HOUSE OF COMMONS
CANADA

SECOND (FINAL) REPORT

of the

SPECIAL COMMITTEE

of the

HOUSE OF COMMONS

on

DRUG COSTS AND PRICES

Presented by

MR. HARRY C. HARLEY — *Chairman*

SESSION 1966-67

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ROGER DUHAMEL, F.R.S.C.
QUEEN'S PRINTER AND CONTROLLER OF STATIONERY
OTTAWA, 1967

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MONDAY, April 3, 1967

The Special Committee on Drug Costs and Prices
has the honour to present its

SECOND AND FINAL REPORT.

CHAPTER I—TERMS OF REFERENCE

On February 15th, 1966 your Committee was constituted with the following Order of Reference:

"RESOLVED,—That a Special Committee be appointed to continue the inquiry into and to report upon costs of drugs, begun by Special Committee 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 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."

On February 24, the following Members were appointed to the Committee: 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.

Messrs. Asselin (*Richmond-Wolfe*), Clancy, Whelan, Mrs. Rideout, Messrs. Scott (Danforth), Olson, MacLean (Queens), Johnston, Goyer, Noble, and Forrestall have also served on the Committee replacing some of the above members.

Dr. Harry C. Harley, M.D., Member for Halton, (Ont.) and Mr. Patrick Asselin, Member for Richmond-Wolfe, were respectively elected Chairman and Vice-Chairman on April 26.

In accordance with a resolution passed on the same date, the following Members were appointed by the Chairman to act with him on the steering subcommittee on agenda and procedure: The Vice-Chairman, Mr. Asselin, Dr. Rynard, M.D., Dr. Howe, M.D., (*Hamilton South*), and Mr. Patterson who was later replaced by Mr. Johnston; Dr. Isabelle, M.D., also served on this steering committee.

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On May 12, 1966, in accordance with the Committee's authority, Mr. A. M. Laidlaw, Q.C. of Ottawa was appointed legal Counsel to the Committee and Mr. W. J. Blakely, C.A. of Kingston, Ontario, was appointed Accountant to the Committee.

Your Committee held 63 meetings during this Session and examined many firms, associations and private individuals who your Committee felt would be useful in assisting it in determining whether or not drug prices in Canada were in fact too high; and, if so considered, in making concrete proposals designed to lower drug prices to the Canadian consumer.

The witnesses appearing before the Committee are set out in Appendix "A" attached hereto; and the evidence at the hearings including the briefs will be tabled later.

CHAPTER II—BACKGROUND TO THE REPORT

1. *The Basic Principles*

Early in the hearings (Page 195 of the Minutes of Proceedings and Evidence) it was pointed out that perhaps the onus lay upon the drug industry to show cause why the various recommendations by previous investigators should not be implemented. This theme kept recurring throughout the hearings, although your Committee remained fully conscious that its responsibilities in fact exceed those of the Commissions in that the Committee's conclusions must be such that any of its recommendations, if adopted, should continue to maintain a proper balance between industry and consumer and take into consideration the importance of continued and increased scientific research in Canada. No recommendations could be considered, which, although designed to lower drug prices in Canada, might produce drugs of questionable safety or have a detrimental effect upon other aspects of the Canadian economy. How such a balance between consumer interest in price and continued pharmaceutical research (one of the professed causes of high drug prices) may be maintained, and the resulting effect on the drug industry will be discussed as this Report proceeds.

2. *Material Available*

Your Committee, prior to receiving evidence, had before it the research studies and findings of three Canadian Commissions—The Royal Commission on Health Services (hereinafter referred to as the Hall Commission) which reported in 1964; the Report of the Restrictive Trade Practices Commission concerning the Manufacture, Distribution and Sale of Drugs, which was presented in 1963 and which was based on an enquiry undertaken by the Director of Investigation and Research under the Combines Investigation Act, (the basic material for the enquiry being summarized in a document described as the "Green Book" which was submitted to the Commission on February 28th, 1961); and the Royal Commission on Patents, Copyright and Industrial Designs, (hereinafter referred to as the Ilsley Commission) which reported in 1960 and in which Section 41 of the Patent Act, 1935, as amended, dealing with patents on foods and medicines was considered and recommendations made thereon.

For purpose of convenience your Committee has set the summaries of the recommendations of each of these Commissions in the form of Appendices to this Report as follows:

Recommendations of the Hall Commission as Appendix "B";

Recommendations of the Restrictive Trade Practices Commission as Appendix "C"; and

Recommendations of the Ilsley Commission dealing with Section 41 of the Patent Act as Appendix "D".

It should also be mentioned that your Committee has had access to other reports and texts dealing with drug costs and prices; and in the case of foreign reports and texts it has attempted, in the preparation of the recommendations that follow, to draw conclusions from these that would take into full consideration any discrepancies not peculiar to the Canadian situation. Perhaps the most important of these reports, apart from the reports from the three Commissions above-noted, is that of the United States Senate Subcommittee on Anti-Trust and Monopoly of the Committee on the Judiciary (referred to as the Kefauver Report) which in considerable detail investigated drug costs and pricing in the United States up to about 1960. There does not seem to be any reason to believe that facts and figures used in that Report have changed to any considerable extent since its publication. Nevertheless your Committee has been extremely cautious in accepting the figures of this Report which, of course, only apply fully to the situation in the United States. The international features of the drug industry, however, indicate that foreign studies and comments are not to be entirely ignored when Canadian aspects are in fact only those being investigated.

Other reports and material made available to the Committee include the final Report on the Cost of Prescribing (referred to as the Hinchliffe Report) published in the United Kingdom in 1959; a Report on the Retail Structure of Drug Prices in Manitoba issued in 1961 by a Joint Committee of the Manitoba Pharmaceutical Association and the Government of Manitoba; a Report on Survey of Dispensing Costs prepared in October 1965, on behalf of the Canadian Pharmaceutical Association of British Columbia; the Alberta Act of April 5th, 1962 which permitted druggists to substitute an equivalent generic drug for a brand name drug in any prescription unless substitution was specifically forbidden by the physician; the Report of the Select Committee of the Ontario Legislature on the Cost of Drugs which issued in 1963; and the Report prepared for the Hall Commission by the Research and Statistics Division of the Department of National Health and Welfare dealing with the Provision, Distribution, and Cost of Drugs in Canada which was published in 1964. The Committee considered the recommendations of the Boyd Committee and the Hilliard Committee who were appointed by the Department of National Health and Welfare to study some aspects of the drug industry.

It is apparent, therefore, that the wealth of material available, arising as it has from exhaustive studies based on evidence rendered by many parties under cross-examination, forms the background of this Report. Evidence given directly before the Committee in response to questions asked by members of the Committee and Counsel has been correlated with the prior background material to bring about your Committee's final conclusions and recommendations.

3. *Introduction of Medicare and/or Other Health Services*

Your Committee has been fully conscious throughout the proceedings of the importance of its task, not only because its recommendations, if carried out, might benefit the consumer of drugs, but eventually benefit the Canadian taxpayer. If any tax supported scheme be introduced to help ease the burden on the individual drug consumer, it is of paramount importance that the causes of high drug costs be identified and remedied now. This will ease the eventual charge on taxpayers generally.

CHAPTER III—THE DRUG INDUSTRY IN CANADA

1. *Types of Industry*

The drug industry in Canada comprises what is generally known as the medicinal and pharmaceutical preparation industry which, in turn, may be divided into four different groups: Chemical, Pharmaceutical, Biological and Proprietary, although these groups are not necessarily mutually exclusive. The manufacture of medicinal chemicals as such, i.e. chemicals which form the active ingredients as the basis of pharmaceutical preparations is not a large industry in Canada for the reason that Canada, economically, is not sufficiently populated to be able to support particular raw material plants of this type; and, in consequence, a large percentage of the active ingredients used in pharmaceutical preparations which appear in eventual solid or liquid dosage forms require importation from the United States, the United Kingdom and other countries. (Refer to page 208, Minutes of Proceedings and Evidence where it was stated that only 20 per cent of therapeutically active substances used in Canada are manufactured in this country).

It is the pharmaceutical industry in Canada which is the industry under investigation by your Committee. It is this industry which prepares and compounds the active ingredients obtained from fine chemical producers and which, through formulating, tabletting, capsuling, etc., provide therapeutic substances for the eventual Canadian consumer. The term "manufacturing" as used by the Pharmaceutical Manufacturers' Association of Canada means the production of a pharmaceutical from its therapeutically active substance or substances. It is noteworthy that Canadian drug manufacturers by and large import the basic raw ingredients that form the basis of Canadian pharmaceuticals. However, the Committee is informed that there is a slight increase in the production of basic ingredients in Canada.

To a lesser extent the biological group comprises a segment of the pharmaceutical industry wherein these companies produce in dosage form drugs which finally appear as vaccines and the like. The final group, namely, the manufacturers of proprietary medicines are in a separate category, as patent medicines or well advertised household remedies which are manufactured by these companies are available to the public directly (without prescriptions required) through over-the-counter sales in drug stores or in other retail outlets. This report is not unduly concerned with the cost of such proprietary medicines as their sale, as in the sale of other goods, is subject to open competition. Home remedies are rarely prescribed by the physician and the buyer may "shop around" for this type of medicine or remedy.

It is reported that in 1963 there were some 173 establishments engaged chiefly in the manufacturing of pharmaceuticals and medicines almost all of whom are concentrated in Ontario and Quebec. Without actual statistics provided for later years it can be assumed that this number approximates those in existence in Canada today, although were there any change in these statistics our findings would not be influenced. The study also states that more than two-thirds of these plants are what might be considered multi-line pharmaceutical manufacturers and approximately three-quarters are multi-line proprietary manufacturers, i.e. which companies manufacture both pharmaceuticals and proprietary medicines. The balance of the number comprise small regional concerns which manufacture a few medicinals only and whose activities may be engaged more with wholesaling and retailing, packaging and the like.

2. *Control of the Industry*

The Committee feels it should point out at this stage the extent of foreign control over the Canadian drug industry At the time the Report of the Hall Commission was written the thirteen largest firms in the drug field in Canada, exclusive of Connaught Research Medical Laboratories, were all branches or subsidiaries in Canada of foreign firms with the exception of one Canadian company. It was reported that all these thirteen companies had annual sales in excess of $4 million each and were the only drug firms in Canada having sales of that magnitude. Since that report was written the last large Canadian firm was purchased by an American corporation.

This overwhelming control of the drug industry in Canada by foreign firms leads to a number of consequences which have been studied by your Committee. International patent control enters the picture. Canadian subsidiaries pay patent royalties to their parent corporations. Dividends received by Canadian subsidiaries pass to their parents except for earnings retained for expansion of the Canadian industry. Foreign corporations charge their subsidiaries for "international" research costs. Most subsidiaries import pharmaceutically active ingredients from their parent corporations. The scientific research involved is lost to this country. All these factors tend to obscure the workings of the industry and the resulting effect on the Canadian consumer; and your Committee has taken these factors into account in the preparation of its Report and the conclusions it has drawn.

3. *Drug Manufacturers*

Viewing the drug industry in Canada in another way (and not considering those manufacturers solely engaged in the preparation of proprietary medicines) the industry may be considered to be divided into three distinct groups: (a) the large manufacturing drug houses which include the well-established Canadian subsidiaries of foreign parent corporations, and which are largely represented by the Pharmaceutical Manufacturers' Association of Canada (referred to as PMAC). This Association has at present some 57 members who produce about 85 percent of the dollar volume of prescription drugs sold in Canada, under both brand and/or generic name.

The second largest group (b) in the drug manufacturing industry in Canada is a recently-formed association called "The Association of Canadian Drug Manufacturers" representing about 10 percent of the entire Canadian pharmaceutical industry. There are some fifteen members of this group. They consider themselves to be Canadian owned and operated as opposed to the large manufacturers which are, of course, Canadian also but whose parent corporations are situated in foreign countries. They are the so called "generic manufacturers" as opposed to "brand name manufacturers", but it should be pointed out immediately that some members of this group also market their products under "brand names" as well. They do little, if any, research in respect to the development of new drugs, as opposed to many but not all members of the PMAC group who carry out certain research activities in Canada. The PMAC group and the "Canadian Drug Manufacturers" are violently opposed in their views on certain aspects of drug manufacturing and pricing of drugs, and the expression of both views was repeatedly given before the Committee. The opposition stems from the issue—discussed later—that one group considers itself the "innovators" in the drug industry, the other being mere "copiers".

The third group (c) in the drug industry in this country represents not more than 5 percent of the industry. These are those who might be named the

"Independents". Included in this group are drug manufacturers who sell their products under brand name and/or generic name, and who by choice do not wish to be members of the first two groups or who might not be permitted to be. Also, small importers of drugs fall into this category. None of these latter small importers appeared before the Committee. It can be safely assumed that the third group does not entertain in any way the views of PMAC.

In any event, all three groups are the suppliers for the Canadian drug market, whether the drugs are manufactured into dosage forms from largely imported bulk material or active ingredients, or whether manufacture consists of completing the procedure from imported semi-finished dosage forms or, indeed, whether the drugs are imported in finished marketable state. It is important to note that patent-protected drugs either in bulk material, semi-finished dosage or final dosage form cannot be imported except by the patentee, his assignee of licensee.

Insofar as the export market is concerned, unless the patent owner is Canadian, the international patent system can prevent, and does discourage further development of the drug industry in Canada. With most foreign owned patents, subsidiary companies of the parent patentees control the market within their own jurisdictions; and export activity must therefore be confined to world areas where patents are not taken out—areas which commercially are not too significant. On a question, for example, addressed to one Canadian subsidiary of a U.S. parent corporation, the answer was succinctly put: "We have so many plants all over the world I just do not know where we would export to".

It should also be added that even if exports of drugs could be increased in certain areas, many domestic patent laws limit importing, requiring manufacturing to take place within their jurisdictions on pain of forfeiture of the patent.

All this is pointed out to indicate that increased production of drugs in Canada—which conceivably could lower prices—is not likely to incur through foreign sales.

As will be described later, one factor in influencing drug prices at the consumer level is the cost of producing drugs at the manufacturer's level, i.e. to that point where the manufacturer sells to the wholesaler or, in other cases, sells directly to the retail druggist, hospital or government department. There is, as mentioned, serious disagreement between those companies represented by PMAC and those other companies represented by groups (b) and (c). The PMAC members consider that their manufacturing and selling costs and pricing generally are "fair and reasonable" while their opposition claims that PMAC manufacturers' costs are excessive for reasons that will be dealt with later. As stated, PMAC alleges that its rival manufacturers are "copiers" as opposed to "innovators" which the PMAC claims to represent. The "copiers" apparently 'suffer' from two arguments advanced by PMAC, first, through the implication that generic named drugs (in the case of the generic drug manufacturers) do not possess the corresponding high qualities possessed by brand name products; and, secondly, that through its members' research program and high quality control in their drug production, better and safer drugs result—an argument violently opposed by the Association of Canadian Drug Manufacturers and the Independents. It might be well at this point to describe in more detail the distinction between generic and brand name products, as this distinction was of considerable importance in laying the basis for some of your Committee's recommendations.

4. *Nomenclature in the Industry*

As a prelude to the study of the drug industry it is necessary to be familiar with the nomenclature of drugs. Drugs constitute, of course, a group of fine chemicals (i.e. therapeutically active ingredients) which can be clearly defined by standard chemical names following standard chemical nomenclature. These follow the ordinary rules of chemistry which describe chemical compounds. However, as the synthesis of chemicals grew in number, the chemical names attached to the new compounds became unwieldy; hence a consequent introduction of a peculiar pharmaceutical nomenclature became necessary to overcome this particular problem. The chemical name still remains the standard of reference for the particular identity of the drug but, because of the difficulties involved in expressing the true chemical name in a manner understandable by those less informed than organic chemists, a system of "recognized names" was developed. This new recognized name of a drug is selected when it is introduced by an official organization, or is designated as such in an official drug publication such as the British Pharmacopoeia, the United States Pharmacopoeia, etc. In Canada, the new name becomes the "proper" name or, in other jurisdictions, the "approved name" or even, inded, the "international non-proprietary name". In any event and regardless of whether the newly-named drug is referred to by any of the above designations, or such name is generally quoted as a "generic name" (in fact, a misnomer) it becomes the abbreviated scientific name to be used prescribing or identifying those particular drugs which have unwieldy chemical names.

It is the Committee's understanding that in most Schools of Pharmacy and Medicine the generic name of a drug is taught to students as the "recognized" or "proper" name of the particular drug. Certainly drugs ordered by hospitals or through government purchasing agencies are ordered by their generic names.

The Committee recommends

That all medical and pharmacy students be instructed during their studies in the generic nomenclature for drugs.

However, it became clear at an early date to drug manufacturers that considerable advantage might be attained if a still more simplified designation for drugs could be found; and accordingly a system developed whereby a manufacturer designated a particular drug under "a brand name" or a "proprietary name" which was registered as a trade mark in that country or countries where the drug was sold. The "brand name" designated the particular manufacturer, and the manufacturer through strenuous promotional activity was thereby able to introduce a system of marketing where drugs would be, and usually were, ordered by their "brand name" as a particular product of an identifiable manufacturer. The "brand name" chosen was, of course, one which generally had an euphonious sound usually involving few syllables and a name more easily retained in the physician's mind because of its simplicity. Each "brand name" continued to have, of course, its corresponding "generic name"; and it is still the "generic name" that is published in pharmacopoeia and formularies. Regardless of the wide use of the "brand name" by manufacturers, we find that the use of the generic name of a drug should by no means be disparaged.

We quote from the study relating to the Provision, Distribution, and Costs of Drugs in Canada prepared by the Research and Statistics Division of the Department of National Health and Welfare as follows:

"In Canada every effort is made to follow the nomenclature of the Expert Committee of the International Pharmacopoeia of the World

Health Organization. Excellent co-operation exists between this organization and the official bodies in the United States and the United Kingdom to maintain uniformity throughout the world in pharmaceutical nomenclature. For practical purposes the names "proper name", "approved name", "adopted name", "pharmacopoeial name", "international non-proprietary name" and "generic name" are used as synonyms in the trade." (page 8)

The "brand name" manufacturer of pharmaceuticals takes every possible step to protect its position by brand name advertising and promotion. It will do this, firstly, because it is in its peculiar interest to identify drug products with its own manufacture, knowing that use of the generic name is more likely to be forgotten or ill-remembered in repeat orders of quantities of such drugs. The "brand name" manufacturer knows that the physician or pharmacist is more likely, after repetitious promotional activity, whether through advertising or through detail men, to become indoctrinated to prescribe and dispense brand name drug products. It appears that most physicians and pharmacists have more confidence in drugs manufactured under a brand name. One of the interesting side lights of this is that the generic manufacturer, as soon as monies become available, tends to create his own form of brand name nomenclature and enters the ranks of those who have preceded him and to whom he was formerly opposed.

Secondly, the feud between the brand name manufacturers and their generic counterparts brings the subject into the realm of safety upon which the Report by your Committee to the previous Parliament was based. It is natural and good business that manufacturers of brand name drugs will, by any reputable means at their disposal, seek to inculcate into the minds of those who order prescription drugs that their products are "safe" because the identity of the manufacturer is clearly revealed by the brand name product. Unfortunately the brand name manufacturer often gives the impression that generic products are not safe. It is the opinion of your Committee, however, that this viewpoint is not necessarily valid, it not only having been challenged by the generic drug manufacturers but also by purchasing agents of some hospitals and government departments who have ordered, and continue to order, (see Minutes of Proceedings and Evidence, page 1497) drugs by their generic names. The Food and Drug Directorate made it clear that, in their opinion based on the testing they perform, generic named drugs and brand name drugs are equally "safe".

5. *Profits in the Industry*

This portion of the report is based on Appendix E: *Profits of Drug Manufacturing Firms in Canada*, prepared for the Committee by the Accountant, Mr. W. J. Blakely.

The Committee believes that the profits of pharmaceutical companies in Canada appear about twice as high as the level of profits of the manufacturing industry as a whole. Your Committee believes this to be true for pharmaceutical companies generally, whether they be so called "innovators" or "copiers"; or brand name or generic producers. It should be pointed out in all fairness (as seen in Table 4 of the Appendix E), that the pharmaceutical industry showed (in 1963) the seventh highest rates of return on resources employed, and are exceeded by distilleries, wineries, motor vehicles, petroleum and coal products, motor vehicle parts and accessories, wire and wire products, and office and store machinery. As may be expected in our free enterprise economy, pharmaceutical manufacturers must work for a profit. The Committee is not concerned primarily with reducing profit below a reasonable level but is concerned with reducing

costs of drugs to the consumer. The Committee is convinced that this can be done within the framework of the free enterprise system.

The financial experience of Canadian pharmaceutical manufacturing firms is shown in the appendix and does not reveal, as some have claimed, that the business risks are greater than in the general manufacturing industry.

6. *Regulatory Control of the Industry*

The regulatory control of the drug industry is administered by the Food and Drug Directorate of the Department of National Health and Welfare.

In keeping with other committees and commissions dealing with the Food and Drug Directorate, the Committee found it to be staffed with competent skilled personnel who worked very closely with the Committee to provide, as diligently as possible, all the information that was requested. The Directorate carries out its functions efficiently and competently, subject only to its limitations of staff. These have been detailed previously in the last Report of the Special Committee of the House of Commons on Food and Drugs and, though the situation has improved, more assistance is still required; and if the present recommendations of this Committee are carried out, then additional staff will be required.

The Food and Drug Directorate has two main functions that are based on criminal law in Canada and administered under the Food and Drugs Act. These functions are to protect the consumer against fraud and hazards to health in the sale of foods, drugs, cosmetics and medical devices.

When a company wishes to test a new drug clinically, it has to send in a "pre-clinical submission" to the Food and Drug Directorate. This is information on the new drug—composition, action, toxicity, side effects, dosage, etc. The Food and Drug Directorate then decides whether the drug should be tested on humans. If justified, the Directorate issues permission to the Company which then releases the drug to the clinical investigator. The clinical investigators (doctors who will use the drug on patients) are known to the Directorate. A careful check is kept by the company of the location of all new drugs so they can be recalled quickly, if necessary. This data on clinical use in the form of a new drug submission is forwarded to the Food and Drug Directorate and finally, it this submission shows the drug is useful and the risks from the drug within justifiable reason, the drug is allowed for sale on the market by issuance of a Notice of Compliance. It remains classified as a "new drug" at the discretion of the Food and Drug Directorate until is has been in use "for sufficient time and in sufficient quantity" to assure the Directorate that it is safe and effective. This time usually exceeds five years. Once it loses its "new drug" status, other companies may produce it (patents and compulsory licence will be discussed later) without further data on the drug for the Food and Drug Directorate other than meeting the requirements for all drug manufacturers. They must however notify the Food and Drug Directorate within thirty days that they have placed this drug on the market. Up to this time, as long as a drug is a "new drug", if other companies wish to market it, they have to go through the same procedures for a "new drug" with the Food and Drug Directorate. Needless to say, companies other than the originator never have manufactured a drug during its "new drug" status, but wait until it loses that status. To do otherwise is expensive in time and money, and actually is a duplication of work done. This matter has been raised in the Hilliard Report.

It is the duty therefore of the Food and Drug Directorate to protect the public against unsafe drugs. The Committee is satisfied that the work done by

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the Directorate is of a high standard, but is hampered by its lack of sufficient staff and adequate facilities. Some of the recommendations of this Committee will increase the work and scope of the Directorate and will emphasize the necessity for more staff. You Committee therefore recommends

> That the personnel and facilities of the Food and Drug Directorate be expanded to make possible the implementations of the recommendations of the Boyd Committee, the Hilliard Committee and this Committee.

7. *The Hilliard Report and the Boyd Report*

This Committee commends and supports the recommendations of the Boyd Report and the Hilliard Report. In the Hilliard Report particularly the Committee makes reference to the section on New Drugs and the Hilliard recommendation for amendment of the definition of "New Drug" to include old drugs in which new or serious or more frequent side effects develop. This was referred to in many committee meetings. The Justice Department has ruled that "the Governor-In-Council has no authority under the Food and Drugs Act to make a regulation to include in the definition of a new drug an old drug if previously unknown serious adverse reactions develop from its use."

It is understood that the Food and Drug Directorate can, under the present Act meet this problem of old drugs that produce unexpected reactions. The Directorate has authority to make regulations respecting the sale or condition of sale of drugs. At the present time the "new drug" regulations require a drug manufacturer to notify the Food and Drug Directorate of unexpected side effects, injury, toxicity or sensitivity reactions. This notification is to be made as soon as possible in every case—and no later than fifteen days—from the date the reaction is reported to the drug manufacturer. The problem of this type of reaction to a drug, not under "new drug" status, can be met by making the above regulation apply to all drugs.

CHAPTER IV—COST OF DRUGS TO THE CANADIAN CONSUMER

Representations to your Committee that drug prices are too high stems from a number of sources. First, the Canadian Pharmaceutical Association supplied the Committee with statistics indicating the number of prescriptions and the value of prescriptions made out in Canada over past years; and these figures indicate that the average price of a prescription in 1949 to the consumer was $1.38 and the average price of a prescription in 1965 was $3.32, an *increase* in the sixteen year period of some 140 percent. The comparable over-all cost of living index prepared by the Bureau of Statistics over the same period of time showed a general increase in consumer goods of only 40.8 percent. Although these percentages are not strictly comparable in view of the fact that many of the "new" drugs introduced during the fifties' and the early sixties' were much more expensive and widely prescribed, nevertheless the figures are at least suggestive that drug prices are now too high, particularly when during that time the number of prescriptions per year in Canada increased sizably. Normally it could be expected that expanded sales would result in lower prices. Although the precise figures for the years mentioned above have not been made available to the Committee, it is interesting to note that in 1955 some 32,908,185 prescriptions were filled and only nine years later in 1964 some 51,635,671 were filled.

To be fair to the Canadian Pharmaceutical Association, however, it was stated in their supplementary brief (page 1934) to the Committee that statistics prepared by the Dominion Bureau of Statistics show "that prices in general increased some 36.8 percent between 1949 and 1964, while drugs increased by

only 20.7 percent". The Bureau's statistics, it is understood, however, were obtained from a survey of some five drugs in the field of antibiotics, sedatives, hypnotics and ataractics; and the drugs used were not necessarily those of the more recent "wonder drug" variety. Two explanations for the discrepancy in the figures can therefore be made: prescriptions in recent years are being filled with more expensive drugs and the Bureau's figures do not reflect the change in medical prescribing over the period of time quoted.

Secondly, a thorough and comprehensive comparison between Canadian drug prices and those in other countries was undertaken by the Director of Investigation and Research under the Combines Investigation Act, which study resulted in the Green Book earlier referred to, and which comparison showed clearly the evidence that Canadian drug prices appeared to be surprisingly high. In fact, one of the conclusions reached by the Director was that "prices of drugs in Canada are among the highest in the world".

Thirdly, more up-to-date figures on the comparison of prices of drugs in Canada with those in other countries having relatively advanced economies were presented to the Committee by the Consumers' Association of Canada. (Minutes of Proceedings and Evidence, page 1182-3). These figures likewise substantiated the conclusions of the Green Book.

Fourthly, PMAC also produced a table of international drug prices (Minutes of Proceedings and Evidence, page 353) in which, on the face of the statistics presented, it also appeared that Canadian drug prices, generally speaking, were among the highest of certain selected countries, although PMAC in an exhaustive argument on this point took the view that these statistics could be read in a manner more favourable to its own presentation. This argument will be dealt with later.

In any event, both the Restrictive Trade Practices Commission and the Hall Commission made findings as a result of their economic studies that dealt with ways and means of bringing drug prices down which fact in itself indicates both Commissions were of the view that drug prices in Canada were too high at the date of conclusion of their enquiries.

Your Committee, in order to assure itself, in the interval between the time both Commissions reported and the date of this enquiry, that the situation remained more or less unchanged, checked on its own behalf from reliable sources the cost of drugs at the retail level in Canada, the United States and six European countries. Twelve of the most commonly used and important drugs were selected. The result, in Canadian dollars, appears as Appendix "F" to this Report.

Your Committee confirms the previous findings now on public record; and it has come to the inescapable conclusion that drug prices in Canada are in fact high and that every fair and reasonable step should be taken to reduce these prices. In conclusion, and in order to discount any claim that these statements are exaggerated, it is well to bear in mind the comment made by the Director of Investigation and Research under the Combines Investigation Act that if drug prices were not too high "they were higher than they need be". (Minutes of Proceedings and Evidence, page 2183).

It is necessary, however, to deal with PMAC's lengthy presentation leading to the conclusion that comparative prices of drugs in foreign countries and in Canada do not by themselves present the whole picture and, in fact, are misleading. The Association's presentation related costs of drugs in various countries in terms of labour income. Wage rates were related to selected drugs resulting in

comparisons of drug prices in terms of labour hours. "Labour Indices" were prepared which indicated that Canadians were able to buy their drugs with less labour than people in most other countries; and in fact the "Labour Indices" showed, for example, (Minutes of Proceedings and Evidence, page 292) that the "real" cost of drugs in the United Kingdom was still appreciably higher than in Canada although on actual tables showing comparable drug prices in terms of Canadian dollars this did not so appear.

Your Committee cannot accept this argument. If any Canadian price of any product was translated into labour income, one is undoubtedly going to find that it costs Canadians less to buy that product than it would cost most foreigners, the United States being possibly the only exception. In the ascertaining of the price of a product, whether at the manufacturers' level or at the retailers' level, it appears to the Committee that real cost should be looked at, namely, the cost of labour, raw materials, research and the capital required. This is the true comparison, together with demand, when explaining price differentials between one country and another. It is a question of total efficiency of an industry which must be looked at and your Committee will deal with this when regarding factors that affect drug costs and prices. The Consumers' Association of Canada discounted PMAC's submission in this respect, and the brief of the Province of Alberta also was critical of the economics of PMAC's argument.

CHAPTER V—THE ROLE OF THE PHYSICIAN, THE HOSPITAL AND THE GOVERNMENT IN DRUG USAGE

1. *The Physician*

The physician is the person who has most control over the purchase of drugs, in an indirect but absolute way. The doctor writes his prescription for the drug and the pharmacist has no choice but to fill this prescription as written (except in Alberta where substitution is allowed). In the hospital the doctor still has this role and in addition may play a large part as a member of the Pharmacy Committee in the purchase of drugs for hospital use. In addition to this, the rural practitioner whose practice is in a remote area, often serves as the pharmacist and is involved in the direct purchase and re-sale of drugs to his patient. Dental practitioners (who prescribe certain medications, particularly analgesics (pain killers) and antibiotics) are not dealt with in this report as the volume of medication is small and their attitudes are probably close to those of the medical practitioner.

The Committee feels that it is to the medical profession that a great portion of this report will be useful. The Committee also realizes the fact that few of the medical profession will actually read this report in full. The doctor's time is limited. While some of the material issued by drug companies is very useful, a great portion of the doctor's mail is never studied and the large volume of product advertisement is wasted as a shower of multi-coloured advertisements hits the wastepaper basket, unread. The "ads" in journals are often not read as the physician prefers more impartial reports in the body of the issue itself. The doctor sees the detail man, with one eye on his demonstrations and the other on his watch. As most detail men represent the large manufacturing firms he never hears actual presentations from the smaller firms. The doctor is concerned with the growing reports of diseases caused by the drugs he can prescribe and by the multiplicity of side effects they can produce. He prescribes those drugs he has heard of, has read of, and has some knowledge of—he is a cautious man and prescribes the drug manufactured by a company known to him. He may or may

not know what the drug costs and he may or may not realize there are cheaper "equivalents" on the market. Much of the physician's information is obtained from commercial and biased sources.

The Committee realizes that to ask the doctor to change his prescription habit is a serious responsibility. It should be done only if the doctor can be assured that the drugs he has the option of prescribing are as safe as possible. To do this the doctors should and, indeed, must have free access to a non-biased current report on drugs which would include the following data:

(i) Generic name of the drug

(ii) Names of all manufacturers of the drug, and brand names of the above drug

(iii) Comparative costs and clinical equivalency of the above drugs

(iv) Therapeutic action of drug

(v) Side effects of drug, contra-indications and toxicity

(vi) Last assay for each company's product, of content and availability of active ingredient, solubility and disintegration

(vii) Any problems with any company's product—toxicity, impurity, seizures, court actions, failure to meet standards, etc.

The Committee feels that the Food and Drug Directorate has been keeping its activities from the medical profession. Its findings on drugs should be openly reported to the medical profession in a public document. If there are poor quality drugs on the market, then the medical profession should be told. The medical profession has to be convinced that the Food and Drug Directorate has full and accurate knowledge of the drug industry and to do this, the Food and Drug Directorate should report fully every aspect of the drug problem to the medical profession.

A major recommendation of the Committee is

> That the Food and Drug Directorate publish not less than once a month an informative bulletin to the medical profession giving complete details on drugs and their actions and reviewing major drug uses in Canada.

This will require the Food and Drug Directorate to increase its staff and is a tremendous undertaking, but it will do a great deal to bring down the cost of drugs if it can assure the medical profession that a less expensive drug may be used with safety. The Committee is confident that such a publication would be of tremendous value to the medical profession and would be used extensively. It would be sent *free* to every medical practitioner, dentist, and pharmacist in Canada. The Committee is satisfied the cost of publication and distribution would be more than met by resulting savings to the drug consumer.

2. *The Hospital*

The hospital is also purchasing large quantities of drugs, which are not subject to the federal sales tax. A good many hospitals now buy their drugs on the tendering system, which reduces the costs even more significantly than the absence of sales tax. In many hospitals this is directed by a Pharmacy Committee on which the medical staff plays a large part. Many hospitals use a type of drug formulary which allows bulk purchases, and which also lowers the cost. The formulary drugs are used by most of the medical staff but individual doctors who insist on certain brands of drugs are allowed to prescribe these as they wish. It seemed apparent to the Committee that doctors were using, in the hospital care

of their patients, drugs manufactured by companies whose products they did not normally prescribe. This suggests that some medical practitioners may be willing to extend their use of a formulary to their office practice.

3. *The Governments*

(a) *Federal*

The Federal government purchases most of its drugs (which in a recent year amounted to approximately $5 million) by the tender system. Most of the drugs purchased are from so-called "generic" houses. Only those companies who can meet the requirements of the Canadian Government Specifications Board—Standard for Manufacture Control and Distribution of Drugs (74 GP 1) are allowed to submit tenders. It is obvious that this competitive method of drug purchase lowers the price of drugs. The federal sales tax on drugs is not paid for drugs in hospital use, which lowers the price of drugs, but it was obvious from the evidence produced before the Committee that this difference did not account completely for the lower cost of drugs purchased by the government.

(b) *Provincial*

The provincial governments are also large purchasers of drugs. They also use the tendering system and some provinces have instituted their own inspection services to ensure quality. This is repetitious and expensive to the government involved and could be carried out by the Food and Drug Directorate.

CHAPTER VI

FACTORS AFFECTING DRUG COSTS AND PRICES

Your Committee realized from the outset of this investigation that there would be no simple nor single recommendation that would lead to the reduction of cost of drugs to the consumer. Lowering of drug prices, it was realized, could only be brought about through a variety of means; and for this reason the Committee has looked at factors affecting drug costs and prices at the manufacturer's level, the wholesale level, the retail level, and the effect of pharmaceutical patents or trade marks on drug prices generally.

1. *At the Manufacturer's Level*

(a) *Anti-Dumping Duties and Tariffs*

The Restrictive Trade Practices Commission in its Report expressed the view that "with respect to ethical drugs and more especially antibiotics and tranquillizers, the dumping duty rules may sometimes operate to increase the cost of some Canadian importers without giving any substantial protection to Canadian manufacturers". Although, as we have indicated, most pharmaceutical drugs used in the manufacture of antibiotics and tranquillizers are not in fact produced in Canada, nevertheless most pharmaceutical preparations containing these drugs are ruled by the Department of National Revenue to be of a class or kind made in Canada for purposes of dumping duty. In short, any drug not made in Canada but which falls within the same class of drugs made in this country is subject to dumping duty if imported at a price less than the "fair market value" of the equivalent drug sold in the exporting country. The Restrictive Trade Practices Commission considered that, for this reason, imported finished dosage forms of drugs might well be priced higher than would normally be the case, especially in those instances where the importer was a subsidiary of the parent exporting company.

The Hall Commission recommended 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. The continuing threat of possible imposition of anti-dumping duties on drug imports apparently was of sufficient concern to be recognized by both the above named Commissions as one factor affecting basic drug costs. The parent exporter of the basic ingredient of a drug in finished dosage forms would be inclined, in its transactions with its related subsidiary, to set its price to its subsidiary higher than perhaps necessary in order to avoid such duty. In any event, it is clear that because "class or kind" has been given such a broad meaning to include different drugs that can be used for the same general purpose (e.g. antibiotics or tranquillizers) a wide variety of imported drugs are subject to possible imposition of this duty. A second reason why the import price of drugs (either the basic drug or in the semi-finished or finished form) may be too high is that there is no reliable guide to determine the "fair market value" of the drug in the foreign exporter's home market. To understand this it is necessary to appreciate the method used concerning custom valuation for imported drugs. The standard basis of valuation, used not only for drugs but used generally to determine whether or not dumping is taking place in Canada is, of course, the determination of "fair market value" in the country of export of the goods, i.e., the value or 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. For finished pharmaceutical preparations in dosage form this is a relatively easy determination. For drugs exported to Canada which consist only of the basic active ingredient, however, or drugs exported in semi-finished form, this determination is not possible as the exporter is not selling in all likelihood that particular form of product in the foreign country in the precise condition as that exported to Canada.

The present practice of the Department of National Revenue, therefore, is to use ministerial discretion under the authority of Section 38 of the Customs Act to charge duty on basic drugs imported into Canada at manufacturing cost plus 50 percent when the drug requires further manufacture with other materials, and to charge manufacturing cost plus 75 percent for pharmaceutical preparations in bona fide bulk for packaging, etc. in Canada (less when the exporter's gross profit on home market sales of the finished product is less than the percentage advance). Undoubtedly, and in view of the extent to which the Canadian industry is made up of subsidiaires of foreign parent corporations, the "manufacturing cost" may indeed be fixed higher than necessary to avoid possible anti-dumping duties. Also, quite apart from the fact that transactions between parent firms and their subsidiaries do not involve "arm's length" transactions there is no comparable customer in the foreign country to which reference can be made and a "manufacturer's cost" accurately determined. The only guide to a "fair market value" may indeed be the price to a wholesaler in the foreign country. Consequently it may mean that the Canadian company may be charged that price, equivalent to the price paid by a wholesaler in the foreign country, if dumping duties are to be avoided.

Your Committee is therefore concerned for the reasons advanced above that a tendency exists for Canadian importers to pay more, or be required to pay more, for the imported drugs regardless whether the drug is imported as a basic ingredient, a semi-manufactured drug or a drug in final dosage form.

Your Committee therefore recommends:

> That present ministerial authority as provided in Section 38 of the Customs Act be amended insofar as the importation of drugs into Canada is concerned, and that future value for duty be set in all cases at the cost of production of the imported drug plus an allowance for gross profit (i.e. an allowance to cover the actual manufacturer's administrative overhead, selling costs and net profit, etc.).

It would be desirable to fix some maximum allowance. It was suggested before this Committee in the presentation made by the Province of Alberta (refer to page 2533, Minutes of Proceedings and Evidence) that perhaps an appropriate study would indicate that a 10 percent allowance for gross profit might be adopted for drugs; and if this were done the motivation for foreign parents to charge high prices to Canadian subsidiaries to avoid anti-dumping duty would be removed.

As already mentioned, pharmaceutical preparations are by and large held to be of a class or kind made in Canada for purposes of dumping duty. It is understood from a statement by the Minister of National Revenue (Minutes of Proceedings and Evidence, page 29) that "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"; and the Minister went on to express the Department's view (page 30) "that it was thought necessary to classify all broadly competitive or substitutable preparations as of one "class or kind" if any protection is to be afforded the Canadian producers". However, your Committee feels that if dumping duties were limited only to affect those drugs *of a kind* made in Canada, the undesirable effect of inflating prices of drugs not actually manufactured in Canada could be eliminated while at the same time Canadian production, both existing and future, would be protected. Your Committee therefore makes this recommendation:

> That the Customs Act be amended to make clear that dumping duties with respect to drugs be limited only to affect those drugs *of a kind* made in Canada.

In making this recommendation your Committee is aware of the difficulties expressed by the Minister of National Revenue in his presentation in applying the "kind" concept to pharmaceutical preparations and the fact that competitors might import substitutes for a Canadian drug product which, although used for the same purpose, would technically be of a kind not made in Canada and consequently free of dumping duty. On balance, however, your Committee considers the consumer's interest to be paramount.

The Hall Commission also proposed that the Tariff Board be requested to review tariffs on drugs with a view to establishing which tariff should be reduced or abolished covering imported drugs included in its proposed National Formulary. Your Committee recommends:

> That the federal government instruct the Tariff Board to review the drug tariff structure.

(b) *Marketing and Promotional Expenses*

PMAC provided the Committee with its annual statistical survey for 1964 which set out in considerable detail, among other things, marketing expenses of 41 of its member companies (Minutes of Proceedings and Evidence, page 350). Marketing expenses include field selling, general advertising and promotional expenses, and administrative costs of departments charged with promotion. Advertising and promotional expenses incurred by the industry include costs for

medical exhibits, advertising in medical and pharmaceutical journals, direct mail advertising, the supply of promotional samples to physicians and additional miscellaneous expenses. For easy reference and to study the break-down of the total of $32,977,561 that was spent by the above-named 41 companies in 1964 alone (and these companies do not represent the entire drug industry), Appendix "G" is attached hereto.

Approximately 23 percent of the manufacturer's sales dollar goes for the provision of physicians' information through detail men, literature and samples, while other marketing expenses primarily directed to the pharmacists account for 6.6 percent of the manufacturer's sales dollar. The net result is that these manufacturers' marketing expenses amount to approximately 11 percent of the prescription dollar; or, to put it another way, it represents 30 percent of the manufacturer's dollar (Minutes of Proceedings and Evidence, pages 286 and 302).

It is interesting to note that the Chairman of the Canadian Drug Manufacturers considered that promotional expense averaged out by members of his Association was about 20 percent, about one-third lower than the expense incurred by the PMAC membership. This would indicate that once a drug company leaves the manufacture of generic named drugs to enter the brand name drug field it becomes entrapped by its chosen method of expansion and incurs automatically increased promotional costs (Minutes of Proceedings and Evidence, page 475). One of the "independent" Canadian drug manufacturers (promoting brand name drugs only) on questioning by the Committee indicated that 20 percent or more of its manufacturing dollar was also devoted to marketing expense.

Your Committee is completely in agreement that the funds expended on promotional activity by the industry is excessive, particularly when it is noted that only an equal amount of the manufacturer's dollar is expended in materials, labour and plant costs; and only 7 percent of the manufacturer's dollar is spent on research and development (Your Committee later received figures indicating that the percentage spent on research and development in 1965 by 37 of 58 members of PMAC amounted to 7.6 percent of sales. The 1965 break-down of the manufacturer's dollar is not provided as these figures were not available).

No one disputes the fact that money spent on marketing by the drug industry far exceeds money spent for similar purposes by other industries. However, it is clear that the drug industry differs uniquely from other industries and that merely a comparison of these costs, without understanding the reason therefor, would be quite unfair. The consumer of drugs has no choice of purchase. It is the physician who chooses the drug, makes out the prescription and it is the pharmacist who fills out the prescription as ordered. Generally speaking, the consumer does not know the name of the drug he is taking, and the labels on the bottles containing his prescription do not inform him. Promotional activities by the drug industry are not directed to the final consumer, as is the case with all other industries, but are directed in the main to the physician and, also to a certain extent, to the pharmacist. The third category, which receives the attention of the drug industry includes the purchasing agents of hospitals and government departments. The Committee was told, and it believes, that under the present system—assuming it will be continued—marketing expenses of the drug industry will not decrease. The intense competition between the drug companies in pushing their own brand name products apparently requires this high marketing expense. The Chairman of PMAC was asked whether it would be possible for members of the Association to exercise voluntary restraint, for example, cut

marketing costs in half with the result that if all members abided by the rules the competition between members could remain the same and the consumer would be the beneficiary (Minutes of Proceedings and Evidence, page 246). PMAC took the view that such a voluntary undertaking by the members might be an offence under the Combines Investigation Act although the Committee's Counsel and the Director of Investigation and Research under the Combines Investigation Act were not of this opinion (Minutes of Proceedings and Evidence page 2230). Your Committee, taking the above into consideration and the evidence that a great deal of drug promotion to the physician is wasted, recommends:

> That drug manufacturers revise their promotional practices on a voluntary basis, as considerable savings could be made and passed on to the consumer.

However, if voluntary restraint of promotional advertising is not successful in lowering costs, other more definitive action may have to be undertaken.

Your Committee feels that the detail man has a definite role to perform in the exchange of information between doctor and manufacturer. The Committee is only concerned with that portion of his role relative to his promotional activities for a particular company and a particular drug. As previously outlined, the Committee has recommended the publication of a drug bulletin by the Food and Drug Directorate; your Committee expects that the publication of the above bulletin will significantly alter the function of the detail man.

Certain drug company representatives are paid salaries and commissions, some receiving commissions on sales alone. The Committee feels that payment by commission leads to unnecessary and repetitive activity on the part of detail men, especially in the marketing of similar drugs under different brand names. Under the commission system, the detail man is more likely to be interested in the sale, rather than in providing information to the physician. On the other hand, a salaried representative, having no personal interest in the volume of sales, would be more likely to act in a more professional capacity. With full realization of the difficulties involved, your Committee feels it worthwhile to recommend to the pharmaceutical industry:

> That the pharmaceutical industry take steps to ensure that all representatives of the drug industry engaged in field selling be paid by salary and not by commission.

Your Committee realizes that the Federal Government has no power to implement this recommendation.

The Hall Commission likewise came to the conclusion that marketing expenses in the drug industry were too high, and recommended a compulsory method whereby this expense might be lowered, namely, "that in the application of the provisions of the Corporation Income Tax Act to the manufacturers, importers and distributors of drugs, consideration should be given to establishing a maximum of 15 percent of total sales as the allowable deductible expense for advertising, sales promotion, 'detail men', and other similar items".

Your Committee repeatedly asked witnesses for their views with respect to this recommendation of the Hall Commission; but most witnesses, whether members of the PMAC, the Canadian Drug Manufacturers Association or others, considered that promotional expenses, although high, could not easily be reduced and, even if attempts were made to reduce these by income tax amendments, promotional expenses would continue to be incurred in the same amounts with such expenses eventually passed on to the consumer. Further, it was considered

that such an approach would amount to direct interference with business practice which should not be entertained in a free enterprise system. And thirdly, such a proposal would react against smaller manufacturers rather than against those who perhaps could afford to reduce their promotional activities.

There are other reasons against the Hall Commission's proposal. Drug costs, i.e. the manufacturer's sale price to the wholesaler or, indeed, to the retailer are one thing; price to the consumer is quite another. The latter can be reduced by open competition; but reduction of the former by disallowing promotional expenditure, which otherwise would be an allowable deductible item of expense, is something else. There is no guarantee that the Hall recommendation, even if the Companies automatically lowered their budgets on marketing costs, would result in savings passed on to the consumer. More than likely the monies budgeted for and remaining unspent would pass to the shareholders. Yet again, regardless of the savings hopefully expected as a result of the recommendation, it might well be that the drug companies would, regardless of increased taxes, press their promotional activity to meet the continued competition of their rivals—which might easily result in higher costs at the manufacturers' level, and then higher drug costs to the consumer.

The answer appears to lie in increased competition (See Chapter 6, item 6). The greater the competition, the greater the pressure against high prices. As prices drop, inefficiency is bound to decline, and a cut-back in promotion and marketing costs is almost bound to ensue. Your Committee, is not prepared to recommend this proposal of the Hall Commission relating to maximum tax allowable promotional expenditures.

(c) *Brand Names*

There is not doubt that the use of brand or proprietary names in the drug industry is a factor contributing to the high price of drugs. As we have seen, the use of brand names invokes extreme and expensive competition within the industry through massive promotion of drugs which actually may be identical or very similar to others already on the pharmaceutical market. Incidentally, it is worthy of note that the supporters of brand names for drug products press the fact that there are no two "identical" drugs, and that even drugs containing the same active ingredient do not necessarily yield the same therapeutic results.

The well-established brand-name firms contend that, quite apart from the active ingredient present in the product, there exist many variables such as stability, disintegration time, solubility, sterility, etc., and because of these factors the generic products are not identical to the brand name products. Your Committee recognizes the truth contained in this statement. The marketing of products sold under generic labels that set out potency values, etc., would have prevented high cost promotional competition without undue risk to the consumer; and indeed, might have once been the proper basis on which to build when the drug industry was in its infancy and when regulations forbidding the sale of drugs under brand names could have been made mandatory without business disruption. However, it seems clear that any regulations that could now be imposed that would prevent the use of brand names in the marketing and sale of drugs would be out of character with present day commercial practice. The problem, indeed, seems to be one of education rather than prohibition.

Having come to this conclusion, however, your Committee further considered the advisability, as recommended by the Hall Commission, "that provincial governments consider legislation enabling pharmacists in the dispensing of prescriptions to use a drug or a drug combination that is a non-proprietary name

equivalent of that named in the prescription unless the physician specifically indicates otherwise". At the moment, legislation to this effect is in existence in Alberta (Statutes of Alberta, 1962, Ch. 61). Your Committee does not consider that such legislation, even if adopted by all the provinces, would bring down prices to the consumer to any measurable extent. If, for example, the pharmacist had a choice of using a brand name product prescribed by the physician, or a generic name product of the same drug of equal potency and pharmacological activity, he would still be more likely to fill out the prescription with the brand name product; and the well-intended purpose of the legislation would be of little avail to the consumer. The Committee's opinion is strengthened in this by surveys reported by the Hall Commission that physicians prescribe brand names over generic names in the proportion of 15 to 1. Also, evidence presented to the Committee by the Province of Alberta indicated disappointment with the results obtained under the above Statute.

(d) *Research and Development*

In the evidence presented to this Committee, much was made of the fact by leading Canadian drug manufacturers that research and development led to higher costs; and because of the necessity for continuing research in a "research oriented" industry, this was a factor that did affect the end price to the consumer. Your Committee is fully cognizant of the necessity for continued and increased research in Canada, not only generally but also in the drug field; and it is hoped and expected that none of the recommendations of this Committee will in any way impair the quality or volume of future scientific research in medical or related spheres. The Committee, therefore, found it necessary to examine in close detail the claims of the Canadian drug companies with respect to research carried on by them in Canada to ascertain the effect of this research, and to determine the effect research has with respect to drug prices to the consumers; and, in general, to ascertain whether or not these claims to research and its resulting benefit to Canadians are valid and worthy of approbation.

As mentioned, your Committee has had before it from the outset the Report of the Hall Commission published in 1964 which, in respect of drugs, was based largely on the earlier report of the Restrictive Trade Practices Commission. The evidence presented before this Committee has merely brought these findings up to date. The Hall Commission found that "in the light of what has already been said, we do not think that there can be any real dispute about the fact that the research conducted in Canada attributable to the commercial drug firms has been modest" (Hall Report, p. 668-669). Your Committee, in the questioning of witnesses appearing before it, was well aware of this earlier situation; and it is glad to confirm that since the Hall Commission Report was published there appears to be increased activity by Canadian drug manufacturers relating to research generally. As explained later, part of this activity has been generated by governmental assistance through tax concessions.

Before pursuing this subject further, however, it is important to know just what the meaning of the words "research and development" is, as it seemed to your Committee that the use of these words may give rise to different interpretations. Although in some instances it is difficult to be precise and nomenclature may vary, your committee considers that, firstly, there is "basic" or "pure" research, which is that research carried out solely in the hope of attaining "breakthroughs" in scientific knowledge. The solving of a particular problem, for example, is not the main consideration. Such research is expensive and generally carried out by governments, universities and the like. This type of research is also carried out to a much lesser extent by the drug industry, but only in specific

centres situated, except in one or two Canadian instances, in foreign countries. Secondly, there is applied research which entails that research necessary to bring into production those products desired by, and of benefit to, the ultimate consumer. It is this form of research that forms the basis of much of secondary industry and is protected by the patent system. And thirdly, there is product development that involves, among other things, clinical research requiring continual testing of a product to ensure high quality and safety both before and after marketing.

It has been difficult to obtain an accurate breakdown of what the Canadian drug companies contribute in respect to basic research that might eventually lead to entirely new drugs likely to score successes by providing remedies for illnesses not combatted by drugs presently known. In making this statement the Committee has in mind, for example, earlier departures made through the discoveries of insulin and the broad range of antibiotics. In any event, basic research of this type is negligible in the Canadian drug industry; and, as mentioned, is extremely costly.

The Committee believes it was to both basic and applied research to which the Hall Commission was referring when dealing with the question of whether the patent system could be defended on the usual grounds that it is necessary to provide incentive for research, they stated: "It appears that Canada, a small country where most of the significant pharmaceutical research is done by other than the drug companies, has copied an institutional arrangement which can only be appropriate to a country like the United States where the higher prices which the patent system permits in fact supports research by the industry on a substantial scale" (Hall Report p. 670).

Much of the research that is in fact carried out by the Canadian drug companies has been generated for two reasons: (a) to satisfy the Food and Drug Directorate of the Department of National Health and Welfare in respect to the introduction of new drugs and substantial clinical testing, with respect to these and other matters pertaining to product development; and (b) to take advantage of Tax concessions granted to Canadian corporations generally for promotion of research. A third reason for heavy expenditures being made for research involves the "working around" of patents issued to others (referred to in the industry as "molecular manipulations") i.e. by replacing specific atoms or molecules in chain or cyclical organic chemical compounds to produce new drugs with perhaps sufficient or even partial pharmaceutical differences to justify active market promotion. This latter type of research activity is apparently not carried out in Canada to any great degree.

Your Committee has been conscious throughout, as already mentioned, that continuing research in the drug industry in Canada should not be inhibited by any recommendations made in this Report; and, for this reason, it is necessary initially to appreciate the fact that basic and applied research as performed in Canada, apart from very few Canadian companies, is relatively modest because of the unique character of the drug industry which has developed on an international basis, not only for historical reasons but for economical reasons as well. It was natural that the important research in the drug industry was begun and carried out in those countries which initially had the most substantial resources; this refers in particular to the United States. With resources available to almost an unlimited extent, with a large consumer population and aided by a strong patent system, American research in the drug industry has clearly dominated the international scene—at least from the Canadian viewpoint. The same situation exists, of course, in other more industrially developed countries such as the United Kingdom, France, Germany, Japan, Switzerland, etc. It seems clear that

Canada was a "late starter"; and, because of this, the true international aspects of the drug industry must be studied with full realization that any aproach to the promotion of further research in the Canadian aspect of that industry should be thoroughly examined before any hasty recommendations are made. For example, any further tax concessions that might be conferred on the Canadian drug industry should be considered in the light of what benefits are likely attainable from the total package of research and development undertaken, or benefits derived solely from basic and applied research. Indeed, if this distinction is not made, it is conceivable that the taxpayer will be asked to pay for clinical research and testing (which are normal expenditures in any industry) and the manufacturer will reap the benefit at the expense of the taxpayer.

The drug industry naturally does not approach the problem of research on the above "dissection" approach. Research of all kinds is considered to "flow together" regardless of its form or type. For example, one of the key witnesses for PMAC stated early in the proceedings (Minutes of Proceedings and Evidence, page 198) that he considered the Committee's Counsel was grading research into first class, second class and third class types. Then he went on to say: "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". However, your Committee is more concerned with prices to the consumer without harming *basic and applied research* in Canada.

Turning now to specific figures that have been brought before this Committee, evidence has been given by PMAC (Minutes of Proceedings and Evidence, page 295) that *international* expenditures on pharmaceutical research now exceed $400 million a year; that specific projects on which such research is carried out are by no means all successful, it being estimated that only 1 in every 3,000 compounds tested yields a drug of sufficient value to justify its introduction. With this in mind the Canadian situation was examined.

PMAC in its survey of 37 of its member companies received information to the effect that the total research and development spent in Canada (i.e. meaning all forms of research) amounted in 1964[1] to $5,504,323 ($8,144,870). In addition, there was charged to the Canadian companies by related companies outside of Canada the sum of $1,579,140 ($1,380,622); and there was paid to non-related organizations located outside of Canada by these Canadian companies $8,703 ($28,987), making a total in all of $7,920,166 ($9,544,479). The "reasonable estimate" of the cost of research and development performed on behalf of these 37 companies by related companies but for which no charge was made was $5,439,303 ($6,389,086) making a total claimed expenditure, either paid by the companies or considered a possible charge against them by related companies (although no such financial payments were made), of $12,531,469 ($15,933,565) (Minutes of Proceedings and Evidence, page 351 and page 2200). Under questioning by members of the Committee it was indicated by PMAC (Minutes of Proceedings and Evidence, page 200) that Canada "benefited" in 1964 to the extent of almost $5,500,000 from *international* research whereas its contribution to *international* research by payment to related companies or others was only approximately $1,500,000. In 1965, the "benefit" to Canada from international drug research was almost $6,400,000 while that same year the Canadian firms contributed to the international picture approximately $1,400,000. Canada, it was claimed, received tremendous advantages from work performed in foreign countries. The differential "favouring" Canada was $4 million in 1964 and $5 million

[1] Later the Committee received PMAC's annual statistical survey for 1965 pertaining to research and development and these figures are given in brackets.

in 1965. This, of course, lends credence to the theory that all countries, whether research oriented or not, benefit equally from research activity regardless of where it is performed, although this is not altogether true as countries carrying out basic and applied research to a great extent benefit from the peripheral blessings created by research, especially the attracting of scientists to those countries and the impetus thereby created to primary and secondary industry.

It is interesting to note that total research and development expenses, either spent in Canada or charged to Canadian companies, (represented by 41 companies in 1964 and 37 companies in 1965) is also capable of being broken down to indicate that laboratory expenses counted for $4,820,833 (6,924,713) whereas clinical investigation (including medical departments) cost $1,917,169 ($2,204,-825) the balance representing research and development grants and unreported break-down. Clinical investigation costs, then, accounted for some 27 percent of the dollar spent on "research" in 1964 and some 23.2 percent in 1965. The statistics clearly indicate that expenditures made by the reporting companies on applied research and product development are increasing; but it should perhaps also be remembered that, at the same time, total sales of packaged human pharmaceuticals by the reporting companies also increased from $110,465,396 in 1964 to $125,054,386 in 1965.

These figures, encouraging as they may seem, must, however, be looked at in a different way to comprehend fully the actual cost of human pharmaceuticals to the consumer who in the long run must bear the cost of research and development. In terms of the manufacturer's dollar, 7 per cent was spent for research and development of all kinds as reported by 41 PMAC companies in 1964. This figure would be somewhat higher for 1965, possibly relating to increased tax concessions for Canadian research. If it can be assumed that the manufacturer receives only 50 percent of the pharmacists' price to the consumer and the suggested list price for a specific drug was $5.00, then the consumer's contribution to research and development as a result of that particular purchase would be 17½¢—in any event, a fairly insignificant sum.

It should also be borne in mind when considering these research figures that most companies outside the PMAC group do not attempt research of any kind, although one or two small but growing independent companies apparently are considering expending money on research.

Your Committee has come to the conclusion that the drug industry in Canada will continue in the foreseeable future to remain largely within the international framework; that the larger Canadian companies will remain subsidiaries of foreign corporations; and that any further noticeable increase in research in Canada by these subsidiaries will in all likelohood not take place, unless stimulated by government policy.

Your Committee has three recommendations to make regarding research and development in the Canadian drug industry. Your Committee recommends:

> That the federal government should make a substantial increase in grants to the Medical Research Council, for the promotion of basic pharmaceutical research.

The results of this basic research whether patentable or not, would belong to the public. Your Committee further recommends:

> That the pharmaceutical manufacturing industry take full advantage of the federal incentive program for research.

Another concern of your Committee is that insufficient research is presently being carried out with respect to the manufacture of the active ingredients of

drugs which, to a large extent, are now being imported. Further and proper development of the drug industry in Canada cannot be expected if research is confined to experimental clinical testing or mere product development that does not involve making Canada more self-sufficient in this secondary industry. The Committee realizes that a balance must be struck between the cost of importation and the cost of manufacture and that normal economic considerations must apply; however, it is conceivable that the drug industry up to now has failed in Canada to direct maximum attention to basic product manufacture.

An interesting suggestion was raised in Committee concerning possible stimulation of research by increasing royalty payments to patentees subject to compulsory licensing (see item 4 of this chapter), provided the patentees affected could prove that research carried out in Canada by them exceeded a basic minimum. Such a recommendation would appear to have considerable merit, particularly if the end result would be to stimulate research in Canada. However, any percentage increase in royalty should, in the opinion of the Committee, be related to research of drugs discovered and initially developed in Canada. The increased royalty would not add significantly to the cost of the drug to the consumer.

Your Committee therefore recommends:

That the Patent Commissioner, on assessing royalties on the granting of a compulsory licence, shall consider that the patentee who discovers and initially develops the drug in Canada should have higher royalties than the drug manufacturer who discovers new drugs outside of Canada.

(e) *Maintenance of Special Drugs for Special Purposes*

In the PMAC brief (Minutes of Proceedings and Evidence, page 301) it was called to the Committee's attention that the research laboratories of the international pharmaceutical companies have developed many products, often lifesaving, that are available for rare illnesses and conditions. A survey of PMAC membership showed that 18 companies listed 84 products of this type and that such products are made available frequently to physicians either free of charge or at factory cost. Few, if any, of these products are in fact manufactured in Canada; most of these are made available to Canadian subsidiaries by parent corporations. They constitute drugs for which there is no great demand.

It was suggested that the cost of these products cannot easily be determined but their value was inestimable. Your Committee considers that their continued availability for Canadian use is a matter of importance and, in this respect, the large drug companies deserve commendation. However, insofar as drug costs and prices are concerned your Committee considers that retention of these items and their availability to physicians is not a factor that significantly affects prices to the consumer.

(f) *Drug Safety and Quality Control*

In the manufacture of drugs, the safety factor is usually referred to as quality control. Until recent years the provision of quality control measures was not obligatory under the Food and Drug regulations. Due to fairly recent changes in the regulations, quality control is now a necessary part of the manufacturing process.

The Committee feels that all the cost of quality control cannot be easily segregated from usual manufacturing costs, as it is often an integral part of the usual manufacturing process in any industry, whether pharmaceutical or other.

In any event the Committee feels that safety must be assured and that any cost of quality control is a necessary part of the cost of manufacture. No recommendation of this Committee will be made in any way that would tend to reduce monies spent on quality control. Safety must be placed above cost. It is realized actually that the cost of quality control although small is essential.

The Special Committee on Food and Drugs' Report to the House of Commons of December 1964 found the dangers from the use of drugs small in proportion to their value. The present Committee in its thorough study of cost has again been deeply interested in the related matter of safety. The Committee notes that the incidence of significant hazards to health is relatively rare in Canada. This does not mean that side reactions to drugs are unimportant, and indeed this aspect of the problem is a worrisome and growing problem to all those concerned with drugs—manufacturer, doctor, druggist and patient and, of course, the Food and Drug Directorate.

Many of the recommendations of the Committee on the safety of drugs have been implemented. The Committee is pleased that the Notification Program for all drug manufacturers, recommended by the Special Committee on Food and Drugs dealing with the safety of drugs, has been implemented by the Food and Drug Directorate.

The Committee feels that the medical profession does not appear to have full awareness of the Adverse Drug Reaction program and therefore recommends:

> That the Food and Drug Directorate publicize the Adverse Drug Reaction program in co-operation with the Canadian Medical Association.

(g) *The Federal Sales Tax*

Federal sales tax applies at the regular rate of 12 per cent on all drug preparations, whether the drug is manufactured in Canada or whether it is imported, except 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 used exclusively in its manufacture. In addition, exemptions are afforded bona fide charitable institutions and hospitals.

Thus, the consumer who receives his drugs as a patient in a public hospital receives them sales tax exempt. But following discharge, he is compelled to pay for his drugs at prices that include sales tax. Thus an anomaly exists in the present situation. When the Committee commended its deliberations the rate was 11 per cent. This was subsequently raised to 12 per cent. All submissions to the Committee with respect to federal sales taxes have been on the basis of the 11 per cent rate.

Considerable discussion of the effect of the sales tax took place before the Committee, the following being perhaps one of the most cogent statements:

> "Because of the nature of demand for prescription drugs, a tax at the manufacturer's level can be pyramided through the various stages of distribution and passed on to the consumer in magnified form." (Province of Alberta). In the same brief we read, "In industries where price competition is largely inactive, and distributors' markups chiefly a matter of tradition or convention, the tax will be dependably and automatically pyramided as the sellers attempt to shift the tax forward to the final consumer by adding their traditional markups to the tax-included prices which they pay".

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Accordingly, the price of drugs to the consumer is increased not only by the sales tax paid but also by the margins added on the tax by the wholesaler and the retailer.

The impact of sales tax upon the price to the consumer will vary depending upon the particular pricing method used at the retail level. The evidence before the committee suggests that there are three basic methods in use: (1) list price, (2) list price plus a dispensing fee and (3) cost plus a professional fee. The Committee understands that the second method is the one most commonly used although the third method is gaining in popularity.

In the "list price" method, the traditional markups above cost are 20 per cent by the wholesaler and 66⅔ per cent by the retailer. In this case the impact of the tax is to increase the final consumer's price by eleven percent over that which it would otherwise be if sales tax did not apply. This increase represents 9.87 per cent of the final consumer price.

The Committee received many and varied calculations of the effect of sales tax upon the price of drugs to the consumer. The basic reasons for these differences in calculations are:

1. Interpretation—Some were dealing with the amount of tax paid only; others were dealing not only with the amount of sales tax paid but also with the result of the application of pricing policies at the wholesale and retail levels.

2. Variable factors—There are variations in the pricing methods in use at the retail level as well as in the amount of the "fee" that is often charged by the pharmacist.

The Committee's accountant has calculated the impact of sales tax upon the average price to the consumer under each of the three basic pricing methods. In these calculations, he used the average prescription prices of $3.43 and $3.67 for the "list plus dispensing fee" and "cost plus professional fee" methods respectively as reported on behalf of the Canadian Pharmaceutical Association and included in the association's brief to this Committee (Appendix to brief: "Prescription Pricing Patterns in Canadian Pharmacies in 1964", page V). The traditional markups above cost were used for the "List price" method. The following results were obtained:

	Per Cent of Price to Consumer		
	List Price	List price plus dispensing fee	Cost plus professional fee
Sales tax	4.96%	4.1%	4.4%
Wholesaler's margin added to sales tax	0.99%	0.9%	0.8%
Retailer's margin added to sales tax	3.92%	3.4%	—
Total	9.87%	8.4%	5.2%

NOTE: These calculations are based on a rate of tax of 11%, not the present rate of 12%.

From these figures one might be inclined to conclude that elimination of sales tax could result in an average reduction of 5 to 10 per cent in the price of drugs to the consumer, depending upon the particular pricing method in use. However, reduction in prices is not ensured simply by the elimination of the

sales tax. This point was emphasized by many who made representations to the Committee. It was pointed out that the elimination of the federal sales tax should be taken as part of a program to reduce drug prices and that this can be better assured by introducing competition into the drug market. Evidence, for example, has been shown that tariff reductions have not always been accompanied by a corresponding decrease in the price of drugs although the cost to the manufacturer was lower.

Both the drug manufacturers and retail pharmacists offered the opinion before the Committee that the benefits of a reduction in sales tax would be passed along to the consumer. However, the Committee concludes that, without more effective operation of competitive forces than presently exists in the drug industry in Canada, the only certain result from removal of the tax would be a reduction in costs to the manufacturers. The consumer must also understand that the removal of the 12 percent federal sales tax on drugs *will not,* (however much drug manufacturers and retail pharmacists honestly co-operate), lower the price of drugs 12 percent for the reasons already discussed in this section.

One other suggestion concerning the federal sales tax on drugs should be mentioned. It was suggested by the Canadian Drug Manufacturers that the tax should continue to be collected and that the revenue obtained should be kept aside and used by the federal government to create a new agency (non-profit) "The Drug Research Institute". This was originally proposed to the committee by Empire Laboratories and endorsed by the Canadian Drug Manufacturers; for details of this proposal see Chaper IX, Item 7 of this report.

Many people have claimed it is unjust to tax the sick, who are often those least able to meet added expenses. In proportion to the total revenue of the government the amount of tax collected on prescription drugs is small, amounting to approximately $20 million last year. It is felt by the Committee that the loss of revenue that would be suffered by the government if the tax were removed, is more than justified if its removal reduces the cost of drugs to the sick who are, in many cases, the needy.

Your Committee is also conscious of the fact that large stockpiles of drugs already exist on which federal sales tax has already been paid. Some time will be required to elapse before warehouses, manufacturers' depots and drug outlets have emptied their shelves of these tax-paid drugs. The public must be aware, therefore, that the removal of the Federal Sales Tax may not mean an instantaneous drop in the price of drugs.

Taking all these aspects of this matter into consideration your Committee recommends:

That the federal sales tax be removed from the sale of prescription drugs.

2. *At the Wholesale Level*

After consideration of the submission of the Canadian Wholesale Drug Association which, it is understood, represents virtually every major full service drug wholesaler in Canada, the Committee has come to the conclusion that net operating profits of the drug wholesalers are not high. According to this Association's 1965 operating survey, net profit after taxes of 10 wholesale drug firms, representing 28 members, was 0.59 percent of net sales while for 1964 net profit after taxes for 15 members was 0.60 percent. Net sales aggregated over $127 million for 1965 as opposed to over $113 million in 1964. The Association was frank to admit that there exists a paucity of information with respect to Canada's

wholesale drug industry, and that the surveys provided insufficient statistical data. Nevertheless, present evidence indicates profits in the wholesale drug industry are not high.

It is interesting to note that a number of pharmaceutical manufacturers carry out their own distribution, acting as direct sellers, and do not channel their products through wholesale houses. These manufacturers generally sell at 40 percent off suggested retail price directly to the pharmacist who is supplied from the manufacturers' depots. Most pharmaceutical manufacturers who make extensive use of drug wholesalers allow a discount of 16⅔ percent with perhaps an extra allowance of 1 or 2 percent for cash (Minutes of Proceedings and Evidence, page 1620).

In any event, it would appear that of all businesses engaged in the chain, making up the pharmaceutical industry, the wholesaler operates in the most competitive area. The submission of the Province of Alberta (Page 74) puts this succinctly: "Drug manufacturers have their markets protected by patents, trade marks, tariffs and dumping duties, sales promotion practices; fewness of numbers and large average size. Druggists have a protective market because of the institution of brand name prescribing and other prescription regulations which put the consumer at a unique disadvantage, plus the advantages associated with being a closed profession regulated by semi-autonomous professional associations which may be able to limit entry. But the wholesaler has no comparably strong bargaining position. If unsatisfied with the performance of wholesalers, drug manufacturers can integrate forward and sell directly to retailers. Similarly, groups of retailers, or even larger retailers, can integrate backward, as it were, and buy directly from the manufacturers. Hence the wholesaler must provide suitable services, reasonably priced, or find himself out of business." Your Committee agrees with this conclusion and makes no recommendation along the lines of the representation of the Canadian Wholesale Drug Association that manufacturers should distribute through wholesale druggists on the ground that there would be a decrease in manpower and related costs (i.e. wholesale houses would replace manufacturers' depots) without diminution of services. Your Committee does not agree with this latter conclusion.

The Committee feels as outlined above, that the wholesaler provides a service for the drug retailer and in doing so does not contribute to the cost of drugs significantly. Your Committee considered the possibilities of the wholesaler purchasing his total drug needs for a certain period of time in bulk form and re-packaging the drugs in quantities as required by the retail pharmacist, in appropriately sized containers. This of course would require the services of a pharmacist. Your Committee wondered whether considerable savings might be made in this maner and passed on to the consumer. This re-packaging was done in some volume in the past but is done to a small extent now.

Control drugs or narcotics are potentially dangerous drugs and are under rigid federal regulation. Manufacturers are required to have a federal licence for the manufacture and distribution of control and narcotic drugs. Distributors are required to have a federal licence which permits the distribution only of control and narcotic drugs and this licence forbids them to re-package and does not allow them to change in any way the form in which it is received from the manufacturer. Approximately 160 narcotic dealers are licensed (including manufacturers) and approximately 300 control drug dealers (including manufacturers) are licensed. Each depot of a manufacturer is licensed separately.

No licence for distribution is required for drugs that are not narcotics and are not control drugs. Any individual or firm may distribute these drugs without a federal licence. If this same individual or firm decides to re-package them (and

therefore re-label them) and distribute them, then by definition under the Food and Drugs Act this individual or firm becomes subject to all the regulations laid down under the said Act. This practice, if it were done to any extent, would greatly increase the work of the Food and Drug Directorate, and the savings would have to be considerable to justify this added work and expense. If many small distributors were to begin business as above, the problems of policing them could be tremendous. With the manufacturer (who is already under Food and Drug Directorate inspection) doing a good portion of the distribution and some of the remaining distribution (dealing with control and narcotic drugs) under federal licence, there seems to be little justification for changing the system when the savings are unknown and questionable.

Another problem in any re-packaging process is that the lot number may be lost and the possibilities of drug recall are gone. To re-package and retain records of lots etc. will add to the cost in the form of more and more documentation.

Most distributors do not have the trained staff or the facilities or equipment to re-package the many varieties of drugs on the Canadian market and to do this in fact might add appreciably to the cost of the wholesaler, and therefore to the cost of the drug.

Your Committee is aware that some retailers group together to get large volume purchase discounts and may to some minor extent do re-packaging, but this is uncommon. It is understood that the pharmaceutical associations discourage for safety reasons this re-packaging at the group retailer level.

Taking all these factors into consideration your Committee is satisfied that changing the present system of drug distribution in Canada would not reduce the cost of drugs to the consumer.

3. *At the Retail Level*

It became clearly evident during the course of the hearings that one of the major factors affecting drug prices was at the retail level; and it was at this level that probably most difficulties would be encountered in any endeavour to introduce competition which could result in lower prices of drugs to the consumer. This became evident from the evidence provided by the Canadian Pharmaceutical Association Incorporated which 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 the Association at an earlier date. Membership in the Association comprises pharmacists in all fields of pharmaceutical endeavour in Canada without exception. (Minutes of Proceedings and Evidence, page 54).

The provincial pharmaceutical associations appear to exercise great control over their pharmacist members through their regulations and "standards of ethics"; and in considering what might be accomplished in reducing prices at the drugstore level your Committee kept well in mind the division of powers between the federal and provincial governments. Basic to the problem is the fact, as previously pointed out, that the physician is the purchasing agent for the buyer, only the agent knows the product to be purchased and the buyer pays the price. Generally speaking, the physician is motivated primarily to order from the pharmacist for his patient that drug most suitable for him, regardless of price; and the pharmacist is required to fill out exactly that prescription (except in Alberta, as previously mentioned). The pharmacist may suggest to the doctor a less expensive alternative but this is not common practice. The retail drug buyer

is at a complete disadvantage. In all likelihood he does not know the name of the drug product he is purchasing, he is hesitant to "shop around", and he feels helpless in the hands of the pharmacist.

Your Committee recommends

> That the drug consumer be made aware that in fact drug prices do vary from pharmacy to pharmacy and it is his right to compare prescription prices before purchase, and that neither the pharmacist nor the physician should deny this right.

In the submission of the Canadian Pharmaceutical Association Incorporated (Minutes of Proceedings and Evidence, page 57) it was stated that in 1964 there were on the average 3,854 customers per pharmacy, each of these procuring 2.68 prescriptions at an average price of $3.31; and that preliminary figures for 1965 indicated a utilization rate of 3.0 prescriptions per person averaging $3.32 each. Further, it was stated that in 1964 an "average" pharmacy dispensed some 30 prescriptions in each day of the year, the sales from which represented only 27.4 percent of the gross sales of the pharmacy.

It was also stated (Minutes of Proceedings and Evidence, page 1936) that the "average" pharmacy, open to the public for 67 hours per week, derived 28.7 percent of its gross income from prescriptions. These statistics, and others which were represented to us, clearly indicate that the average pharmacist in an average community could not hope to survive unless he operated his pharmacy also as a small goods retail outlet. Less than a third of his income is derived from the sale of prescription drugs. Also, statistics indicate that serious inefficiency exists as a result of too many drug stores serving too few people, and inefficiency leads to higher prices. European practices exist whereby new pharmacies cannot be established unless there exists proof that a sufficient number of customers require services not provided by existing establishments. In Canada, however, there are many small communities requiring a pharmacist and a drug store, and any methods of governmental control over their number as related to population would not be practicable except possibly in large urban centres.

Another factor enters the picture, and that relates to the profession of pharmacy itself. The pharmacist is a highly qualified professional who requires four years of university training before he is eligible to practice his profession. The knowledge of pharmacology is absolutely essential for many persons engaged in drug research, clinical testing of drugs and employed in hospital laboratories, etc. To a lesser extent this is also true in the average drug store but there the role of the professional has changed. By and large the pharmacist now is only required to issue drugs as tablets, capsules, ampules, etc. in their final dosage forms. Often it is only a case of handing across the counter a specific package or bottle as prepared by the manufacturer, or to make up packages for the consumer from larger containers the pharmacist carries in stock. The pharmacist's role is indeed changing from a compounder of medicines to a merchandizer of drugs and other manufactured products. There is no doubt in the Committee's view that his function will change even more in this direction. Your Committee cannot of course make recommendations for legislation in this respect, but does wish to suggest that provincial governments and provincial pharmaceutical associations consider seriously the future role of the pharmacist in the economy and the non-competitive position he finds himself in vis-à-vis the consumer. By retaining the existing non-competitive position, inefficiency results, drug sales are reduced, unnecessarily high prices maintained, and the pharmacist himself harmed. It may well be that pharmacy associations will have

to re-think through their professional activities, e.g. provide in the future for two groups of professionals: one group of thoroughly trained pharmacists and another group (with less training) from which the dispensing druggists would be chosen.

It was also brought to the attention of the Committee that a practice exists where pharmacists "code" filled prescriptions so that if a customer asks for a repeat order at a different retail outlet the other druggist will know what the patient paid for the drug on his first purchase and will in all likelihood charge the same on the repeat order. It is the understanding of the Committee that the practice has been discouraged by the pharmaceutical associations on ethical grounds. The practice, however, does indicate the lengths some may go to prevent competition at the retail level.

Ordinarily there are two ways by which the druggist charges for a prescription. The first is by a mark-up over the cost of drug products delivered by the manufacturer or the wholesaler, plus a dispensing fee. The second method is the charging of a professional fee which is usually fixed (for example, $2.00) over and above the cost to him. The second method of establishing the price to the consumer appears to be gaining favour with the provincial pharmaceutical associations and the druggists themselves. This second system will lower the cost of the more expensive drugs and will increase the cost of the less expensive drugs. Either method results in the same approximate income over a period of time.

It is apparent that if the pharmacist adds a fixed percentage as his mark-up for the consumer price, then the higher the cost, the higher his profit in dollars and cents. This could be a factor in the pharmacist suggesting, if he has the option, a higher rather than lower cost drug. If this mark-up also includes mark-up on the federal sales tax, then this again aggravates the problem of cost. Your Committee therefore recommends (but realizes it has no power to implement)

> That pharmacists use the "cost price plus professional fee" method for determining drug prices to the consumer.

This recommendation is not to be construed as any proposed arrangement which might be an offence under the Combines Act.

The method of filling prescriptions by cost to the druggist plus a "professional" fee has a distinct financial advantage to the consumer particularly if physicians prescribe drugs for their patients by generic names. A pharmacist could fill such a prescription by the lowest price high quality drug consistent with that prescription whether it be a generic or brand name product. Pharmacists would make reasonable profits at savings to their customers. However, prescription by generic name would, at the present, be resisted by many physicians, all of whom are quite properly safety minded but who have more confidence in brand name products. The Committee feels this is a matter of continuing education or experience; and the Committee's recommendation concerning a non-biased drug publication will in the course of time enable physicians to prescribe reliable and safe drugs without recourse to advertising and marketing techniques undertaken by pharmaceutical manufacturers.

The pharmacist is in many ways the servant of the doctor rather than the public. He most often buys his drugs direct from the manufacturer, or from a wholesale drug distributor. A pharmacist's role has changed tremendously over the past twenty years—he now rarely compounds medicines but now buys these already compounded and ready for "instant use", however his professional

training is still necessary under the present system of prescribing. His paper work has increased with various government regulations, forms, narcotic prescriptions, drug schedules, etc.

There is no question that drug prices in various pharmacies, of the same drug from the same company, in same dosage form, vary widely. This is of course true of most commodities available in Canada and is not specific for drugs. Some pharmacies appear able to sell a drug much cheaper than others and this is true whether it is a so-called generic or brand drug. It is also true whether they are bought in large or small amounts, although large volume buying does result in lower prices.

A suggestion has also been made that, to create more competition at the retail level, it might be advisable for pharmacists to label all prescription drugs sold to customers with the generic and/or trade name as ordered by the physician so that the contents of the prescription is indicated and the customer patient will know his precise medication.

One of the problems is the risk that patients might associate a particular drug with a particular illness, either accurately or mistakenly. In most cases this would not be a concern but in certain cases this could be highly undesirable from both a medical and psychological viewpoint. It should be pointed out that if the doctor wishes the name of the drug prescribed on the label at the present time, he has only to indicate this to the pharmacist.

It has also been suggested to the Committee that one factor that might affect drug prices might be pharmacies established by physicians and pharmacists acting in partnership. Your Committee is pleased to report that no evidence has come before it to justify this suggestion.

A further suggestion was put forward to this Committee that the particular regulation under the Food and Drugs Act relating to advertising of prescription drugs should be rescinded in order to allow their advertisement through publicity media by name only. It was considered that by the use of such advertising the patients might be made aware of where to shop and purchase their prescription drugs, that competition between drug stores would thus be enhanced and prices to the consumer would accordingly drop. All pharmaceutical associations are extremely sensitive on this point and have even gone to Court to exercise their very wide powers of restraint contained in their regulations and applicable to their large membership. Advertising cut-rate prices by druggists is considered unethical by the Pharmaceutical Association as being unprofessional. Our Committee makes no firm decision on this point except to wonder how a pharmacist whose sales of prescription goods amount to only 25 to 30 percent of his total sales can consider himself "professional" on the one hand yet on the other, can advertise cut-rate prices on the majority of goods he has in stock to sell. There is no question that general advertising has benefited an occasional large retail pharmacy, but this has proceeded in considerable defiance of the Provincial Pharmaceutical Association. It is claimed that this can be done successfully anywhere in Canada, particularly in the large urban centers, and this type of drug supermarket would in the opinion of the Committee be one effective method of reducing the price of drugs. However, as stated earlier, this is a matter under the control of the provincial governments under whom the Provincial Pharmaceutical Associations are permitted to operate.

"Mail order pharmacies" are being established successfully in Canada and apparently are helpful in reducing the price of drugs especially in local areas for beyond the reach of retail pharmacies. They cannot supply the full drug needs of any community.

It is possible that advertisement of drugs could bring active competition into the cost of drugs at the retail (drug store) level, but advertising does have disadvantages. It could produce in the consumer's mind the conviction that he should or should not use a particular drug for his particular illness or condition, based on price considerations alone. He might therefore suggest to his doctor that he should use a certain drug, and the doctor would be placed in the unenviable position of justifying his particular prescription. The patient would not usually have the background to discuss this matter on therapeutic grounds, which would be the main consideration of the doctor, rather than cost itself.

In keeping with the many factors dealt with in this section, your Committee recommends:

> That the Canadian Pharmaceutical Association and all Provincial Pharmaceutical Associations, Faculties of Pharmacy and the Provincial governments should meet to discuss the practice of pharmacy in Canada, bearing in mind the following matters:
>
> 1. Ethics of the profession particularly concerning advertising and merchandizing, and the role of discount and mail order houses;
> 2. Qualifications and training necessary for dispensing pharmacists;
> 3. Promotion of competition within the profession, in the public interest;
> 4. Distribution of pharmacies, both in heavily populated urban areas and less developed rural areas;
> 5. Ownership of pharmacies by non-pharmacists.

Your Committee expresses the hope that provincial governments and provincial pharmaceutical associations will take whatever steps are necessary, in the light of changing circumstances to ensure that sufficient competition can be engendered in the retail drug business to lower prescription drug prices.

4. *Drug Patents and Compulsory Licensing*

When reference is made to drugs or pharmaceuticals in this section of the Report, it means only those products whose active ingredients are patented or the processes by which they are produced are patented.

In the consideration of this subject, it is important to appreciate the background of patents, especially pharmaceutical patents, as they affect the Canadian economy. Not only are the patent laws in each country at variance but patent ownership in each country may be either in domestic hands, or under foreign control or both. In the United States, for example, by far the greatest number of pharmaceutical patents are held by Americans whereas in Canada virtually no such patents are issued to Canadian inventors. The vast majority are issued to foreigners; the large Canadian pharmaceutical manufacturers operate, in the main, under patents assigned or licensed to them from their parent corporations. Although no breakdown is given with respect to pharmaceutical patents issued in Canada, the latest report of the Commissioner of Patents indicates that from the period 1st of April 1965 to the 31 March 1966, 92.33 percent of *all* Canadian patents issued in 1965 went to foreigners. The pharmaceutical patent situation would show even a more adverse trend, the reason being that the industry apparently is not geared to research in comparison to other more populated countries and more research oriented economies.

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Were drug patents issued in Canada to be absolute and unconditional for the normal seventeen year term, as is the case in the United States, monopoly domination of the Canadian drug market would rest almost entirely in the hands of foreign corporations through their subsidiaries. But monopoly domination in the drug industry, through legislation, has not been permitted in Canada since 1923 nor in the United Kingdom for some years prior to that date. The Canadian legislation is based upon the United Kingdom legislation. The erosion of absolute monopoly was introduced into patent legislation under a licensing system, known as compulsory licensing, which permitted a third party under certain conditions to manufacture a drug product by the patentee's process upon payment to the patentee of a royalty. Regardless of the real reason for the introduction of the compulsory licensing system into the United Kingsom, and which was later adapted to Canadian law, the fact is that this sytem has prevented absolute monopoly control in the drug industry for over forty years.

The Committee found that up to 1949 no application for compulsory licences had been made in Canada (Minutes of Proceedings and Evidence, Page 1425). The reason for this appears to be that up to that date there were no drug "winners", i.e. drugs which were "breakthroughs" in the industry and which forecast volume sales with record profits. Normally, of course, no manufacturer is going to the expense of obtaining a compulsory licence until he is certain of a lucrative market; and the various compulsory licences granted since 1949 clearly indicate this. Since 1949 the Commissioner of Patents has had to deal with thirty-four applications for licences upon medicinal products. Fourteen were granted, thirteen were abandoned or withdrawn, one was refused and six are pending. As of September 1966, which was the date these statistics were made available to the Committee, negotiations by the parties concerned towards settlement of the pending applications were taking place in respect of four cases. All the drugs which formed the subject matter of compulsory licensing applications were no longer under new drug status and had a large well established market. In summary, there seems no doubt that the present compulsory licensing provisions of the Patent Act, insofar as the more expensive and newer drugs are concerned, have assisted greatly in the lowering of prices of the particular drugs involved; and this is borne out by statistics which have been presented in evidence before this Committee.

There is no doubt whatsœver that the manufacturer who introduces a new drug should be allowed certain time to promote the drug and establish his position in the market following appropriate clinical testing and satisfying the requirements of the Food and Drug Directorate, so that for a period of time at least he retains his monopoly position. There is no doubt also that the introducer of the drug has need of recouping research expenses not incurred by his licensee competitor. What length of time a patentee should be allowed to retain his monopoly is arbitrary. The Committee had considered a length of time dating from the time of application for the patent of the particular drug involved, or a term of years following the date the patent issues. In either case, difficulties can be anticipated from artifical delays that may be introduced by the patentee during the course of prosecution of the application which could lengthen enormously the period between date of application and the date the patent issues. The monetary rewards to a patentee as a result of delaying a compulsory licence application can be substantial.

After full consideration, your Committee is of the opinion that under the present system, the patentee has ample time to establish and consolidate his position in the market (and thereby recoup his research costs) by virtue of the fact that it takes some 4 to 5 years for the drug to lose its "new drug" status as

determined by the Food and Drug Directorate. As explained earlier it is most unlikely that a compulsory licence will be sought prior to the date that the drug loses its status as a "new drug". (See Ch. III, Item 6).

Serious representations made to the Committee by the PMAC, certain large drug manufacturing corporations and the Patent and Trademark Institute of Canada suggested that the compulsory licensing system in Canada insofar as foods and medicines were concerned should be abolished.[2] They feel that these products should be treated in the same way as all other products are treated under the general provisions of the Patent Act. It would be natural in the interests of the companies that this step be urged. It is also natural for the Patent and Trademark Institute to take the same position, for such an association concerns itself with maintenance of the patent system for the encouragement of research. They refer disparagingly to the "copiers who ride on the coattails of others" which, although true is a sense, does not take into consideration the paramount importance of the public interest that has long permitted encroachments on monopoly positions where foods and medecines are concerned.

Your Committee believes that in no circumstances should the general policy of permitting compulsory licensing applications for patents relating to foods and medicines be eliminated. Indeed, your Committee has four recommendations regarding compulsory licensing

(1) Applicant for compulsory licence to have Food and Drug Directorate approval;

(2) Extension of compulsory licensing to imports;

(3) Payment of Food and Drug Directorate Inspection services outside Canada; and

(4) Licences of right in cases of undue delay;

all of which will now be elaborated upon.

The controversial section relating to compulsory licensing of foods and medicines is subsection (3) of Section 41 of the Patent Act, R.S.C. 1952, c. 203 as amended, which reads as follows:

> 41. (3) In the case of any patent for an invention intended for or capable of being used for the preparation or production of food or medicine, the Commissioner shall, unless he sees good reason to the contrary, grant to any person applying for the same, a licence limited to the use of the invention for the purposes of the preparation or production of food or medicine but not otherwise; and, in settling the terms of such licence and fixing the amount of royalty or other consideration payable the Commissioner shall have regard to the desirability of making the food or medicine available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention."

A number of Court decisions have taken place with respect to the interpretation of various clauses and possible ambiguities in this section. Under the terms of the Section, the Commissioner has the sole discretion to grant the licence. Further, he may grant the licence forthwith and, at a later time, determine the amount of royalty. Again, further, the Commissioner need only have regard to

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[2] This is not entirely true in the case of the Patent and Trademark Institute of Canada. Although recommendations were made to abolish S.41 in its entirety, it was felt that S.41(3) be replaced by a provision defining objectively the obligations of the public to the holder of a drug patent, and the basis upon which such drug patent holder is to be remunerated for the use of his invention upon grant of a compulsory licence.

the desirability of making the medicine available to the public at the lowest possible price; and in this determination it is of interest to note that the royalties fixed must be consistent with *giving to the inventor, not the patentee,* due reward for the research that leads to the invention.[3] Naturally the decisions have been somewhat disturbing to the patentees and their assignees. Realizing, perhaps, that the compulsory licensing feature of the Canadian patent law might not be changed after some forty-four years, the PMAC considered that certain alleviation might be given "innovators", at least to the extent of recouping their research costs, by making provision to allow higher royalties to patentees who came under compulsion to grant licences. It was claimed that present royalty as determined by the Commissioner of Patents and paid under the Section amounted to a "pittance".

As stated, your Committee considers that any changes suggested along these lines would be inadvisable in view of the lengthy period of time the section has been in existence; and further, because the section has been of undoubted benefit to the drug consumer in a number of important cases. Although the drug licensors would have benefited more had larger royalties been allowed, nevertheless there is no indication that the companies concerned have suffered to any appreciable or unfair extent.

The first recommendation in the proposed amendments to subsection (3) of Section 41 of the Patent Act deals with safety. During the hearings, much concern was expressed with respect to the safety of new drugs introduced in the market by manufacturers working under compulsory licences. The PMAC attempted through correspondence with the Food and Drug Directorate to have an old drug under compulsory licence reinstated as a "new drug", in order to compel the licensee to repeat the many requirements called for by the Food and Drug Directorate after the drug had first passed its pre-clinical tests. The Justice Department ruled that the Regulations under the Food and Drugs Act could not be interpreted to permit such a change in the definition of "new drug" (See Chapter III, Section 7).

The Hilliard Committee in its report to Parliament tabled on the 12th day of May, 1966, considered that the Food and Drug Directorate should collaborate closely with the Commissioner of Patents in all applications for compulsory licences. However, because of the Commissioner's sole statutory prerogative with respect to the issuing of such licences, the Hilliard Report was not implemented in this respect. Instead, and to cooperate with the intent of the Report, the Commissioner of Patents requested the voluntary cooperation of the Food and Drug Directorate in all future compulsory licence applications. This was readily granted; and, at the moment, the Food and Drug Directorate advises the Commissioner whether or not, from the viewpoint of the Food and Drug Directorate, a licence should be granted from the standpoint of safety. This arrangement has been working well.

The question remains whether or not subsection (3) of Section 41 should be amended to make statutory that what is now being done informally. There seems to be only one argument why this formality should not be carried out, and this is the question of whether or not further delays would be encountered in the granting of compulsory licences by the addition of a second official body in the handling of such licences. The Committee has been informed that the time necessary to process an application by the Commissioner varies considerably with different cases. According to the established practice of the Patent Office, it would take six months provided there were no delays. However, many delays are encountered and of the fourteen compulsory licence applications mentioned

[3] Refer to Committee recommendation concerning royalties, Chapter VI Item 1 (d).

earlier, the shortest period of time for the licence to issue was 5½ months, with the longest taking 2½ years. The Ilsley Commission was also concerned by the possibility of delays: "In view of the possibility of large profits on some patented foods and medicines, particularly drugs, the field is such that a substantial delay may be of great financial advantage to the patentee" (Report on Patents of Invention, page 96). The Ilsley Commission went on to recommend stringent rules for the minimizing of delays in compulsory licence applications. On balance, however, your Committee considers that the safety factor is of such importance that the Food and Drug Directorate should participate in the disposition of applications relating to compulsory licences, basing its views also on the fact that no delays of any consequence can be expected to originate with the Food and Drug Directorate, particularly when such applications are few and far between.

During the hearings, it was suggested that a triumvirate consisting of the Commissioner, a representative of the Food and Drug Directorate and an economist comprise a tribunal to decide on the terms of a compulsory licence—the economist to decide upon the appropriate royalty to be awarded the patentee. Your Committee has concluded, however, that this would present an additional complication not in the public interest. The fact that decisions respecting royalty payments are arbitrary in any event detracts from such a proposal.

Your Committee therefore recommends

That Subsection (3) of Section 41 of the Patent Act be amended to indicate clearly that the granting of a licence by the Commissioner of Patents is subject to a report by the Food and Drug Directorate of the Department of National Health and Welfare to the effect that the applicant for the compulsory licence has satisfied the Directorate that he has met the regulations under the Food and Drugs Act.

The Second amendment to Subsection (3) of Section 41 which your Committee is prepared to recommend deals with the proposal put forward by the Hall Commission which was heavily endorsed in the submission of the Province of Alberta. This is the awarding of compulsory licences to import, but again only with the approval of the Food and Drug Directorate. As seen earlier, approximately 80 percent of all the active ingredients in drug manufacture are now being imported in bulk form. In addition, nonpatentable drug items are being imported in bulk, semi-finished dosage forms, the imports being subject to inspection by officials of the Food and Drug Directorate. However, drugs manufactured in Canada under patents are not now imported as the importers of these almost certainly would immediately become subject to patent infringement actions; and hence Canadians are automatically prevented from being able to buy such foreign drugs, regardless of their quality, at any price. There is no doubt that some drugs being manufactured in foreign countries are safe and inexpensive.

To date, there has been a natural reluctance to amend the law to allow the grant of import licences respecting patented drugs in the belief that Canada would gain more by having drugs produced domestically than by being able to import drugs more cheaply, even if of the highest quality. No one questions the fact that if compulsory licenses to import are granted, the large drug manufacturers would find themselves in open competition with Canadian importers purchasing like drugs, perhaps with identical trade names (see next item 5), from foreign sources. The proposed injection of this open type of competition into the drug industry naturally causes certain perturbation which was feelingly expressed from time to time by the witnesses representing the larger segments

of the drug industry to whom such suggestions were put. However, the Committee does not consider that if this recommendation were to be adopted into legislation, the result would be dire or catastrophic as feared.

The section in the United Kingdom legislation of 1949 corresponding to our Section 41(3) (but not identical thereto) authorizes compulsory licences for imports, and this fact does not seem to have militated against the British drug companies to any great extent. In the representations of Hoffmann-La Roche Limited (Minutes of Proceedings and Evidence, pages 802, 809) two unreported decisions under the corresponding United Kingdom Patents Act, 1949, were brought to the Committee's attention which dealt with applications for compulsory licences to import. Both cases held that under the specific United Kingdom section such licences could be granted and exercised solely through importation, although the Comptroller under that Act felt that he ought not, in the circumstances of the particular cases involved, to exercise the power which he had under the particular section unless he was satisfied that the balance of public interest demanded it. In other words, power to grant compulsory licenses to import was available, but considered by the licencing authority in the circumstances not to be used carelessly or automatically. Your Committee appreciates and recognizes this view, i.e., that the Commissioner, although in ordinary cases of compulsory license applications, shall grant the licenses "unless he sees good reason to the contrary"; in the case of compulsory licences to import he should only grant the licence in his discretion if it is in the public interest so to do. The "public interest" would be, the Committee feels, that need of bringing lower drug prices to the consumer weighed against the effect of such import licence on the Canadian producer(s) of that drug in question.

The differentiation between the two types of compulsory licensing should be carefully observed. "Unless he sees good reason to the contrary" involves only simple discretion on the part of the Commissioner wherein the "public interest" may or may not be included. In the determination of the question involving a compulsory licence to import, however, the "public interest" is the sole consideration.

Your Committee feels that safety must be paramount. The compulsory license to import must not be granted except where the Food and Drug Directorate has inspected to its satisfaction the manufacturing facilities in the country of origin, and in accordance with the same regulations that pertain to Canadian drug manufacturers.

Your Committee recommends

> That Subsection (3) of section 41 of the Patent Act be amended to include applications for compulsory licenses to import drug products in all forms, subject to inspection of manufacturing facilities by the Food and Drug Directorate and provided such importation is in the public interest as may be determined by the Commissioner; and to this end, your Committee recommends that the Rules under the Patent Act be amended to permit the Commissioner to seek and receive outside independent expert advice in the determination of this question.

The Committee feels that the cost of such inspection services outside of Canada should be borne by the importer and therefore recommends

> That the importer of drugs under compulsory licence pay the cost of Food and Drug Directorate services outside of Canada.

It should be stated immediately that in the determination of "public interest" or, indeed, in any determination relating to Section 41(3) of the Patent Act, the Committee is most conscious of the serious responsibility placed upon the Commissioner of Patents. The Ilsley Commission also recognized this problem and considered that such determinations be taken by a higher authority. The recommendations of the Ilsley Commission have not as yet been studied for implementation or otherwise; but when this is done, your Committee emphasizes its concern in like manner to that expressed by the Ilsley Commission.

Another recommendation of your Committee is that Subsection (3) of Section 41 be amended so that if the granting of a compulsory licence takes longer than 12 months, the Commissioner may be empowered to issue the licence subject to revocation if any appeal against such a compulsory licence is upheld, providing however that such licensee provide sufficient evidence to satisfy standards of the Food and Drug Directorate.

The question of duration of term of patent protection for drugs and medicines also was raised before the Committee. The suggested term ranged from no term at all, i.e. complete abolition of patent protection on drugs and medicines, as proposed by the Restrictive Trade Practices Commission in its Report, to leaving the term precisely as it now is and no shorter than the 17-year protection afforded any other types of inventions. Should any term between zero and seventeen years be taken as the appropriate length of time for patent protection on pharmaceutical substances and processes, such a figure would naturally be purely arbitrary as is the present term which is only historical. The Committee, however, was impressed with the argument that there is a high degree of obsolescence in the drug industry, and that many medicinal substances rapidly outlive their usefulness and are replaced by more active drugs with increased therapeutic value within a few years after the patents issue. Also, in those instances where a "wonder drug" continues to remain so and stays in demand throughout the entire length of the patent term, this situation is or can be cured, insofar as high prices to the consumer are concerned, by the compulsory licensing system. Therefore, your Committee has no recommendation to make with respect to limiting the present term of patent protection on pharmaceutical products.

The Patent and Trademark Institute of Canada recommended the abolition of Subsection (2) Section 41 of the Patent Act. The subsection reads as follows:

> "41(2) In an action for infringement of a patent where the invention relates to the production of a new substance, any substance of the same chemical composition and constitution shall, in the absence of proof to the contrary, be deemed to have been produced by the patented process."

The Committee considered also the recommendation contained in the submission of the province of Alberta that the patent law should be amended to put the burden of proof in infringement suits on the plaintiff. As can be seen from the present subsection, the burden of proof lies on the defendant to show that he has not produced the substance of the same composition and constitution by the patented process. In the opinion of the Committee there would be no advantage to changing the burden of proof inherent in Section 41(2) particularly considering this Committee's recommendations regarding compulsory licences and the difficulties that may be encountered in patent infringement suits. The Committee therefore does not recommend any change to this section.

Before leaving the conclusions it has reached regarding Section 41 of the Patent Act, the Committee would like to comment on subsection (1) of that Section.

Subsection 41(1) reads as follows:

> "In the case of inventions relating to substances prepared or produced by chemical processes and intended for food or medicine, the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents."

Both the Ilsley Commission and the Patent and Trademark Institute of Canada (the latter in evidence before the Committee) recommended the repeal of this section, noting in each instance that the corresponding provision in the United Kingdom patent law was repealed in 1949. The effect of repealing this section would be to allow patents on the drug itself as well as the process by which the drug is made. This would strengthen the patent system. The present section tends to encourage discovery of new processes which are patentable, for drugs already marketed. The effect of repealing this section would, in the Committee's opinion, be negligible, while leaving it alone may encourage research into new processes; therefore your Committee makes no recommendation in this regard.

In its report the Hall Commission recommended that Section 19 of the Patent Act be expanded to include governments of the Provinces. Section 19 reads as follows:

> "19. The Government of Canada may, at any time, use any patented invention, paying to the patentee such sum as the Commissioner reports to be a reasonable compensation for the use thereof, and any decision of the Commissioner under this section is subject to appeal to the Exchequer Court."

Although your Committee has been advised that this section has not been used insofar as drug patents or drug processes are concerned,—probably because government agencies, whether Federal or Provincial, meet their drug requirements through tendering—nevertheless there does exist the possibility that use may sometime be required of such a section in the interests of the consumer. Your Committee feels however that this should remain a federal responsibility, and not be extended to the provinces. Patents and drugs are under federal control and the Committee feels that no change should be made that would give this authority to the provinces.

Certain evidence also suggested that Section 67 of the Patent Act (which sets out the circumstances under which exclusive rights under a patent shall be deemed to be abused, such as non-working, or production being prevented by the importation from abroad of the patented products by the patentee, or if the demand for the patented article was not being met on reasonable terms and to an adequate extent, etc.,) was in itself sufficient to correct those circumstances wherein the patentee was not properly using his monopoly privilege; and, if that were not enough, then Section 30 of the Combines Investigation Act R.S.C. 1952 Ch. 314, might well be used to remedy situations where prices were being fixed and patent rights were being misused. However, your Committee considers that, although these Sections of these Acts may be helpful overall in dissuading a patentee from acting in a manner harmful to consumers, nevertheless they appear to lack teeth sufficiently sharp to correct easily and readily all monopoly abuses.

5. *Trade Marks*

Earlier your Committee considered that regulations could not now be imposed that would prevent the use of brand names in the marketing and sale of drugs, as this could be out of character with present day commercial practice. Nevertheless, trade marks have an inhibiting influence on free and open competition in the pharmaceutical industry; and for this reason the Hall Commission recommended that the Trade Marks Act be amended to allow the importation of trade-marked drugs which have been produced by a company related to he Company owning or possessing the same Canadian trade mark, recognizing that trademark law can influence the level of drug prices directly and indirectly. Under present law the Canadian subsidiary of a foreign parent company can prevent the importation of drugs into Canada if these bear trademarks identical to those owned and used by it. This, of course, eliminates entirely any possibility of legally importing brand name drugs which may be selling at lower prices outside Canada and which, in fact, may in many instances be identical to those drugs manufactured by the subsidiary from bulk active ingredients imported from the parent corporation.

Prior to 1953 a trademark could not be assigned or transferred to another corporation, even a subsidiary corporation, without at the same time transferring the goodwill of the business. Under the Trade Marks Act, 1953, this situation was reversed and subsidiaries (or licencees) were permitted to become legally entitled to use the trademarks of their parent corporations under a "registered user" system. The subsidiary, for example, provided it operated strictly under a registered agreement with its parent corporation, obtained equal rights to the trademarks of the parent. This also included the right to bring infringement actions against third parties who might attempt to use the trademarks in association with similar wares that were imported from companies related to the Canadian subsidiary. The Patent and Trademark Institute of Canada considered that if the Canadian company does not own the Canadian registration but merely uses the mark as a "registered user" thereof, the trademark being actually owned by the foreign related company, such sale of the trademark wares imported from the foreign related company would not constitute an infringement of the registration (Minutes of Proceedings and Evidence, page 1369). In the Institute submission it was further stated (at page 1368) that a trademark is a badge, for the wares on which it appears, of their origin, their character or quality and the conditions of their manufacture. A "registered user" guarantees under the trademark law character or quality and the conditions of the manufacture of the product through the registered agreement between the trademark owner and the user; but it is not precisely true to say that these trademarks necessarily function as a badge of origin—not only with regard to the plant of manufacture but with regard to the country of manufacture. The "badge of origin" feature of trademarks can, therefore, be misleading in that it is true to say that a particular pharmaceutical product can be manufactured in several countries of the world under the same terms of quality and manufacture and yet bear the same trademark.

Be that as it may the Patent and Trademark Institute doubted the need for any new or special provisions in the Trade Marks Act in respect of drugs in view of the special remedies provided in Section 30 of the Combines Investigation Act where the Exchequer Court of Canada could decide, for example, that the registration of a trademark be expunged in any case where the privileges conferred by a trademark are misused as to unduly prevent or lessen competition in the manufacture of any particular article or commodity. Your Committee, however, agrees with the submission of the Province of Alberta that the expense,

delay and general cumbersomeness and uncertainties of such proceedings make this remedy in every sense of the phrase a last resort. (Minutes of Proceedings and Evidence, page 2578).

The Institute (again at page 1369) puts its finger directly on the problem by stating that, "if the public interest in the expected lowering of the price of some trademark drugs by forcing Canadian companies to compete in the Canadian market with their foreign related companies under identical trademarks is considered to be paramount and greater even than the public interest in the integrity of trademarks, then it will require a very carefully drafted provision affecting the whole scheme of the Trade Marks Act and not merely Section 20 as suggested in the Hall Report". Your Committee, in attempting to determine whether or not Canadian trademark law should be "watered down" in respect of trademarks as applied to drugs, is conscious of the fact that the Institute agrees that it is not qualified to deal with the economics of the patent system or trademark system as it affects competition in the drug market; the Institute, by its very nature, is primarily directed to the maintenance and, if possible, the enhancement of these laws insofar as they encourage research, stimulate invention, prevent secrecy and bring due reward to inventors for their contribution to the art. The ascertainment of the "balance of the public interest" is not necessarily the purpose of this professional association.

Your Committee has carefully considered both sides of this dilemma and recommends that it is in the public interest to adopt the recommendation of the Hall Commission, namely,

> That Section 20 of the Trade Marks Act be amended to make clear that no infringement can be claimed where imported drugs are manufactured by a "related" company.

If this recommendation is found acceptable, your Committee directs the attention of the drafting authorities, however, to the cautions expressed by the Patent and Trademark Institute.

It was suggested that if this recommendation found acceptance it would be of little avail in reducing drug costs because if any Canadian company was being injured by importation of identically trademarked wares from related companies abroad, it would change the trademark concerned. This is perhaps true but the Canadian company, if it followed such a course, would lose the goodwill associated with the probably widely known advertised brand name; and to change the trade name to another might well be short-sighted from a marketing view-point.

Your Committee considers that if such a recommendation were adopted little, if any, harm would actually be incurred by the more well established and well known owners or "registered users" of the trademarks concerned. Certainly, importation of identically trademarked drugs from abroad at lower prices would introduce open competition in the Canadian market with resulting benefit to the Canadian consumer.

6. *The necessity for Price Competition*

From the factors set out in this chapter that affect drug costs and prices, it becomes immediately obvious that the introduction of increased and open competition at all levels of the drug industry is the obvious essential element in reducing the costs of drugs to the consumer. A variety of recommendations are therefore required, and these have been set out following discussion of each phase or aspect studied. It is price competition, *not product competition*, that will

lower prices. Product competition breeds increased expenditures at the manufacturer's level. Price competition at all levels promotes lower costs through increased efficiency and cuts through extravagant promotional activity.

Very recently Drug News Weekly, in its edition of 20th February, 1967, at page 13, made specific reference to the effect of competitive factors as being "partially the cause of price cuts" on Parke Davis & Company's Chloromycetin (chloramphenicol). As a result of the expiration of Parke, Davis' basic patent on this drug some two months earlier, "other manufacturers began bringing out low price chloramphenicol capsules—generically and under brand names." The news report went on to say that "Parke Davis' price cut had been widely expected by trade observers as a result of the chloramphenicol competition that started developing in January. Right after the company's basic patent expired, other manufacturers requested approval from the United States Food and Drug Administration to market their own. Their product did not begin appearing on the market until early January. *Most of the chloromycetin competitors are generics...*"

It is interesting to note that this competition developed in the United States *after* the principal patent expired. There is no compulsory licensing system in the United States as in Canada. Had there existed such a system doubtless a price reduction would have occurred long before.

CHAPTER VII—OTHER PROPOSALS MADE AND CONSIDERED

1. *A National Drug Formulary*

An important recommendation of the Hall Commission was "that the Food and Drug Directorate, with the assistance of the Advisory Committee, (i.e. that Committee responsible for advising the Department of National Health and Welfare), prepare and issue a National Drug Formulary which would be maintained on a current basis. This Formulary would include only those drugs which meet the specification of the Directorate, and would be identified as such, and therefore eligible for inclusion in the Prescription Drug Benefit within the proposed Health Services Programme, one of the objects being to minimize the cost of prescribed drugs. There should be established an appeals procedure for dealing with rejected applications, and an information service which would issue periodic bulletins providing the latest information on drugs and drug therapy to physicians, pharmacists, and hospitals."

Your Committee did consider a National Formulary. It was suggested that drugs would be placed on it which met the requirements of the Food and Drug Directorate. These would be purchased by the retail druggist (individually or collectively) on the tendering system. Physicians could prescribe by generic name and the druggist would dispense the drug that he had in stock. (He might stock only one brand of each generic drug). This would eliminate large drugstore stocks of various brands of the same generic drug, saving on inventory and space. It has been suggested this would eliminate the need for promotional advertising to the doctor. This could however merely shift this promotional activity from the doctor to the pharmacist. Your Committee feels that this represents a major change in medical and pharmaceutical practice which at this point would be unacceptable to these professions, and actual implementation would be very difficult. It should be pointed out that a great many hospitals now use a drug formulary which their staff apparently find satisfactory. As the experience grows with this hospital formulary, it may be possible that the use of the drug formulary will gradually extend outside the hospital.

Your Committee has already recommended a Food and Drug Directorate bulletin on drugs, which would be current and non-biased. It would contain (as discussed earlier) much of the information that a National Drug Formulary would supply to the medical and pharmaceutical professions.

2. *Appeals from the Decisions of the Food and Drug Directorate*

Representation was made to the Committee that some decisions of the Food and Drug Directorate are final and binding and that no appeal is possible. In many instances, the decision is actually made in a court of law when a manufacturer is charged by the Directorate with an offence under the Act. This decision is appealable of course to a higher court.

At the present time, under the Food and Drug regulation (C.08.009) an appeal procedure is laid down concerning decisions affecting the notice of compliance (date of placing drug on sale). If a manufacturer does not agree with the decision of the Directorate in this matter, a "new drug" committee is set up. One member is nominated by the manufacturer, one is nominated by the Minister of National Health and Welfare (he cannot be an employee of the Directorate), and the third member, who is Chairman, is chosen by the other two members. If the other two members cannot agree on a choice for chairman, then the Minister of National Health and Welfare may appoint him.

It is understood that the only other area of complaint concerning appeals involves the decision of the Directorate as to whether a drug should retain or lose its "new drug" status. The Committee feels that an appeal in this matter would be reasonable and therefore recommends

> That the Food and Drug Regulation C.08.009 be amended to extend appeals to the decision as to "new drug" status.

3. *Insurance Plans for Drug Prescriptions*

The Committee heard interesting testimony from Prescription Services Incorporated, authors of the "Green Shield Plan", a voluntary prepaid plan where Prescription Services Inc. acts as fiscal agent for group subscribers from the public and for pharmacy members of the Corporation. The Plan provides group insurance to cover drug costs incurred by their subscribers. Premiums under the plan appear normal and moderate; and there is no doubt that membership in the plan can relieve anxiety on the part of those to whom the price of drugs, if required, would undoubtedly be excessive. Much was made of the fact that the problem of high drug prices was no problem at all if Canadians were insured against possible drug costs under this or similar plans. Prescription Services Incorporated was not itself apparently concerned with methods that might bring down the price of drugs to the consumer. Higher drug prices would only affect premiums, and increases in premiums would probably be minimal or, at least, bearable.

This attitude, of course, begs the whole question. Insurance plans can be devised to protect any person from any eventuality. Your Committee, although acknowledging the merit of pre-paid drug plans, and their great benefit to subscribers considers it irrelevant to this inquiry. The presence of such plans should not affect recommendations primarily directed towards lowering drug costs for the unprotected consumer.

4. *Abolition of "Suggested List" Prices by Manufacturers*

Since the Canadian law was changed to make retail price maintenance an offence under the Criminal Code, it has been the common practice of manufac-

turers, including pharmaceutical manufacturers, to "suggest" list prices to retailers for retail sale by marking the suggested list price on the containers of their products or in their sales listings. In most instances, therefore, the suggested list price becomes in fact the "fixed" price charged to which is added the dispensing fee with the corresponding result that competition on this basis in the open market in fact ceases to exist. This practice, it should be noted, is changing in those cases where the pharmacist charges a professional fee over and above actual cost to him.

With this growing interest shown in the professional fee, it would seem advisable, as an additional link in the chain of promoting increased open competition at all levels within the industry, to conclude that "suggested list" prices be abolished. It could be expected that a careful shopper for prescription drugs will soon learn the amount of the professional fee charged by the pharmacist in his Province; and with that information will ascertain the cost of prescription drugs as delivered to the drug store of his choice. The pharmacist, in his turn, will have opened up to him the possibility of studying the retailing pricing of colleagues in the same area.

Although it cannot be said without actual experience whether such a recommendation may be helpful in lowering drug prices to the consumer, nevertheless your Committee makes this recommendation, namely,

That the pharmaceutical industry abolish suggested list prices.

5. *Drug Price Restraint Programme*

The Hall Commission 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 programme for Canada, for implementation on a trial basis."

Such a voluntary price regulation scheme now exists in the United Kingdom and has been operating for over eight years. Under the U.K. programme, representatives of government and industry settle by common agreement the prices charged for drugs in the National Health Service. Apparently only one-third of the pharmaceutical output is sold to the state, but the state pays for three-quarters of the pharmaceuticals that the industry sells in the home market. With the state politically concerned with accusations that drugs of possible benefit to patients might be held off the market, and with the industry concerned with representations that it was making large profits out of health-sustaining and curative products, a state of compromise or give-and-take is presumably reached to permit such a voluntary scheme to work with comparative success.

Your Committee considers, however, that a corresponding programme of voluntary drug price restraint would be neither necessary nor of help in Canada. Firstly, the tendering system in operation between government agencies, hospitals and the industry minimizes excessive profits in public purchases; and secondly, the British industry can perhaps be more flexible with self-imposed domestic monetary discipline because of its large export drug market—a factor not of consequence in the Canadian industry.

6. *A Drug Institute for Canada*

An interesting submission put forward by Empire Laboratories Limited received the attention of your Committee. This proposal suggested the establishment of a Drug Institute in Canada to be administered by a Council drawn from the professions of medicine, pharmacy, pharmacology and chemistry. It was considered that the significance of drugs in the practice of medicine had changed

remarkably in the last generation; and to prevent the situation from getting "out of hand", all matters relating to drugs must and should be brought back entirely under professional supervision (Minutes of Proceedings and Evidence, pages 1115-6), presumably as opposed to present commercial instigation and control. The functions suggested for the new Drug Institute were as follows:

(1) To examine the areas of therapy in which new drugs may or may not be needed;

(2) To regulate some pre-clinical and all clinical trials of a new drug;

(3) To solicit, receive and correlate all reports of side effects, contra-indications and alternative uses of drugs, new and old;

(4) To solicit and correlate all reports about efficacy of drugs;

(5) To establish the official (generic) name of a new drug;

(6) To participate in multiple screening tests for discovery of new drugs;

(7) To accomplish fundamental research in pharmacology and medicine;

(8) To promote the development of preventive medicine in Canada.

Your Committee can see many benefits that might accrue to Canadians through the creation of such a Drug Institute. It was made very plain that such an establishment would initially have to be subsidized by government (although charges for services rendered to profit-making organizations would be made) and that it must operate entirely outside the jurisdiction of federal or provincial government. It would supplement the present activities of the Department of National Health and Welfare.

It was proposed that one means for providing the funds necessary for the creation and subsidization of the Drug Institute would be an allocation to it of a portion of the monies normally netted by the federal government through sales tax revenues derived from sales of pharmaceuticals. The latter suggestion was seemingly based on the assumption that if the Committee saw fit to recommend the abolition of sales tax with respect to pharmaceuticals, and this recommendation was found acceptable, in all likelihood the savings effected on sales tax would not be entirely passed on by the manufacturer; and hence the public should derive some additional benefit as a result of an almost certain loss of revenue to the federal government. All the taxpayers would benefit from such a plan which however would be financed only by the sick. If such a plan were to be implemented it should be influenced by general taxation.

After careful consideration, your Committee has come to the conclusion that this proposal also does not fall within its terms of reference. Because of the possible merits of the scheme, however, it was decided to set out the suggestion in some detail for consideration by others at a future time.

7. *Ten-Year Moratorium on Drug Patents*

A ten-year moratorium on drug patents was recommended to the Committee. This proposal was considered when the question of patent term was under review; and in the light of its recommendations concerning compulsory licences on patented processes in drug manufacturing, your Committee has no such recommendation to make.

8. *Triple Damages in Patent Actions*

It was suggested that a defendant in patent litigation, if successful in an action for patent impeachment, should be awarded triple damages based on actual out-of-pocket costs. This proposal was advanced on the theory that such a recommendation would of itself make a patentee hesitate before instituting an expensive action against an "infringer" and would discourage or prevent harassment against innocent parties. Your Committee does not consider that drug patents should be singled out from any other patents involved in patent cases and that punitive action of this type is neither necessary nor desirable.

9. *Patent Actions and the Exchequer Court*

It was suggested patent actions should be confined to the Exchequer Court of Canada. The Exchequer Court of Canada receives its jurisdiction on patents under Section 91 of the British North America Act. However, patents are also included under Property and Civil Rights, and are also subject to provincial laws under Section 92 of that Act. Therefore, this proposal cannot be considered although it does possess merit in that it would confine all patent actions to one court and give uniformity in legal decisions.

10. *Circumvention of Food and Drug Directorate*

Another proposal was that governmental agencies be permitted to use "alternative sources" for "new drugs" on their own responsibility without interference from the Food and Drug Directorate, as these could be used under the supervision of qualified professionals and would not be available for general distribution. Your Committee does not consider that any proposal which encroaches upon or lessens the present responsibility of the Food and Drug Directorate of the Department of National Health and Welfare should be accepted. There must be a final authority dealing with drug safety.

11. *Other Recommendations of the Hall Commission*

The Hall Commission made other recommendations relating to educational programmes regarding drugs, centralization by the federal government of all its drug purchases, encouragement of the provinces to adopt bulk purchasing and methods of tendering, expansion of research grants, continuing cost price analyses of drugs, etc. which have have not been considered by this Committee as not being precisely related to its terms of reference. By not considering these various recommendations of the Hall Commission, however, your Committee does not wish it to be assumed that these should not be acted upon.

CHAPTER VIII—CONCLUSIONS

Your Committee has therefore come to the following conclusions:

(1) That the price of drugs in Canada is at least higher than it need be;

(2) That no significant change has taken place in the drug-cost structure since the recommendations of the Hall Commission which were primarily based on the recommendations of the Restrictive Trade Practices Commission;

(3) That there exists no single method nor simple approach which can be taken to reduce the price of drugs to the consumer, and it is therefore necessary to present a series of recommendations to effect this purpose;

(4) That since Canadians are paying a significant portion of the cost of international pharmaceutical research, more of this research should be done in Canada by the pharmaceutical industry;

(5) That the medical profession is responsible for the prescribing of most drugs, and for these Committee recommendations to be fully effective, the medical profession must be fully assured of the safety of all durgs by the Food and Drug Directorate;

(6) That the implementation of the recommendations could lessen marketing and promotional expenses and reduce excessive profits;

(7) That the implementation of the recommendations could alter in some respects the form of the drug industry as it exists today, removing inefficiencies in the industry and increasing competition;

(8) That in anticipation of national and provincial welfare programmes or the further development of other forms of health services, it is of paramount importance that legislation be introduced at the earliest practical date to implement the recommendations of this Committee.

SUMMARY OF RECOMMENDATIONS

These recommendations are listed in order of their presentation in the report and not necessarily in order of their importance.

1. That all medical and pharmacy students be instructed during their studies in the generic nomenclature for drugs;

2. That the personnel and facilities of the Food and Drug Directorate be expanded to make possible the implementation of the recommendations of the Boyd Committee, the Hilliard Committee and this Committee;

3. That the Food and Drug Directorate publish not less than once a month an informative bulletin to the medical profession giving complete details on drugs and their actions and reviewing major drug uses in Canada;

4. That present ministerial authority as provided in Section 38 of the Customs Act be amended insofar as the importation of drugs into Canada is concerned, and that future value for duty be set in all cases at the cost of production of the imported drug plus an allowance for gross profit (i.e. an allowance to cover the actual manufacturer's administrative overhead, selling costs and net profit, etc.);

5. That the Customs Act be amended to make clear that dumping duties with respect to drugs be limited only to affect those drugs *of a kind* made in Canada;

6. That the federal government instruct the Tariff Board to review the drug tariff structure;

7. That drug manufacturers revise their promotional practices on a voluntary basis, as considerable savings could be made and passed on to the consumer;

8. That the pharmaceutical industry take steps to ensure that all representatives of the drug industry engaged in field selling be paid by salary and not by commission;

9. That the federal government should make a substantial increase in grants to the Medical Research Council for the promotion of basic pharmaceutical research;

10. That the pharmaceutical manufacturing industry take full advantage of the federal incentive program for research;

11. That the Patent Commissioner, on assessing royalties on the granting of a compulsory licence, shall consider that the patentee who discovers and initially develops the drug in Canada should have higher royalties than the drug manufacturer who discovers new drugs outside of Canada;

12. That the Food and Drug Directorate publicize the Adverse Drug Reaction program in co-operation with the Canadian Medical Association;

13. That the federal sales tax be removed from the sale of prescription drugs;

14. That the drug consumer be made aware that drug prices do vary from pharmacy to pharmacy and it is his right to compare prescription prices before purchase and that neither the pharmacist nor the physician should deny this right;

15. That pharmacists use the "cost price plus professional fee" method for determining drug prices to the consumer;

16. That the Canadian Pharmaceutical Association and all Provincial Pharmaceutical Associations, Faculties of Pharmacy and the Provincial governments should meet to discuss the practice of pharmacy in Canada, bearing in mind the following matters:

1. Ethics of the profession particularly concerning advertising and merchandizing, and the role of discount and mail order houses;

2. Qualifications and training necessary for dispensing pharmacists;

3. Promotion of competition within the profession, in the public interest;

4. Distribution of pharmacies, both in heavily populated urban areas and less developed rural areas;

5. Ownership of pharmacies by non-pharmacists;

17. That Subsection (3) of section 41 of the Patent Act be amended to indicate clearly that the granting of a licence by the Commissioner of Patents is subject to a report by the Food and Drug Directorate of the Department of National Health and Welfare, to the effect that the applicant for the compulsory licence has satisfied the Directorate that he has met the regulations under the Food and Drugs Act;

18. That Subsection (3) of Section 41 of the Patent Act be amended to include applications for compulsory licences to import drug products in all forms, subject to inspection of manufacturing facilities by the Food and Drug Directorate and provided such importation is in the public interest as may be determined by the Commissioner; and to this end, your Committee recommends that the Rules under the Patent Act be amended to permit the Commissioner to seek and receive outside independent expert advice in the determination of this question;

19. That the importer of drugs under compulsory licence pay the cost of Food and Drug Directorate services outside of Canada;

20. That Subsection (3) of Section 41 be amended so that if the granting of a compulsory licence takes longer than 12 months, the Commissioner, if in his opinion the delay is unwarranted, may be empowered to issue the licence subject to revocation if any appeal against such a compulsory licence is upheld, providing however that such licensee provide sufficient evidence to satisfy standards of the Food and Drug Directorate;

21. That Section 20 of the Trade Marks Act be amended to make clear that no infringement can be claimed where imported drugs are manufactured by a "related" company;

22. That the Food and Drug Regulation C.08.009 be amended to extend appeals to the decision as to "new drug" status;

23. That the pharmaceutical industry abolish suggested list prices.

Your Committee would like to thank all those organizations, industries and individuals who appeared before the Committee or submitted material for consideration. In addition, your Committee would like to thank in particular its legal counsel Mr. A. M. Laidlaw, Q.C., and its accountant Mr. W. J. Blakely, C.A., who participated actively in the hearings and whose assistance was of particular value in the preparation of this report. The Committee commends the Committees and Private Legislation Branch of the House of Commons for its efficient assistance and in particular thanks the Clerk of the Committee, Miss Gabrielle Savard, for her tireless work on the Committee's behalf.

A copy of the Minutes of Proceedings and Evidence (*Issues Nos. 1-34 inclusive*) will be tabled later.

Respectfully submitted,

HARRY C. HARLEY,
Chairman.

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APPENDIX A

WITNESSES HEARD

(Listed in order of appearance before the Committee)

The Hon. Allan J. MacEachen, Minister of National Health and Welfare

Dr. R. A. Chapman, Director-General, Food and Drug Directorate, Department of National Health and Welfare

The Hon. Edgar J. Benson, Minister of National Revenue

Mr. A. R. Hind, Assistant Deputy Minister, Customs

The Canadian Pharmaceutical Association, Inc.
- Mr. D. A. Denholm, B.S.A., President
- Mr. J. C. Turnbull,, B.S.P., Executive Director
- Mr. J. K. Lawton, Ph.C.
- Mr. R. E. Wilton, Phm.B.
- Mr. D. M. Cameron, B.Sc. Pharm., Register of the Alberta Pharmaceutical Association

The Pharmaceutical Manufacturers Association of Canada
- Dr. Wm. W. Wigle, President
- Mr. Robert F. Daily, Chairman of the Board of Directors PMAC, and Vice President and General Manager, Smith Kline and French Inter-American Corporation
- Mr. E. Glyde Gregory, Vice-Chairman of the Board PMAC and President, Ayerst Laboratories
- Mr. Harry D. Cook, Immediate past Chairman of the Board PMAC and President Abbott Laboratories Ltd.
- Dr. Peter C. Briant, Vice Dean and Director, School of Commerce, McGill University
- Mr. Gordon F. Henderson, Q.C., Patent Attorney
- Mr. Peter Howsam, Vice-President and General Manager, Warner-Chilcott Laboratories
- Mr. Fred R. Hume, Q.C., Legal Counsel, PMAC
- Mr. Roger Larose, Vice-President, CIBA Company Limited
- Dr. Brian Stewart, Director, Pharma-Research Canada Limited
- Mr. Guy Beauchemin, Executive Secretary PMAC

The Canadian Medical Association
- Dr. Ramsay Gunton, M.D., Chairman of CMA Committee on Pharmacy Professor of Therapeutics, University of Toronto
- Dr. Fred Fallis, M.D., Member of CMA Committee on Pharmacy, General Practitioner of Toronto
- Dr. Arthur Peart, M.D., General Secretary
- Dr. Donald Aitken, M.D., Assistant Secretary

The Canadian Drug Manufacturers

Mr. Leslie L. Dan, B.Sc. Phm., M.B.A., Chairman

Dr. George F. Wright, Ph.D., Research Consultant, CDM and Professor of Chemistry, University of Toronto

Mr. Lawrence Wilson, Member of a firm of Consulting Biologists

Cyanamid of Canada Limited

Mr. S. R. Stovel, President

Mr. F. W. Pope, Executive Vice-President

Dr. Claude Gendron, M.D., Medical Director

Mr. J. A. Bertrand, Manager Medical Products Department

Hoffman-La Roche Limited

Mr. John S. Fralich, President

Mr. Robert Hunter, C.A., Director of Roche-England

Mr. C. A. Nowotny, Assistant Secretary

Mr. R. G. McClenahan, Solicitor

Ayerst, McKenna and 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

Smith Kline and French, Montreal

Mr. Robert F. Daily, Vice-President and General Manager

Mr. Ross F. Bethel, Technical Manager

Mr. Alban 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

Mr. Russell A. Fraser, Senior Hospital Representative

Charles E. Frosst and Co.

Mr. James E. Frosst, President

Dr. R. S. Stuart, Director of Research

Mr. A. F. Coffin, Vice-President—Sales

Mr. J. M. Blanch, Vice-President—Finance

Parke, Davis and Company, Ltd.

Mr. Clifford A. Rogers, Vice-President and Manager

Mr. John M. Godfrey, Q.C., Legal Counsel

Empire Laboratories Ltd.

Dr. George F. Wright, Ph.D., President

The Consumers' Association of Canada

Miss Glenora Pearce, National President

Dr. M. Pernarowski, Vice-President, CAC, Associate Professor, Faculty of Pharmacy, University of British Columbia

Dr. H. G. English, Executive Vice-President CAC, Economist, Head of the School of Commerce of Carleton University
Mrs. A. F. W. Plumptre, Past President

Dr. Alan S. Davidson, M.D. (Director of a Clinical Research Unit for the Alcoholism and Drug Addiction Research Foundation of Ontario)

The Medical Post
Mr. Charles E. Wilson, Publication Manager
Mr. R. W. Robertson, Executive Officer

London Drugs Limited
Mr. S. S. Bass, Proprietor, Vancouver

Patent and Trademark Institute of Canada
Mr. William L. Hayhurst, Q.C., President
Mr. Russel S. Smart, Councillor

Canadian Society of Hospital Pharmacists
Miss Mary Gannon, Executive Secretary
Mr. D. J. Stewart, Past President
Mr. Nathan Fox, Council Delegate, Quebec Branch

Department of Defence Production
Mr. D. M. Erskine, Director of General Purchasing Branch

Department of Industry
Dr. H. A. Showalter, Chairman, Inter-Departmental Advisory Board on Standards for Pharmaceutical Manufacturers, Distributors and Agents

Department of National Defence
Mr. H. H. Poyntz, Director, General Requirements
Major A. R. Friesen

Department of National Health and Welfare
Mr. M. G. Allmark, Assistant Director General—Drugs, Food and Drug Directorate
Mr. I. C. Ellis, Pharmacist and Chief, Materiel Services Division

Department of Veterans Affairs
Dr. K. S. Ritchie, Assistant Deputy Minister
Mr. B. J. Larocque, Pharmacist

Canadian Wholesale Drug Association
Mr. C. M. Peel, President
Mr. Geoffrey C. Pitcher, Vice-President
Mr. Douglas R. Weston, Secretary Manager

Canadian Cystic Fibrosis Foundation
Mr. Callum MacIver, First Vice-President
Dr. J. M. Park, M.B., Ch.B., Member of the Medical Advisory Board
Mr. W. Mac McKenzie, National Executive Director

Jules R. Gilbert, Ltd.
Mr. Jules R. Gilbert, Ph.G., B.S.Chm.E.

Micro Chemicals Limited, Gryphon Laboratories Limited and Paul Maney Laboratories Canada Limited

Mr. J. M. Cook, President of M.C.L.

Mr. William S. Miller, President of P.M.L. Canada Limited

Hon. Joseph T. Thorson, P.C., Legal Counsel

Prescription Services Inc.

Mr. W. A. Wilkinson, President

Mr. Richard R. Walker, Q.C., Legal Counsel

Food and Drug Directorate, Department of National Health and Welfare

Dr. R. A. Chapman, Director-General, Food and Drugs

Mr. M. G. Allmark, Assistant Director-General, Drugs

Dr. A. C. Hardman, Director, Bureau of Scientific Advisory Services

Mr. A. Hollett, Director, Bureau of Operations

Dr. L. Levi, Chief, Pharmaceutical Chemistry Division

Dr. Jeffrey Bishop, Chief, Medicine and Pharmacology Division

Mr. K. M. Render, Chief, Field Programmes Division

Dr. R. C. B. Graham, Division of Medicine and Pharmacology

Dr. Irwin Hilliard, M.D., F.R.C.P. (C), (Physician-in-Chief, Toronto Western Hospital)

Department of the Registrar General

Mr. David H. W. Henry, Q.C., Director of Investigation and Research (Combines Investigation Act)

Mr. F. N. McLeod, Senior Combines Officer, Combines Branch

Mr. R. M. Davidson, Officer in Charge, Merger and Monopoly Section

Government of the Province of Alberta

The Hon. J. Donovan Ross, M.D., Minister of Health

Dr. P. B. Rose, M.D., Deputy Minister of Health

Mr. J. J. Frawley, Q.C., Special Counsel

Dr. Henry B. Steele, Ph.D., Associate Professor of Economics, University of Houston, (Texas)

APPENDIX B

(As extracted from the Report of the Hall Commission: Recommendations with respect to Drugs).

The Commission recommends:

58. That the Federal Government contribute grants to the province (50 per cent of the cost of the programme) for the purpose of introducing a Prescription Drug Benefit within the Health Services Programme.

59. That in the provision of the drug benefit, there should be required a $1.00 contributory payment by the purchaser for each prescription, subject to such discount as the retailer may offer. This charge should not be applied to drugs required for long-term therapy.

60. That the programme should cover such quantities of drugs for each prescription as are required by good medical practice taking into account the need for flexibility to assure an adequate but not wasteful supply. Further, prescribing practices should be reviewed periodically to ascertain whether and to what extent any over-prescribing of pharmaceuticals takes place, followed by appropriate changes in the regulations covering quantities of drugs paid for under the programme.

61. That the functions of the Drug Advisory Committee which is responsible for advising the Department of National Health and Welfare be expanded, and its membership enlarged to include representatives of the Canadian Medical Association, l'Association des médecins de langue française du Canada, the Canadian Pharmaceutical Association, the Canadian Hospital Association, the provincial Schools of Pharmacy, the provincial Colleges of Pharmacists, and the provincial Departments of Health.

62. That the Food and Drug Directorate, with the assistance of the Advisory Committee, prepare and issue a National Drug Formulary which would be maintained on a current basis. This Formulary would include only those drugs which meet the specifications of the Directorate, and would be identified as such, and therefor eligible for inclusion in the Prescription Drug Benefit, one of the objects being to minimize the cost of prescribed drugs. There should be established an appeals procedure for dealing with rejected applications, and an Information Service which would issue periodic bulletins providing the latest information on drugs and drug therapy to the physicians, pharmacists, and hospitals.

63. That the budget of the Food and Drug Directorate of the Department of National Health and Welfare be increased to enable it to recruit and train the personnel necessary to fulfil the additional functions and responsibilities that it is essential for it to assume.

64. That in the application of the provisions of the Corporation Income Tax Act to manufacturers, importers, and 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, "detail men", and other similar items.

65. That the federal sales tax be removed from all drugs listed in the Formulary.

66. That Section 19 of the Patent Act extending the right of the Crown in the name of the Government of Canada to use patented inventions "paying to the patentee such sum as the Commissioner reports to be a reasonable compensation for the use thereof" be expanded to include provincial governments and their agencies.

67. That Section 41 (3) of the Patent Act be amended to extend compulsory licensing to include the licensing of imports. The quality of such imported drugs should be assured by:

(a) requiring examination to ensure that they meet the specification of the Food and Drug Directorate, and

(b) continuous checks of quantities imported.

68. That the Federal Government consider delaying for five years a decision to implement the recommendation of the Restrictive Trade Practices Commission that patents on drugs be abolished, in order to ascertain whether the alternatives recommended above achieve the same results.

69. That provisions and administration of procedures with respect to granting of compulsory licences by the Commissioner of Patents be revised to remove unnecessary delays with respect to a decision to grant. Provision should be made to establish a standard royalty payment comprising a fixed fee on application and a percentage of sales over the period of the licence to speed up proceedings and to encourage responsible applicants.

70. That the Trade-marks Act should be amended (Section 20) to make clear that no infringement can be claimed where imported drugs are manufactured by a "related" company.

71. That the Canadian Tariff Board be requested to review tariffs on drugs with a view to establishing which tariff should be reduced or abolished covering imported drugs included in the National Formulary.

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 to contribute to a reduction of drug prices.

73. 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 programme for Canada, for implementation on a trial basis for a period of five years.

74. That provincial governments consider legislation enabling pharmacists in the dispensing of prescriptions to use a drug or drug combination that is the non-proprietary name equivalent of that named in the prescription unless the physician specifically indicates otherwise.

75. That educational programmes be conducted by the Food and Drug Directorate, the medical and pharmaceutical professions, and the provincial health service agencies to create greater understanding and co-operation between practitioners and pharmacists concerning the cost of drugs, and their prescription by proper names whenever possible.

76. That universities through their faculties of medicine and pharmacy strengthen their courses in pharmacology taken by medical students by providing instruction in the economics of prescribing, including examination of comparative costs of drugs with similar therapeutic quality and efficacy; by short refresher courses dealing with pharmacology for physicians; and by extension work with medical practitioners in such fields as evaluation and therapeutics.

77. That the Federal Government centralize all its drug purchases in one agency.

78. That provinces be encouraged to adopt bulk-purchasing of drugs for all hospitals and public agencies, and that all tenders for drugs should be based, whenever possible, on specifications of the ingredients of the pharmaceutical.

79. That hospital pharmacies under the direction of a licensed pharmacist be permitted to provide narcotics and control drugs on prescription under the Food and Drug Act and the Narcotics Control Act.

80. That the Federal Government expand considerably research grants by the Health Sciences Research Council to universities and non-professionl institutions to encourage the development of new drugs and/or improvement of existing drugs in Canada. In case of patentable discoveries these should be vested in the Crown.

81. That the Research and Statistics Division of the Department of National Health and Welfare undertake continuing cost-price analyses of drugs and periodically publish the results. Such studies would:

(a) assist in the compulsory licensing under the Patent Act of drugs to be manufactured in Canada,

(c) assist in the compulsory licensing of drugs to be imported into Canada,

(c) assist in the review of tariff items on drugs, undertaken by the Canadian Tariff Board,

(d) assist the Director of Investigation and Research under the Combines Act,

(e) assist public agencies at the federal and provincial level in calling for tenders for drugs.

(f) assist the Federal and Provincial Governments in formulating fiscal and procurement policies concerning drugs,

(g) assist drug manufacturers and drug distributors in examining their relative cost position and facilitate increasing competition where appropriate.

(h) assist the general public in acquiring an understanding of the various factors entering into drug costs and drug prices.

82. That the Research and Statistics Division of the Department of National Health and Welfare and the Dominion Bureau of Statitics co-operate in developing more comprehensive and up-to-date statistics relating to the supply costs of, and expenditures on, drugs covering both prescribed and non-prescribed pharmaceuticals.

APPENDIX C

Summary of Recommendations of the Restrictive Trade Practices Commission

1. There should be more stringent regulations under the Food and Drugs Act with respect to the manufacture, promotion and introduction of drugs, in order to give reasonable assurance that all prescription drugs offered for sale in Canada are safe to use and of good quality.

2. The staff of the Food and Drug Directorate should be enlarged considerably to ensure thorough enforcement of the regulations.

3. In the opinion of the Commission, the following changes should be made in the Food and Drug Regulations:

(a) All premises in which drugs are manufactured should be subject to inspection by the Food and Drug Directorate.

(b) Requirements in connection with new drug submissions should be extended to include detailed reports of the tests made to establish the therapeutic effectiveness of the drug as well as the present requirement of reports of tests to establish the safety of the drug. Such a change would make mandatory a joint evaluation of toxicity and efficacy before a new drug is put on sale.

(c) The Food and Drug Directorate should be given the duty of inspecting and assaying samples from a sufficiently large number of batches of every prescription drug manufactured in Canada or imported from abroad to make it reasonably certain that it meets minimum standards of purity and therapeutic efficacy.

(d) All labels, advertisements or other descriptive material relating to single drugs and official compounds should be required to carry the proper name prominently and in type at least as large as that used for the brand name. A study should be made to ascertain if and to what extent a similar requirement would be feasible in respect of compound ethical drugs.

4. Consideration should be given to the advisability of bringing under the supervision of the Food and Drug Directorate all advertising and promotion activities related to drugs, including the distribution of samples and the content of advertising literature.

5. Consideration should be given to the establishment, under the auspices of the federal government, of an authoritative publication giving all necessary particulars concerning new drugs.

6. The compulsory licence provision of the Patent Act with respect to drugs has been used infrequently and in the opinion of the Commission cannot be relied upon to achieve the purpose intended by Parliament of ensuring that medicines should be available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention. The Commission has considered whether such an objective would be assured if compulsory licences under section 41(3) of the Patent Act were made issuable as of right and has concluded that such a change would make no appreciable

difference in the present situation. 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.

7. The retail pharmacists' practice of coding prescriptions to indicate the price charged or quoted should be abandoned and consideration should be given by pharmaceutical associations to removing from their rules any provisions in any way related to the practice.

APPENDIX D

S. 41 of U. K. Patents Act, 1949

(As recommended by the Ilsley Commission to replace

S. 41 of the Canadian Patent Act)

"41.-(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, medicines 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 part of a surgical or curative device, but for no other purposes.

APPENDIX E

PROFITS OF DRUG MANUFACTURING FIRMS IN CANADA

Prepared by W. J. Blakely, C.A., Accountant for the Committee

A review of the profits earned by Canadian drug manufacturers is pertinent for the purpose of ascertaining whether or not the industry is realizing excess profits. This point was made in the testimony of Hoffmann-La Roche Limited.

> "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." (Minutes of Proceedings and Evidence, page 722).

This naturally leads to a judgment of what represents a fair profit. An appropriate definition may be found in Cyanamid's statement of objective for the conduct of its pharmaceutical business: "a rate of return consistent with the resources committed and the risks involved". The definition is much more easily arrived at than the determination of the rate, however. In attempting to reach a judgment on the question, it is helpful to compare the return and risks to the pharmaceutical industry with those of manufacturing industries in general as well as other specific industries.

Rate of Return on Sales

In the report of the Restrictive Trade Practices Commission, a comparison of the profitability of the pharmaceutical industry with that of all manufacturing was made on the basis of profits in relation to sales (report, pages 373-375). In this study, the rates of return on sales for the years 1953-1960 were calculated. These rates are reproduced in Table 1 together with corresponding rates for the years 1961 to 1964.

It is apparent from Table 1, that the operating results for 1961-1964 do not indicate any material change in trend from that shown for the period 1953-1960, dealt with by the Restrictive Trade Practices Commission. Although the average rate of return on sales of pharmaceuticals decreased noticeably in 1961 and 1962, there was a significant recovery in 1963 to a rate of 10.05 per cent, the fourth highest rate in the twelve-year period 1953-1964. The average rate of return for this entire period was 9.55 per cent for pharmaceuticals and 5.82 per cent for all manufacturing, the former being approximately 64 per cent higher than the latter. It is also noted that the rate of return on sales was declining for manufacturing in general but remained relatively stable in pharmaceuticals. The rate for all manufacturers appears to have levelled off at 5-5½ per cent of sales; the rate for drug manufacturers seems to run between 8-10½ per cent of sales.

A similar relationship is shown by the rates of return for profit companies only. Over the twelve-year period, the average rate for profit companies in the pharmaceutical industry was about 57 per cent higher than the average rate for

all manufacturing (11.22 per cent as compared to 7.15 per cent). Again, it is noted that the rate of return in all manufacturing generally declined during this period, whereas in pharmaceuticals it has increased. In pharmaceuticals it rose substantially from 1953 to 1957, and, while declining in the four years thereafter, to the low point of the period in 1961, rose again in 1962 and 1963, and in 1964 was the second highest rate of the twelve-year period.

It should be noted that the above-mentioned rates pertain to the total operations of the drug industry. It is reasonable to expect that the rate of return on sales of packaged human pharmaceuticals only would be somewhat higher. Supporting this conclusion, the Pharmaceutical Manufacturers' Association of Canada, in its brief to this Committee, reported an average rate of return (before taxes) of 10.8 per cent of sales for the total operations of the 41 companies replying to its 1964 survey (brief, page 3.5). The rate of return on sales of packaged human pharmaceuticals only was estimated at 15.0 per cent (brief, page 2.3). Six individual members of the association, in their submissions to the Committee, reported the following rates:

Company	Total Operations	Human Pharmaceuticals
A	17.7%	25.7%
B	21.5%	
C	10.9%	
D	15.4%	17.2%
E	18.2%	
F	—	16.0%

From the foregoing it is concluded that, as a percentage of sales, profits in the pharmaceutical manufacturing industry are significantly higher than those of all manufacturing industries combined and, further, that during the period 1953-1964, the pharmaceutical industry effectively resisted or was immune to the influences which caused a decline in the rate of return to manufacturing in general.

Return on Investment

The Consumers' Association of Canada criticized use of the rate of return on sales as a basis of comparison:

> "I would certainly admit that this is a common proportionate measure of profit often employed, but, again as an economist, I must argue that it is not a very meaningful measure, because, after all, people who earn profits are those who have invested their capital, and the meaningful judgment on profit is the level of profit per dollar of investment, not per dollar of sales" (Minutes of Proceedings and Evidence, page 1136).

A similar opinion was expressed in the brief of the Pharmaceutical Manufacturers Association of Canada:

> "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."
> (brief, page 3.5).

Although these views are considered valid, it is noted that the rate of return on sales is useful for the purpose of indicating the potential scope for unit price reductions, other than through reduction of costs. Generally speaking, the higher the rate of return on sales, the greater the scope for reduction in unit prices, assuming a satisfactory rate of return on capital employed.

A comparison of the return on investment in pharmaceutical manufacturing with that in all manufacturing for the years 1953-1960 was made by the Restrictive Trade Practices Commission. The Commission's calculations of the rates of return on capital invested are reproduced in Table 2 as well as the corresponding rates for the years 1961 to 1964.

In general, the same characteristics and trends shown in Table 1 are apparent in Table 2. The main difference is that Table 2 makes the pharmaceutical manufacturing industry appear even more profitable relative to all manufacturing. The average rate of return on investment over the twelve-year period was 20.0 per cent for all drug manufacturers (profit and loss companies) as compared to 10.30 per cent for all manufacturing, or approximately 96 per cent higher. During this period, the return on investment to the pharmaceutical industry tended to increase (from 16.62 per cent in 1953 to 23.22 per cent in 1964) although there was a decline in 1961 and 1962. However, there was a significent recovery in 1963 and, in 1964, the highest rate of return of the twelve-year period was experienced. At the same time the return on investment for all manufacturing showed a substantial decline, going from 15.03 per cent in 1953 to 9.20 per cent in 1964. Manufacturing in general showed a levelling off in 1957 and from 1957 to 1964 the average rate of return on investment was 8.97 per cent. During the same period, it was 20.65 per cent for pharmaceuticals.

A rather similar situation is shown by the rates for profit companies only. Over the twelve-year period, the average rate of return of the pharmaceutical companies was approximately 79 per cent higher than for all manufacturing (23.49 per cent as compared to 13.15 per cent). Again, while the rate of return of all manufacturing declined by 31.6 per cent, that of the pharmaceutical manufacturing firms increased by 43.4 per cent over the twelve years.

The Pharmaceutical Manufacturers' Association of Canada, in its submission to the Committee, suggested a different method for calculating return on investment. It suggested that earnings be related to the resources (assets) employed. It reported 15.6 per cent as the rate of return (before taxes) on resources employed in the total operations of the 41 companies included in its 1964 survey (brief, page 3.5). From figures appearing in its brief, the corresponding rate for packaged human pharmaceuticals only was calculated at 21.1 per cent.

The rates of return on resources employed were calculated for the entire pharmaceutical industry and for all manufacturing from material shown in Taxation Statistics, published by the Department of National Revenue. These rates appear in Table 3. It will be noted that the rate of 15.6 per cent quoted above is comparable to the average rate for profit and loss companies in the pharmaceutical industry as shown in Table 3. The above rate for human pharmaceuticals only (21.1 per cent) is much higher, however.

It will be noted that Table 3 supports the observations made above in the discussion relating to Tables 1 and 2. For all pharmaceutical manufacturing companies, the average rate of return on resources employed is 14.50 per cent for the period 1953-1964. This is 65.1 per cent higher than the average rate of 8.78 per cent, which was experienced by all manufacturing companies in the same period. Also, while the rate of return of all manufacturing declined by 31.3 per cent, that of the pharmaceutical manufacturing companies increased by 11.7 per cent over the twelve years.

With respect to profit companies only, it is noted that an average return of 17.14 per cent was realized by pharmaceutical manufacturers, whereas the average rate for all manufacturing was 10.92 per cent. The average rate for pharmaceuticals is 56.7 per cent higher than the rate for all manufacturing.

An indication of the profitability of the pharmaceutical industry relative to other classifications in the manufacturing industry is shown by Table 4 which summarizes the seven highest rates of return (profit before taxes) on resources employed for manufacturing companies in 1963. These rates are taken from the fourth edition of "Ten Significant Ratios for Canadian Manufacturers" as prepared from Taxation Statistics by the Canadian Manufacturers' Association. It will be observed that the pharmaceutical industry is listed as seventh out of a total of 63 industrial classifications. Out of 178 companies included in pharmaceutical preparations, 71 of them had an above average return on total assets. The average rate for these 71 companies was 26.7 per cent. The average rate for the remaining 107 companies was 8.6 per cent which is only slightly less than the average rate of 9.2 per cent for companies in all classifications.

Individual members of the Pharmaceutical Manufacturers' Association of Canada reported to the Committee a variety of calculations for rate of return on investment. Because of this, it is difficult to generalize but they appear to be comparable to the average rates reported by the association in its brief.

It should be remembered that the rates shown for pharmaceuticals in Tables 2, 3 and 4 relate to the total operations of the companies involved. Evidence presented by the PMAC indicates that the corresponding rates for operations relating only to packaged human pharmaceuticals would be higher.

From the above analysis of the return on investment, it is concluded that the rate of return for drug manufacturers is significantly higher than for all manufacturing. For packaged human pharmaceuticals only, the rate appears to be at least twice as high as the average for all manufacturing. Moreover, during the period of 1953 to 1964, the pharmaceutical manufacturing industry effectively resisted or was immune to the influences which caused a decline in rate of return on investment for manufacturing in general.

Risk

Several of the manufacturers' briefs contained statements attempting to justify the rates of profit experienced by the drug manufacturers in terms of the risks run by those companies. The following are typical of these statements:

> "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 availability of new and better drugs" (PMAC brief, pages 3.4 and 3.5).

> "Our rate of profit reflects the cost of doing business in a limited market such as Canada, the kind of industry we are in, which involves high risks of many kinds including product obsolescence, and our relatively heavy long-term commitment to research" (brief, Charles E. Frosst & Co., page 14).

On the question of product obsolescence, the Province of Alberta (page 62 of brief) had this to say:

> "Drug firms complain of the high rate of obsolescence of drugs, and argue that such risks justify high profit rates. The argument is not irrelevant under present circumstances, but the risks of obsolescence are not inherent but result from the way in which drugs are developed and promoted. High risks do not justify high profits in this instance because the risks and profits are both symptoms of the same disease: sales promotion rivalry substituting for price competition."

In testimony on the above brief before the Committee, it was stated:

> "The fact that a new drug which is developed in one particular market may be superseded a few months later by a more reputable rival is definitely a risk-increasing circumstance but you cannot say very well that the industry is a high risk." (Minutes of Proceedings, page 2327)

In the same brief, page 22, with respect to the "substantial expenditures on research", the following statement appears:

> "...the share of total research and development outlays in the sales dollar of the Canadian drug firm is not as great as the industry would like to have us believe."

In the submission of the Pharmaceutical Manufacturers' Association of Canada, research and development costs for 1964 were said to represent 7 per cent of the sales dollar (brief, page 2.3). This is small by comparison to marketing costs which were identified as 30 per cent of the sales dollar (brief, page 2.3). Moreover, it is noted that the practice in the industry is to amortize research and development costs as incurred and thus charge them against current revenue. Further, from the evidence before this Committee, it appears that the particular firms which incur these costs not only recover them in full but realize profits in addition. While industry spokesmen have maintained that expenditures on research are "substantial" or "relatively heavy" and that there is a significant financial risk involved as a result of them, it appears that all of the research and marketing costs are being adequately compensated.

On the other hand, analysis of the negative rates of return for loss companies as shown by Tables 1 and 3 reveal that losses in the pharmaceutical industry, when incurred, tend to be higher and vary more widely than for manufacturing in general. The rate of loss on sales for drug manufacturers averaged 9.22 per cent over the period 1953-64 as compared to 4.71 per cent for all manufacturers. For pharmaceuticals, the rate of loss varied from 3.18 per cent to 16.18 per cent; for manufacturing in general, this ranged from 3.66 per cent to 6.15 per cent. Similarly, from Table 3 it is observed that the average rate of loss on resources employed by drug manufacturers was higher than that for all manufacturers: 7.18 per cent as compared to 2.52 per cent. Also, there was greater variability in these rates for drug manufacturers than there was for all manufacturers.

It should be pointed out, perhaps, that the ratios for loss companies as shown in Table 2 have not been analysed because it is felt that many of the figures used in the calculation of these negative rates of return are not truly representative of the pharmaceutical industry. For example, in 1964 the amount of capital invested in loss companies was $2.6 million. This represents only 2.4 per cent of the total capital invested in the pharmaceutical industry. Also, it financed only about 12 per cent of the total assets of the loss companies whereas, for profit companies, the capital investment of $105.8 million financed approximately 65 per cent of the total assets. Obviously, the loss companies in this year were, by comparison, greatly under-capitalized, a situation which can be shown to exist in other years as well. The lack of adequate capital is probably a significant factor in the incurrence of the losses.

As noted above, it is apparent that when losses are incurred they tend to be higher in the pharmaceutical manufacturing industry than in all manufacturing. However, it is significant to note, from Table 5, that losses do not involve a higher proportion of the total pharmaceutical companies than they do of all manufacturing companies. In fact, the proportion of companies incurring losses is about the same for each group. Also the pharmaceutical loss companies

represent a much smaller segment of the total industry than is the case for all manufacturers when measured both in terms of total assets and total sales (see Table 6). On average, over the period 1953-1964 the loss companies in all manufacturing represent 16.40 per cent of total assets and 11.57 per cent of total sales; the loss companies in the pharmaceutical manufacturing industry represent only 10.92 per cent and 8.42 per cent respectively.

Risk is inherent in any enterprise. In the circumstances, the question is whether the risks for pharmaceutical manufacturers vary significantly from those for all manufacturing. The above analysis and review of the evidence before this Committee seems to indicate that, in comparison to manufacturing in general, the effect of losses on the pharmaceutical firms as a group does not indicate the presence of greater risk. In fact the rates of return on investment demonstrate that, over the period 1953-1964, the pharmaceutical industry in Canada has been increasingly less risky as compared with manufacturing in general. The rate of return for the pharmaceutical manufacturing industry has been consistently higher and, relative to the rate of return for all manufacturing, it has been increasing in this period.

Other Considerations

The Royal Commission on Health Services suggested that:

> "....the earnings of the Canadian drug industry are not a satisfactory test of the over-all pricing policies of the industry because they are understated". (Report, page 679)

This statement appears to recognize the possibility that prices paid to a foreign parent company by a Canadian subsidiary for raw materials purchased from the parent may result in some profit being diverted to the parent which is more properly attributable to the operations of the Canadian subsidiary. It would also appear to be in reference to what may be somewhat arbitrary charges by the parent to the Canadian subsidiary for research and management services performed by the parent company.

With respect to the prices paid for raw materials purchased from parent companies, there is little before this Committee to indicate what degree of diversion of profits may take place and therefore it is not possible to estimate what this "understatement of profit" may amount to for the Canadian drug manufacturing industry. However, one is inclined to believe that it probably occurs due to the lack of operation of free market conditions in dealings between parent and subsidiary.

With respect to payments by Canadian subsidiaries for foreign royalties and management services, some indication of the significance of this was given in the brief of the Pharmaceutical Manufacturers' Association of Canada. From the detail in this brief, it is estimated that, in 1964, the rate of net profit (before taxes, royalties and management fees) on total resources employed was 18.2 per cent for total operations and 24.5 per cent for human pharmaceuticals only. In the calculation of these rates an assumption made by Dr. Briant of the Pharmaceutical Manufacturers' Association of Canada was accepted and used (Minutes of Proceedings, page 574). This assumption may or may not be correct. If the assumption is in error the rates would be even higher: 20.4 per cent for total operations and 27.4 per cent for human pharmaceuticals only. These rates are significantly higher than those shown in Table 3.

SUMMARY

Based upon the foregoing analysis and the evidence available to the Committee, it is concluded that the financial experience of the Canadian pharmaceutical manufacturing industry in the period reviewed does not indicate that the business risks to it are greater than to manufacturing in general. On the contrary, there is evidence that it has been less risky by comparison.

In fact, the Canadian pharmaceutical manufacturing industry has enjoyed consistently higher returns than manufacturing in general. For packaged human pharmaceuticals, the profits appear to be running at approximately twice the level of the manufacturing industry as a whole. This leads to the belief that the factors which permit this situation to exist may also and at the same time appear to permit uneconomic practices and costs.

TABLE 1

RATE OF RETURN ON SALES

Year	Profit Companies		Loss Companies		Profit and Loss Companies	
	Pharmaceuticals	All Manufacturing	Pharmaceuticals	All Manufacturing	Pharmaceuticals	All Manufacturing
	(per cent)	(per cent)	(per cent)	(per cent)	(per cent)	(per cent)
1953	9.91	8.62	−13.33	−4.15	9.25	7.48
1954	10.40	7.73	− 8.64	−5.07	9.08	6.13
1955	11.65	8.07	−13.33	−4.59	9.96	7.59
1956	12.19	6.97	−16.18	−5.37	10.90	6.10
1957	12.67	6.90	−11.54	−6.15	10.59	5.40
1958	11.79	6.61	− 6.22	−5.28	9.88	5.09
1959	11.68	7.06	− 7.28	−4.73	10.42	5.53
1960	10.62	6.73	− 3.18	−4.39	9.24	5.28
1961	8.87	6.86	− 7.48	−3.89	7.81	5.19
1962	10.77	7.00	− 8.39	−4.77	7.93	5.47
1963	11.88	6.87	− 7.99	−4.47	10.05	5.53
Average	11.13	7.22	− 9.42	−4.81	9.56	5.89

SOURCE:

1953–1960 reprinted from page 374 of Report of the Restrictive Trade Practices Commission. Percentages were calculated from Department of National Revenue, *Taxation Statistics*.

1961–1963 calculated from Department of National Revenue, *Taxation Statistics*.

DEFINITION:

Return—net profit before taxes and bond and mortgage interest, excluding investment income and other revenue.

TABLE 2

RATE OF RETURN ON CAPITAL INVESTED

Year	Profit Companies		Loss Companies		Profit and Loss Companies	
	Pharmaceuticals	All Manufacturing	Pharmaceuticals	All Manufacturing	Pharmaceuticals	All Manufacturing
	(per cent.	(per cent)	(per cent)	(per cent)	(per cent)	(per cent)
1953	18.32	17.42	−10.72	− 7.89	16.62	15.03
1954	19.95	14.44	−19.90	− 9.32	17.63	11.42
1955	21.58	15.61	−31.58	− 7.55	18.73	13.69
1956	25.58	13.38	−17.19	−10.00	21.93	11.68
1957	25.03	13.41	−18.18	− 6.42	20.47	9.54
1958	23.85	11.85	−10.53	− 5.23	19.59	8.26
1959	27.25	12.90	− 9.32	− 5.07	23.05	9.25
1960	26.85	11.30	− 3.40	− 6.63	20.55	8.74
1961	21.23	11.45	−16.43	− 4.57	18.57	8.11
1962	21.87	11.93	−47.26	− 7.37	17.79	9.20
1963	24.15	12.20	−60.71	− 6.15	21.92	9.49
Average...	23.24	13.26	−22.29	− 6.93	19.71	10.40

SOURCE:

1953–1960 reprinted from page 376 of the Report of the Restrictive Trade Practices Commission. Percentages were calculated from Department of National Revenue, *Taxation Statistics*.

1961–1963 calculated from Department of National Revenue, *Taxation Statistics*.

DEFINITIONS:

Return—net profit before taxes and bond and mortgage interest, excluding investment income and other revenue.

Capital Invested—sum of amounts for "due to shareholders", "mortgage debt", "other funded debt", "common stock", "preferred stock", and "surplus" less "deficit".

TABLE 3

RATE OF RETURN ON RESOURCES EMPLOYED

Year	Profit Companies		Loss Companies		Profit and Loss Companies	
	Pharmaceuticals	All Manufacturing	Pharmaceuticals	All Manufacturing	Pharmaceuticals	All Manufacturing
	(per cent)	(per cent)	(per cent)	(per cent)	(per cent)	(per cent)
1958	17.82	10.09	−5.88	−2.28	14.28	7.38
1959	18.16	10.91	−2.76	−1.93	15.87	8.28
1960	17.02	9.44	−1.24	−3.11	14.28	7.33
1961	14.08	9.14	−9.01	−2.22	12.44	6.66
1962	15.77	9.52	−7.48	−3.43	11.99	7.38
1963	16.34	9.63	−9.39	−2.43	13.77	7.51
Average	16.53	9.79	−5.96	−2.57	13.77	7.42

SOURCE: Department of National Revenue, *Taxation Statistics*.

DEFINITIONS:

Return—net profit before income taxes and bond and mortgage interest expense.

Resources employed—total assets less accumulated depreciation.

TABLE 4

SEVEN HIGHEST RATES OF RETURN ON RESOURCES EMPLOYED: 1963

	Companies with:			
	Above average return on assets		Below average return on assets	
	No.	%	No.	%
1. Distilleries and Wineries	9	41.3	22	14.0
2. Motor Vehicles	4	40.2	39	All
3. Other Petroleum and Coal Products	5	35.8	13	less
4. Motor Vehicle Parts and Accessories	40	31.0	89	than
5. Wire and Wire Products	36	28.5	78	8.6
6. Office and Store Machinery	16	27.2	39	9.1
7. Pharmaceutical Preparations	71	26.7	107	8.6

SOURCE:

Fourth Edition of "Ten Significant Ratios for Canadian Manufacturers", published by The Canadian Manufacturers' Association, percentages calculated from Department of National Revenue, *Taxation Statistics.*

DEFINITION: Return—net profit before income taxes.

TABLE 5

LOSS COMPANIES AS PERCENTAGES OF ALL COMPANIES

	Pharmaceuticals	All Manufacturing
	(per cent)	(per cent)
1953	25.65	27.65
1954	27.54	31.94
1955	26.05	26.95
1956	18.35	24.33
1957	30.64	26.69
1958	32.24	28.27
1959	26.32	25.94
1960	23.91	31.28
1961	22.73	32.85
1962	42.86	29.89
1963	22.28	27.12
Average	27.14	28.45

SOURCE:

1953–1960 reprinted from page 372 of Report of The Restrictive Trade Practices Commission. Percentages were calculated from Department of National Revenue, *Taxation Statistics.*

1961–1963 calculated from Department of National Revenue, *Taxation Statistics.*

TABLE 6

Year	Total assets of loss companies as a percentage of total assets of all companies		Total sales of loss companies as a percentage of total sales of all companies	
	Pharmaceuticals	All Manufacturing	Pharmaceuticals	All Manufacturing
	(per cent)	(per cent)	(per cent)	(per cent)
1958	15.07	21.93	10.60	12.83
1959	10.92	20.47	6.64	13.00
1960	15.02	16.78	10.01	13.03
1961	7.08	21.91	6.52	15.61
1962	16.28	16.54	14.82	12.97
1963	9.97	17.54	9.19	11.83
Average	12.39	19.19	9.63	13.21

SOURCE: Department of National Revenue, *Taxation Statistics*.

APPENDIX F

TABLE SHOWING COMPARATIVE PRICES TO THE RETAILER OF TWELVE OF THE MOST COMMONLY USED DRUGS IN DIFFERENT COUNTRIES

London

	Trade Name	Generic Name	Strength	Manufacturer	Original Size	Foreign Price	$ Canadian Equivalent
1.	Chloromycetin	Chloramphenicol	250 mgm.	Parke Davis Co.	100 tabs	3.14.2	11.18
2.	Achromycin	Tetracycline	250 mgm.	Lederle (Cyanamid)	100 tabs	3.5.2	9.83
3.	Gantrisin	Sulfisoxazole	0.5 Gm.	Hoffmann-La Roche	100 tabs	16.0	2.40
4.	Pentids	Penicillin G potassium	600,000 units	Squibb	100 tabs	not sold	
5.	Decadron	Dexamethasone (methylprednisolone)	0.75 mgm.	Merck Sharp & Dohme	100 tabs	4.13.8	14.11
6.	Librium	Chlordiazopoxide	10 mgm.	Hoffmann-La Roche	100 tabs	1.0.0	3.02
7.	Equanil	Meprobamate	400 mgm.	Wyeth & Co.	100 tabs	19.0	2.85
8.	Enovid	Norethynodrol with Mestranol	5 mgm.	Searle	50 tabs	1.5.8	3.85
9.	Butazolidin	Phenylbutazone	100 mgm.	Geigy	250 tabs[1]	1.15.2	5.29
10.	Mobenol	Tolbutamide	0.5 Gm.	Horner	100 tabs	not sold	
11.	"222"	(Acetylsalicylic acid phenacetin, caffeine & codeine phosphate gr. ½)		Frosst	1000 tabs	not sold	
12.	Premarin	(Estrogenic substances)	1.25 mgm.	Ayerst, McKenna & Harrison	100 tabs	1.18.6	5.78

[1] Enovid, 5 mgm. 100's not sold.
[2] Butazolidin, 100 mgm. 100's not sold

1 Pound = $3.02 Cdn.
December 1966

Paris

	Trade Name	Generic Name	Strength	Manufacturer	Original Size	Foreign Price	$ Canadian Equivalent
1.	Chloromycetin	Chloramphenicol	250 mgm.	Parke Davis Co.	100 tabs	not sold	
2.	Achromycin	Tetracycline	250 mgm.	Lederle (Cyanamid)	100 tabs	not sold	
3.	Gantrisin .03 per pill	Sulfisoxazole	0.5 Gm.	Hoffmann-La Roche	20 tabs	2.81	0.61
4.	Pentids	Penicillin G potassium	600,000 units	Squibb	100 tabs	not sold	
5.	Decadron	Dexamethasone (methylprednisolone)	0.50 mgm.[2]	Merck Sharp & Dohme	40 tabs	15.70	3.42
6.	Librium	Chlordiazopoxide	10 mgm.	Hoffmann-La Roche	50 tabs	8.40	1.83
7.	Equanil	Meprobamate	400 mgm.	Wyeth & Co.	100 tabs	not sold	
8.	Enovid	Norethynodrol with Mestranol	5 mgm.	Searle	20 tabs	8.10	1.76
9.	Butazolidin 1.4 per pill	Phenylbutazone	100 mgm.	Geigy	50 tabs	4.25	0.92
10.	Mobenol	Tolbutamide	0.5 Gm.	Horner	100 tabs	not sold	
11.	"222"	(Acetylsalicylic acid phenacetin, caffeine & codeine phosphate gr. ½)		Frosst	1000 tabs	not sold	
12.	Premarin	(Estrogenic substances)	1.25 mgm.	Ayerst, McKenna & Harrison	100 tabs	not sold	

[1] Listed products not sold in 100's.
[2] Decadron, 0.75 mgm. not sold.

1 Franc = $0.21 Cdn.
December 1966

Berne

	Trade Name	Generic Name	Strength	Manufacturer	Original Size	Foreign Price	$ Canadian Equivalent
1.	Chloromycetin	Chloramphenicol	250 mgm.	Parke Davis Co.	100 tabs	39.45	9.86
2.	Achromycin	Tetracycline	250 mgm.	Lederle (Cyanamid)	100 tabs	89.60	22.40
3.	Gantrisin	Sulfisoxazole	0.5 Gm.	Hoffmann-La Roche	50 tabs[1]	8.70	2.17
4.	Pentids	Penicillin G potassium	600,000 units	Squibb	100 tabs	not sold	
5.	Decadron	Dexamethasone (methylprednisolone)	0.50 mgm.[2]	Merck Sharp & Dohme	100 tabs	17.50	4.37
6.	Librium	Chlordiazopoxide	10 mgm.	Hoffmann-La Roche	100 tabs	10.95	2.73
7.	Equanil 3	Meprobamate	400 mgm.	Wyeth & Co.	250 tabs[3]	51.50	12.87
8.	Enovid 4	Norethynodrol with Mestranol	5 mgm.	Searle	60 tabs[4]	20.35	5.08
9.	Butazolidin	Phenylbutazone	100 mgm.	Geigy	150 tabs[5]	14.00	3.50
10.	Mobenol	Tolbutamide	0.5 mgm.	Horner	100 tabs	not sold	
11.	"222"	(Acetylsalicylic acid phenacetin caffeine and codeine phosphate gr. $\frac{1}{8}$)		Frosst	1000 tabs	not sold	
12.	Premarin	(Estrogenic substances)	1.25 mgm.	Ayerst, McKenna & Harrison	100 tabs	32.95	8.23

[1] Gantrisin, 100's not sold.
[2] Decadron, 0.75 mgm. not sold.
[3] Equanil sold as Guname, and in 250's.
[4] Enovid sold as Enavid and in 60's.
[5] Butazolidin sold in 150's.

1 Franc = $0.25 Cdn.

Rome

	Trade Name	Generic Name	Strength	Manufacturer	Original Size	Foreign Price	$ Canadian Equivalent
1.	Chloromycetin	Chloramphenicol	250 mgm.	Parke Davis Co.	10 tabs	6.40	1.08
2.	Achromycin	Tetracycline	250 mgm.	Lederle (Cyanamid)	16 tabs	18.40	3.12
3.	Gantrisin	Sulfisoxazole	0.5 Gm.	Hoffmann-La Roche	20 tabs	4.45	0.75
4.	Pentids[2]	Penicillin G potassium	2000,000[2] units	Squibb	12 tabs	5.85	0.99
5.	Decadron	Dexamethasone (methylprednisolone)	0.75 mgm.	Merek Sharp & Dohme	10 tabs	9.36	1.59
6.	Librium	Chlordiazopoxide	10 mgm.	Hoffmann-La Roche	25 caps	6.10	1.03
7.	Equanil[3]	Meprobamate	400 mgm.	Wyeth & Co.	24 tabs	6.00	1.02
8.	Enovid	Norethynodrol with Mestranol	5 mgm.	Searle	20 tabs	22.62	3.84
9.	Butazolidin	Phenylbutazone	200 mgm.[4]	Geigy	20 tabs	3.90	0.66
10.	Mobenol	Tolbutamide	0.5 Gm.	Horner	100 tabs	not sold	
11.	"222"	(Acetylsalicylic acid phenacetin, caffeine and codeine phosphate gr. $\frac{1}{8}$)		Frosst	1000 tabs	not sold	
12.	Premarin	(Estrogenic substances)	1.25 mgm.	Ayerst, McKenna & Harrison	20 tabs	11.60	1.97

[1] The only sizes available are those listed, "Original Sizes" are not hundreds.
[2] Italian name is Penchim and only strength available is 200,000 units.
[3] Italian names is Quanil.
[4] Butazalidin 100 mg is not sold.

1 Lira = $0.0017 Canadian
December 1966

Trade Name	Generic Name	Strength	Manufacturer	Original Size	Foreign Price	$ Canadian Equivalent
1. Chloramycetin	Chloramphenicol	250 mgm.	Parke Davis Co.	100 tabs	65.56	17.70
2. Achromycin	Tetracycline	250 mgm.	Lederle (Cyanamid)	100 tabs	90.95	24.55
3. Gantrisin	Sulfisoxozole	0.5 Gm.	Hoffman-La Roche	100 tabs	9.51	2.56
4. Pentids	Penicillin G potassium	400,000 units	Squibb	100 tabs	not sold	
5. Decadron	Dexamethasone (methylprednisolone)	0.5 mg[1]	Merek Sharp & Dohme	100 tabs	29.33	7.91
6. Librium	Chlordiazopoxide	10 mgm.	Hoffman-La Roche	100 caps	11.60	3.13
7. Equanil	Meprobamate	400 mgm.	Wyeth & Co.	100 tabs	not sold	
8. Envoid	Norethynodrol with Mestranol	5 mgm.	Searle	100 tabs	not sold	
9. Butazolidin	Phenylbutazone	200 mgm.[2]	Geigy	100 tabs	15.51	4.18
10. Mobenol	Tolbutamide	0.5 Gm.	Horner	100 tabs	not sold	
11. "222"	(Acetylsalicylic acid phenacetin, caffeine & codeine phosphate gr. 1/8)		Frosst	1000 tabs	not sold	
12. Premarin	(Estrogenic substances)	1.25 mgm.	Ayerst, McKenna & Harrison	100 tabs	not sold	

[1] Decardon, 0175 mg not sold.
[2] Butazolidin, 100 mgm. not sold.

D Mark=$0.27 Canadian
December 1966

Trade Name	Generic Name	Strength	Manufacturer	Original Size	Foreign Price	$ Canadian Equivalent
1. Chloromycetin	Chloramphenicol	250 mgm.	Parke Davis Co.	100 tabs	30.60	33.04
2. Achromycin	Tetracycline	250 mgm.	Lederle (Cyanamid)	100 tabs	14.96	16.15
3. Ganstrisin	Sulfisoxazole	0.5 gm.	Hoffman-La Roche	100 tabs	2.94	3.17
4. Pentids	Penicillin G potassium	400,000 units[1]	Squibb	100 tabs	9.94	10.73
5. Decadron	Dexamethasone (methylprednisolone)	0.75 mgm.	Merck Sharp & Dohme	100 tabs	14.54	15.70
6. Librium	Chlordiazopoxide	10 mgm.	Hoffman-La Roche	50 caps[2]	3.50	3.78
7. Equanil	Meprobamate	400 mgm.	Wyeth & Co.	100 tabs	5.80	6.26
8. Envoid	Northynodrol with Mestranol	5 mgm.	Searle	100 tabs	8.76	9.46
9. Butazolidin	Phenylbutazone	100 mgm.	Geigy	100 tabs	5.85	6.31
10. Mobenol	Tolbutamide	0.5 Gm.	Horner	100 tabs	not sold	
11. "222"	(Acetylsalicylic acid phenacetin, caffeine & codeine phosphage gr. 1/8)		Frosst	1000 tabs	not sold	
12. Premarin	(Estrogenic substances)	1.25 mgm.	Ayerst, McKenna & Harrison	100 tabs	6.29	6.79

[1] Pentids, 600,000 units not sold.
[2] Librium, 100 caps not sold.

$1.00 U.S.=$0.92 Canadian
December 1966

Chicago

	Trade Name	Generic Name	Strength	Manufacturer	Original Size	Foreign Price	$ Canadian Equivalent
1.	Chloromycetin	Chloramphenicol	250 mgm.	Parke Davis Co.	100 tabs	30.60	33.04
2.	Achromycin	Tetracycline	250 mgm.	Lederle (Cyanamid)	100 tabs	14.96	16.15
3.	Gantrisin	Sulfisoxazole	0.5 Gm.	Hoffmann-La Roche	100 tabs	2.94	3.17
4.	Pentids	Penicillin G potassium	400,000 units	Squibb	100 tabs	11.33	12.23
5.	Decadron	Dexamethasone (methylprednisolone)	0.75 mgm.	Merck Sharp & Dohme	100 tabs	14.50	15.66
6.	Librium	Chlordiazopoxide	10 mgm.	Hoffmann-La Roche	50 tabs	3.30	3.56
7.	Equanil	Meprobamate	400 mgm.	Wyeth & Co.	100 tabs	6.50	7.02
8.	Enovid	Norethynodrol with Mestranol	5 mgm.	Searle	100 tabs	8.76	9.46
9.	Butazolidin	Phenylbutazone	100 mgm.	Geigy	100 tabs	5.85	6.31
10.	Mobenol	Tolbutamide	0.5 Gm.	Horner	100 tabs	not sold	
11.	"222"	(Acetylsalicylic acid phenacetin, caffeine & codeine phosphate gr. 1/8).		Frosst	1000 tabs	not sold	
12.	Premarin	(Estrogenic substances)	1.25 mgm.	Ayerst, McKenna & Harrison	100 tabs	6.29	6.79

[1] Pentids, 600,000 units not sold
[2] Librium, 100 caps not sold

1 dollar U.S. = $0.92 Canadian
December 1966.

Los Angeles

	Trade Name	Generic Name	Strength	Manufacturer	Original Size	Foreign Price	$ Canadian Equivalent
1.	Chloromycetin	Chloramphenicol	250 mgm.	Parke Davis Co.	100 tabs	30.60	33.04
2.	Achromycin	Tetracycline	250 mgm.	Lederle (Cyanamid)	100 tabs	14.96	16.15
3.	Gantrisin	Sulfisoxazole	0.5 Gm.	Hoffmann-La Roche	100 tabs	2.93	3.16
4.	Pentids	Penicillin G potassium	400,000[1] units	Squibb	100 tabs	9.94	10.73
5.	Decadron	Dexamethasone (methylprednisolone)	0.75 mgm.	Merck Sharp & Dohme	100 tabs	14.50	15.66
6.	Librium	Chlordiazopoxide	10 mgm.	Hoffmann-La Roche	50 caps[2]	3.56	3.84
7.	Equanil	Meprobamate	400 mgm.	Wyeth & Co.	100 tabs	6.80	7.34
8.	Enovid	Norethynodrol with Mestranol	5 mgm.	Searle	100 tabs	8.76	9.46
9.	Butazolidin	Phenylbutazone	100 mgm.	Geigy	100 tabs	5.85	6.31
10.	Mobenol	Telbutamide	0.5 Gm.	Horner	100 tabs	not sold	
11.	"222"	(Acetylsalicylic acid phenacetin, caffeine & codeine phosphate gr. 1/8).		Frosst	1000 tabs	not sold	
12.	Premarin	(Estrogenic substances)	1.25 mgm.	Ayerst, McKenna & Harrison	100 tabs	6.29	6.79

[1] Pentids, 600,000 units not sold
[2] Librium, 100 caps not sold

1 dollar U.S. = $0.92 Canadian
December 1966.

Trade Name	Generic Name	Strength	Manufacturer	Original Size	Canadian Price
1. Chloromycetin	Chloramphenicol	250 mgm.	Parke Davis Co.	100 tabs	23.64
2. Achromycin	Tetracycline	250 mgm.	Lederle (Cyanamid)	100 tabs	17.62
3. Gantrisin	Sulfisoxazole	0.5 Gm.	Hoffman–La Roche	100 tabs	4.14
4. Pentids	Penicillin G potassium	600,000 units	Squibb	100 tabs	11.10
5. Decadron	Dexamethasone (methylprednisolone)	0.75 mgm.	Merck Sharp & Dohme	100 tabs	17.44
6. Librium	Chlordiazopoxide	10 mgm.	Hoffman–La Roche	100 tabs	7.20
7. Equanil	Meprobamate	400 mgm.	Wyeth & Co.	100 tabs	7.20
8. Enovid	Norethynodrol with Mestranol	5 mgm.	Searle	100 tabs	11.70
9. Butazolidin	Phenylbutazone	100 mgm.	Geigy	100 tabs	6.18
10. Mobenol	Tolbutamide	0.5 Gm.	Horner	100 tabs	7.50
11. "222"	(Acetylsalicylic acid phenacetin, caffeine & codeine phosphate gr. 1/8)		Frosst	1000 tabs	15.87
12. Premarin	(Estrogenic substances)	1.25 mgm.	Ayerst, McKenna & Harrison	100 tabs	6.36

COMPOSITE TABLE OF COMPARATIVE PRICES TO THE RETAILER

Trade Name	Quantity	London — England	Paris — France	Berne — Switz.	Rome — Italy	Bonn — Germany	Boston — U.S.A.	Chicago — U.S.A.	Los Angeles — U.S.A.	Canada	Remarks
Chloromycetin	100	11.18	---	9.86	11.08*	17.70	33.04	33.04	33.04	23.64	U.S. prices shown for chloromycetin have been reduced almost 50% since this price was quoted due to patent expiration.
Achromycin	100	9.83	---	22.40	19.50*	24.55	16.15	16.15	16.15	17.62	
Gantrisin	100	2.40	3.05*	4.34*	3.75*	2.56	3.17	3.17	3.16	4.14	
Decadron	100	14.11	---	---	15.90*	---	15.70	15.66	15.66	17.44	
Librium	100	3.02	3.66*	2.73	4.12*	3.13	7.56*	7.12*	7.68*	7.20	
Equanil	100	2.85	---	5.15*	4.25*	---	6.26	7.02	7.34	7.20	
Enovid	100	7.70*	8.80*	8.47*	19.20*	---	9.46	9.46	9.46	11.70	
Butazolidin	100	2.12*	1.84*	2.33*	---	---	6.31	6.31	6.31	6.18	
Premarin	100	5.78	---	8.23	9.85	---	6.79	6.79	6.79	6.36	

Pentids, Mobenol and 222's are not included in composite table as they are not sold as such outside of Canada.

--- not sold or sold in a different strength making comparisons impossible.

* Calculated from prices for quantities other than 100.

APPENDIX G

MARKETING EXPENSES (1964) OF 41 COMPANIES (MEMBERS OF PMAC)

	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 Space	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

CODE OF CONSUMER

CODE OF CONSUMER ADVERTISING PRACTICES FOR NON-PRESCRIPTION MEDICINES

Single copies of this code may be obtained free from the office of the Proprietary Association of Canada, 1819 Yonge Street, Toronto, Ontario M4S 1X9, or the Advertising Standards Council, 1240 Bay Street, Suite 302, Toronto, Ontario, M5R 2A7.

PUBLISHED BY
CANADIAN ADVERTISING ADVISORY BOARD

October, 1974

BACKGROUND

This Code has been developed by the Canadian Advertising Advisory Board, in co-operation with The Proprietary Association of Canada and appropriate government departments, to complement the Canadian Code of Advertising Standards and the Broadcast Code for Advertising to Children.

The provisions herein recognize the growing concern for the manner in which the advertising of non-prescription medicines is generally perceived. These provisions are to be adhered to for intent as well as in the specific stipulations.

CONFORMITY WITH LEGISLATION

This Code supplements Federal and Provincial regulations regarding the advertising of non-prescription medicines, as well as the guidelines issued by the Health Protection Branch of the Department of National Health and Welfare.* All broadcast advertising for such products will continue to require review by the Health Protection Branch through the Canadian Radio-Television Commission before being accepted for broadcast scheduling by stations.

DEFINITIONS

For the purpose of this Code, the following definitions shall apply:

1. Non-prescription medicine means proprietary medicines and over-the-counter drug products which are advertised directly to the consumer.

2. Advertising is any representation by any means whatever for the purpose of promoting the sale or disposal of any non-prescription medicine. This excludes the inner and outer labels which are specifically reviewed and approved for compliance with the Federal drug regulations.

*The latest issue of this "Guide for Drug Advertisers" (dated July, 1973) is available to any member of the public without cost from the Health Protection Branch of the Department of National Health and Welfare, Ottawa, Ontario.

CODE CLAUSES

1. **Safety and Protection of Children**

   (a) Advertisers of non-prescription medicines must exercise particular care to avoid encouraging unsafe practices, particularly among children.

   (b) Advertising for non-prescription medicines must not be placed on programmes or in any publications specifically directed to young children.

   (c) A non-prescription medicine must not be advertised in a manner likely to lead to its use by young children without parental supervision.

   (d) When children are included in advertising for non-prescription medicines intended primarily for adult use, they must not commend the product or handle the product.

2. **Unwarranted Expectations**

   (a) Advertisements must not arouse unwarranted expectations of product effectiveness, through the use of text, illustrations, or sound effects. Individual words should be carefully selected in terms both of their dictionary definitions and their general use by the public.

   (b) Product advertising must not mislead, directly or by implication, or through emphasis, comparisons or contrasts, with regard to usage or immediacy of relief.

   (c) Non-prescription medicines which are formulated for the relief of symptoms must not be advertised in such a manner as to claim or imply a cure.

   (d) Advertising must not misrepresent, or be likely to mislead the consumer as to, the contents, package size, price, or appearance of the product.

3. **Claim Substantiation**

   (a) Advertising must not make claims for product effectiveness without available supporting data, such as clinical or other scientific evidence, responsible medical opinion, or experience through long use. The advertiser must, on request from the enforcement bodies, provide evidence supporting such claims.

   (b) Consumer or other studies referred to in the advertising of a non-prescription medicine must represent professionally performed and interpreted research, with results or conclusions presented honestly and accurately.

4. **Improper, Irresponsible or Excessive Use**

   (a) Products must not be advertised in a manner which is likely to suggest or imply their use for conditions other than those indicated on the product label.

   (b) Advertising must not encourage nor imply a less than responsible attitude toward the use of medicines.

   (c) Advertising must not depict consumers relying on medicines as a simplistic solution to emotional or mood problems.

5. **Products for Internal Use**

   (a) Advertising must not include scenes or illustrations of products being ingested (that is, being taken orally).

   (b) Advertising for products which are ingested must include a reference to follow label directions.

   (c) Advertising for ingested products must not include contest promotions, competitions, or offer prizes.

6. **Persistent Symptons**

   "Directions for Use" labelling for appropriate products must include a statement such as "Consult a physician if symptoms persist."

7. **Sedatives and Stimulants**

   Advertising for products designed to calm, sedate, or stimulate should refer to the temporary symptomatic relief provided and must include a recommendation that label directions be followed.

8. **Testimonials**

(a) Testimonials used in advertising must be obtained only from actual users of the product and be published only with their authorization.

(b) Testimonials must be confined to statements of actual experience with the product and not include statements which exceed reasonable expectations of product results.

9. **Good Taste**

Advertisers should make every effort to insure that advertising is free of statements, illustrations, or implications which are offensive to good taste.

10. **New, Improved**

(a) Advertising must not use the word "new" to describe a product, unless it is a new brand or one that has had a qualitative change in one or more active ingredients. The use of "new" must be limited to a period of time, usually not to exceed one year.

(b) Advertising must not use the word "improved" unless the change in an existing product is one beneficial to the consumer. The use of "improved" must be limited to a period of time, usually not to exceed one year.

CODE ADMINISTRATION

11. **Enforcement and Jurisdiction**

The enforcement bodies for this Code will be The Advertising Standards Council (English) and Le Conseil des Normes de la Publicite (French) or a committee of these. The Council/Conseil is the self-regulatory arm established by the Canadian Advertising Advisory Board.

12. **Pre-clearance and Consultation**

Advertisers may submit layouts, texts or storyboards to the Council/Conseil for pre-clearance on a consultative basis. This may be particularly helpful with television advertising when the time and expense involved in creating the finished commercial is considerable. The pre-clearance fee is $50.00 for advertisers that are not regular supporters of the Board, $25.00 for advertisers that are regular supporters.

13. **Inquiries and Complaints**

(a) Inquiries and comments about the Code and complaints regarding alleged violations should be made to The Advertising Standards Council, 1240 Bay Street, Suite 302, Toronto, Ontario M5R 2A7 or to Le Conseil des Normes de la Publicite, Case Postale 35, Succ. Mont-Royal, Montreal 304, Quebec.

(b) Any member of the public may submit a complaint to the Council/Conseil, but telephone complaints will not be acted upon unless confirmed in writing.

14. **Enforcement Procedure**

If the Council/Conseil finds that an advertisement is in the breach of the Code, the advertiser will be notified and asked to amend or withdraw the message. Should such corrective action not be taken, the appropriate media will be notified that the advertising is not acceptable.

15. **Effective Date**

This Code applies to all advertising for non-prescription medicines produced after January 1, 1975. Advertising produced prior to that period that does not conform to the Code, will, unless deemed dangerous or actually deceptive, be permitted to run until September 1, 1975.

The following organizations agree to abide by the Code of Consumer Advertising Practices for Non-Prescription Medicines:

Association of Canadian Advertisers, Inc.
Canadian Association of Broadcasters
CTV Television Network
Institute of Canadian Advertising
Magazine Association of Canada
Outdoor Advertising Association of Canada

The code has also been endorsed in principle by the Canadian Broadcasting Corporation.