to a head as a result of comments which your predecessor made in the House of Commons. At that time she raised some specific questions—and this is Dr. Jones—with regard to the safety of this type of therapy. She raised questions with regard to pigmentation and certain other side effects that resulted from long-term use. These are given in detail in Smith, Kline & French's description of the product but they are not even mentioned in the Paul Maney description of the product.

This is why at least I, as a physician, am disenchanted with the compulsory licensing procedure as it presently exists in Canada. Much of this would be corrected—and again it is not my intention to read back the Hilliard Committee report to you—if the Food and Drug Directorate had the legal capability, where indicated, for instance if something new or unexpected side effects occurred with any product of being able to reclassify this as a new drug, so it would then become subject to the demanding requirements of the "new drug" portion of the regulations.

Mr. MACKASEY: May I ask Dr. Moriarity a question, at this moment?

Do you not think that the public interest would be better served because of the peculiar and particular nature of the drug industry, if the request for a compulsory licence be submitted to a tribunal rather than having only a representative of the legal side of it? I am thinking of a tribunal set up naturally with the legal side of it being covered, but also with a representative

from the Food and Drug Directorate. It seems to me we cannot divorce the two problems. I think this is what the Hilliard report was saying. Do you have any comment on that?

Dr. MORIARITY: I am not qualified to discuss the legal technicalities of it, but the crucial issue, of course, is that the patent commissioner and the Food and Drug Directorate get together.

Mr. MACKASEY: I think they get together voluntarily, according to the Hilliard report; at least the Hilliard report mentions the close co-operation between the two bodies. But it seems to me that, as a matter of course, it should now be law that the case for the granting of a compulsory licence should be submitted not only to the patent office but, at the same time, to representatives of the Food and Drug Directorate who cannot divorce it from the over-all problem. I think this is what we are all saying.

Dr. MORIARITY: I agree completely.

Mr. DAILY: John Martin, would you care to comment on this? The reason I am bring Mr. Martin into the picture, Mr. Mackasey, is that he has worried about this whole question from a legal and control point of view for some months now. I think he could throw some lucid commentary on the whole issue.

Mr. John C. MARTIN (*Director of Administration and Finance, Smith Kline & French*): I was just thinking that a direct answer to your question might be useful here, Mr. Mackasey, in connection with the possibility of a tribunal, which is one of the suggestions which has been made. I think the position of our company would be that there should not be compulsory licensing at all, and this is obvious. But if there were compulsory licensing and if it were considered necessary in the public interest, a properly constituted tribunal would certainly be a great improvement over what we have at the moment. In addition to the medical, the food and drug, and the patent and legal aspects, I think it would be essential that there should be an economic representation on such a tribunal.

The ACTING CHAIRMAN (*Mrs. Rideout*): Dr. Brand, have you finished?

Mr. BRAND: I just want to finish this off. Perhaps the examples of the assays, with your permission, Madam Chairman, could be included in today's report. We will need a motion for this. I think it is important we see the assays and have on the record the differences between presumably the same drug manufactured by two different firms and the differences in the content of the actual drug in the pills.

Mr. Ross F. BETHEL (*Technical Manager, Smith Kline & French*): Perhaps I can give you verbally, first of all, an example of what we have found. I think this will best illustrate my concern as a quality control man. For example, approximately last May we tested two lots of these tablets in our own laboratory and found that they contained, on the average, about 84 per cent potency by our standards. I think this is obviously low.

In mid-summer we had occasion to test three more lots and we found that they ran about 93 per cent potency in terms of the base, which is a little low, and this means about 110 per cent potency in terms of the salt, which is a little on the high side. It seems to me that they were trying to straddle the two definitions of potency here.

Then somewhat later we tested a further lot and we found that this averaged 102 per cent in terms of the base and 120 per cent in terms of the salt. To me as a control man this is not a good situation, because the only inference I can draw is that really they do not appreciate the technicalities of formulating with drugs of this nature.

Mr. BRAND: When you test your own drugs, what per cent of variation do you allow?

Mr. BETHEL: Our standard for our Stelazine tablets is not less than 95 per cent nor more than 105 per cent of stated label potency.

Mr. ORLIKOW: There is not much difference between 95 and 93, is there?

Mr. BETHEL: No, there is not but the point I was making is that they have run the gamut of potency all the way from 85 per cent to 120 per cent, and we are not sure if they have established a standard as yet or not.

Mr. MACDONALD (*Prince*): May I ask a supplementary question at this point? Does the potency of a product vary with the light and time it is standing on a shelf?

Mr. BETHEL: This is a difficult question on which to generalize. Certainly the stability of drugs is highly important and, if I can generalize to a degree, my answer would be that the potency tends to drop with age. This may be due to gradual decomposition of the drug itself, changes due to storage conditions, temperature, humidity and so forth.

Mr. MACDONALD (*Prince*): What I was really trying to ask is whether or not it would be difficult to take a drug of another firm, perhaps not knowing under what conditions or for how long the drug has been stored since its manufacture, and then try to assess it against a drug which you yourself produced when you know when it was produced and under what conditions you stored the drug. I would be impressed by these figures more, I think, if an independent source had been able to acquire a drug of a comparable nature from different firms and then came up with some kind of an over-all report of the situation.

Mr. BETHEL: We have no way, of course, of knowing the actual age of these competitive products. We have, however, had our product and the competitive product tested by an independent laboratory at the same time. We do not know the age, of course, of the competitive product.

Dr. MORIARITY: But in the development of a new product, if we are not satisfied we go through essentially all the accelerated stability testing and shelf life stability testing, and we would not be satisfied in putting out a new product unless we were sure that it would stay within Mr. Bethel's limits for, at least, two years.

Mr. MACDONALD (*Prince*): 95 per cent to 105 per cent?

Dr. MORIARITY: That is right, 95 per cent to 105 per cent.

Mr. MARTIN: I think there is no reason to suspect these figures which Mr. Bethel has been discussing in that this particular licence was only granted on June 21 of this year, so the products cannot have suffered too much from age.

The Acting CHAIRMAN (*Mrs. Rideout*): Dr. Brand, are you still interested in having that material appended to today's proceedings?

Mr. BRAND: Yes. But he put a lot of it on the record and this may be sufficient. Is there anything else significant that you have not put on the record, sir?

Mr. BETHEL: I have another one here. I might save the time of the committee by having it included as an appendix to today's report. I can present this in written form to the committee.

The ACTING CHAIRMAN (*Mrs. Rideout*): Is it agreed that we include this material as an appendix to today's proceedings.

Some hon. MEMBERS: Agreed.

Mr. MACKASEY: Perhaps, Madam Chairman, at the same time, we may write the company in question and ask them if they would like to offer a rebuttal to the evidence, which we could also append at the same time?

Mr. BRAND: Yes, that would be fine?

The ACTING CHAIRMAN (*Mrs. Rideout*): Is that agreed?

Some hon. MEMBERS: Agreed.

Mr. MACKASEY: Do you have with you an annual statement of your Canadian firm because your balance sheet here is spread right through? I think we should have a comparison.

Mr. DAILY: Mr. Mackasey, we, like many companies in Canada, do not publish, for public consumption, an annual report. We have an annual report of our worldwide operation that we could table with the committee, but beyond what we have divulged in our brief here—Mr. Martin I am sure, could answer some specific questions about our financial operations which may or may not be included—we do not have any annual report.

Mr. MACKASEY: Is there any reason why you do not have an annual report?

Mr. DAILY: For publication purposes?

Mr. MACKASEY: Yes.

Mr. DAILY: Perhaps Mr. Martin can better answer this question, as a financial man but, generally speaking, it is because we are not a public company in Canada.

Mr. MACKASEY: Do you wish to comment further on that?

Mr. MARTIN: I think that is true, Mr. Mackasey. If we were a public company I think we would take a great deal more care with our accounts and a great deal more care with the way they are presented than we actually do, as a relatively small subsidiary company.

I think with Mr. Daily's permission, we might be well prepared to provide to Mr. Blakely, in confidence, all the information he wishes; but apart from that, I think, any information which we give—and we have thought about this question fairly carefully—we would like to give with whatever explanations we feel are appropriate.

Mr. MACKASEY: Mr. Martin, as a financial man I presume you are a chartered accountant or better would you be satisfied that the figures in here

are a true picture of the operation of the Canadian subsidiary of this international firm? Would you be satisfied as a student of accountancy, we will say, to piece all this together and get a true picture? Do you think the picture would be a true one, or do you think there are many gaps here?

Mr. MARTIN: I think there are some gaps in it, Mr. Mackasey. As I said a few moments ago, as a young company and as a subsidiary company we have an accounting system which is not what a public company would have. I think some of the figures we have given here do require some explanation.

Mr. MACKASEY: Mr. Martin, what does the fact you are a young company have to do with the question I have just asked you? Surely you are not groping for a format? Why is the fact that you are a young company an excuse for the fact that there is only partial information in the brief?

Mr. MARTIN: For example, sir, a more mature company might have an inter-company charge for research. Whether it is that our parent company does not feel that this is relevant to our particular operation, I do not know. Certainly it does tend, in my estimation, to influence the figures we have shown here—that kind of lack.

Mr. MACKASEY: In other words, you feel there is a lack of information here?

Mr. MARTIN: There are certain things that we do not do in our accounting in Canada which, as a public company, we might.

Mr. MACKASEY: Let me put it this way. Are there certain things you do not do which you would do if you were an all-Canadian company whether you are a public company or not?

Mr. MARTIN: Do you mean by an all-Canadian company, owned by Canadians?

Mr. MACKASEY: Not only owned but not within the influence, let us say, of a head office?

Mr. MARTIN: If we were not within the influence of a head office elsewhere I feel that our figures would be different.

Mr. MACKASEY: Different in what way?

Mr. MARTIN: Our expenses would be higher in a number of respects.

Mr. MACKASEY: Would they be lower in others?

Mr. MARTIN: No; I cannot think of any in which they would be lower.

Mr. MACKASEY: In other words, it would not reflect in lower prices of drugs?

Mr. MARTIN: No.

Mr. MACKASEY: On page 4, perhaps, Mr. Martin—you may excuse me, Mr. Daily if I direct my questions to Mr. Martin—in view of the fact that we do not have more detailed information, might explain the first paragraph under the table which states: "Inter-company service charges, included as part of the cost of general administration, amount to approximately $500,000 on an annual basis." How is this $500,000 arrived at; is it an annual fee? Is it always $500,000?

Mr. MARTIN: No, sir, there is a management group at our head office which looks after the international affairs of all the worldwide companies and their expense is divided among the various companies on a sales basis.

Mr. MACKASEY: In other words, the $500,000 is tied directly into sales?

Mr. MARTIN: Yes, sir.

Mr. MACKASEY: And not into actual expenses of the company?

Mr. MARTIN: No, sir.

Mr. MACKASEY: In addition to this $500,000, last year there was $153,000 earnings remitted to the parent company. Is this just a surplus after the earnings retained in Canada?

Mr. MARTIN: That is right.

Mr. MACKASEY: To what use were these earnings retained in Canada put to, since you are not a public company?

Mr. MARTIN: They were used in the general expansion of our business.

Mr. MACKASEY: In other words, would this $500,000 be a share of management fees outside the country?

Mr. MARTIN: Yes.

Mr. MACKASEY: In other words, you differ in this respect from other firms who have been here, who, in answering the same question, state that they have no administration cost outside the country, that their moneys were going strictly for research.

Mr. MARTIN: This charge is definitely based upon management services, which we receive from outside the country.

Mr. MACKASEY: Is there an additional charge beyond the $500,000 for your research that is being done in some central area outside of Canada?

Mr. MARTIN: No, sir.

Mr. DAILY: All of the research money we show here, Mr. Mackasey, is spent in Canada. There are no royalties, there are no service charges paid to our parent company.

Mr. MACKASEY: Is that the $534,000 shown on page 4?

Mr. DAILY: Yes. While we do get the benefit of the international research efforts, which present us, in Canada, with product discoveries and so forth, it is our particular company's accounting system which—

Mr. MACKASEY: What do you get in return for the $500,000, Mr. Daily, that goes out of the country? What are you getting in return in your Canadian subsidiary?

Mr. DAILY: Will you repeat that?

Mr. MACKASEY: The $500,000, since it has nothing to do with—

Mr. DAILY: We are making payment for services rendered.

Mr. MACKASEY: What type of services?

Mr. DAILY: In our parent company, we have a wide variety of corporate services, we have a medical department—perhaps a better description of that

would be a science information department—which accumulates scientific data from around the world, places it on computers and provides us with pertinent information about the therapeutic uses of our drugs whenever we require it. We obviously have financial services down there, to look after my salary, and a few other people's salaries around the world. We have a broad range of services over every area of our operations.

Mr. MACKASEY: Is your salary, as president of a leading operation, then, paid by the international office?

Mr. DAILY: No; it is paid out of our Canadian operation, but I presume my boss worries now and then whether I am being paid properly in the light of services rendered.

Mr. MACKASEY: Too much or too little?

This $500,000 simply intrigues me. It seems to be an abnormally high ratio of the part of the balance sheet that I have been able to piece together. This is why I would like a bit more detail. You say corporate services, such as information gathered all around the world and transmitted I imagine...

Mr. DAILY: That is only one example.

Mr. MACKASEY: What are others?

Mr. DAILY: Any international corporation, obviously, when it is responsible for developing, producing and marketing products in every country of the world, has a heavy overhead. This overhead, as Mr. Martin has indicated, is distributed in a way which prorates it according to the sales of the companies in the countries concerned. It just so happens that our share of this, as I understand it, works out to be $500,000.

Mr. MARTIN: In that particular year.

Mr. MACKASEY: It is tied into sales, even though some of the sales are generated perhaps by items that you manufacture entirely in Canada?

Mr. MARTIN: In fact, we manufacture most of our items in Canada.

Mr. DAILY: Mr. Mackasey, this type of service charge is something which is common to every company and every international organization doing business.

Mr. MACKASEY: I am not presuming there is anything wrong with it, Mr. Daily. I am just asking for more information on it, because $500,000 is such a nice round figure.

Mr. DAILY: It was arrived at in consultation, I understand, with the tax authorities.

Mr. MARTIN: The figure was not, but the principle of the charge was certainly arrived at in consultation with the tax authorities, and so far it has been made every year of our operation and has never been questioned.

Mr. MACKASEY: In other words, you can tie in this $500,000 in a particular year and this is not taxable by the Canadian government?

Mr. MARTIN: If it is a deductible item.

Mr. MACKASEY: I imagine eventually you will have to pay tax on this $500,000 to someone in the world, otherwise it would be to Utopia. You must pay it to someone.

Mr. MARTIN: I cannot quite understand the question.

Mr. MACKASEY: You are permitted by the Canadian Department of Revenue to send $500,000 out of the country, in this particular year, to head office, or, as you call it, the international office. Who eventually collects the taxes on that $500,000? How is it distributed afterwards?

Mr. MARTIN: It is income in the hands of the parent company.

Mr. MACKASEY: Let me put it another way: Who does the parent company pay taxes to?

Mr. MARTIN: To the United States federal and state authorities.

Mr. MACKASEY: Mr. Daily, at the risk of boring the Committee, I will come back to research. I would like to refer to the bottom of page 2. There is a line which intrigues me.

(*Translation*)

Mr. GOYER: I have a supplementary question.

Would you have any objection to your Company being subjected to some kind of a form of disclosure, such as exists at the present time in the United States?

(*English*)

Mr. DAILY: Mr. Goyer, if I might be permitted to reply to you in my own language, your question is: Would we object, or would we be willing to submit our company financial data on an annual basis for publication?

Mr. GOYER: Yes.

Mr. DAILY: We would certainly have no objection to this, if this were the law of the land, but we do not feel that any one company or a group of companies should be singled out for this purpose; as in the case of research tax incentives, or in the case of direct grants, where, I think, procedures already exist for the federal government to gain a better insight into how these moneys are being spent. The area of research is an example.

Mr. ORLIKOW: Mr. Chairman, I would like to ask a further supplementary. We have been here for weeks, months and years to look at this very question of the price of prescription drugs. How can this Committee, or the Canadian public, know whether they are paying the right price, too much or too little, with this figure? I am not being too critical, because, as you say, if the government wants this different, they should pass laws requiring all companies to do it.

The supermarkets have been telling the Committee on consumer problems that their earnings on sales are running between 2 and 2½ cents on the dollar. Yours are substantially more. Surely the only way one could tell anything is if we had the kind of figures which your parent company in the United States publishes, which show profit in terms of investment, and show for each year what profits are paid out to the shareholders and what profit is retained and ploughed back into expanding the company? These kinds of figures really give us no information at all.

Mr. DAILY: You mean this information is not satisfactory for your purposes?

Mr. ORLIKOW: I submit to you that percentage of the profit shown as a percentage of sales really gives no indication of whether the profit a company is making compares with the profits of other companies in the industry, or other companies in other industries.

Mr. MACKASEY: Mr. Daily, did not you or Mr. Martin say that the information which Mr. Orlikow and myself have suggested we would like to have would be placed at the disposal of our accountant? Am I wrong in that assumption?

Mr. DAILY: Mr. Mackasey, what information are you referring to?

Mr. MACKASEY: We would like to get the balance sheet.

Mr. MARTIN: I think that certainly can be done, Mr. Mackasey.

Mr. MACKASEY: You are entitled to your privacy as long as your competition is there; I think that is only normal.

Mr. MARTIN: I would like to make a direct answer, if I might, to Mr. Orlikow's comment. I do agree with him absolutely that the key figure we are interested in here is what is the return to the shareholder as compared to the public.

In preparation for this session, I did some work of my own with the Department of National Revenue's taxation statistics for 1965. We discovered there some figures which relate the dividends paid by Canadian companies to the taxes which they pay. We find that the total industry in Canada pays 85 cents in taxes for each $1 of dividends which it pays. In the case of Smith Kline & French we pay approximately double that, and as an additional statistic on this I would like to refer to the dividends paid as a percentage of net worth. To my mind it is not necessarily informative what the company itself earns on its net worth; it is what the shareholders earn on the net worth that I think Mr. Orlikow is referring to.

Again, for Canadian industry in total, the shareholders in the last year for which there are statistics earned 4.3 per cent of their investment in the form of dividends. Our remittance to our shareholders came to 3.8 per cent in 1965; therefore, I suggest we are comparable.

Mr. ORLIKOW: If I could interject, that may be, and this is why I submit that your figures leave a great deal to be desired. You retain $4 million odd, which you ploughed back into the company. It may be that, by keeping the dividends down for the next few years and ploughing back your profits into expanded facilities, your profits will be that much greater five years from now. I am not saying this is bad, what I am saying is that the public of Canada is entitled to know, in order to make up its mind about these important questions.

Let me make it clear again that I am not saying that your company is any worse than any other company. Very few companies give any more information than the government requires, and I think the fault for this lack of information rests on past Canadian governments.

Mr. MACKASEY: Madame Chairman, Mr. Orlikow has anticipated one of my questions. The fact that Smith Kline & French is willing to invest $4 million in expansion in Canada, it seems to me, should be something they

should be praised for, not something they should be condemned for. If they have enough faith in Canada and the drug industry in this country to increase their research facilities and their physical assets in this country by $4 million, that is precisely what we are trying to do in this Committee—to get them to act as Canadian firms to a greater degree. I am talking in general, not just about Smith Kline & French.

Therefore, the portion of the brief where you mention your willingness in the next short while to spend $4 million more in Canada, rather than spending it in Switzerland, England, Mexico or the United States, to me is the one encouraging aspect of the brief this morning. Rather than being condemned for it, I think you should be praised for it, because we need more of this. We have been trying to get the drug companies, in general, to become even greater Canadian participants in the future of this country.

(*Translation*)

Mr. GOYER: I have a supplementary question to my question, because I am not quite satisfied with the answer I got. Of course, I am quite ready to accept your figures but it so happens that we must report on our policies to the Canadian public. You would like us to help you and your industry to work hand in hand and you are even claiming more money than the Federal would be willing to grant you in tax deductions for research. The more you ask from the Canadian public, the more you should be ready to report to the Canadian public. And now I would like to come back to my question, would you be ready to submit yourself to a form of disclosure which would not only cover the income of your Corporation but even go as far as to investigate the displacement of capital that takes place between the subsidiary Company here and the parent Company in the United States? That could perhaps reveal their financial activities, not necessarily to the public, but at least to the Government, financial activities both of the Canadian subsidiary and of the parent company. This in practice is taking place to a certain extent in the United States. Would you be ready to submit to such a similar form of disclosure?

(*English*)

Mr. DAILY: To answer your question, Mr. Goyer, it only requires a simple yes, so long as this applied to all companies doing business in Canada. As a matter of fact, I think that some agency of the government—perhaps it was Mr. Winters' department—has already conducted a very thorough questionnaire of the financial activities and behaviour of a select group of companies, and perhaps this will lead to something more comprehensive for industry, as a whole. Therefore, yes, we would.

Dr. MORIARITY: In fact we do. As you know, there are a number of questionnaires with regard to specific research which we fill out both for the federal government and the Quebec government.

Mr. MACKASEY: Madame Chairman, to get back to my original questioning, I would like to get it completed. At the bottom of page 2 it says:

> Our sales have grown steadily since the company was established in Canada. However, net earnings have tended to drop as a percentage of sales from their peak in the mid-fifties—apart from the impact during

> the past three years of the Federal government tax incentive for research investment.

Would you care to elaborate on that part, please?

Mr. DAILY: Yes; that requires qualification, and quite honestly I think I should turn this question over to our tax expert, Mr. Martin.

Mr. MARTIN: I could refer you, Mr. Mackasey, to page 3 of our brief in which we show in the last three years a figure of net earnings as a per cent of sales. You will see that in 1963 the figure, excluding the research tax incentive, is some 4 per cent below the figure and, in 1964 it is some 13 per cent below the figure of the total earnings.

I think that tax incentive needs a little explanation and it falls into three categories. As you know, the government established a tax incentive for research in Canada, which was partly a capital incentive and partly an expense incentive, and over these three years we have received in the form of expense incentives, which is reimbursement of Dr. Moriarity's expenses on research, $145,000 in tax, and for increased production facilities we have received $36,000 over the three years in tax relief.

During that same three-year period we have, however, received almost $1 million, to be exact $973,000, in the form of deferred tax allowance on the capital construction which we have made in Senneville. This, of course, has to be paid back to the government over the life of the Senneville property, and, therefore, these figures on the left hand side, the 19, 20 and 10 per cent, I submit, are perhaps misleading and one should look more at the figures on the right hand side.

Mr. MACKASEY: All right; you have made my point.

In addition, then, you would say that in general your company has responded to the efforts of the Department of Industry to substantially increase research in Canada?

Mr. DAILY: Mr. Mackasey, perhaps a word of explanation is required there. Yes, we have responded, but—

Mr. MACKASEY: You are now going to tell me about the patent laws.

Mr. DAILY: I will leave that to someone else. I indicate this somewhere in the brief. On page 15 we say:

> It is the general SK&F policy to develop our research commitment in line with the importance of the national market and also the quality of scientific activity in a country.

Therefore, in line with this objective, for some years we had considered the desirability of doing more than just production and selling of our products in Canada. We started with a rather small scientific nucleus, but it has been built up over the years to the point that in 1962, which is the year before the tax incentives program was announced by Minister Drury, we actually made the commitment to build a research laboratory in Senneville, and you might say that the government's aid will help us in years to come in improving upon this facility.

Mr. MACKASEY: Mr. Daily, I have just one or two questions, because I think we should share the time.

Getting back to page 43 and Dr. Brand's question: Does the British pharmacopoeia allow for tolerances—does it indicate tolerances plus or minus from the standard potency recommended?

Mr. BETHEL: Yes, it does.

Mr. MACKASEY: What is the tolerance?

Mr. BETHEL: In this case the tolerance is a lower limit of 92.5 per cent of declared potency, and an upper limit of 107.5 per cent. In other words, plus or minus seven and one half per cent.

Mr. MACKASEY: Which means that there is an over-all of 15 per cent.

Mr. BETHEL: That is correct.

Mr. MACKASEY: And the example you have been giving of this firm, Paul Maney, is that it has been 20 per cent.

Mr. BETHEL: Yes, it has been in the order of 20 per cent.

Mr. MACKASEY: I ask this because I expect we will have a representative from the Food and Drug Directorate on the stand one of these days.

Mr. Daily, one last question: What steps, apart from playing around with the patent laws—which I think we will get into a little later—would you recommend the Canadian government take to increase production and research in the pharmaceutical industry in Canada?

Perhaps, before you answer this, I might throw in another question to which you may want to give the same answer. On page 3, I think it is, of your opening remarks—I always like information which is volunteered—you say: "Last year 7 per cent of our sales revenue came from exports"—that is why I am talking about manufacturing in Canada—"We manufacture products notably for the Latin American, Japanese and Philippine markets." Is this the finished product you manufacture and export?

Mr. DAILY: Pardon me?

Mr. MACKASEY: Is this a finished product which you manufacture and export?

Mr. DAILY: Yes; we manufacture the bulk finished product in all cases, I believe, or in most cases.

Mr. MACKASEY: Do you package in these countries then?

Mr. DAILY: I believe in a majority of cases; as an example, the Japanese market which we have an interest in, will receive our product manufactured in bulk and do their own packaging.

Mr. MACKASEY: If you export to these countries, what type of real competition exists between your export and the export from head office in the United States, or do you compete?

Mr. DAILY: We are an international organization and as such the export of products, because we deal in a finished trade-name products, is necessarily subject to licensing arrangements and area distributorship arrangements around the world. To answer your question specifically, we do not compete on the open market with our parent company in the export field.

Mr. MACKASEY: Is the product called Stelazine manufactured in the United States as well as in Canada?

Mr. DAILY: We supply finished Stelazine tablets, as well as, I believe, the chemical which we synthesize in our plant in St. Laurent, to agencies in distributorships in various parts of the world.

Mr. MACKASEY: You are not specific about what parts of the world although you are in your brief here. Does the United States office do the same thing in these various parts of the world? In other words, does your finished capsule compete for export dollars—

Mr. DAILY: No; because it is all subject to the distributorship arrangement, Mr. Mackasey; we are not dealing in an open market situation.

Mr. MACKASEY: I am just speaking as a Canadian who is interested in the balance of payments problem and also in developing more exports from Canada. That is my main point.

Mr. DAILY: I think we are all sympathetic with the need for encouraging exports. When you asked what could be done however, of what could be done about encouraging research and production and exports and so forth you made a qualification by excepting patents. I find it a little difficult to accept that.

Mr. MACKASEY: I will remove the exception.

Mr. DAILY: Pardon me?

Mr. MACKASEY: I will remove the exception.

Mr. DAILY: In my judgment, not everything, but a good part of the problem, does stem from the patent situation.

It seems to me—just to restate what has already been stated in the brief—that the Canadian government, with its stated objectives of increasing employment, increasing exports, increasing research, and so forth, would be well advised to take a good look at the patent situation as it applies to pharmaceuticals, because in two key respects there is a definite—you might say—discouragement not only of research in the way the patent law is now administered but also of fine chemical production. There is absolutely no incentive for a manufacturer, the way the patent law now exists, to actually work at patents in Canada and engage in basic fine chemical production facilities. Now, in our own experience, despite the fact that we are synthesizing trifluoperazine, this does not have any effect on the patent commissioner's judgment, although it would have had if the law had been administered under Section 67. Our own experience with this synthesis operation is that it was a definite contribution to our own company, we think, in that it enabled us to get involved in more basic chemical technology, and, once having done this, it enabled us to look beyond our own Canadian market requirements for opportunities to sell this within the company's interest abroad.

Mr. MACKASEY: Mr. Daily, if that section of the patent law, section 41, were eliminated entirely, or at least revised to the satisfaction of the pharmaceutical industry, what tangible effect would it have?

Mr. DAILY: I think the industry as a whole has got to answer this question, and I hope that we will be able to provide an answer.

Mr. MACKASEY: How would your company answer it? What effect would it have on your operation?

Mr. DAILY: It would definitely have a very beneficial effect, I think.

Mr. MACKASEY: In what way?

Mr. DAILY: I think it would give us reassurance that we are doing the right thing in investing in research in Canada.

Mr. MACKASEY: How much more research would you invest in, and how much more production would you invest in?

Mr. DAILY: This is something, of course, which would have to be contingent upon our over-all corporate policy, but I think it would have a definite beneficial effect on our own research attitude towards this country, as well as provide stimulus for fine chemical production.

We would find it to our advantage to work our patents in this country and thereby gain protection for the investment which we have in the product. I think this would have a definite effect on our own company's plans for the future.

Now, I cannot be more specific than that because I have not calculated the dollars and cents of the situation.

Mr. MACKASEY: The point I am primarily getting at, Mr. Daily, is that on Tuesday, I think—I was not here, but I read the brief—Ayerst stated that they spent over three million dollars on research in Canada. Your figures show about one half a million dollars. As I understand it, they were originally a Canadian-based firm.

Mr. DAILY: They do research for the whole of the world.

Mr. MACKASEY: This is my point: When and how can we get other parts of the international operations to start doing research for the world, and manufacturing for the world, at least in some bulk form, in some other areas and some other products? How can we get Smith Kline & French, for instance, to start doing research in some fields in Canada for the world, and how can we get Smith Kline & French to start manufacturing in Canada some products for a designated international market—perhaps a North American market or a little larger market, or a western Europe market? What can we do here to—

Mr. DAILY: The Department of Industry, I believe, has already concerned itself with certain areas of activity, including automotive parts, and I would think that it would be very desirable for a study group to be formed of the pharmaceutical industry and the Department of Industry officials to see what could be done to develop the Canadian pharmaceutical industry in these specific areas, with the encouragement that would have to be rendered by a change in the patent.

Mr. MACKASEY: Then, you are under the same type of pressure in every country.

Mr. DAILY: I cannot speak with too much authority on this question but I do know that every country in the world is desirable of increasing its exports.

Mr. MACKASEY: And so are we in Canada.

Mr. DAILY: There are only so many places in the world where we can export.

Mr. MACKASEY: The point is, how do you pick one country over another, is it because we are just pleasant, modern people that you can—

Mr. DAILY: This very question was posed in the last page of my opening statement when I said: "Should we invest in research in Canada or Australia?" Now, how do you pick the countries? I guess in the final analysis it depends on the future prospects of the country, the scientific requirements available as well as the incentives which are offered by the country concerned.

Mr. MACKASEY: Have you any misgivings about the future of our country?

Mr. DAILY: I am quite bullish about the future of Canada and I think everybody should be.

Mr. MACKASEY: Would you say that the climate is conducive to research?

Mr. DAILY: I think with the exception of the Patent Act—

Mr. MACKASEY: I am asking you what you would do if we rectified the Patent Act. In other words, if we took the last impediment away, what would you tangibly do with the firm in Canada to increase exports and to increase manufacturing and to increase research in Canada?

Mr. DAILY: I think I would be beating a path down to my parent company in Philadelphia more vigorously than I have to date in order to induce them to enable us to do more exporting from Canada.

Mr. MACKASEY: If this Committee were to ask you to come up with something concrete in return for amending part of the Patent Act to defend you, what would you do? What would you bring back?

Mr. DAILY: I think we could bring back certain export opportunities, as an example. I think it is a little difficult for me to say how much further we should expand our research operations because, as Dr. Moriarity well knows, we have already invested quite heavily in this area and, as a matter of fact, we just had approval the other day to employ 11 new scientists at our research laboratory.

Mr. MACKASEY: Was it your decision or the parent company's decision?

Mr. DAILY: Pardon me?

Mr. MACKASEY: Is it your decision to make or the parent company's decision to make?

Mr. DAILY: In the final analysis research, I think, has to be subject to world wide policy, so I cannot say it is my decision although my recommendation would, I think, carry a fair amount of weight.

Mr. MACKASEY: Thank you, Madam Chairman.

The ACTING CHAIRMAN (*Mrs. Rideout*): Just before we continue if I might have the indulgence with the other witness, of the Committee, it was hoped that we might finish the questioning of the witnesses this morning. Now, I still have Mr. Orlikow and Mr. Howe. Mr. Goyer, I anticipated, had some questions. I am wondering what you would like to do. Would you like to continue until 12 o'clock and adjourn until after Orders of the Day?

Mr. MACKASEY: Maybe we should sit until one o'clock and then we will be finished.

The ACTING CHAIRMAN (*Mrs. Rideout*): Well, this is the dilemma I am in. I have a very important appointment at 12.30 that I should keep.

Mr. MACKASEY: I would gladly take the chair.

The ACTING CHAIRMAN (*Mrs. Rideout*): Would the Committee agree to let Mr. Mackasey sit in my place?

Mr. MACKASEY: Maybe Mr. Orlikow could take your place but then he could not ask his questions. I have exhausted mine.

The ACTING CHAIRMAN (*Mrs. Rideout*): Is it agreed then that we will continue to one o'clock and Mr. Mackasey will—

Mr. ORLIKOW: Well, why do we not see what happens.

Mr. ENNS: I think so. I wonder if the Chair might look at some of the questions asked and make certain they deal with the costs of drugs. The line of questioning which Mr. Mackasey asked about research and so forth, while it is interesting to me, I am wondering if it is really relevant—

Mr. MACKASEY: I would like to reply to Mr. Enns. It is because the research is affecting the price. Such a big part of the balance sheet goes to the international office under the guise of research. All the way through their brief, and everybody else's brief, they emphasize the point that their industry is not the same as anybody else's because it is dependent on new products found through research. So every nickel spent ambiguously is shoved in under research. This has a direct effect, I believe, on prices. In conclusion, their only argument against the lower cost of the generic firms is that these firms do research which a generic firm does not. This is how they justify the differential in prices.

Mr. DAILY: That is not our only argument, Mr. Mackasey.

Mr. MACKASEY: Well, quality control—I am not saying they are not valid arguments but it is a very big part of—

Mr. ORLIKOW: Well, we will not finish by one o'clock, I can tell you that.

The ACTING CHAIRMAN (*Mrs. Rideout*): All right, Mr. Orlikow.

Mr. ORLIKOW: Madam Chairman, representatives of this company have taken the same position with regard to our patent laws as the pharmaceutical manufacturing association and all the other companies that have been here before them and, I am sure, all the other companies that will be here after them. I know they realize that they are in direct opposition to the recommendations which have been made by the restrictive trade practices commission and by the Hall Commission and so on, while not giving exactly the same recommendations certainly felt that the patent laws, as they are now, far from hurting the companies helped the companies to keep the prices up.

Now, as I said earlier, Madam Chairman, we are here because we are concerned, the public is concerned, about the cost of drugs.

On page 6, in these five examples which the company gives us, they give us five commonly used prescription items and the average prescription price. One

of them, the third item, is 'Dexamyl' Spansule. I am sorry that I do not have all the information that Dr. Howe has—I do not have anything on 'Dexamyl' Spansule—but I have a table of information taken out of the "Drug Topics" red book for 1964. I do not think things have changed very much. While they do not list 'Dexamyl' Spansule they list one of the earlier types of the same drug, Dexedrine tablets. This is what it says. Smith Kline & French Dexedrine tablets, 100 tablets, price $2.66. The same drug sold by Pitman-Moore, which is a division, Madam Chairman, of Dow Chemical, which is not one of these small, fly-by-night drug companies we have heard so much about; it is one of the biggest basic chemical companies in the world, the same product sold by Dow Chemical, 100 tablets, which are sold by Smith Kline & French at $2.66, sell by this subsidiary of Dow Chemical for $1.00. This is the kind of problem which the public is worried about, and I would like to know what explanation you have for this. What is your answer to the people who are concerned about the high price of drugs? This is one example.

Mr. DAILY: Well, Mr. Orlikow, I believe you are quoting from an American reference book "Drug Topics". I am afraid that I cannot speak with any degree of authority on the price differentials that exist in the American market but, just generalizing from a strictly Canadian point of view, I do not know whether Pitman-Moore have the product available in Canada or not. But, even if they do, I do not know what led them to price their product the way they did. All I know is that we have certain essential costs of doing business which are recurring in nature, including our research and medical information program which our products have to pay for in their pricing. We, of course, feel that our products are priced competitively with similar therapy, and we can give you any kind of information which would support this point of view. To answer your question specifically, Mr. Orlikow, we have our own cost to meet and this is what has led us to price our products the way we have.

Mr. ORLIKOW: I know, but the consumer has the cost to meet. Let us take Stelazine. What is Stelazine? It is a tranquillizer?

Mr. DAILY: Stelazine is a tranquillizer which has both high potency as well as low potency usage. In other words, in a psychotic as well as mild—

Mr. ORLIKOW: Let us take a person living and operating at home, not in a hospital. What would be the average dosage per day of Stelazine?

Mr. DAILY: Dr. Moriarity, could you bail me out on this one?

Dr. MORIARITY: Two milligrams, twice a day.

Mr. ORLIKOW: Twice a day. Then let us use your own figure. I thought it was three a day. But twice a day, using your figure of 30 tablets selling for $4.46, becomes expensive. A person taking this kind of prescription could take it for a long time. It is not something they take for a week or two. A person could take a tranquillizer for a year or two, or for the rest of his life. There are many people in Canada who have been taking tranquillizers for ten years now.

Dr. MORIARITY: Yes sir, but there are two different areas. One, the low dose area where, by and large, medication of this type is used to get a patient over a difficult period. That is where most of the usage would be, sometimes only for five or six days, and much of it just for a few weeks. The other area, of course, is hospital usage or for serious mental patients, and these, of course, can be out

of hospital where usage is on a daily basis for months and even years, as you have said. They have not been able to take Stelazine for ten years but it has been on the market for eight years, and we have very actively followed some of the patients who have taken it for three and four years. This is part of our great detailed follow-up study to look into all the ramifications and the safety features, as well as the medical benefits to the patient, of long-term therapy.

Mr. ORLIKOW: My point—and perhaps it is because I am an ex-druggist—is that I know people who have been taking tranquillizers for five years or more. My point is that you are dealing with your own figures. This is something which a person—if Stelazine works, and it obviously works for some people—could be paying, at the figure you have given, over a $100 a year over a long period of time to take this drug. It is obvious, therefore, that they are going to be concerned about the cost.

Dr. MORIARITY: Absolutely, and the really crucial issue here is that many of the patients that you are talking about, of course are in this position. The use of a drug such as this makes the difference between keeping them out of hospital and on their feet and at a job, as opposed to being in a hospital and unable to work.

Mr. ORLIKOW: Exactly, but the point I am trying to make is this. I did not have a chance to find out how many other companies, if any, besides the one you mention sell Stelazine or something with another name, but I know that with Meprobamate, for example, which is very commonly used, the price to a person can vary very much. Let us take the most commonly used, I suppose, in Canada, Equanil. The price a person pays for Equanil can go down by anywhere up a half or a third of the present price. According to Dr. Nickerson, who is the professor of pharmacology at the University of Manitoba, every Meprobamate tablet sold on the American continent is made by the same company and sold to all the other companies that sell it.

Dr. MORIARITY: That is not so, sir, I know Dr. Nickerson very well but Meprobamate, as you know, is now made available by a variety of companies in the United States.

Mr. ORLIKOW: He told me that they are all produced by the same company. But the point I am making is that the public simply is not going to accept the tremendous costs and the wide variation of costs unless there are justifiable reasons, which have not yet been shown.

Dr. MORIARITY: As a physician—I have been in practice and I am fully sympathetic with everything that you are saying—I think that the cost of this type of therapy has to be fully judged in relation to the situation. If $100 a year keeps a patient out of a hospital and whether it should be $75 or $125 I do not know—you know as well as other people what the cost of a hospital bed is in this country, even a mental hospital bed where the services are not all that we would like. A hundred dollars a year is a significant figure. On the other hand, there are many people such as myself, with large families and, for instance, I drop half of this $100 a year every week at the supermarket for food.

Mr. ORLIKOW: There is no question that it is a lot cheaper, and not only in money. It is a lot better to pay $100 and not be in a hospital, and to be able

to operate. But one resents paying $100 if the cost should be $35, and that is the point of the inquiries we are holding, and which other government agencies in Canada and the Kefauver committee have been looking at for probably ten years. It is necessary to pay these high costs?

Dr. MORIARITY: I well appreciate it, and I think that this is certainly something that the Committee is very justified in looking into, but along with this, along with relative price, I want you also to consider relative quality and also the figures related to the alternatives of treatment. If medication such as this does keep a patient out of a hospital, perhaps it is worth $35, $45, or even $75.

Mr. ORLIKOW: It is worth a lot more, but is that the proper price? I would like to go, Mr. Chairman, to this question of research and development. I want to turn to page 15, the figures for 1965, which is the last year you show. Research and development is $534,000. Could we get some explanation of how that breaks down? How much of that is research and how much of that is development, and what do each of these terms mean?

Mr. DAILY: I think that our authority on this field has the floor. Dr. Moriarity, would you continue?

Dr. MORIARITY: I would very much like to explain this particular figure for you and, perhaps, develop the figure, itself, because statements that were made earlier were somewhat misleading from a research and development point of view with which I am most concerned.

For instance, the figure for 1965 is given as $534,000, roughly. I would like to place this in the over-all context of what Smith Kline & French has done in Canada since I joined the company in 1960.

Our cumulative research spend—and I am using the term in a broader fashion at the moment—spend for research and development in Canada since 1960, and this includes capital expenditure, has been $3,876,933.27. That is our spend as of this month in Canada. I am sorry that I do not have the split on 1955 but could I use the 1966 split for you? Research and development is in Montreal, and included in this are clinical work, all of our pharmacy research, our pharmaceutical development, as well as certain types of more essentially the money that we spend in my division in Smith Kline & French basic research which we have been doing in Montreal.

Again, just to develop the over all concept, we started this development back in 1960. We started with the clinical work; we organized the medical department; we now have three physicians on the staff in the research and development division. Mr. Bethel and the control people are outside the research and development division so we now have three physicians on our staff who are concerned with the testing of new drugs in Canada and all of the follow-up required to approve and ensure safety and equivalency or effectiveness.

In addition to this we have a fairly substantial pharmacy research department. At the moment we have three graduate pharmacists on the staff. I will give you the specific figures in head count later. We have three graduate pharmacists on our staff in Montreal and we are looking for two more now. It is most difficult to hire people such as this in Canada; for a variety of reasons the Canadian graduates go elsewhere. We are even thinking of having to

train our own pharmacists. Initially, of course we look for a graduate pharmacist with research training, and we are now in the process of hiring graduate pharmacists from school and giving them the research training ourselves in our own laboratory in Montreal.

Beyond this we have been doing research work in biochemistry, in mirobiology and, as Mr. Daily just mentioned a minute ago, we are looking for the people now, we have approval for an additional 11 people with an additional over-all expenditure of something in the order of a quarter of a million dollars. So the new people we are looking for now—again, this will be confirmed by other people responsible for research in Canada—are very difficult to come by. Dr. Nickerson, whom you referred to earlier, trains many of the best pharmacologists in Canada.

Pharmacologists right at the moment are worth their weight in gold. We are looking for three pharmacologists. We are looking for two senior bio-chemists and a junior bio-chemist plus all the ancillary people who will go along with them. This means an animal man to look after the animals, technicians, literature scientists, people who will do all the literature background work for the working scientist so that more of the scientist's time can be spent at the bench actually doing the experiments. I believe this is the type of run-down that you wanted as to specifically the order of magnitude and the type of things we are doing in Canada.

As I said, I do not have the earlier figure. I think this would satisfy Mr. Mackasey. He had inquired about a commitment. We are committed, provided we can get the people, to spend in full research and development —again, a full division of activity—of $800,000 for next year. This will amount to 40 people in our own division, our own research building at Senneville, Quebec, first on the right as you come off the trans Canada bridge onto Montreal island.

We have the split you asked for in our medical department. Again, I do not want to run down all of the responsibilities in the medical department, as you have heard them before and they are detailed very clearly in the association brief. Our medical department spends $160,000 a year. Our pharmaceutical development department, the pharmacy area that is spelled out later, will spend $193,000 in 1967, and the research department, which will include the pharmacology, biochemistry and other related disciplines, will spend $198,000. In addition to this, and I shy away from it because of the previous discussion of the figure, I have a budget which includes my own salary but in the research and development administration budget is included a library, we have a full-time librarian, we have and will have literature information scientists and all of the ancillary services. We have somebody to look after the cafeteria for our scientists because we believe they should be well fed too. The figure is $247,000 for research and development administration.

I can give you even more detailed splits on these if you want what we spend on outside grants; perhaps just a percentage outlay. This is different from the over-all spent. I believe the figure we have in the brief for salaries amount to in Canada for Smith Kline & French as a whole something in the order of 30 per cent of the dollar. We, personally, are somewhat pleased that salaries in research development, and this is basically the experience of everybody, account for 50 per cent of the research dollar. Our overhead, the

cost you write off on the building, the heat and electricity and other things such as this, come to 25 per cent of the research dollar; supplies and other expenses, the chemicals the glassware, all of the equipment that is capitalized, amount to 15 per cent of the research dollar, and 10 per cent of our research dollar is spent at universities across the country, including the University of Manitoba which you referred to. We give them grants, sometimes specifically for projects we are interested in, sometimes just because they are working in a related area or sometimes just because they are doing an excellent piece of work that industry has some responsibility to support. This is, basically, the type of work we do in Canada. All of this basically was set up because we felt that we could and would get some adequate patent support for this research in Canada. This is one of the reasons we started synthesizing trifluoperazine in 1961, the same year that the patent was issued. This is the same reason why for a variety of reasons, we just cannot compete with another company that does not do any of this work in Canada. I think the cumulative figure is very interesting in that we have, to date, almost to this stage, spent $3,876,933 and some odd cents.

The patent situation is a very difficult one for organizations such as ours because we are now beginning to compete—Mr. Mackasey will be interested in this—on the international scene. This week, for instance—other companies have done this—we filed patents in 21 countries of the world for one of the developments we did all on our own in Canada. In the last few years, there are a number of products we have developed in Canada that are being sold elsewhere around the world. We are very proud of this. I would like, as a research man to point out that this is only the beginning; that we are really only just getting the team organized. Speaking as a Canadian, Canadians, whether they like it or not, if they want to participate in the modern technology of this particular field, have got to pay research somewhere, and I think it is to everybody's advantage to see research paid for and undertaken in Canada, and research of this order.

Mr. Daily seemed to hedge somewhat on the question of Mr. Mackasey, "What will you do additionally". I was finding it difficult to remain quiet at that time, but right at the moment we are basically spending about the same rate per sales dollar that our company spends elsewhere in the world.

Mr. MACKASEY: How would your ratio of sales dollar spent in Canada for research compare with the industry in general in Canada? How does it compare to Ayerst, McKenna?

Dr. MORIARITY: Ayerst is in a completely different situation as they are doing research for their American market as well. I do not know their over-all figure but I think you would have to measure their research dollar against Canada and United States sales dollars. In our particular case, our research dollar related to industry as a whole is somewhat more, including the research spend that is transferred in.

Our research dollar compares favourably with what our company does elsewhere. Again, Mr. Mackasey, I heard some discussion the other day and I was prepared for this. Our company for some time now, even prior to the time of the research incentive, has been devoted to de-centralization of research. At the moment, as I am sure most of you are aware, our research commitment is in the order of $26 million a year, a factor of two or three times what the Medical Research Council spends for research every year in Canada. Our company spends most of this in Philadelphia where the main laboratories are located. We

also have a very substantial research establishment in Welwyn Garden City just outside London, England, and of course there is our own commitment here in Montreal. Beyond this we have veterinary research facilities out in the midwest United States. We are also a participant in, a part owner of another pharmaceutical research group in Brussels, and we do some research and development type of work in one of the particular proprietary lines in Reno, Nevada. We have to look at Smith Kline and French Montreal's contribution in terms of what the company does world wide. Since 1933, Smith Kline and French has spent over $150 million for research and development of the order I described for you previously.

Mr. ORLIKOW: Could I interrupt and ask you how much of this research is for basic research in new products and how much is for variations of old drugs? One of the most common complaints—and I am not a doctor—of the doctors at medical colleges, the really professional people, is that a fantastic percentage of the so-called research is for a new product. In other words, "Let us get a variation of dexadrine tablets, because if we get something that is a little different, and if we get it before somebody else, we can sell it. So let us find something else". But that does not really contribute to basic medical knowledge.

Dr. MORIARITY: This is something which has been discussed at great length. Dr. Nickerson has written on the subject, and it is something which we in research have been concerned with, chiefly because of the unknowns involved. This is the so-called molecular manipulation, or whatever you call it. Unfortunately this is a confused term. For instance, it is true of all the steroid molecules which have been manipulated, if you use this term, but to great advantage to everybody.

As you know, the original steroids, in addition to their anti-inflammatory effect, or, to use a simple example, their straight anti-arthritic effect, had profound effects on the electrolytes of the body as well. They helped patients with blood pressure problems and swelling problems. By manipulating this molecule, the industry and everybody involved in therapeutic research have been able to come up with molecules that retain and even have enhanced anti-arthritic effects with much less, if minimal, effects on the electrolytes of the body. This, by the usual definition of molecule manipulation, is molecule manipulation, but of a very responsible and desirable order.

I know what you are referring to really, that this is essentially competition by a related product as opposed to competition by price. Perhaps, in all honesty, I would have to say that this has been a factor in the industry in the past, but it is a diminishing factor, if for no other reason than the high cost of research now.

For instance, even in our own little set up we have to think in terms of the North American concept—if we come up with a new product tomorrow, which has cost us hundreds of thousands of dollars to put in the first patient. We have decided, from our own company's philosophical point of view, that we are not interested in a compound which is not any better than presently available medication. So that then if it costs us hundreds of thousands of dollars to do all of the work to get it into the first patient. These are all reasonable requirements.

Again, much of this has developed since the thalidomide time; the whole industry has changed so much with the advent of new drug regulations. But taking you beyond this, before we start testing—and I have to use figures for North America because we participate in it—at the end of the first year in the clinic we spend at least at the rate of $1 million a year in the development of the new product, and it takes from three to five years to get that new product on the market from the time you first have some feeling that it might have some clinical utility. Therefore, the industry just cannot afford to spend this amount of money for a product that is no better than something that is already on the market. Certainly, we, in a Canadian setting, cannot afford to do this.

For instance, the animal work, just to satisfy the Canadian Food and Drug Directorate, is just as expensive as it is for the whole North American setting. If, by any chance, a new product came along, which was available only to Smith Kline and French in Canada and nowhere else in the world, it would cost Smith, Kline and French just as much money to get it on the Canadian market as it does to get it on the United States' market, as well, which is more than ten times bigger. Our safety criteria are just as rigid as they are elsewhere in the world.

Mr. ORLIKOW: I have a supplementary question and then one other question. Does it make sense to you, and would it not save money for the company, and, therefore, hopefully, for the consumer if, taking Canada and the United States, the two government departments concerned could reach an agreement on standards and testing procedures and so on, so that testing approved by one government department would be acceptable in the other country?

Dr. MORIARITY: This is a very good suggestion. In fact, from the industry side, we do this. This is why I gave you joint figures, such as the one of the research spend of at least $1 million at the end of the first year of the clinic. In fact, there is a Canadian contribution and a United States contribution. We submit United States' studies and United States' development work along with our own to the Canadian Food and Drug Directorate. Canadian clinical studies are submitted to the United States Food and Drug Directorate along with theirs; so that at least on the industry side there is complete collaboration between the two units.

I do not know what the legal, political problems would be in trying to get the two Food and Drug Directorates to do the same.

Mr. ORLIKOW: Just one more question, Mr. Chairman. It is a question which I have asked of other companies as a general line, and I am not going to go into detailed background.

You show on page 39 a figure of 24 per cent of the sales dollar as the cost of medical information and marketing activities. You show the breakdown there. That is a little lower than one of the companies which was here last week, which, I think, showed 31 per cent. But whether it is 24 per cent or 31 per cent, in the final analysis it is the consumer who pays. I think you will agree on that?

Dr. MORIARITY: Yes.

Mr. ORLIKOW: That is part of your cost of producing and selling the product.

Now, because all the companies are in competition, what one company does in the way of having professional service representatives, or mail literature, or samples to doctors and hospitals—I could go right down the list—really has to be met by another company if it wants to stay competitive. Would you agree that that is a fair statement?

Mr. DAILY: Certainly competition is a factor, but also a really large factor, Mr. Orlikow, is the fact that we have a unique situation in our industry, as compared with other industries, with respect to the problems, the objectives of marketing activities, advertising, medical information, call it what you will, in that our efforts are not completely directed towards selling the products. The costs that are outlined here reflect not only the cost of selling the product, in other words presenting the advantages of the product to he physician, they also include—I think I have to restate what has already been said many other times—a very large percentage of technical information which outlines not only the dosage but also possible side-effects that the user or the prescriber of the product may run into. This question of full disclosure of information, as Dr. Moriarity showed you, in the Vade mecum, where we list full disclosure on our products, is a characteristic which is perhaps unique in our industry, and it certainly does add to the cost of marketing.

Mr. ORLIKOW: A question I want to put to you, as I put it to other companies, is: Would your company be hurt in comparison, or in relationship with other companies, your competitors in the industry, if the government were to pass tax regulations which would limit, in the drug industry, the amount of money which could be spent by a company for this type of expenditure? It is so high, and it reflects so largely on the price of drugs, that it seems to me that the government should, set a figure. I believe the Hall Commission said 15 per cent, and that is one figure, but perhaps that is not the right amount. The amount should be limited because the more money you spend the more money the consumer pays.

Mr. DAILY: If such an arbitrary ceiling were imposed, Mr. Orlikow, I think it would, perhaps, hurt us, but it certainly would not hurt us nearly as much as it would hurt the smaller company just starting up in business, the company which has an important new product to launch and all of whose activities are devoted to this new product. It may be a very important product which the physicians of this country should be aware of. How on earth such an arbitrary ceiling could be administered, apart from the merits or the demerits of the situation, so as to give justice to every situation, every company and every product, is something that is beyond me.

Mr. ORLIKOW: Let us be realistic. It is not the small, new, poor company which can put dozens or hundreds of detailmen on the Canadian scene to do a quick job of educating the doctors on why they should use a product. It is the big companies.

Mr. DAILY: I know of one company which you might call a big company overseas, but they recently set up in Canada, and they have a very excellent research activity which has led to the introduction of very excellent products on the Canadian market. They have set themselves up only in the past several years. They have a tremendous initial as well as sustaining expense which enables them to launch a product in the Canadian market and maintain it.

Certainly in the first years they are suffering a loss situation in so far as any returns are concerned. Therefore to me, very definitely, and to fix an arbitrary limit of say 15 to 20 per cent, call it what you will, which companies would deduct as business expenses for their advertising as a percentage of their sales, would work to the disadvantage, I think, of legitimate companies who have something to contribute to the Canadian economy as well as to the health picture.

Mr. ORLIKOW: When we are finished we will probably have seen 90 per cent of the major drug companies in Canada, and we could get our accountant to total the amount of money which is spent for this kind of thing. It runs into the millions of dollars a year in terms of payment of salaries and expenses for detailmen. You do have it here . . .

Mr. DAILY: $536,000.

Mr. ORLIKOW: And you are not the biggest company; so it runs into tens of millions of dollars and it is the consumer who is paying this, in the final analysis. This is the problem. Each individual thing that you and the other companies say may make sense from the point of view of straight, ordinary legitimate business and certainly from the point of view of the individual company, but it adds up to the fact that the Canadian consumer is paying the highest prices in the world for prescription items. This is the problem which we have to face up to.

Mr. MARTIN: If I might be permitted, Mr. Orlikow, I think we should be aware of the possibility of this having exactly the opposite effect from what you intend. We feel that these expenses are what is needed to sell the product and to be successful. If we feel that, we would probably not reduce them substantially. This means to say that our taxes would go up to the same extent, and our costs going up would, naturally, as an industry, reflect on our prices. So there is the possibility that the effect could be exactly opposite.

Mr. ORLIKOW: How could your costs go up? I am not an accountant. You have me puzzled. If the tax laws said that instead of 28 detailmen calling on the doctors six times a year, or whatever you said, you could only have 14 detailmen who could call on the doctors three times a year, how would that increase the cost of the drugs. It seems to me you would reduce your expenses and the cost could go down, not up.

Mr. MARTIN: What you are saying, sir, is not that we must reduce our representatives, but that we cannot claim them as a tax reduction. That increases our taxes.

Mr. DAILY: I think there is another detriment which would come about if some arbitrary ceiling were imposed. I think there would be a great temptation for companies—perhaps our own company—to concentrate on selling activities to the exclusion of these other services and the important medical information which comes about through full disclosure of our product information which is now being made availale and, necessarily so, to the medical profession.

Mr. ORLIKOW: I do not know how you could do more than you are doing. You are now spending a great deal more for this selling job than you are on other things. Your own figures demonstrate that. The figures of every drug company that has been here demonstrate that.

Mr. DAILY: I am pointing out that all of this figure here in marketing is not devoted to selling, in the traditional sense.

The ACTING CHAIRMAN (*Mrs. Rideout*): I was just going to ask Mr. Orlikow if he was finished. Mr. Howe has been waiting patiently to speak. If there is time, Mr. Orlikow, we will come back to you.

Mr. ORLIKOW: No, I am through.

Mr. HOWE (*Wellington-Huron*): Madam Chairman, it is hard to find anything to question on when we get around to this time of the day. However, I would like to continue along the same theme as Mr. Orlikow, and also has to do with the question Mr. MacLean was asking, in regard to the selling of these products and getting them on the market.

I notice that on page 2 of your presentation you say that some 75 per cent of your sales come from what are known as ethical pharmaceuticals; that is, drugs which are not advertised to the general public. In other words, you distribute them by samples and through the medical journals.

Mr. DAILY: I am referring there, Mr. Howe, to the ethical part of our business which confines itself to the development and marketing of products which are solely for the use of the medical profession and, therefore, promoted only through the medical profession.

Mr. HOWE (*Wellington-Huron*): What does the other 25 per cent pertain to?

Mr. DAILY: This involves itself in what we would call the proprietary side of our business, which has been set up to take products out of our research laboratory that are suited to public consumption and advertised directly to the public. It is a completely separate operation called Menley and James. This, as I tried to indicate earlier, does not have too many of the characteristics of the pharmaceutical business.

Apart from the proprietary business we also are in the toilet goods business through a line of suntan lotions that we have, and we also, as I indicate here in the brief, hope to become more heavily involved in medical and scientific instruments, as well as surgical sutures and veterinary products, all of which, as I understand it, are outside the scope of this particular inquiry.

Mr. HOWE (*Wellington-Huron*): You mean the money required to put these other products on the market is not included in this brief which you have presented to us?

Mr. DAILY: Yes; it is included on page 4, which covers the over-all distribution of the revenue of the company.

Mr. HOWE (*Wellington-Huron*): Yes; well, is this included in the medical information and marketing activities?

Mr. DAILY: No; it is not.

Mr. HOWE (*Wellington-Huron*): Which item is it?

Mr. DAILY: The promotion of these other products, apart from ethical pharmaceuticals, is proprietary product marketing and advertising, $843,100.

Mr. HOWE (*Wellington-Huron*): In other words when you add that to the percentage of the sales dollar it will come to a lot more than 24 per cent, would it not?

Mr. DAILY: Yes, it would; but this is a completely different company operation that we are discussing here. It has different factors, completely different problems of operating.

Mr. HOWE (*Wellington-Huron*): That is right; but in deciding your margin of profit you take all these into consideration, do you not?

Mr. DAILY: Oh, yes.

Mr. MACKASEY: I have a supplementary question. In the sales dollar are you including or excluding the proprietary side when you bring your percentage in?

Mr. DAILY: It is excluded.

Mr. MACKASEY: I think that is what Mr. Howe wants to know.

Mr. DAILY: It is not included in the ratio of medical information to sales, which is outlined at page 38. But it obviously is included in the sales outlined on page 3.

Mr. HOWE (*Wellington-Huron*): One other thing in connection with the question Mr. MacLean was asking, dealing with professional sales representatives, do I understand that you have a detailman who does not take any order, who goes and calls on doctors and hospitals and pharmacists and who just promotes the product.

Mr. DAILY: May I ask Mr. Dalby to answer this?

Mr. DALBY: What I did say was that all our detailmen take few orders.

Mr. HOWE (*Wellington-Huron*): Take few orders?

Mr. DALBY: Right; their position in the company is mainly to detail the physician, and this is why the distribution network is 100 per cent through wholesalers.

Mr. HOWE (*Wellington-Huron*): You do not have a follow-up by your own traveller to take the order?

Mr. DALBY: He can take orders.

Mr. HOWE (*Wellington-Huron*): No. Do you have a man following the detail man to take orders?

Mr. DALBY: No, no. This is the responsibility of the wholesaler, whom we pay for performing this function.

Mr. HOWE (*Wellington-Huron*): You do not market your own product at all. It is marketed through wholesalers?

Mr. DALBY: It is all distributed through wholesalers, yes.

Mr. HOWE (*Wellington-Huron*): You do not have your own warehouses in connection with your products?

Mr. DALBY: No, we have one warehouse in Canada, in Montreal. We distribute to wholesalers across the country.

Mr. HOWE (*Wellington-Huron*): Everything you sell is sold through wholesale outlets.

Mr. DALBY: Exactly, through wholesale channels, except hospitals; we do sell direct to hospitals. The prescription product goes through wholesalers to the retail pharmacist, who does all the dispensing.

Mr. HOWE (*Wellington*): This is the way all your products are distributed. Does the wholesaler charge you, or sell your product—every product—at the same commission.

Mr. DALBY: Yes, he does.

Mr. HOWE (*Wellington-Huron*): You have a flat rate that you pay the wholesaler for everything he sells?

Mr. DALBY: That is right.

(*Translation*)

Mr. GOYER: I would have a question to put. You stated that research, in your organization, was decentralized. You also mentioned in your brief that your head office requires no other contribution than that $500,000 per annum.

(*English*)

The ACTING CHAIRMAN (*Mrs. Rideout*): Mr. Goyer, excuse me; there seems to be some difficulty; we are not getting the translation.

Mr. MACKASEY: Some of us were getting it.

(*Translation*)

Mr. GOYER: I will repeat my question in that case. You stated that your company carried out decentralized research, that is in various countries. You stated in your brief that your company head office requires no contribution beyond the half million dollars you were speaking about—a figure which is rather difficult to check, as you will no doubt recognize. These products are provided without any dues from one subsidiary to another. I have heard it stated that no patent rights are paid to Smith, Kline & French (Canada) in respect of its discoveries by your foreign subsidiaries. Is that a fact?

(*English*)

Mr. DAILY: We have not so far, Mr. Goyer. We have not, unfortunately, been in a position to negotiate with other companies within our organization.

By the way, as I understand it, you were asking whether other companies within the Smith, Kline and French organization pay Canada for any of the patented discoveries that we make and that are made available to them?

Was that the question, Mr. Goyer?

Mr. GOYER: No. I am not satisfied with the system. I would like to wait if you think you can get somebody to come.

Mr. MACLEAN (*Queens*): Some time ago Mr. Mackasey asked a question regarding a figure of $500,000 on page 4. Either I did not understand the answer, or it was misleading. He asked where the tax was paid on these $500,000. It would seem to me that these $500,000 were received by the parent company for services rendered, and that they represent gross income rather than net income, and it would only be the profit, if any, on the transaction that would be taxable in the United States, not the whole $500,000?

Mr. MARTIN: There is, in fact, no profit on this transaction, Mr. MacLean. I too, was a little confused by Mr. Mackasey's question. I think what he was referring to was the fact that, by transferring this sum of money, we do in fact reduce our tax bill in Canada and increase our tax bill in the United States. If I understood his question correctly, that is the answer to it.

Mr. MACLEAN (*Queens*): Yes; but the whole $500,000 are not taxable income necessarily for anybody.

Mr. MARTIN: No, it is an offset against expense.

Mr. MACLEAN (*Queens*): That is right.

Now, we had a great deal of discussion about why research is done in one country rather than in another, and there has been a great deal of concentration on patents and so forth, but certainly there must be other factors involved. I would imagine that, generally speaking, a company that originates in a country tends to do its research there. Perhaps some of these subsidiary reasons could be arrived at if one could know why the research is done in a certain place in Canada rather than somewhere else? It seems to me that a great deal of pharamceutical research is based in Montreal. I do not know the figures, but we have had several companies here and their research organization is, in each case, based in the Montreal area. Why, in God's name—without any offence meant for Mr. Mackasey—is this concentration in one part of the country? Is it because of the scientific base that happens to be there, a pool of scientists, or is it the large market immediately available in the area. What are the considerations that make a company—especially a foreign company—decide to have it set up in Montreal?

Mr. DAILY: Mr. MacLean, this has historical roots. The pharmaceutical industry essentially is concentrated in the two largest cities of the country, Montreal and Toronto, and most of it is headquartered in the Montreal area.

It is because the head offices and manufacturing facilities have sprung up in these areas that the research installations have followed, so there is good communication between one side of management and the other.

Mr. MACLEAN (*Queens*): Do these same considerations operate in the international field, too—take, for instance, a large company who has, for sake of argument, its main research centre in London or somewhere in Europe, and would look on even Montreal as an outpost in relation to world research and world markets.

Dr. MORIARITY: I think that is very true. They have grown up this way, and from the point of view of medical research, at least, Montreal and Canada were just nothing but an outpost up until 10 or 15 years ago. Fortunately for everybody, the whole climate is changing. With a change in the patent position in Canada it would change even faster, and I think you will find differences there. I can perhaps answer your question in part as to why we are located in Montreal, apart from the fact that my boss is there and it is easier for me to communicate. We are in the Montreal area also because there are excellent universities. One is a specialist school of pharmacy at the Université de Montréal; it is one of the best in the country. We have a close working arrangement with them as well as with chemistry groups at McGill and other institutions in the area.

We are relatively close to Ottawa, to deal with all our requirements from the food and drug point of view, and with the National Research Council. But on the other hand, pharmaceutical industrial organizations have set up and undertaken research in the Toronto area as well and, eventually, this will spread to other parts of the country.

The point we are trying to make is that research is an integral part of the company. Even marketing decisions cannot be taken in a research or medical void. Our research medical people are an integral part of the management group at Smith, Kline and French. We have to be close; we have to be part of them, and we want to be part of them. Right at the moment there is about a 15 mile hiatus between our St. Laurent operation and our Senneville operation. We initially bought 30 acres of land in Senneville, and we are looking forward to the time in a couple of years when we will be back together again, the control laboratories with our pharmacy laboratoires, the medical people talking to the sales people.

Mr. MacLEAN (*Queens*): That answers my question. What I am getting at is that unless you have a situation where research is liable to occur in any province in Canada, as in Montreal, then, taking it on a different level, you cannot expect that there are not some advantages in having research in larger countries, and that smaller countries have a built-in disadvantage.

Dr. MORIARITY: Except that you had a beautiful example the other day of Switzerland. It is one of the smaller countries in the world yet obviously it is one of the most productive from a pharmaceutical research point of view.

Mr. MacLEAN (*Queens*): Yes, but they are in the heart of Europe.

The ACTING CHAIRMAN (*Mrs. Rideout*): I think we have overcome our technical difficulties, Mr. Goyer, if you would like to continue.

(*Translation*)

● (12.40 p.m.)

Mr. GOYER: My question was related to the research—I apologize for bringing this up—but there are some moments when things just go beyond the normal bounds and we have to spill out. In the research field you said that your research took place on a decentralized basis in several countries, you also say in your brief that headquarters require only the sum of $500,000, approximately, per annum and you say that the products are supplied without charge from one affiliate to another. I understand from this sentence that you do not sell your patent rights to anyone of your subsidiary agents or anyone of your affiliates in Europe, for instance. All you do is transfer your rights and you receive no odd money for the transfer of such rights, is that true?

(*English*)

Mr. DAILY: Mr. Goyer, that is not necessarily true, because we really have not reached the stage—unfortunately, you might say—of having had to negotiate with any of our affiliate companies in the world for the transfer to them, or the sale to them, of the rights for any of our patented discoveries.

Dr. Moriarity did mention that we are registering patents for one of our discoveries in various countries of the world, but it has not yet reached the stage of having to decide what the international quid pro quo would be,

financially speaking, for this transaction. So, quite honestly, I cannot answer what would happen under those circumstances. Perhaps Mr. Martin can.

Mr. MARTIN: Up to date it has been general company policy throughout the world that there has been no charge for the product rights which a subsidiary uses. We in Canada have never had to pay for all of the products which we have on the market at the moment. I believe that this will probably change, and it seems to be fortunate that it is changing just at the time when Canada, for the first time, is going to be producing products. It seems to have worked in our favour all along.

(*Translation*)

Mr. GOYER: In all countries of the world—here, you are not obliged to answer this question, but I just want to know what takes place here in relation to other subsidiaries in other countries—do you always have the same proportion in your other companies of about 50-50 in relation to the amount that you transfer to the parent company for inter-company charges and the amount devoted to research? Because I note from your brief that over a period of 15 years, you have reinvested in the Canadian company about the same amount as that which you disbursed to the parent company for inter-company costs. Is that a general policy that is accepted throughout the affiliate companies?

(*English*)

Mr. MARTIN: No, sir. It is entirely a coincidence that these two amounts happen to be about the same order of magnitude in the Canadian history. In fact, with regard to the other subsidiaries, particularly those which are under the wing of the international group which I mentioned previously, we are much more favourably situated than they because we do have the research expenditure in Canada, and most of these others do not have.

(*Translation*)

Mr. GOYER: But you will recognize that the coincidence happens to be rather head on, over a period of 15 years you have had 50-50 and in 1965 you also have 50-50, the same proportion. Does this really remain just a pure coincidence?

(*English*)

Mr. MARTIN: So far as I am concerned yes, indeed, it is. Dr. Moriarity as he mentioned, is now going into a $800,000 program next year. Our sales estimates indicate that we will not be paying anything like this amount in inter-company charges.

(*Translation*)

Mr. GOYER: I understand that you are saying "insofar as you are concerned," because on the one hand it is not you who carry out the accounts, the amount that you receive from the parent company for inter-company charges. But I note that a great deal of your research nevertheless does take place in Canada and that furthermore, you are asking that the Government should extend further assistance to you, directly or indirectly, in order to engage into research here in Canada. Do you not think that the question of rights in inter-company charges should be corrected immediately?

(*English*)

Mr. DAILY: Mr. Goyer, I see Mr. Martin is looking at me so I assume he thinks I should answer the question. All I can do is say that while we have been spending this money in support of our Canadian research effort, there have been no discoveries that have been an outgrowth of this research effort to date which have been transferable, through patent rights and so forth, to other countries. Beyond that, I cannot really answer the financial aspects of the argument.

(*Translation*)

Mr. GOYER: You are being extremely humble, Mr. Daily. But what I would like is that your company should draw up its policy before discovering an important product which would involve important charges and which would be an asset for the Canadian company. What we are interested in is that the more the Canadian company gets in revenue, the more we hope it will reinvest in research and the more will the Canadian citizens be happy with our policies, because we are not here to finance research for the benefit of other countries, scientifically speaking of course, we are not here to give it to other countries without their paying any charges for such research carried out in this country. Because you say very well in your brief that it is the consumer who is paying for the research and that that will have to be continued though it takes place on a direct basis with the assistance of the Government. I agree to the general principle, but I think that the other consumers in other countries should also pay research charges. Would you agree with this very general outline?

(*English*)

Mr. DAILY: I think I agree with the philosophy of your argument, Mr. Goyer; you have given me a lot of reasons why this should be done. It will help strengthen my own position when it comes to discussing this question with our parent company in Philadelphia.

The ACTING CHAIRMAN (*Mrs. Rideout*): Mr. Laidlaw, did you wish to make a few remarks?

Mr. LAIDLAW: Madam Chairman, could I in about two or three minutes ask a few questions. I would like to refer back to the licensing situation, and I would ask the committee to turn to page 42.

Mr. Daily, you stated that your company signed a voluntary licensing agreement with Mowatt and Moore with respect to stelazine, and that the royalty arrangements were satisfactory to both parties. Are you in a position to state what those royalty rights were by this voluntary licence?

Mr. DAILY: Mr. Laidlaw, I do not know whether we have with us the fine details of the agreement that was worked out with Mowatt and Moore, but I think Mr. Martin, if he does not have the details, could generalize on the question.

Mr. MARTIN: I think that the details could be provided to Mr. Laidlaw, once again in confidence, because I think he will realize that this information would be of great assistance to the competitors of Mowatt and Moore.

Mr. LAIDLAW: I understand. If they could be supplied in confidence, it would be appreciated. The reason I asked the question was that later apparently

Micro Chemicals Limited applied for a compulsory licence from the Commissioner of Patents and I was wondering how much lower the Commissioner of Patents granted for royalties than the ones you apparently worked out satisfactorily on a voluntary basis. This is the reason for my question.

Mr. MARTIN: This is one of the anachronisms of the system, Mr. Laidlaw. The Commissioner has not set the terms yet either on royalty or on any other of the terms which we had recommended.

Mr. LAIDLAW: Is this still before the Commissioner?

Mr. MARTIN: It is still before the Commissioner.

Mr. LAIDLAW: Oh, I am sorry; I thought it was settled.

Mr. MARTIN: Well, the licence has indeed been granted and Paul Maney is selling the product, but he is selling it without any knowledge of the terms and conditions.

Mr. MACKASEY: May I ask a supplementary question. How can they establish a price with any accuracy, not knowing what the royalty eventually is going to be.

Mr. MARTIN: We have asked the same question, sir.

Mr. MACKASEY: You do not know the answer.

Mr. MARTIN: No, I do not, sir.

Mr. LAIDLAW: I have one question arising also along the same lines, Mr. Martin. How is it that Mowatt and Moore can market the product which you licensed to them voluntarily at a price less than your own when, presumably, they are paying some form of royalty to you as a result of a voluntary licence?

Mr. MARTIN: We are in the same position with respect to Mowatt and Moore as any other person coming along a few years after the product is introduced. Mowatt and Moore does not have the expenses we have had to introduce the product and, therefore, their costs are lower than ours.

Mr. LAIDLAW: It just seems strange to me that you have licensed another firm to market the same product when the firm which you are licensing is underselling you.

Mr. MARTIN: I do not think I can answer the question very intelligently, sir. There is a differential there by which Mowatt and Moore can afford to undersell us to some extent.

Mr. MACKASEY: May I ask a supplementary question. In other words, what you are saying is that you are still amortizing the cost of producing this product, in a sense. You have gone through all your testing and it has been established on the market. You are still selling higher than Mowatt and Moore because of the initial cost that you incurred. Are you amortizing these costs over a certain period of time, or are you permitted to do so?

Mr. MARTIN: No, sir. It is my view that the present price of stelazine and the returns which we are getting from all of our product lines do not amortize the cost of those products but go to pay for the research which we are doing today.

Mr. MACKASEY: On products in general.

Mr. MARTIN: On new products, yes.

Mr. MACKASEY: Is this not also true of Mowatt and Moore? Where do they get their funds for their research?

Mr. MARTIN: So far as I know, sir, they are not doing any research.

Mr. LAIDLAW: Just to repeat this again, presumably, Mowatt and Moore are making a profit or they would not be selling it at that price. If they are making a profit and paying you a royalty and underselling you, then is it not axiomatic that your price is too high?

Mr. MARTIN: No, sir, I do not believe it is. Our price has to go to pay for services which we provide and for continuing research, which Mowatt and Moore are not doing.

Mr. LAIDLAW: Then, why did you license Mowatt and Moore voluntarily to cut into your market?

Mr. MARTIN: We had many reasons for licensing Mowatt and Moore, and some of them are commercial. We believe that Mowatt and Moore, by their activities, with an additional 40 detail men, could expand the market and over the lifetime of their selling the product we would, by this means, produce more net income than by not licensing them. I think that was the main reason.

Mr. LAIDLAW: Turning to just another question. As you are aware, Mr. Martin—and I will only take from 1949 on—under the United Kingdom Patents Act and their compulsory licensing provisions, a comptroller will allow a licence to import, whereas this does not form part of the Canadian legislation, although it has been recommended by the Hall Commission. I was wondering if you have any knowledge as to your sister corporation in the United Kingdom, how it is faring financially since 1949 in spite of the compulsory licensing provisions in the United Kingdom, which are even broader than our own?

Mr. MARTIN: I am afraid, sir, I do not have any direct knowledge myself. Mr. Henderson, who just spoke to me, feels that there is perhaps some error in your assumption, and no licences to import have in fact been granted.

Mr. LAIDLAW: This is true; I realize this. Nevertheless, the legislation does provide for that. It is broader than ours.

Mr. MARTIN: It does indeed, but I have some information in front of me about the U.K. situation which, as I say, I do not know too much about; but it appears to date that only 40 applications have been received for ethical pharmaceuticals in the United Kingdom and only two have been granted, so I do not believe that the situation there is very much different than it is here.

Mr. MACKASEY: Why would the 38 companies matter? What other criteria do they have that we do not have?

Mr. MARTIN: I cannot answer the question, sir.

Mr. MACKASEY: Would it be on safety? Would it be on lack of knowledge of where these exports are originally procured, or do they come from some country that England does not recognize, for instance, Poland?

Mr. MARTIN: I do not know.

Mr. MACKASEY: Does anybody know?

Mr. SHELDON: Could I break in for one moment I have here a general statement of the figures which might be helpful. It says that, to date, of 45

applications for compulsory licences in the United Kingdom, submitted under section 41, 40 relate to ethical pharmaceuticals. Compulsory licences have been granted in 9 cases but 7 were subsequently abandoned, and only two licences are currently being worked. I think, in general, there was a more stringent looking-into the compulsory licence applications than there has been in Canada from a variety of points of view.

Mr. LAIDLAW: Would this not indicate to you, Mr. Sheldon, that there is really nothing to fear from compulsory licensing provisions.

Mr. SHELDON: Not in Canada, but I am referring to the English situation.

Mr. LAIDLAW: In the United Kingdom.

Mr. SHELDON: Nothing to fear, I think, is an exaggeration. So long as the law is there there is is always something to fear. It is a question of how it gets interpreted, and interpretations can change.

Mr. DAILY: The pharmaceutical industry in England, if I may interject, has been just as exercised as it has been in Canada and other parts of the world about the way compulsory licensing has evolved, judging from the amount of discussion, briefs and so forth that have been submitted to various bodies in England on this aspect of the patent law, both by the pharmaceutical industry as well as, I understand, the Royal Institute of Patents who, by the way I believe, also feel that section 41 (3) has outlived its usefulness, if it ever did have any usefulness, in England. So, I would say that people are concerned in England the same as we are concerned in Canada.

Mr. MACKASEY: Your main concern about the Canadian interpretation of the section, is not really that it will be applied in Canada but it may be the source of jurisprudence to be followed by other countries.

Mr. DAILY: I think that certainly would have an effect. Anything that is done in Canada or, for that matter, in any part of the world these days, does have an increasing influence on other countries because the world is getting smaller. Canada has always been looked to by countries abroad as being a well-run country, a well-administered country. The Food and Drug directorate, in particular, has had a great deal of support and interest from underdeveloped countries around the world. If Canada decided to turn the clock back and further weaken an already intolerable situation with regard to patents in the pharmaceutical industry, we would be concerned about the effect this would have elsewhere.

Mr. LAIDLAW: Madam Chairman, I see that one o'clock has come. There are a number of technical questions that I would like to ask Mr. Daily, and I wonder if the committee would give me permission to write to him eventually and then table my letter and his reply. I think that would be more satisfactory.

Mr. MACKASEY: I would like to get a copy of the technical questions. I am interested as well.

The ACTING CHAIRMAN: Mr. Laidlaw, I am sure, would be glad to give you a copy, Mr. Mackasey.

Mr. DAILY: We would be very happy to follow this procedure ourselves.

The ACTING CHAIRMAN: We will then adjourn until next Tuesday morning, gentlemen.

The meeting is adjourned.

APPENDIX "I"

SUBMISSION

to the

SPECIAL COMMITTEE

on

DRUG COSTS AND PRICES

of the

HOUSE OF COMMONS

by

SMITH KLINE & FRENCH/MONTREAL

October, 1966.

CONTENTS

INTRODUCTION

This presentation is made by Smith Kline & French of Montreal, the Canadian operation of Smith Kline & French Laboratories, an international research-based pharmaceutical company.

Smith Kline & French Laboratories originated in 1830 in a Philadelphia apothecary shop. The Canadian operation was established in 1949, our products being distributed previously through a sales agency. Our building in St. Laurent, housing both plant and head office, has been considerably enlarged since then, and we have established a research laboratory at Senneville, Quebec. We have about 300 employees, of whom 20 per cent hold university degrees. All but two of the members of senior and middle management are Canadian citizens. In terms of sales of prescription pharmaceuticals we are at present the fifth largest Canadian company.

The basic presentation for our industry concerning the cost of drugs has been made by the Pharmaceutical Manufacturers Association of Canada, an organization to which we give our strong and continuing support. In this submission we will try to illustrate some of the principles set out by PMAC in terms of the activities of a particular company. We will also enlarge on certain matters relating to the provision and cost of prescription drugs that appear to us to have a direct bearing on the proper development of health services in this country.

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SMITH KLINE & FRENCH IN CANADA

Smith Kline & French is first and foremost a manufacturer of prescription drug products, either discovered or developed in the company laboratories. While we market preparations in an increasing number of therapeutic categories, for the past decade our main activity has lain in the psychotropic field. Notably, the company was a pioneer in the development of the phenothiazine tranquilizers.

In recent years we have been enlarging the base of our operations through diversification. Here in Canada, our proprietary division, known as Menley & James Laboratories, markets the 'Contac' line of cold products and 'Sea & Ski' suntan preparations. However, our parent company has launched into several other spheres of activity, including medical and scientific instruments, surgical sutures and veterinary products, and we expect to see this expansion reflected quite soon in the scope of our own operations.

Our sales have grown steadily since the company was established in Canada. However, net earnings have tended to drop as a percentage of sales from their peak in the mid-fifties—apart from the impact during the past three years of the Federal government tax incentive for research investment.

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	Sales (Excluding Federal sales tax)	Net Earnings	Percentage of Sales	
1950	$ 645,000	$ 72,000	11	
1951	700,000	85,000	12	
1952	855,000	123,000	14	
1953	1,160,000	176,000	15	
1954	1,420,000	238,000	17	
1955	1,881,000	362,000	19	
1956	2,219,000	414,000	19	
1957	2,364,000	372,000	16	
1958	2,667,000	212,000	8	(flood damage of $300,000)
1959	3,287,000	540,000	16	
1960	4,026,000	574,000	14	
1961	4,749,000	700,000	15	
1962	4,976,000	697,000	14	
				Excluding research tax incentive
1963	6,307,000	1,186,000	19	15
1964	6,073,000	1,194,000	20	7
1965	7,326,000	743,000	10	9

The intensified growth in sales during the past three years is due in large measure to the establishment and success of our proprietary division; it accounts currently for about 25 per cent of our total business. In addition, there has been a substantial increase in exports, reaching a total wholesale value of $511,000 in 1965.

The following figures for expenses, taxes and earnings in 1965 relate to the total operation of our company.

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Expenses, Taxes and Earnings—1965 (based on audited statement)

Cost of Goods including Quality Control	$1,175,000
Distribution (including warehousing)	198,000
Research and Development	534,000
Medical Information and Marketing Activities	1,382,900
Proprietary Product Marketing and Advertising	843,100
Marketing Administration	543,000
General administration and inter-company service charges	1,043,000
Income Taxes	824,000
Total Expenses and Taxes	6,543,000
Net Earnings	743,000
Earnings remitted to parent company	153,000
Earnings retained in Canada	590,000

Inter-company service charges, included as part of the cost of general administration, amount to approximately $500,000 on an annual basis. This payment represents a proportionate share of the management services provided by and through the international division of Smith Kline & French Laboratories.

The parent company makes no other charges. Products are available free of inter-company royalty, and no specific Canadian contribution is required to its research and development expenditure, which amounted last year to more than

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$23 million. Raw materials are sold to us at cost, a contributing factor to the comparatively low cost of manufacturing in relation to total expenditures.

From our first year of operations in 1950 up to the end of 1965, Smith Kline & French sales in Canada amounted to $50,655,000, and generated earnings after taxes of $7,687,000. Of this sum, $4,023,000 was reinvested in the business here, while $3,664,000 was remitted to the parent company. Earnings remitted from Canada amounted over the 16-year period to approximately 7 per cent of sales.

If our earnings are compared with the average reported for members of PMAC, SK&F appears one of the more profitable companies. In this we reflect the record of our parent company. However, the prices of our products, whether patented or not, are fully competitive. And a good rate of profit in this highly competitive industry is proof, we believe, of successful management in the broadest sense: the ability to develop useful and desirable products, and market them at prices which appear reasonable to those who determine their purchase. We would emphasize here that the value of what we sell lies not only in the quality and therapeutic advantages of the actual products, but also in the scientific services with which they are supported.

Further, it is important that the profit earned by the drug manufacturer be related to the cost of the prescription product to the consumer. The following chart shows the average cost of a prescription for five major SK&F products in 1965, together with the effect on that cost of eliminating all our company's profit.

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Product	Most Common Rx Size*	Average Rx Price*	SK&F Selling Price less Sales Tax**	SK&F Profit***
'Stelazine' Tablets 2 mg.	30	$4.46	$1.72	17 cents
'Maalox' Suspension 12 ozs.	1	2.11	.80	8
'Dexamyl Spansule Capsules No. 2	30	6.16	2.84	28
'Eskatrol' Spansule Capsules	30	5.29	2.41	24
'Stelabid' Tablets No. 2	30	4.83	2.07	21

*Independent market survey.
**Price to pharmacy less 15 per cent wholesaler markup, less Federal sales tax.
***Profit after taxes in 1965 at 10 per cent of sales.

During the sixteen years we have been in business in Canada we have steadily increased our investment, having built and twice extended the plant in St. Laurent and established a pharmaceutical research laboratory at Senneville at a cost of $1,700,000. Investment in fixed assets was valued at cost at the end of 1965 at $3,297,000. To meet the continuing growth in our business we expect in the near future to undertake a further major building program, costing approximately $4,000,000.

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However, one characteristic of this industry is the heavy investment in people—scientists, technicians and other skilled personnel. In our own case, salaries, wages and benefits now amount to 35 per cent of operating expenditures. Five years ago they accounted for about 30 per cent.

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MANUFACTURING

Since our company was established in Canada we have built up by stages a complete pharmaceutical manufacturing operation. This means that we can synthesize chemicals as well as formulate, manufacture and package all dosage forms and strengths, including a complex long-acting medication, 'Spansule' sustained release capsules. More than 85 per cent of the products we sell are manufactured in this country, while 10 per cent are imported in semi-manufactured state.

One result of developing a complete manufacturing operation is that we are able to offer a flexible and reliable source of products to fellow members of the SK&F organization and so expand our export activity. The sources of pharmaceutical chemicals in Canada are quite limited, so that most of these must be imported. Nevertheless about 60 per cent of the materials we use—chemicals, packaging, etc.—are purchased from Canadian suppliers.

The company is qualified to tender for Federal government business under the Canadian Government Specifications Board, having been inspected in October 1963. Before the CGSB standards were put into effect we assisted the government by giving in-plant training to two of its inspectors.

Quality Control

A distinguishing feature of the manufacturing operations of a reputable

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pharmaceutical company is the time and attention devoted to quality control. In our Manufacturing Division one person is employed on testing and inspecting for every five production employees.

Quality control procedures go far beyond the checking of finished products. They are designed to ensure that high standards are maintained throughout the chain of production—formulation, manufacture, packaging and distribution. They give assurance of product identity, purity, uniformity, potency and stability. Basic standards for quality control personnel and procedures have been drawn up by the Canadian Government Specifications Board, but long-established company requirements are considerably more demanding.

The pursuit of quality of the research-based manufacturer can be traced back to his original research and development work, including clinical investigation. This will provide a well-developed product with defined therapeutic attributes, a product to which quality control concepts are then applied. Such a depth of know-how cannot be duplicated merely by meeting the standards set out in a compendium. Dr. Edward G. Feldmann, Chairman of the Committee of revision of the National Formulary, made the following statement in a speech entitled "The Relationship of Control Procedures to Drug Standards" (American Journal of Hospital Pharmacy, September 1964):

> "Many people in pharmacy have the mistaken notion that if a product meets all the specific tests and requirements detailed for that

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> article in the U.S.P. or N.F. monograph, then that particular product has to be perfectly satisfactory. While I wish this were true, I am sorry to say that it is not, and the nature of the problem is such that we can never hope to develop compendium monographs which will give complete assurance of any product's absolute suitability."

"Yellow Sheet" Control

Quality control per se begins during the development of a product for sale, being based on what is referred to as "Yellow Sheet" Control (Appendix A).

To ensure that there is a thorough investigation into all the factors which can affect pharmaceutical quality, the "Yellow Sheet" must be signed, section by section, by the responsible executive. His signature certifies that the results of a particular investigation have proved satisfactory; the final signatures, those of the Director of Manufacturing and the General Manager, give approval for the release of the product.

"Green Sheet" Control

Frequently, during the life of a product, improved materials become available or more efficient production methods are developed. Before these can be introduced, a similar detailed control is undertaken, based on a document known as a "Green Sheet". The scientific evidence required for completion of a

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"Green Sheet" will depend on the nature of the contemplated change, but there is a thorough new investigation in all relevant areas. (Appendix A)

Control during Manufacturing

Scientifically established manufacturing processes must be backed up by proper administrative procedures.

When a batch of any product is to be prepared, the formula is taken from the Master Formula Card. Each batch is given its own number. A batch card identifies the material at every stage of production, and batch identification must appear on the final package.

Before manufacturing begins all raw materials are identified and weighed, with double-checking. In addition, a check of the active ingredients is carried

out by a pharmacist or qualified chemist. Related tests to ensure quality and purity are carried out at each stage of manufacturing. The yield of the active ingredient has to measure up at all times to the expectations established for it.

Analytical Control

Analytical control is fundamental to the assurance of pharmaceutical quality. It begins with the laying down of specifications for both active and inactive ingredients. This requires detailed knowledge of the chemical and physical processes used by the supplier in the preparation of the materials, and

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resultant awareness of what impurities are most likely to occur. Any new supplier must first provide samples of his goods for testing and quality evaluation.

All deliveries of materials are tested to ensure that they measure up to specifications. Modern techniques used for testing include: fluorimetry, ultra-violet and infra-red spectroscopy, microscopy, liquid/liquid and liquid/solid chromatography, including thin-layer techinques, gas/liquid chromatography, polorimetry and microbiology.

Analytical control continues throughout the production process, with the tests varying according to the type of product. For instance, the following control tests are carried out on every batch of tablets produced:

(a) *Appearance* Samples are compared to a standard tablet to ensure that there is batch-to-batch uniformity.

(b) *Identity* Tests are carried out to ensure that tablets contain the correct ingredients.

(c) *Hardness* Tests ensure that the tablet is robust enough to stand up in transit to the wholesaler and the retailer, and in subsequent handling.

(d) *Disintegration* In vitro testing ensures that the tablet will disintegrate within a given time, so that the active ingredient is properly

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available to the patient.

(e) *Potency* The quantity of active ingredient is checked; it must be present within closely defined limits.

Inspection Control

Physical tests, based on predetermined specifications, are used to control the quality of packaging materials. These are sampled and tested before they can be used in production.

Quality control personnel carry out tests on all products as they are being packaged. The type, number and nature of the tests will vary with the product, but they cover such matters as appearance, identity, absence of foreign matter, labelling, quantity, etc. Samples of the finished product are taken out of each packaging lot and retained for reference.

Buildings and Equipment

Manufacturing facilities must be specifically designed to safeguard the quality of each product, and ensure there is no cross-contamination of one product with another. Our installations therefore have to provide the following characteristics:

(a) Proper reception and storage of raw and packaging materials;

(b) Adequate segregation and identification of materials during manufacture and packaging;

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(c) Ease in maintaining cleanliness and avoidance of contamination;

(d) Isolated areas for particular activities to prevent "dust migration";

(e) Suitable facilities for sampling;

(f) Sufficient laboratory space and facilities;

(g) Proper storage conditions for finished products.

Cost

The cost of quality control includes, but substantially exceeds, the cost of maintaining an analytical laboratory. Proper quality control requires special attention to cleanliness and efficiency throughout the manufacturing process: it depends upon the recruiting and training of qualified staff with a high sense of responsibility.

Whatever new steps are taken to improve the efficiency of the quality control operations, its costs can be expected to increase. Therapeutic compounds of growing complexity and potency will require still more intricate analytical techniques, employing delicate and expensive apparatus.

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RESEARCH AND DEVELOPMENT

Research and development (R&D) has been a major operating cost for this company for many years, and in 1965 the company as a whole spent $23,806,000 on R&D. In the table below we have set out: 1) the amounts spent on R&D in Canada in 1961-65; and 2) the percentage of sales of prescription products these amounts represent.

	R&D expenditure in Canada (other than capital expenditures)	% of Canadian sales of prescription products
1961	$156,547	3.5
1962	236,826	5.2
1963	290,719	5.2
1964	445,211	8.6
1965	534,547	9.3

In contrast, the expenditure of Canadian industry in general on R.&D. amounts to less than 1 per cent of sales.

It is the general SK&F policy to develop our research commitment in line with the importance of the national market and also the quality of scientific activity in a country. We began to set up a pharmaceutical research centre in Canada before the Federal government announced its research tax incentive. In so doing, we took what appears in retrospect to have been an unduly optimistic view of the administration of Section 41 of the Patent Act. In this industry compulsory licensing, as now practised, seriously undermines any

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encouragement provided by tax incentives.

Pharmaceutical companies, competing strenuously in important therapeutic fields, perform a research function which could not be performed as efficiently through any other system. The research break-throughs may or may not come from the laboratories of industry; many have done so in the past, many others have originated in university laboratories with the collaboration and financial support of industry. In future the universities my well provide more of the fundamental discoveries leading to new medicines. However, application of the initial concept becomes increasingly demanding, and this is a task which only industry is fitted to carry out. Further, the heaviest costs are incurred during the application stages of research, costs that relate directly to the assurance of drug safety.

The sequence and relative cost of R&D activities are illustrated by the history of a recent product of this company, a diuretic which we marketed in the United States in 1964 and in Canada in 1965. The compound, triamterene, is sold by Smith Kline & French as 'Dyrenium'; it is also a component in the combination product 'Dyazide'.

Triamterene was discovered through a program of research which the company was conducting into diuretic agents. A patent was applied for in 1959. Though it is impossible to allocate the costs exactly, at that time our total expenditure probably did not exeed $50,000. Then came the major part of the

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R&D effort, the transformation of the chemical compound triamterene into the medical preparation 'Dyrenium'. In the United States this work took five and one-half years and is estimated to have cost over $2 million. In Canada we incurred additional costs of about $200,000.

Throughout this lengthy period we were investing in a hazardous speculation; that is the requirement of therapeutic progress. At any time the product might have been shown to have some property which would have made it unsuitable for human administration, and our work and expenses would have gone for nothing.

The risk in pharmaceutical research is a continuing one; it remains high until the final official approval of the product, and indeed goes beyond that. Further, the rare market successes which result must carry the cost of the failures; the odds against any chemical compound proving to be a valuable medicine are estimated to be at least three thousand to one. The figures for 'Dyrenium' given above relate only to that specific product.

Pharmaceutical R&D is specific to this industry; there is little resemblance to procedures in other industries. The only way in which the medicinal value of a compound can be assessed is through exhaustive testing, first in animals, then in humans. For the most part universities do not have the time or facilities for the required animal testing, nor is such work in keeping with their academic purpose. The research-based pharmaceutical company has both the facilities and the experience of testing chemicals in animals. For instance, Smith Kline & French uses more than 500,000 animals annually in its testing programs.

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After it has been shown through animal tests that a compound may prove medically useful, we face the greater problem of determining its activity, effectiveness and safety in man. The company works closely with hospitals and other medical centres in setting up controlled studies of performance, applying our specialized skills to evaluation of the resulting data. This phase of developing a medicinal product can involve hundreds of physicians and thousands of patients, proceeding by stages, with the initial tests directed by a small number of highly qualified specialists. Finally, if the evidence indicates that the drug is both safe and effective in humans, it is submitted to the regulatory authorities for permission to market.

Concurrently, our development chemists have been preparing suitable dosage forms designed to ensure that the active ingredient is properly available in the patient's body.

Research and development constitute a single, inter-woven activity. Both the earlier and the later phases require scientific skill and intellectual application of a high calibre. The toxicologist who investigates the action of a compound on the liver, the clinical investigator who evaluates its performance in a group of patients are engaged in the total activity just as much as the pharmacologist who first determined that it was biologically active.

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Another important characteristic of pharmaceutical research is that it is a continuing process. Research on the biological properties of a drug may well continue for many years after its introduction. Certain properties, both useful and undesirable, can take considerable time to become apparent. They will require renewed evaluation, including work in the laboratory, before their true significance can be assessed. For instance, there are a number of studies being conducted today on both the therapeutic qualities and the side effects of the potent tranquilizer trifluoperazine, which we market as 'Stelazine', yet this drug was introduced in 1958, and has been very widely used in both hospitals and physicians' practices.

In the past our main sphere of activity has been the provision of drugs for mental illness. However, the company's research interests are considerably wider than this, and may be expected to change and develop in line with the advance of scientific knowledge.

The Annual Report for 1965 of Smith Kline & French Laboratories contained the following statement:

"In research and development we continue to explore new approaches in most of the major areas of medicine, including the search for

new, improved drugs for the treatment of mental and emotional illnesses, diseases of the heart and blood vessels and arthritis. We are also investigating the drug treatment of diabetes, drugs to control weight by altering body chemistry, and drugs to relax muscles and reduce pain. We are looking for antibacterial agents with a spectrum of activity different from the antibiotics now available. We are also looking for compounds that are effective against viruses, particularly those associated with upper respiratory infections."

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Pharmaceutical research, like other medical research, must be international. Smith Kline & French has research and development laboratories in the United States, Great Britain and Canada, and an interest in a research establishment in Belgium, and conducts active programs of clinical investigation in several countries. We expect our research centre in Canada to develop as a partner in this international activity. Already, Canadian personnel have performed many valuable services for Canada and other countries through pharmaceutical development work and the organizations and assessment of clinical studies.

The Medical Department

The responsibilities of the Medical Department, part of the R&D Division, begin in the early stages of a product's history and continue throughout its existence.

The department is actively concerned with the testing and introduction of new products. Our physicians initiate and supervise clinical testing programs. They are also directly responsible for the research and medical sections of submissions to the Food and Drug Directorate, both the Preclinical Submissions and the final New Drug Submissions. They discuss with FDD any queries that may arise and arrange to obtain any additional information that is required.

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Our new diuretic, 'Dyazide', can be taken as an example. The FDD notice of compliance, permitting the marketing of this product, was based on a combination of Canadian and international evidence of safety and effectiveness. The Canadian evidence included a study by 71 M.D.'s relating to 598 patients. In addition, special studies were made in metabolic units of teaching hospitals in Montreal and Halifax.

Continuing studies on 'Dyazide' include the collation and analysis of reports from some 200 physicians relating to use of the preparation in patients suffering from hypertension. We expect this will cover about 1,000 patients.

With another new product used for the control of nausea, vomiting and vertigo, 'Vontrol', arrangements have been made with 16 physicians to carry out controlled studies with a statistical structure to determine efficacy and safety in various areas of use. Each doctor will report on 25 to 50 patients, and the study is expected to take at least a year to complete.

Repeated clinical studies are required if we are to keep up to date on the effectiveness as well as the incidence of side effects of even well established

products. For instance, 'Stelazine', our major tranquilizer, was introduced in

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1958, and it has now been prescribed for millions of patients throughout the world. However, here in Canada, as elsewhere, we continue to set up new studies of its therapeutic performance. A recent study involving some 30 physicians provided detailed data relating to 540 patients.

Naturally, the physicians taking part in these clinical studies are very carefully selected according to their specialty, training and established interest in this type of undertaking. They include members of university faculties, other specialists and general practitioners.

Medical Department physicians perform a number of other essential functions. They act as an information service on company products for the Canadian medical profession, answering queries and requests for documentation that come direct to the department or are first received by our representatives. More than 300 such enquiries were handled in 1965. They collect and analyse reports of any side effects with our products that are signalled in Canada, and receive and study reports from other members of the SK&F organization. Information on side effects is immediately channeled to the Food and Drug Directorate.

The medical staff also edits the material developed by the Marketing Department to inform physicians and advertise our products, and assists in the training of field representatives.

Finally, the department controls the distribution of products which are not marketed commercially, but are employed in research studies or have proved valuable in the treatment of rare diseases and conditions.

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MARKETING

Distribution Policy

The entire range of our prescription products must be available throughout Canada at all times. We believe this can be best attained through use of the wholesaling network, and do not distribute direct to either retail pharmacies or dispensing physicians.

Hospitals, government and other institutions usually purchase products direct from the company.

Pricing Practices

The general considerations on product pricing set out in the PMAC brief (Section 5) cover our own practices. We would only add that Smith Kline & French in Canada has full responsibility for establishing its own prices; these are determined in the light of Canadian operating costs and the Canadian market. The prices of most of our products, expressed in U.S. dollars, are somewhat lower than in the United States, even with the Federal sales tax included.

There has been no increase in the prices of any of our products since 1958 except as required by a change in the rate of sales tax. During this period the Consumer Price Index has risen by 19 per cent and the index of disposable income per capita by 31 per cent.

It is the company's policy to sell to all customers, including both pharmacists and hospitals, at the same price for the same package size. Usually the unit

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price is lower on large package sizes than on smaller ones, but we do not provide any special discounts for large orders. However, for two of our products there are package sizes sold only to hospitals, and special prices may be quoted when tendering for government contracts.

In 1965, we removed the suggested price to the public from our catalogues for products available solely on prescription; the suggested price to pharmacy only is now listed. We believe that the pharmacist should determine the proper compensation for his professional services.

Returns Policy

In order to minimize any adverse effects on therapy due to the deterioration of our products with time or through improper storage, we maintain one of the most liberal returns policies in the industry. We accept all refund claims at the discretion of the pharmacist, with certain customary minor exceptions. This policy encourages the pharmacist to stock a full range of SK&F products, so that no patient is kept waiting for his medication. Further, we pay the wholesaler an additional 15 per cent on the value of any returns in order to ensure that his representatives, as well as ours, check regularly that pharmacies' stocks of SK&F products are in good condition.

We believe that this continuing concern for the reliability of its products is a distinguishing characteristic of the reputable pharmaceutical company. Those with less concern for the reputation of company or brand name do not go to the same lengths.

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Marketing—Means and Purposes

The requirements for successful pharmaceutical marketing were presented to your committee in the submission made by PMAC. Briefly, our marketing activity must serve two purposes. On the one hand, we sell products of considerable significance, potency and complexity. It is essential that those who determine the use of such products should be provided with complete and up-to-date information about their advantages and also their disadvantages. The requirement here is for an active and reliable information service, alert to change and new knowledge, and obtaining such knowledge from world-wide sources. On the other hand, we can exist only as a competitive, profit-making enterprise. Smith Kline & French has discovered and made available an important range of therapeutic advances, but these products must be effectively advertised and promoted. We have not only to inform doctors about our drugs, we must also arouse their interest and, frankly, sustain that interest.

Our marketing policies are designed to serve these two purposes as efficiently as possible. We begin with a very careful selection of products. The therapeutic need must be clear before a product is introduced. It will not necessarily be unique in its field, but it will offer the prescribing physician definite advantages.

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Smith Kline & French does not employ an advertising agency to prepare material for prescription products. All the work is done by our own marketing

personnel, under the supervision of the Medical Department. In addition, the staff in Montreal can call on scientific information and marketing experience from around the world. Notably, the Scientific Information Department in our Philadelphia headquarters has achieved international recognition from governments and medical authorities.

In all material—detailing instructions, journal advertising and direct mail—we work according to a firm policy of full disclosure. Although some mailing pieces and reminder advertisements cannot, themselves, carry full product information—e.g. detailed statements on dosage and side effects—they draw attention to the need for such information before prescribing, and indicate where it is to be found. The marketing program for each product include literature containing the full information disclosed to and accepted by the Food and Drug Directorate, and our representatives are trained to present a complete and balanced picture. Extensive information about side effects, precautions, contra-indications and overdosage is included in the information on all SK&F products printed in Vademecum International, as well as in the new Compendium sponsored by the Canadian Pharmaceutical Association. Our 1966 Vademecum listings take up 25 pages of the publication, and run from a quarter page to three pages, depending on the nature of the product.

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The extent of the marketing effort required for a particular product is a matter of judgment, based in the first instance on the advice of the Market Research Department. Many factors will influence both the initial plan and subsequent modifications. Our products generally have the therapeutic significance to justify an active program. However, we might introduce a new form of an existing product to meet the requests of a limited number of physicians; this would not call for any special marketing effort. And, on occasion, the product itself may be of restricted application. For instance, we distribute 'Stoxil' aphthalmic solution, which has shown itself valuable in control of herpes simplex keratitis, a rather uncommon viral infection of the eyes. This product was introduced with a descriptive booklet, but we have not maintained any advertising program.

The Market Research Department follows closely the performance of our various products—in relation to competitors within their therapeutic category. Marketing programs are generally developed on an annual basis, and the department will consider at regular intervals whether to maintain, slacken or intensify the effort, and where the emphasis should be placed—on detailing, direct mail, journal advertising, etc. The performance or potential of a product must justify the planned expenditure, and there comes a time in the life of most products when the emergence of new types of therapy renders further expenditure unjustifiable.

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The development of scientific knowledge may also influence the extent of informational activity. For instance, new indications may be discovered. Equally, it is vital to present physicians with full and rapid information about new side effects or contra-indications.

Such a case occurred in 1964 in connection with the MAO-inhibitor tranylcypromine, or 'Parnate', a drug for the relief of depression, which was also a component in the combination products, 'Parstelin' and 'Parstelin S-2'.

The Food and Drug Directorate considered that these products should be withdrawn from retail distribution, and their sale be restricted to hospitals and similar institutions. Subsequently, the total withdrawal of 'Parstelin' was decided on, but 'Parnate' was allowed back on the market with specific labelling and other restrictions.

The following is an outline of the action taken by the company:

1. We telephoned our wholesale distributors informing them of the FDD decision, asking them to embargo their inventories, and ship them immediately, freight collect, back to SK&F in Montreal. We informed them that a letter would follow dealing with returns from retail stores, which were to be credited according to the normal SK&F policy.
2. This announced letter was followed by a second letter reporting on the progress of the withdrawal, and setting a cut-off date for returns.

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3. Two letters were sent to all physicians drawing the FDD decision to their attention.
4. Two letters were also sent to all retail pharmacists, enclosing and enlarging on the letters to physicians.
5. A special letter was sent to all hospital pharmacists.
6. Our representatives were instructed to telephone or see personally all the physicians who they normally detailed to bring them up to date with the situation.

We believe that only a well-organized marketing department could have carried out this problem with speed and efficiency. Essential contacts were all made and letters mailed within three days of the decision to recall the product. Happily, this is not the kind of situation which occurs frequently. But any responsible pharmaceutical company should be able to recall a product promptly at the request or requirement of the Food and Drug Directorate. We included this within the conditions laid down when we granted a voluntary licence for our major tranquilizer, trifluoperazine, and have recommended to the Commissioner of Patents that it should be a condition of any compulsory licence.

Pharmaceutical companies use a variety of informational and promotional media and techniques. The balance between them can vary significantly from

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company to company, and from product to product. Our own company, for instance, tends to place its emphasis rather differently to most of our competitors. We are, for instance, the fifth company in sales in Canada, but only 23rd in the size of the detailing force. On the other hand, we have, we believe, a rather strong Market Research Department, and we employ more direct mail than do most other companies.

Visits by service representatives and direct mail advertising constitute the two major activities directed to obtaining medical acceptance of pharmaceutical

products. With both activities we endeavour to be as selective as possible, using a computer to develop our mailing lists and also the calling instructions for representatives. Selectivity is based upon a doctor's specialties and known interests.

Immediate action is taken to meet the wishes of any physicians who inform us that they do not want to receive mail or to see representatives. We have listed at present 309 doctors who do not receive mail, 102 who do not receive samples, and 384 who do not see representatives. We send litrature to 15,500 practising physicians; 8,500 are visited by SK&F representatives.

Professional Service Representatives

Experience has shown that a national network of responsible and well-trained representatives is the foundation of a proper medical information program.

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Representatives perform a dual function: they bring doctors information about our products, and also report back to the company any reactions, favourable or unfavourable, that they hear. Similarly, as noted on page 29; they play a very important role should a drug recall become necessary. Their knowledge of the company's products enables them to answer many of the questions posed by physicians, but they are specifically instructed to refer to the Medical Department any enquiries of greater complexity.

Our detailing force at present consists of 28 regular representatives and seven hospital representatives, who deal mainly with mental hospitals and the psychiatric departments of general hospitals. Six men, who have shown particular ability and have at least five years' service with the company, hold the position of senior representative. The force is supervised by four regional managers.

Representatives are selected for a number of qualities. Education, experience, personality, character must all be considered. A university education is a decided advantage, but we do not regard this as a sine qua non. Some of our best representatives find a rewarding and satisfactory career in field work, particularly in the specialized tasks of hospital relations. Others have been promoted to a variety of market research and marketing positions.

Training is a continuing activity, and we have a full-time technical lecturer on staff. The new representative receives three weeks of training before he calls on physicians, and then works for at least one week under direct supervision.

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Also, during his first six months he must complete a special course of home studies. These deal with the medical and scientific background to our products as well as the products, themselves.

Towards the end of his first year the representative is called in for a ten day seminar covering all aspects of his work, concluding with written examinations. All representatives attend such a seminar at least once every two years. In addition there is an annual contest in technical knowledge, with awards for the best informed representatives.

Special courses are set up for new products, and the lecturer is called in by the regional managers if they find any of their men weak in particular areas of

knowledge. Also, the regional managers hold regular meetings with their men, and include technical tests and training.

In general, a representative is responsible for calling on and informing about 300 doctors. His year is divided into eight detailing periods. In each period, he handles one main detail and two shorter details, and may in addition deliver samples of certain relatively uncomplicated products, for instance, an antacid preparation. The information he should present is prepared in a booklet under the supervision of the Medical Department. Certain information—for instance, warnings on the side effects and contra-indications which can be encountered with a particularly potent preparation—must be presented to any physician he details.

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Hospitals representatives have similar duties. Our most important hospital products are in the psychotherapeutic area, and these men become very knowledgeable both in the behaviour of the products and in the broader aspects of mental health and mental illness. To support them in their work, the company maintains an extensive film library on these subjects, and also provides a number of other special services, referred to below. Naturally, we expect the reputation of the company as a responsible, service-minded enterprise to assist our men in establishing good relations in the hospitals they visit; we do our best to ensure that this reputation is justified by both the conduct of the representatives and the quality of the services they provide.

In this connection, we would quote from a letter received last year from the superintendent of an important Ontario hospital:

> "At a Medical Advisory Board meeting, your hospital representative, Mr. Russell Fraser, made representation to our medical staff which favourably impressed them. As you know, our hospital had made a decision to exclude detail men from visiting physicians and, instead, represent their firm at exhibits in the lounge at the first of the month. In a well-prepared, documented talk Mr. Fraser convinced the Medical Advisory Board of the need for hospital representatives being allowed to see each clinician who wished to see him and, not only that, but caused

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> us to re-examine our policy with regard to the exhibits in general.
>
> "It was the final decision of the Medical Advisory Board that we reverse our suggested policy of exhibits and return to our former method of allowing the representatives to visit the physicians who desire to see them. May I also state that Mr. Fraser brought to our attention several points about ethical detailing of which some of us were not aware, and I think this will be to the betterment of relations in general."

Direct Mail and Samples

The PMAC presentation reviewed in some detail the uses of direct mail and pharmaceutical samples. Both, we believe, can be valuable, even necessary elements in a marketing program.

Direct mail is a fast means of getting medically controlled information to physicians, including those not visited by representatives. The range of our

direct mail literature is considerable—from reminder cards to detailed brochures and reprints of scientific papers. Its usefulness and suitability will, we believe, be best demonstrated through a display of recent productions.

Government regulations allow samples of prescription products to be given to a physician only in answer to his signed order; he may, however, sign for a six-month program of deliveries. Every order form presented to a physician for signature must contain exact information about the quantity, formulation and potency of the products concerned.

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Each sample of an SK&F product delivered to a physician is sufficient to provide a meaningful clinical trial for one or more patients. Full prescribing information accompanies each sample.

As a convenience to the profession, we have developed the SK&F Sample Subscription Service covering a six-month program of deliveries of our most significant products. A physician may sign an order for the total service or for only those products which he considers will be valuable to him in his practice.

In addition, we fill any special requests for our products from licensed physicians. In 1965, these amounted to 22,000 separate requests, many of them covering a number of products.

Special Services

We like to think of Smith Kline & French as a company with a public personality as well as a line of products. This personality has resulted in part from the development of a number of special services for medicine, pharmacy and nursing, as well as for lay groups interested in mental health and other health questions. We believe that the financial outlay such activity requires is well justified from a long-term marketing viewpoint. While corporate good citizenship is never wholly altruistic, we also believe that the value of these services to the community far outweighs the very slight effect on the price of our products.

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We have sponsored and distribute a number of films for information and training purposes, with particular emphasis on psychiatric and mental health subjects. In 1964, "Mrs. Reynolds Needs a Nurse", a training film on how to cope with a worried and troublesome patient, produced by Robert Anderson of Ottawa, won the Canadian Film Award for instructional films. In 1966, "Le Troisième Oeil", a film on psychiatric nursing made in both French and English by Robert Anderson at Notre Dame Hospital, Montreal, was one of three nominations for the award in this category.

SK&F representatives are trained to teach closed chest cardiac massage in the event of heart arrest, combined with mouth-to-mouth breathing. Under medical supervision, demonstrations of these techniques are given frequently to hospital staffs as well as to interested lay groups. One of our representatives, Mr. Glenn McKinnon, had the privilege of appearing before a meeting of the Voluntary Health Committee of the House and Senate earlier this year.

For a number of years we have provided facilities for closed circuit colour television to medical conventions, allowing operations and other medical proce-

dures to be broadcast to a large professional audience. This has come to be an appreciated feature of the meetings of the Royal College of Physicians and Surgeons and the Canadian Medical Association. In 1967, special programs will

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be presented at the CMA convention, the international assembly of l'Association des Médecins de Langue Française du Canada, and the convention of the Canadian Orthopedic Association. The equipment is carried in a mobile unit which travels throughout the year across the United States and Canada, and the entire technical side of the production is handled by SK&F personnel.

We have also set up international telephone links for medical and pharmaceutical meetings, including both trans-Atlantic and trans-Pacific conferences for major pharmacy conventions.

The company regularly sponsors and organizes conferences on mental health matters, dealing notably with the requirements of the discharged mental patient (Aftercare), and effective group therapy in mental hospitals (Remotivation).

In 1965, the Canadian Mental Health Association presented the company with a National Recognition Award, "in recognition and appreciation of outstanding public service in the field of mental illness and mental health." This is the only time this award has been made to a company.

SK&F distributes two magazines which have won considerable acclaim: 'Consultant', a monthly publication for the general practitioner, contains practical articles on medical problems and methods by top men in their field; 'Consultations' is the French version. 'Psychiatric Reporter', which appears

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quarterly, is directed to psychiatrists and others concerned with mental health and mental illness. Both publications carry some product advertising, but there is no promotion in the editorial content.

The Costs of Medical Information and Marketing Activities

The figures given on page 4 of this brief for the company's expenses in 1965 cover our total operations. The cost of medical information and marketing activities has been a subject of particular discussion and criticism, and so this cost is reviewed below in greater detail. The figures relate only to the sale of prescription products.

Year	Sales	Medical Information and Marketing Activities	Percentage of sales
1960	$3,835,700	$1,068,200	27.8
1961	4,532,100	1,090,600	24.1
1962	4,525,900	1,000,100	22.1
1963	5,561,000	1,176,600	21.2
1964	5,176,000	1,120,400	21.6
1965	5,771,800	1,382,900	24.0

The following breakdown for 1965 shows the relative significance of various activities and expenses.

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Activity	Cost	Percentage of SK&F sales dollar
Professional Service Representatives		
Salaries, etc.	$319,600	5.5
Travel, etc.	217,800	3.8
	537,400	9.3
Mailed literature and sampling service	329,200	5.7
Samples delivered by representatives	98,600	1.7
Journal advertising	67,400	1.2
Other product material and activities	81,600	1.4
'Consultant', 'Consultations', and 'Psychiatric Reporter'	79,200	1.4
Vademecum, SK&F catalogue and special product services	63,100	1.1
Films and other non-product services	126,400	2.2
	1,382,900	24.0

Information and advertising constitute a heavy expense for a pharmaceutical company that depends upon its own products and reputation to obtain and hold its market. We believe it an unavoidable expense in a competitive, research-based industry, in which full disclosure of information is an absolute requirement.

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PRODUCT INTEGRITY

Smith Kline & French products are selected for their therapeutic value. They are as safe and reliable as extensive know-how and strict quality control can make them. Like the majority of reputable pharmaceutical companies, in Canada and elsewhere, we use brand names to identify our products.

Any move to weaken the validity of pharmaceutical brand names would endanger the integrity of the medication Canadians receive. It is a truism that quality cannot be inspected into a product; quality is the end result of corporate philosophy and controlled production. The brand name or the manufacturer's name is the only assurance physicians and patients have of therapeutic integrity.

The Danger from Counterfeiting

In this connection, we would draw attention to the lack of legislation in Canada against the counterfeiting of branded products. The ability of counterfeiters to copy a well-known product, using the same format, colour, etc. encourages substitution, whether voluntary or involuntary. This can create a serious threat to the health of the recipients, for the counterfeiter is not likely to be over-zealous in his control of product safety or reliability. Indeed, like other companies, we have well-tested evidence of the inadequacy of a number of counterfeit copies of our own preparations. Incidentally, since the counterfeit

is designed to be passed off as the known brand, it is often dispensed at a similar price.

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With certain of our products, those containing amphetamines, there is an added health hazard, for counterfeits, already tainted with illegality since they usually violate the law governing trade marks, find their way most easily onto the black market.

We would strongly recommend to the Committee that it consider the desirability of legislation to prevent counterfeiting, whether or not trade mark protection can be invoked. Recent U.S. legislation in this field is attached as Appendix B.

The Importance of Patents

The benefits which pharmaceutical patents can provide for the public may be summarized as follows: they underwrite the continuation of meaningful research; they ensure that valuable new preparations are made rapidly available throughout the country; they encourage research-based companies to provide the authorities with detailed information about their products, both at introduction and on a continuing basis; they encourage such companies to develop clinical studies into therapeutic behaviour, and publish the results; in general, they stimulate the serious exchange of information between the manufacturer and the medical profession.

However, the power of the patent system in Canada to provide these benefits has been seriously diminished by the way Section 41 of the Patent Act has been interpreted and administered.

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The resulting situation was reviewed at length in the brief of PMAC. We strongly support the recommendations made in that brief for a more thoughtful definition of the public interest, and for a related administrative treatment of compulsory licence applications, based on Section 67 of the Patent Act.

In the meanwhile, we believe that effective implementation of the recommendations of the Hilliard Committee would help to ensure that adequate attention is paid to drug safety when patents are licensed. However, safety is only one of the problems which arise from the administration of Section 41. The public interest clearly requires particular care that drug patents should not be abused, with regard to price or in any other way, but it is at least equally important that the ability of pharmaceutical companies to serve major social and economic purposes as effectively as possible should not be endangered through the treatment of compulsory licence applications.

Earlier this year, this company signed a voluntary licensing agreement with Mowatt & Moore, which enabled them to market their brand of trifluoperazine in competition with our product 'Stelazine'. The royalty arrangements, satisfactory to both parties, provide us with what we consider a fair return. The agreement also contains provisions for the control of manufacturing processes and medical information, so that the integrity of the medication is protected.

Micro Chemicals Limited, with which is associated the distributing firm of

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Paul Maney, obtained during the summer a compulsory licence for trifluoperazine under Section 41 (3) of the Patent Act. Since trifluoperazine is no longer

classified as a "New Drug", crucial safety-oriented proposals of the Hilliard Committee cannot be applied to this product. The published prices of Paul Maney, Mowatt & Moore, and Smith Kline & French provide the following comparison. (In the cases of Paul Maney and Mowatt & Moore, the prices represent a 40 per cent discount off the suggested retail selling price. SK&F quotes only a price to pharmacy.)

Prices to Pharmacy for Trifluoperazine Tablets—Packages of 50

Strength	SK&F	Mowatt & Moore	Percentage difference with SK&F	Paul Maney	Percentage difference with SK&F
1 mg	$2.85	$2.55	10.5	$2.28	20.0
2 mg	3.75	3.15	16.0	3.00	20.0
5 mg	5.28	4.95	6.2	4.23	19.9
10 mg	7.02	6.75	3.8	5.10	27.4

It should be noted that the 2 mg. tablet accounts for the greatest part of retail volume, and that there is very little retail sale of the 10 mg. tablet, which is extensively used in mental hospitals. It should also be noted that Smith Kline & French alone markets ampuls, concentrates and suppositories, in addition to tablets.

Trifluoperazine tablets B.P. have according to the monograph specification recently included in the British Pharmacopoeia a potency approximately 16 per

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cent lower than the standard established over the years for our 'Stelazine' tablets. Paul Maney, in a notice published earlier this year, referred to its product as being of B.P. standard. However, tablets sold by Paul Maney have assayed across a considerable range of potencies from the lower limit of the B.P. standard to the upper limit of our own—that is, from 92 per cent of B.P. standard to 120 per cent. A patient taking Paul Maney trifluoperazine tablets may thus suddenly receive a 20 per cent increase or decrease in dosage, besides receiving on average 16 per cent less of the drug than if he were taking 'Stelazine'.

In recent weeks the firm of Jules R. Gilbert Ltd. has started to sell in Canada trifluoperazine tablets made from imported raw materials "with no knowledge as to how the said substance is manufactured", according to the company's own admission. Assays of these Gilbert tablets have shown similar variations in potency as well as a generally lower level of potency than 'Stelazine'. Yet the selling prices appear to be only slightly below those of our product. In fact, the cost per mg. of active ingredient is higher with the Gilbert tablets than with 'Stelazine'. In addition, the Gilbert tablets are so coloured that they closely resemble 'Stelazine', lacking only the initials SKF and the number designating product strength.

So far as trifluoperazine is concerned, products of this calibre could not appear on the Canadian market if the drug were classified by the Food and Drug Directorate as a "New Drug", an administrative procedure which, we believe, would conform to the spirit and intentions of the Hilliard Committee.

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However, the Directorate does not believe it has the legal right to take this step.

We would ask your Committee to assess carefully the real value to Canadians of obtaining the price reductions represented by the Paul Maney and Gilbert products.

Further, we would ask you to consider whether Section 41 of the Patent Act does not in fact constitute a disservice to the true national interest. It discourages serious research and investment—and there is always a danger of a forced licence getting into the wrong hands, which could create significant drug safety hazards. Conversely, effective use of Section 67 of the Patent Act would not only prevent any abuse of pharmaceutical patents, it would also encourage the expansion of research-based manufacturing in Canada.

Finally, we would draw to the attention of the Committee a further way in which Section 41 weakens drug patents and so discourages investment by research-based companies. The section states that process patents only can be granted "in the case of inventions relating to substances prepared or produced by chemical processes and intended for food or medicine." In compulsory licence cases this has been treated by the Commissioner of Patents and the courts as a reason to base royalty rates on the price of the chemical substance to which the patent refers rather than that of the finished product, which provides the true

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significance of the patent. The Ilsley Committee recommended that the Act should be revised to allow product patents, and we suggest that the Committee endorse this recommendation.

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THE RESPONSIBILITIES OF A PHARMACEUTICAL COMPANY

We have endeavoured in the preceding pages to set down what we believe should be the responsibilities of a pharmaceutical company in Canada, and to illustrate these from our own operations. They may be summed up as developing useful products of a high standard, making them available throughout the country at a fair price, and ensuring that the medical profession receives sufficient and up-to-date information about them. We have increased our investment in Canada in line with the significance of our business through the expansion of manufacturing facilities and the establishment of a research and development laboratory. This laboratory forms part of an international research network, on which all the countries we serve depend for new and better Smith Kline & French products. We can operate efficiently only as an integral part, a contributing member of an international enterprise.

We believe that we can make a worthwhile contribution to the Canadian balance of payments both by increasing the Canadian content of our production and by expanding our exports. However, as part of an international organization represented in most of the markets of the world, we can develop export lines and markets only through intercompany cooperation. In other words, there must be definite corporate advantages in building up the Canadian operation as an important production centre.

As a company, we have responded to the advantages which do exist,

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notably the availability of well-qualified scientific and technical manpower and

the existence of an important scientific community. However, the state of the Canadian patent law and the ambiguity which marks some official attitudes towards the research-based international industry do militate against the Canadian case.

In conclusion, we would urge the Committee, when recommending any course of action, to bear clearly in mind both the value to Canada of a growing research-based pharmaceutical industry and the realities of the economic and industrial structure of this country. We believe that the responsible pharmaceutical companies truly serve the national interest with their products and services as well as through their contribution to the economy. There is every reason to expect they will continue to do so, providing the conditions under which they can do business offer an incentive both to therapeutic progress and to greater investment.

Appendix "A"
to the Brief

INTERNATIONAL
TECHNICAL APPROVAL TO MARKET

9C-6 (REV. 7/64)

PRODUCT	CODE NUMBER

1. EFFICACY AND SAFETY IN USE	This is to certify that adequate clinical trials have been carried out on this product and that it has been found to be both effective and safe in use. MEDICAL DIRECTOR (SIGNATURE) PRINT OR TYPE NAME | DATE
2. BASIC CIRCULAR CRITERIA	This is to certify that all promotional material will conform to the claims in the basic clinical circular for this product. These claims are adequately supported by clinical evidence and dosage, known side effects, contraindications and cautions are completely described. MEDICAL DIRECTOR (SIGNATURE) | PRINT OR TYPE NAMES | DATE DIRECTOR OF MARKETING (SIGNATURE) | PRINT OR TYPE NAMES | DATE
3. PHYSICAL AND CHEMICAL STABILITY	This is to certify that the physical and chemical stability of this product is satisfactory for marketing based upon data available now. Long term stability studies are continuing to confirm satisfactory stability exists under normal market conditions. PHARMACEUTICAL DEVELOPMENT PRINT OR TYPE NAME | DATE
4. PRODUCTION METHODS, EQUIPMENT AND PACKAGE SPECIFICATIONS	This is to certify that adequate manufacturing methods, equipment and satisfactory package specifications are available and that adequate safety precautions have been devised and explained to the necessary personnel. PLANT MANAGER PRINT OR TYPE NAME | DATE
5. SPECIFICATIONS AND ANALYTICAL METHODS	This is to certify that complete specifications have been set and analytical methods devised for both the finished product and all raw materials used therein. ANALYTICAL CONTROL PRINT OR TYPE NAME | DATE

SIGNATURES		
DIRECTOR OF R&D OR MANUFACTURING		DATE
SUBSIDIARY MANAGER		DATE
PHILADELPHIA REVIEW	TECHNICAL SERVICES DIRECTOR	DATE
	MEDICAL DIRECTOR	DATE
PHILA. APPROVAL		DATE

NOTE: THIS FORM MUST BE FORWARDED IN TRIPLICATE BY REGISTERED MAIL TO THE MEDICAL DEPARTMENT IN PHILADELPHIA COMPLETE WITH ALL SUPPORTING DATA.

FORMULA CHANGE-INTERNATIONAL

8C-7

PRODUCT	CODE NUMBER
☐ REQUEST FOR APPROVAL OF FORMULA CHANGE ☐ ADVICE OF FORMULA CHANGE	DATE

1. EFFICACY AND SAFETY IN USE

☐ No further clinical studies considered necessary.

☐ Additional clinical studies have been made and this product is both effective and safe in use.

MEDICAL DIRECTOR (SIGNATURE)

PRINT OR TYPE NAME | DATE

2. PHYSICAL AND CHEMICAL STABILITY

This is to certify that the physical & chemical stability of this revised formulation has proven satisfactory as evidenced by lots under test for a minimum of months.

PHARMACEUTICAL DEVELOPMENT

PRINT OR TYPE NAME | DATE

3. PRODUCTION METHODS AND EQUIPMENT

This is to certify that adequate manufacturing methods and equipment are available and that adequate safety precautions have been devised for the manufacture of this product.

PLANT MANAGER

PRINT OR TYPE NAME | DATE

4. SPECIFICATIONS AND ANALYTICAL METHODS

This is to certify that complete specifications for this revised formulation have been set and analytical methods devised for both the finished product and all raw materials used therein.

ANALYTICAL CONTROL

PRINT OR TYPE NAME | DATE

5. PACKAGE SPECIFICATIONS AND LABEL COPY

☐ This is to certify that satisfactory package specifications reflecting the formula change have been devised for this product.

☐ No package or label copy change required.

PLANT MANAGER

PRINT OR TYPE NAME | DATE

FORMULA CHANGE APPROVED

SUBSIDIARY MANAGER | DATE

PHILADELPHIA APPROVAL | DATE

NOTE: This form must be forwarded in duplicate to Philadelphia Operations complete with all data supporting the signatures; and an explanation of the revisions made in the original formulation must be affixed to this form.

Appendix "B"

to the Brief

Public Law 89-74
89th Congress, H. R. 2
July 15, 1965

AN ACT

To protect the public health and safety by amending the Federal Food, Drug, and Cosmetic Act to establish special controls for depressant and stimulant drugs and counterfeit drugs, and for other purposes.

Be it enacted by the Senate and the House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Drug Abuse Control Amendments of 1965".

COUNTERFEITING OF DRUGS

The congress finds and declares that there is a substantial traffic in counterfeit drugs simulating the brand or other identifying mark or device of the manufacturer of the genuine article; that such traffic poses a serious hazard to the health of innocent consumers of such drugs because of the lack of proper qualifications, facilities, and manufacturing controls on the part of the counterfeiter, whose operations are clandestine; that, while such drugs are deemed mis-branded within the meaning of section 502(i) of the Federal Food, Drug, and Cosmetic Act, the controls for the suppression of the traffic in such drugs are inadequate because of the difficulty of determining the place of interstate origin of such drugs and, if that place is discovered, the fact that the implements for counterfeiting are not subject to seizure, and that these factors require enactment of additional controls with respect to such drugs without regard to their interstate or intrastate origins.

(b) Paragraph (g) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended (1) by inserting "(1)" immediately after "(g)", (2) by redesignating clauses (1), (2), (3), and (4) thereof as clauses (A), (B), (C), and (D), respectively, (3) by striking out "clause (1), (2), or (3)" and inserting in lieu thereof "clause (A), (B), or (C)", and (4) by adding at the end thereof the following:

"(2) The term 'counterfeit drug' means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor."

(c) Paragraph (i) of section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(c)) is amended by inserting "(1)" immediately after "(i)" and by adding at the end thereof the following new subparagraphs:

"(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

"(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug."

(d) Section 303 of such Act (21 U.S.C. 333(c)) is amended by inserting immediately before the period at the end thereof the following: "; or (5) for having violated section 301(i) (2) if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 301(i)(3) if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug".

APPENDIX "II"

Smith Kline & French Inter-American Corporation • 300 Laurentian Blvd. Montreal 9, Quebec

TRIFLUOPERAZINE TENDERS

NOTE: IMPORTANT MEDICAL CONSIDERATION

Trifluoperazine tablets as mentioned in the B.P. monograph are formulated in terms of the hydrochloride salt. 'Stelazine' tablets (SK&F's brand of trifluoperazine), which has been the standard for development of dosage levels and therapy regimens are formulated in terms of the trifluoperazine base.

Trifluoperazine tablets B.P., therefore, contain approximately 15 - 16% *less* of the active ingredient than 'Stelazine' tablets (SK&F's brand of trifluoperazine).

The preceding brief notice was included by us in a recent reply and quotation on a request for tender. This is a condensed statement for a particular purpose and some expansion on the background of it may be useful for you.

As you know, we will in a product line use different forms of the active component dependent upon the particular dosage form. We may use the base form of the drug or perhaps one or more salt forms to give us the best physical characteristics for that dosage form, stability, ease of formulation and so on. However, we will always come back to an expression of the active portion in terms of the base so that we have a common denominator for purposes of potency comparison and dosage determination.

Generally, the salt portion is inactive medically so that more of the salt form is required to produce the equivalent effect of a given amount of the base form. In the case of trifluoperazine, 1.18 grams of trifluoperazine dihydrochloride is required to equal the activity of 1.0 grams of trifluoperazine base. 'Stelazine' tablets, while formulated with the hydrochloride salt, are declared as to active ingredient content in terms of trifluoperazine base, that is, for example, 'Stelazine' tablets 1 mg. contain in each tablet 1 mg. of trifluoperazine as the dihydrochloride salt. Therefore, each 1 mg. tablet of 'Stelazine' contains 1.18 mg. of trifluoperazine dihydrochloride.

Trifluoperazine Tablets as mentioned in the B.P. monograph are formulated in terms of the hydrochloride salt, and therefore a 1 mg. tablet in B.P. terms contains very considerably less of the active base.

'Stelazine' Tablets SK&F have been the standard for development of dosage levels and therapy regimens for the past eight years and now in consideration of the above it becomes apparent that these established treatment levels can be disrupted through the use of the misleading strength B.P. Tablets.

It is entirely possible that unwittingly a patient may suddenly receive approximately a 20% reduction in dosage, with the further possibility of resultant therapeutic variation, from that established through use of 'Stelazine' Tablets SK&F.

Our analysis of a competitive product which has recently appeared discloses anomalies which could be disturbing both to patient and physician. Several months ago this product when assayed contained in the order of 100%

of claim, but as the hydrochloride salt. More recent assays of current lots of three different strengths (5 mg., 10 mg., and 20 mg.) disclose an average of about 92%-93% in terms of the base, and a resultant average of about 108 - 109% in terms of the hydrochloride salt. This almost appears to be an attempt to line in two different standards at the same time. However, a fourth lot of 20 mg. strength assays at around 120% in terms of the hydrochloride salt. This product appears, on this basis, to run the full range of possibilities without being specific as to its basic formula intent.

Montreal,
September 7th, 1966

OFFICIAL REPORT OF MINUTES
OF
PROCEEDINGS AND EVIDENCE

This edition contains the English deliberations and/or a translation into English of the French.

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LÉON-J. RAYMOND,
The Clerk of the House.