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CANADA. PARLIAMENT. HOUSE OF COMMONS. SPECIAL COMMITTEE ON DRUG COSTS AND PRICES. 1966/67

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HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966-67

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 27

THURSDAY, JANUARY 12, 1967

WITNESSES:

Mr. J. M. Cook, of Toronto, President of Micro Chemicals Limited; Mr. William S. Miller, of Toronto, President of Paul Maney Laboratories Canada Limited, and the Hon. Joseph T. Thorson, P.C., of Ottawa, Legal Counsel.

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

25514—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

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

and

Mr. Brand,
Mr. Clancy,
Mr. Côté (*Dorchester*),
Mr. Enns,
Mr. Forrestall,
Mr. Goyer,
Mr. Howe (*Hamilton South*),
Mr. Howe (*Wellington-Huron*),
Mr. Hymmen,
Mr. Isabelle,
Mr. Johnston,
Mr. MacDonald (*Prince*),
Mr. Mackasey,
Mr. MacLean (*Queens*),
Mr. O'Keefe,
Mr. Orlikow,
Mrs. Rideout,
Mr. Roxburgh,
Mr. Rynard,
Mr. Tardif,
Mr. Whelan,
Mr. Yanakis—24.

(Quorum 10)

Gabrielle Savard,
Clerk of the Committee.

MINUTES OF PROCEEDINGS

THURSDAY, January 12, 1967.
(37)

The Special Committee on Drug Costs and Prices met this day at 9.50 a.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout, and Messrs. Brand, Forrestall, Harley, Howe (*Wellington-Huron*), MacDonald (*Prince*), Mackasey, MacLean (*Queens*), O'Keefe, Orlikow, Tardif (11).

In attendance: Mr. J. M. Cook, of Toronto, President of Micro Chemicals Limited; Mr. William S. Miller, of Toronto, President of Paul Maney Laboratories Canada Limited, and the Hon. Joseph T. Thorson, P.C., of Ottawa, Legal Counsel.

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

The Chairman introduced the witnesses.

The Committee proceeded to the consideration of the submission of Micro Chemicals Limited, Gryphon Laboratories Limited, and Paul Maney Laboratories Canada Limited.

Mr. Cook made a short opening statement and was questioned. He was assisted by Mr. Thorson.

Agreed,—That the above submission be printed as part of today's proceedings (*See Appendix A*).

On motion of Mr. Brand,

Resolved,—That the letter of the Vice-President and General Manager of Smith Kline & French Inter-American Corporation, copies of which were distributed to the Members of the Committee on December 13, be printed as an appendix to the proceedings (*See Appendix B*).

Mr. Laidlaw also asked questions.

On behalf of the Members, the Chairman thanked the witnesses for their appearance before the Committee.

At 12.55 p.m. the Committee adjourned to 9.30 a.m., Tuesday, January 17, 1967.

Gabrielle Savard,
Clerk of the Committee.

25514—1½

EVIDENCE

(Recorded by Electronic Apparatus)

THURSDAY, January 12, 1967.

The CHAIRMAN: Lady and gentlemen, I think we might start meeting. We have with us this morning representatives of Micro Chemicals Limited, Gryphon Laboratories and Paul Maney Laboratories Canada Limited. I would like to call on Mr. Cook, who is the president of Micro Chemicals in Toronto, to make as short statement.

Mr. J. M. COOK (*President, Micro Chemicals Limited*): Mr. Chairman, Mrs. Rideout and gentlemen, we would like to extend our thanks to the Committee for asking us to attend and present our brief.

We have put our submission in four parts, as indicated on page 2 of the brief. Basically, we have tried to give the Committee the benefit of our experience in connection with section 41(3) of the Patent Act.

I have with me this morning Mr. J. T. Thorson, who has been our solicitor in many of our applications for compulsory licences. Also present is Mr. W. S. Miller, who is the president of Paul Maney Laboratories.

If there are any specific questions relating to section 41(3) of the Patent Act, Mr. Thorson will probably be able to help this Committee.

This is all I have to say by way of introduction and I shall do my best to answer any questions that are put to me by the members. I again thank this Committee for the opportunity of appearing. Thank you very much.

The CHAIRMAN: Lady and gentlemen, the meeting is open for questioning. Mr. O'Keefe.

Mr. O'KEEFE: Just one question, Mr. Chariman.

At the bottom of page 23 and the top of page 24 you state:

> They then put the prices of the "winners" at all that the traffic will stand and continue to charge such prices.

Would you give us one or two examples of this?

Mr. COOK: Yes. Actually, trifluoperazine is a splendid example of this, in that these prices that have been charged over the last few years have never come down. Chlorpromazine is another example of this. We obtained a licence in 1962. Until that time there had never been a price decrease, notwithstanding the fact that the usage of the drug had increased year by year the popularity of the drug had increased. There was no relief because of this increase.

Mr. O'KEEFE: And in your opinion there should have been a price decrease?

Mr. COOK: Yes. I would say under normal circumstances, if you have a competitive situation, as volume increases and competition increases you normally get a price decrease.

Mr. O'KEEFE: Could you give me any ratio of how that price should decrease with increased use?

Mr. COOK: Yes. Actually in our brief we have set out the example of chlorpromazine and I think if you will turn to page 34 of the brief you will find since 1960, when we made our application for chlorpromazine and we obtained the licence in 1962, that we are now supplying the trade with the various strengths as pointed out here; 25 milligram, 40 per cent of what they were paying in 1960; 48 per cent of what they were paying for the 50 milligram and 38 per cent of what they were paying for the 100 milligram. This is at the level at which the individual would obtain the benefit of the medicine. In the case of large hospitals—

Mr. O'KEEFE: Excuse me. You would have no personal knowledge whether this benefit of a price decrease was passed along to the customer?

Mr. COOK: No. We just make it available. We make it available at the manufacturing level.

Mr. O'KEEFE: You just assume, then, that it is passed along to the consumer. In the normal course of events, of course, it would be and it should be.

Mr. COOK: Oh, yes.

Mr. O'KEEFE: Do you know if it has?

Mr. COOK: I beg your pardon?

Mr. O'KEEFE: Do you know if it has been passed along to the consumer?

Mr. COOK: We find that doctors have indicated to our representatives, and even indicated to myself, that the patient has found monetary relief.

Mr. O'KEEFE: From the druggist?

Mr. COOK: Yes.

Mr. O'KEEFE: Thank you, Mr. Chairman. I will pass.

Mr. MACLEAN (*Queens*): On page 31 of the brief there is a statement on which I would like some clarification. You say, starting at the bottom of page 30:

> "consistent with giving *to the inventor* due reward for the *research leading to the invention.*" The meaning of this condition was the subject of controversy until the decision in the case referred to. The controversy was settled by Mr. Justice Abbott. He made it clear that the reward referred to meant reward to "the inventor—not the patentee—".

Are you contending that a patentee has no rights with regard to royalties, for example, if the patentee is not the inventor?

Mr. COOK: If you would allow me, I would like to pass this along to Mr. Thorson, who is more familiar with this part of the proceedings.

Mr. J. T. THORSON (*Legal adviser, Micro Chemicals Limited, Toronto*): It seems to me that this is the clear meaning of what Mr. Justice Abbott said. Basically it is on this premise, that the section says that the Commissioner must have regard to the desirability of making the drug available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention. Most of these companies in Canada are

subsidiaries and they are not the inventor of the invention and they have not contributed any research leading to the invention. This has been clearly stated by Mr. Justice Abbott and he puts the position of the Supreme Court just as I have put it in the brief, that in such a case the owner of the Canadian patent is not entitled to any reward. That is really what the Supreme Court has decided.

Mr. McLEAN (*Queens*): Well, I am not a lawyer, which is probably obvious, but this would seem to me to be a—

Mr. THORSON: Oh, when this decision came out it really threw a bombshell into the camp. Mr. Justice Abbott was quite clear. When he came to this statement he underlined the words "the inventor" and then wrote "—not the patentee—" and made it quite clear that he gave this literal interpretation of section 41(3). Of course, this was the first real clarification of that part of the section.

Mr. MACLEAN (*Queens*): This would mean, I take it, that there is no point any more in a company acquiring a patent for a drug in Canada from a subsidiary, for example, or another company acquiring the patent rights of a drug so that—

Mr. THORSON: I do not think it follows, because there was a statement made to the effect that even if you had licences, the person who was the first originator of the drug would command at least 60 per cent of the market. He is not going to have all of the market, but the patentee still has a very considerable advantage. The licencee, in a sense, is put on the same footing as the patentee but everybody else is excluded from manufacturing and selling the drug, that is, everybody who does not have a licence. It is nearly tantamount, of course, to giving the right person a licence almost as a matter of right. It really has almost come down to that because the amount of royalty that is computed is a comparatively small amount.

Mr. MACLEAN (*Queens*): What is the position, if this be so, of the National Research Council, for example, if it is not the inventor of the process or the patentable idea? It may be invented by one of the employees of the National Research Council but, as I understand the law, as he is an employee the N.R.C. would have the patent rights on it if a patent was taken out.

Mr. THORSON: I do not know what the situation would be in the case of a patent owned by the Crown. I do not know what that situation would be because that particular situation has not come before the Supreme Court. The Crown might be in a preferred position under those circumstances. However, so far as any other patentee is concerned, that patentee falls under the language used by Mr. Justice Abbott.

Mr. MACLEAN (*Queens*): Therefore, if you happen to have the situation where—although it would be unlikely—a chemist happened to invent a new drug and was not in a position to process it, to market it, and so forth, but he had it patented, how could he then get reasonable reimbursement for his patent if he were precluded—I take it from this—from selling his patent to an appropriate company?

Mr. THORSON: He would probably get his compensation from the purchaser of the patent, based to some extent on the fact that he was the inventor. Then, of

course, a person who applied for a licence under that situation would not be in the same advantageous position as a present applicant.

Mr. MacLEAN (*Queens*): Perhaps I did not put my question very clearly. What I have in mind is what incentive would there be for a company to buy a patent owned by an individual?

Mr. THORSON: Not a great deal, not to buy the patent, because they would have to buy it with the knowldge that someone would come in as an applicant for a licence and get the benefit of the decision of the Supreme Court as to the meaning of the section.

Mr. MacLEAN (*Queens*): Well, it would seem to me that this waters down very considerably the advantages of patents.

Mr. THORSON: Oh, tremendously, tremendously. Of course it does, and that seems to have been the basic policy underlying section 41(3) which, in a sense, makes an exception to the whole monopolistic scheme of patents. Yes, definitely it does.

Mr. MacLEAN (*Queens*): It would seem to me, as a result of this, then, that the whole concept of patents and the stimulation of research, because of the patent law, is reduced.

Mr. THORSON: Mr. Cook suggests that he might answer that.

Mr. COOK: I think the Patent Act, first of all, gives a monopoly to the patent holder. Now, this patent holder, I assume, has come to some reasonable value which he has placed on it with the inventor, so that now we can say that the inventor has been suitably compensated or he should be, even if he has to look after his own affairs. However, our brief points out that if this product is marketed under the patent and a reasonable return is obtained and that the prices are not excessive and are not maintained at an excessive rate, that the patentee will not have any fear of a compulsory licence because a company such as our company is in business for exactly the same reason he is in business. My object to be a successful businessman or else lose my job, is to manufacture pharmaceutical products and make a profit. If the patentee makes a reasonable profit and does not leave the incentive open for other people to also make a profit on what he is doing, then if he conducts himself in this manner he will enjoy the benefits of his patent rights. Our position is that he should not enjoy the benefits of his patent rights to the detriment of the Canadian public.

Mr. MacLEAN (*Queens*): Yes, but it would seem to me that if a patentee has no advantages which a licensee does not have, there is no point in his purchasing a patent.

Mr. COOK: I think there is. The fact of the matter still is that Rhone Poulenc, after all these years, does a very nice business in chlorpromazine at very respectable prices and no doubt is making a very nice profit. I cannot see your reasoning in this matter because if he makes a normal profit, and we must remember that we are not talking about an industry that is in Canada per se, we are talking about roughly 3 per cent of a world-wide industry in which the executives of the Canadian corporations of these subsidiaries, even if they wanted to, can exert very little pressure on their parents.

Mr. MacLEAN (*Queens*): You are saying in effect, if I follow you correctly, that the royalties paid by a licensee are equivalent to any benefits that a patentee might have.

Mr. COOK: Could you put that a little more clearly? I just do not get the meaning of that question.

Mr. MacLEAN (*Queens*): Well, as I see it, there is no incentive to anyone to try to acquire a patent rather than a licence.

Mr. COOK: I would have to disagree with you. I can see untold benefits to acquiring patents. The proof of this is that if a man gets the edge, he gets the prestige. He sets his initial prices. It is just a matter of economics. You just cannot say that he will not maintain his position. I believe that Eli Lilly had patents years ago on some of the barbiturates. This company is a successful company. They sell a lot of barbiturates and they sell them at prices which are probably higher than you would pay any place else. Every pharmaceutical company has barbiturates, and yet they are in business and they make a good profit. They are still reaping the benefit of this original patent, which was the first on the market. They are still reaping the benefit and the patent no longer applies.

Mr. MacLEAN (*Queens*): I would assume that the benefits they are reaping are due to their successful marketing and the establishement of their brand name in the market generally, not due to any legal protection they have. That is the point I am trying to make.

Mr. COOK: I think the legal protection gave them the initial springboard, but no amount of legal protection is going to save you from bad management. If these companies are highly successful at the marketing level, then this is what they should be.

Mr. MacLEAN (*Queens*): I think I will leave it there at the moment and pass to someone else.

Mr. MACKASEY: Mr. Cook, I read your brief with a great deal of interest and I think it is very comprehensive and, for a layman like myself, very instructional as to the different steps and procedures which are taken to arrive at the finished product. I was a little disappointed that, unlike most briefs that have been submitted—and I was under the impression that this was supposed to be included, Mr. Chairman—there was absolutely no financial story included pertaining to your company. There are no balance sheets or anything of this nature in the brief.

Mr. COOK: Well, first of all, while this is a cost and price committee, we were asked primarily to come here on another occasion because of certain statements that were made against our company. A wealth of figures and facts and percentages are available now but it would just be too repetitive. It was our opinion that we had a specialized point to add to this Committee on matters such as marketing costs to everybody of between 20 and 30 per cent, or something like that. There is nothing new.

Mr. MACKASEY: Are you between 20 and 30 per cent?

Mr. COOK: Yes, we are about 20 per cent on marketing. We thought that we could contribute to this Committee something a little different, something very

specialized and something that we had some facts on that were different from the facts that you have been normally looking at, and that was the operation of section 41(3) of the Patent Act.

Mr. MACKASEY: I appreciate that because you have put the other side of the picture very clearly and concisely. I think the average person does not understand patent laws too well and it is pretty hard to match wits, Mr. Chairman, with as eminent a Canadian as Mr. Justice Thorson. If anybody should be familiar with the rulings of the Supreme Court, I suppose it is learned counsel. Nevertheless, there are questions I must ask even if I am called out of order by the judge.

I gathered from reading your brief that you have a very efficient operation. In comparing it with Smith Kline & French's submission—I suppose some of the statements in their brief led to your appearance here today—I was particularly interested in the detailman's phase of the whole operation. I noticed last night in reviewing their brief that they employ about 300 people in their operation—this was also mentioned in the Committee—whereas you run your efficient organization on less than 30. Am I correct in that assumption?

Mr. COOK: Between 30 and 40, I think. Somewhere in here there is a heading for personnel. Yes, between 30 and 40 people.

Mr. MACKASEY: Well, do you have some secret that the rest of the industry does not have that you can run as large a concern as you have and still manage to do that with 30 people, including your Ph.D's and chemists and engineers?

Mr. COOK: The whole thing is relative to the size of our business, and although we would like to have the same volume and the same organization as Smith Kline & French, unfortunately we do not. I think on a comparative basis you might say that we have sufficient personnel. Our organization and our sales capacity is proportionate to them.

Mr. MACKASEY: Proportionate to their volume of sales?

Mr. COOK: I would think so.

Mr. MACKASEY: Because without a balance sheet this is something I cannot determine. This is why I would have appreciated one.

Mr. COOK: Our volume is around the half million dollar mark, so if you take that into consideration—

Mr. MACKASEY: That is a fair proportion.

Mr. COOK: In that way we are probably a little over-staffed because I do believe their sales are a little better than $3 million.

Mr. MACKASEY: With such a tightly knit operation are you in a position to properly service all of Canada with your products?

Mr. COOK: Yes, we do. We are continually expanding our sales effort. The problem has been that you must make a choice and this choice is normally one of business foundations. We have a limited amount of capital. We had a certain amount of earnings that were coming back to be worked into the business. We had the choice of either momentarily halting our sales expansion—which takes money—or putting this money to work at the manufacturing, technical and chemical end of our business. We made this decision six years ago. Our sales

organization has been relatively static. Mind you, we have always been creative in the sales field by getting distributors to handle products instead of putting our own men in the field. We have been essentially concentrating on putting the foundation on the house, because you cannot put the roof on before you do that.

Mr. MACKASEY: You have outlined the very logical growth steps that your particular company must take; you must creep before you walk and so on. If your marketing is between 20 and 30 per cent, which seems to have been the figure that most of the big P.M.A.C. members have quoted in their balance sheets, why is there the tremendous spread, according to your statement, between their product and your product?

Mr. COOK: I would say that the secret to this probably lies with them, not with us. We have no idea of their inter-company charges. Well, we have some idea—as I think is mentioned in the brief here—but it is only to the extent that it is given to us or obtained by us in the course of hearings such as this or through the patent office proceedings. It would seem to us that there are relatively high amounts of money being vaguely accounted for. I am not saying that they should not be handled this way. A man should be able to handle his money any way he wishes. After all, it is a free country. If we are able, and we are proving the point, I believe, year after year, to do what we believe is an efficient job—not in comparison with them particularly—and sell the product for less, then there must be something on their side of the fence to be shown for the difference.

Mr. MACKASEY: I come back to marketing because one of the points emphasized contniuously, and perhaps with a certain amount of validity, against the brand names is their emphasis on marketing—slick promotional pieces, high pressure detailmen—which are all grouped in this 20 to 30 per cent marketing cost. From reading your brief I infer that you do not use this method of pushing your product; you are not top heavy in detail men and slick promotion. What brings your marketing quite so high, why the comparable?

Mr. COOK: Our marketing is high because, from an economic point of view, there are certain costs which are fixed costs. There are certain costs which are variable costs and there are also, I do believe, certain costs which are semi-variable. Our sales are a fraction of one of these large companies. However, there are certain basic things that we must have whether we make a dollar's worth of sales or a million dollars' worth of sales. I would hope to see my sales go up and I would try to make it the policy of my organization to see that percentage come down.

Mr. MACKASEY: Because the fixed would grow and the variables, of course, would be just nominal?

Mr. COOK: Yes, I would think so.

Mr. MACKASEY: I think you have made a very valid point to someone interested in economics. In other words, once you get up to maybe a million dollars worth of sales and because of your fixed expenses in the marketing end you presume that you will be able to reduce this 20 or 30 per cent to a lower level. Are you in favour of the recommendation of the Hall Commission Report that this particular area be limited to 15 per cent?

Mr. COOK: No, I am not.

Mr. MACKASEY: Would you elaborate?

Mr. COOK: I believe that basically everyone has a right to run his business as he sees fit and I do not think we should pick on the drug industry and say, "You are different from somebody running a corner grocery store". I think to a certain degree my costs will come down in competition. If I can operate and get larger and larger in this business, then the man who has a 40 per cent marketing cost is going to be looking at a red number at the bottom of his balance sheet and he is not going to like this. He is going to have to do something. This back and forth assessment in open competition will ultimately give you the lowest possible price available to the Canadian public. Our basic system—our basic philosophy in this country—should handle this very nicely without any undue strain put on the industry.

Mr. MACKASEY: Thank you very much. I have only a few more questions for the first round, at least. I will skip to page 25, if I may. I think you mention in subparagraph (b) of Section (1) an Italian firm as an example of the fact that trifluoperazine can be manufactured for $270 a kilogram, as compared to the $460 mentioned in the first paragraph. In section (c) you point out that your own record, in comparison to the Italian firm, is not the happiest in the world.

Mr. COOK: This section, now that I look at it, is not as explanatory as it should be. I believe this was meant to mean in packaged form it would be $500, because our raw material cost is roughly in that $270 bracket. This should have read—taking section (a)—$460 for putting chlordiazepoxide in usable dosage form. I must apologize that this $500 should have been in that same category.

Mr. MACKASEY: It only proves that we read your brief; otherwise we would not have picked it up.

In section (b) you do not state whether the $270 per kilogram of the Italian firm is in usable dosage form.

Mr. COOK: No, that is in bulk.

Mr. MACKASEY: It is in bulk?

Mr. COOK: In most cases imports would be in bulk.

Mr. MACKASEY: It is fair to introduce a comparison between the $460 of Hoffmann-La Roche, for instance, and the $270 of the Italian firm when they are in different forms?

Mr. COOK: It would not be fair to make a comparison because it is two different products as well.

Mr. MACKASEY: But you have made it?

Mr. COOK: We have only made it to the extent that the products are similar. After all, some people are talking in terms of thousands of dollars and we are talking in terms of between $100 and $500.

Mr. MACKASEY: But in actuality, then, that page would be just as well left out because it is ambiguous and not quite—I should not say fair—but it can be confusing. I think the judge would be happy to get off with that.

In one section you are quoting a finished product and in another one a raw material. You do not state this and yet you are comparing the same prices.

Mr. THORSON: It might have been better to make that qualification which you suggest. One was in its raw state and the other was in dosage form.

Mr. MACKASEY: That is fair. Thank you.

On page 19—and I apologize for jumping around—you have this letter which I am happy to see—from Dr. Chapman to the Commissioner of Patents indicating a degree of co-operation between the Food and Drug Directorate and the Patent Office before a compulsory licence, or something, is granted. Is it not also fair—and this is a question—to point out that this letter does not necessarily guarantee the end product, it guarantees the cleanliness of the premises, am I correct in that?

Mr. COOK: No. I think you can go back to the first brief. I do not have a copy of it here. Dr. Chapman made a remark and I think the essence of it was that the dependability, the reliability and the sincerity of the people involved in an operation is just as important as their premises.

Mr. MACKASEY: I agree with this. However, I am just looking at the letter coldly.

Mr. COOK: I would think that he would take this into consideration before he would issue a licence.

Mr. MACKASEY: Do you think that in the future letters between the Patent Office and the Food and Drug Directorate could be clearer in this respect and that over Dr. Chapman's signature should include an evaluation of all these other qualities that you have just stated?

Mr. COOK: You could enumerate them, yes, but this would be a matter for Dr. Chapman. Perhaps you could bring that up when he appears.

Mr. MACKASEY: Mr. Chairman, I have one final question at this time. It deals with the Hilliard Committee Report. Again, I appreciate your endorsation of Section 1, I think, of the Hilliard Report, which emphasizes this co-operation between the Patent Office and the Food and Drug Directorate. Do you have any comments on the Hilliard Report's section on new drug status or new drug definition?

Mr. COOK: The definition of a new drug, in my opinion is a very complicated one. My observation is that the Food and Drug Directorate is very, very careful in evaluating what is to be a new drug and how long it is to be considered a new drug. They have a tremendous staff available to them which is highly qualified and this staff is charged with coming up with this opinion and it would be beyond our company to contest this.

Mr. MACKASEY: You have not quite answered the question. Would you accept the Hilliard report in its entirety?

Mr. COOK: I think we would, yes.

Mr. MACKASEY: Fine, I appreciate that. I am concerned about an old drug that has conceivably been on the market for 12 or 15 years and then suddenly it is found that this drug, perhaps in conjunction with something that is not on the market—it could be a new type of soft drink or a new type of food product —would have a very bad side effect reaction which, of course, would concern the Food and Drug Directorate. It seems to me that our laws are such that the Food

and Drug Directorate would find it very difficult, even under those circumstances, to reclassify that old drug as a new drug. Do you agree with that or am I wrong?

Mr. COOK: I do not think there would be any hesitation on the part of the Food and Drug Directorate. They are charged with the public safety and if this hypothetical case were to come true I think you would find that they would act very swiftly.

Mr. MACKASEY: In the case of trifluoperazine, which you are now manufacturing and which Smith, Kline & French are manufacturing, I imagine, under the name stalazine, let us suppose in a few years time we found some bad side effects from stelazine or from this other particular product. As one of the manufacturers would you then be able to meet all the requirements that are placed on manufacturers of new drugs such as the reports?

Mr. COOK: Yes, we would.

Mr. MACKASEY: Thank you, Mr. Chairman.

Mr. ORLIKOW: Mr. Chairman, like the last speaker I am interested in the financial operations and in the profits of all the drug companies. As I mentioned to you before the meeting started, it is my intention at the next meeting to present a motion which, if passed, would require all the companies which have testified and all the companies which belong to the various pharmaceutical manufacturing associations to submit the same kind of financial records to this Committee as the companies which appeared before the consumers' committee submitted to that committee, that is, information with regard to the volume of business they do, the capital which they have invested, the gross profit, the net profit they make and the payments in royalties or fees they make to their parent company in the United States or anywhere else. That kind of information I think, Mr. Chairman, is of the utmost importance if the people of Canada, through this Committee, are to get to know whether they are paying too much or a fair price for the very important prescriptions which they have to buy.

Mr. Chairman, these companies are here to a large extent because of the very sharp attacks on their reliability and on their reputation which were made by one of their competitors, Smith, Kline and French, and I think that rather than ask any specific questions right now I would like one of the representatives of this company to summarize briefly—because some of us have not read this brief in detail and it may not be recorded by the press—the last part of their written submission in which they answer the charges made by Smith, Kline and French about the products which they sell.

Mr. COOK: Mr. Orlikow, we do not agree with the findings of Smith, Kline and French. It is our opinion that the information submitted is misleading and false. We have very good control on our products. Our company, from the very outset of the establishment of 74 GP 1, has been a qualified company. If you could check the records, and they are not available to me, I think you would find we were one of the first companies to be so approved. We have manufactured this product very, very carefully because we knew from the very outset that our manufacturing would have to be up to the highest standards and this is where we could be attacked. We have shown a comparative analysis on page 45 of our brief, which is straight statistical data. However, I would like to take a minute in

connection with the calibration of this product. There has been a movement afoot, not only in this Committee but at the competitive level, to indicate that our product is not calibrated on the same basis as SKF, that it is a different product than SKF and that ours normally would give 16 per cent less potency, along with some very undesirable variations.

On December 12, I believe, some information was given in a rebuttal to Mr. Gilbert's brief concerning clarification of the opinion of SKF on the calibration of their product. We contend that we have exactly the same drug in our product in exactly the same potencies and that our calibration is, in effect, the same. In addition to this if you will just take a look at the labels on page 46 A and 46 B you will see that Smith, Kline and French indicate that their tablets are trifluoperazine tablets B.P. We also indicate that our tablets are trifluoperazine tablets B.P. The B.P. specifies that each tablet shall contain trifluoperazine hydrochloride. Mr. Bethel of Smith, Kline and French admitted in his most recent statement in December that his product contains trifluoperazine hydrochloride. Our product states clearly on the label, and we do put in, trifluoperazine hydrochloride, B.P. So now we have come to the situation where we have two products, and I think Smith, Kline and French will now agree that they have the hydrochloride salt in it, as we have the hydrochloride salt.

Now, let us come to how much hydrochloride salt we have in this product and how much base. Smith, Kline and French state that they calibrate the strength of their product on the base. This is a logical calibration. It is a calibration that has been accepted on the market. The British Pharmacopoeia states that the calibration should be in terms of the hydrochloride salt. There is a way around or there is a meeting between these two. The Food and Drug Directorate's regulation C.01.003 states:

> Except as provided in C.01.008 no person shall sell a drug that is not labelled as required by these regulations.

The regulations, I think—if we can give a fair interpretation of them—state that when there is an official monograph in a pharmacopoeia that is recognized in Canada this monograph shall be used. When this drug became an official monograph in the B.P., Smith, Kline and French had to change their label to trifluoperazine tablets, B.P., because the regulations required it. However, they were interested in maintaining the product that they had been selling, which is a very sensible conclusion. They were interested in maintaining the same therapeutic effect. The B.P. does not state how much of the product should be in the tablet or other dosage form; it just states that everyone should know how much of the hydrochloride salt should be in there. Therefore, section (b) (v) of C.01.004 of the Food and Drug Regulations requires the label of a drug to carry the quantitative list of the medicinal ingredients contained therein by their proper names—and this is the point, their proper names—or if they have no proper names, by their common names.

According to our regulations this product now has a proper name. Therefore if we have been selling a product that contains one milligram trifluoperazine base which, after all, is the active portion, and we are forced to label our product in terms of the hydrochloride salt, then we must comply with all the regulations and state thereon the amount of the hydrochloride salt. We have done this on our labels. Our label is summarized on page 44 and it also appears on page 46, but the summary is essentially the same, and to maintain one milligram of the base

we have to put in 1.18 milligrams of the hydrochloride salt. There is no regulation which says that we cannot do this. We can make a 1.75 milligram or a 2.04 milligram, there is no stipulation. It just stipulates that whoever reads the label should be able to interpret it in some common denominator. The common denominator is trifluoperazine hydrochloride and not trifluoperazine base.

Smith, Kline and French have done exactly the same thing. They have put in their tablets 1.18 milligrams, or 1 milligram, of the hydrochloride salt to maintain their original product of 1 milligram of the base. Unfortunately their label does not comply exactly with this section of the Food and Drug Act, in my opinion, because they state on their label:

Each tablet contains trifluoperazine

Now, trifluoperazine is the base and the regulations state that the monograph is trifluoperazine hydrochloride. But they qualify this by saying at the bottom:

. . . as the dihydrochloride.

Now, they admit that they put the dihydrochloride in, and to get one milligram of the base you must put in 1.18 milligrams of the dihydrochloride. Therefore what they have been trying to prove different, is beyond my comprehension. In my opinion it is a matter of confusion.

Mr. ORLIKOW: What brief comments would you care to make on the so-called analysis of your product which SKF said was made for them by an independent company which showed that there were great variations?

Mr. COOK: Could you give me the first part of your question again, please?

Mr. ORLIKOW: At one point in their testimony SKF said that they had had your products tested by an independent company and that they varied greatly in potency and the implication was there—I do not have their testimony in front of me—that your products were not up to standard. What comments do you have to make on that?

Mr. COOK: Their statements, if they are read carefully, would certainly leave that impression, but it is hard to say between ourselves and Mr. Gilbert whose tablets finally got the independent assay. I do not think it is quite definite just how many independent assays were done and on whose products they were done. In my opinion, from looking at the last brief of SKF, they were done on Gilbert's products, as far as independent assays are concerned, not on ours.

Mr. ORLIKOW: But anyone reading that testimony would get a pretty poor impression of your company?

Mr. COOK: Very definitely.

Mr. ORLIKOW: I think you say in your brief that you are prepared to submit to a testing of your products and SKF's at the same time by any independent organization that does this testing?

Mr. COOK: Yes, we certainly are.

Mr. ORLIKOW: Are you still prepared to do that?

Mr. COOK: By all means.

Mr. ORLIKOW: I would now like to switch to the question of the sale of these prescription items, which are so important to so many people, by you and by

SKF could you give us some idea of the sale breakdown of your products as between, let us say, on the one hand retail drug stores or prescription pharmacies and on the other hand hospitals and so on?

Mr. COOK: Yes. At present, while I do not have any definite figures, I would say possibly 60 per cent of our total trifluoperazine or more is being handled in hospitals, but from a detailing point of view it takes quite a while, to build up this other end of the business. This will change. We have only been effectively on the market since roughly July of last year.

Mr. ORLIKOW: Could you give us examples of the hospitals in the different provinces which have purchased your product?

Mr. COOK: Yes, we have sold to the Manitoba mental institutes, the Ontario Government for their mental institutes, the Winnipeg General Hospital, the Douglas Hospital, formerly the Verdun Protestant Hospital, which is a large mental institute in Montreal.

Mr. MACKASEY: They should have left the name "Verdun" in there. I have never forgiven them.

Mr. ORLIKOW: That is the hospital of which Dr. Lehman is the medical director?

Mr. COOK: That is true.

Mr. ORLIKOW: Dr. Lehman, who was one of the first users of this type of drug on the North Amercan continent?

Mr. COOK: He is considered an authority on phenothiazines, yes.

Mr. ORLIKOW: He has no objection to his hospital using your company's products?

Mr. COOK: No.

Mr. ORLIKOW: I will not put words in your mouth, but I assume therefore that is must be pretty reliable.

Mr. COOK: There are other hospitals as well. There is the Montreal General, the Hotel Dieu and the Royal Victoria in Montreal. These are all major hospitals and we have had no complaints.

Mr. ORLIKOW: Can you tell me approximately the price per thousand which the hospitals are paying for your product?

Mr. COOK: Let me have a look here. It depends a lot on quantity. Our pricing structure is based on quantities and if you would not mind a delay, I think I have in my bag a reasonable price breakdown on this product. Would you excuse me for a moment?

Mr. ORLIKOW: Yes, certainly.

The CHAIRMAN: While Mr. Cook is getting the information, is it agreed that we print today's submission as part of today's proceedings?

Mr. ORLIKOW: I so move.

The CHAIRMAN: The other thing I should mention at this time is that I have asked the accountant of the Committee to study figures released by the Dominion Bureau of Statistics and various taxation statistics to see if he could provide the

Committee with some picture of the profits of the pharmaceutical industry in general as compared to other industries in Canada. I took the liberty of doing that to see if he could come up with a study of this. This would go along with what Mr. Orlikow has been suggesting, but it would be of a general nature rather than a specific one.

Mr. BRAND: While we are on this subject Mr. Chairman, as the name and the labelling of the Gilbert firm has come up in the hearings today quite often and I know that a letter went to you from the vice president of SKF regarding the Gilbert charges about labelling. I wonder if that could be tabled for the perusal of the Committee?

The CHAIRMAN: Was this the letter—

Mr. BRAND: It came to you as Chairman.

The CHAIRMAN: I am sorry, I get so many letters that I do not remember it specifically.

Mr. BRAND: If you just look it up or have your secretary look it up and perhaps table it for our information. I think it is important in view of what we have heard.

The CHAIRMAN: Did we not all get copies of that? Was that not reproduced? Was that not the one that was given to the Committee members the same day that Mr. Gilbert actually testified before us? It did not become part of the record, it was merely given to members of the Committee.

Mr. MACKASEY: That is right. I had asked to have it included in the record at the time but the idea was rejected.

Mr. BRAND: Why?

The CHAIRMAN: The Committee members felt they should read it before it became part of the record and they would decide later on whether it would become part of the record.

Mr. BRAND: I move that it become part of the record. I have not seen it yet.

Mrs. RIDEOUT: You have not read it?

Mr. BRAND: I did not get one.

The CHAIRMAN: If you had been here the day Mr. Gilbert was testifying you would have received a copy.

Mr. BRAND: Yes, but I did not, and there must be a lot of other people who have not received it as well.

The CHAIRMAN: Is it agreed that it become part of today's record?

Some hon. MEMBERS: Agreed.

Mr. COOK: You specifically want to know the difference in our prices as against SKF's?

Mr. ORLIKOW: No, at the moment I want the price which you recently have been charging, let us say, the Crease Douglas Institute in Toronto or the Manitoba hospitals.

Mr. COOK: In the case of the Manitoba government the quantities were extremely large. I hope it is sufficient to indicate this to you on a total price basis

because, for competitive reasons, in our brief we put our price in at roughly $66,000, for what would have cost approximately $130,000.

Mr. ORLIKOW: What did that work out to for 1,000 tablets?

Mr. COOK: Well, they were all different strengths and different quantities for strengths. This is the complicated—

Mr. ORLIKOW: Can you give me the price which you would charge for 1,000 5 milligram tablets?

Mr. COOK: Yes. Let us take a look at a hospital which would normally purchase 25,000 tablets. We would charge $16.95 for 1,000 1 milligram; $21.60 for 1,000 2 milligram; $34.55 for 1,000 5 milligram; $46.10 for 1,000 10 milligram, and these are prices that we have established.

Mr. ORLIKOW: All right. Have you got any information about the comparable quotations that Smith Kline & French have made?

Mr. COOK: Yes, to my knowledge they would charge $21.20, $27.00, $43.20 and $57.60.

Mr. ORLIKOW: How much more would that be on a percentage basis?

Mr. COOK: It is roughly 20 to 30 per cent, or something like that. I have not calculated it.

Mr. ORLIKOW: Mr. Chairman, the reason I am asking these questions is that in Tuesday's *New York Times*—Tuesday of this week—there is a news article which reports that the State Controller of New York wants an investigation of Smith Kline & French because of their consistent overcharging the state for these prescription items which the state buys in the amount of $2.5 million a year. I think it is very important that we know what the institutions are paying, from whom they are buying and what the ordinary citizen who buys individually will have to pay for this kind of prescription.

Mr. Chairman, I think that is all I want to ask. I think it is clear, however, that this company have not only supplied the people of Canada with prescription products which are of high quality, but they have sold them at consistently lower prices than some of the old companies and they have, indeed, forced all these companies to bring their prices down.

Mrs. RIDEOUT: Mr. Chairman and Mr. Cook, I must first explain to you that I am neither a lawyer nor an economist, nor am I knowledgeable about drugs and drug companies, therefore I think I represent quite a large portion of the Canadian population. I am just sorry that there was not an opportunity for me to have had a crash program or an education in innovators and copiers, and all of these various differences of opinion, because I must say that I am having a great deal of trouble associating my thinking in line with your thinking and then again my thinking with the thinking of the larger companies. If I am correct, this Committee's function is to study the cost of drugs and, as you have explained today, you did not have a financial statement in your brief because you were here in defence of your company as a result of statements made by one of the larger drug companies. Am I correct in this?

Mr. COOK: Yes, and I would also point out that we did want to present what we felt was some very good information on section 41 (3).

Mrs. RIDEOUT: Now I want you to understand the questions I am asking are just to clarify my own thinking on these things which you have brought up in your brief which I have read very carefully. If I can refer to page 23, you speak of the excessive costs and prices of patented drugs. What interested me was where you say:

> The great drug companies spend large sums in research, frequently resulting in failures, but occasionally resulting in "winners"...

Then you go on to explain that the prices of the drug companies are excessively high compared to the prices of the drugs that you can produce under a different name, but the same product really. Am I correct in that?

Mr. COOK: Yes, I would say that our brief tends to indicate this, yes.

Mrs. RIDEOUT: I would like to relate my question to an article I read in the paper, I think just during the last week concerning a meeting in Toronto. Dr. Wigle, I believe, said that through research they hoped soon there might be new drugs discovered to cure some types of the cancer. These things are of great interest and concern to me. Do you not feel that these companies which spend all this money on research have to charge the prices they do? How can we obtain the benefit of research if drug companies are not financially able to do the work?

Mr. COOK: I think there is adequate proof that they are more than financially able to do the work. The significant point is that while their cost of research is a very impressive dollar figure, it is not an excessive percentage of their business. I think on the average it is somewhere around 7 per cent—it is less than 10 per cent of their business. Now every industry has to research, because if you are—

Mrs. RIDEOUT: Do you do research; do you have research facilities?

Mr. COOK: Yes we do in a very limited way.

Mrs. RIDEOUT: Can you give me just a rough idea of what your costs would be for research?

Mr. COOK: We have been spending on research and development approximately 12 per cent of our dollar volume.

Mr. MACKASEY: I have a supplementary question. Would not the same caveat apply to your original argument that marketing costs have to be between 20 and 30 per cent because your volume is low, and that the same thing distorts the percentage you have spent on research?

Mr. COOK: No. This to me is a controllable variable. Let us just take a hypothetical question. Let us assume that we have drug company (a) which spends 20 per cent on research and enjoys a tremendous market with a tremendous mark-up. Something happens economically, either their sales decline, or their profits decline, but something happens to them. I have no doubt that back in the board room somebody is going to get the chart out and is going to start saying: "All right, where are we going to cut down." And I am quite sure that they will start cutting down on every angle, just like a government would go through a budget. And I am quite sure that they would control the amount of research to ensure that they get a profit. Because if they do research and come up with consistent losses, then they go out of business, so that you have lost your research anyway.

Mrs. RIDEOUT: But if they come up with a winner?

Mr. COOK: If they come up with a winner, then they can maintain a respectable profit and a respectable operation. My opinion is that there is no yardstick for anybody to say what is respectable, what is a decent profit and what is an excessive cost, because you have nothing to put up against it. Now there is one thing that can be set up against this thing, and that is competition. This is what will be set up against it. If a man spends 40 per cent on distribution and somebody does it for 20 per cent, and competes with him, he will find out that his 40 per cent is too high; but until that point, nobody knows.

Mrs. RIDEOUT: But will he also destroy the ability of the company to continue research for a winner. I am thinking in terms of people today who live in hope of a cure for a disease that right at the moment is incurable.

Mr. COOK: No, I do not think so. Although this has been repeated and repeated, I go back to the combines investigation that we had. There was an economist in there and he said that the proof pointed to the fact that the originator maintains the lion's share of the business, maintains his good profits, notwithstanding.

Mrs. RIDEOUT: We cannot compare because we do not know your profits or your financial statements. It is difficult to know your position related to others. I am not complaining, but I was wondering why—I notice you are not a member of the PMAC.

Mr. COOK: No.

Mrs. RIDEOUT: Would it not be better for you to be associated with this group, or do you feel it would not be?

Mr. COOK: I do not think so.

Mrs. RIDEOUT: You just have no interest in it?

Mr. COOK: We are interested in doing business in an independent way.

Mrs. RIDEOUT: I would gather from your brief that you have been quite successful.

Mr. COOK: We hope that we have been successful in what we have done. I might point out here that our success, as far as we are concerned, is in developing the technical personnel and the basis for a basic chemical industry in the pharmaceutical field today. And with this we hope that our success will take us further.

Mrs. RIDEOUT: But it has allowed you to keep the price of your drugs at a reasonable level and certainly you can offer them at considerably less than the—

Mr. COOK: Yes, but we are motivated. I mean people who run businesses are motivated primarily by economic reasons, and we are motivated to sell our products. This is called competition. I mean this is why I feel that what we are doing is ancillary to the effects that you want, or in conjunction produces the effect that you, in this Committee, want. But we are not doing it to lower drug costs, let us put it that way. You people are interested in lowering drug costs. My interest is in maintaining a corporation or a group, and a profit. But the system that we have outlined here will automatically produce the desirable effect that the Canadian public want. And I think this is all you can ask of an economy.

Mrs. RIDEOUT: I was interested in the history your Micro, Paul Maney and Gryphon Laboratories, am I correct in my pronunciation?

Mr. COOK: Sometimes I wish we would forget about that name because we have every kind of pronunciation. We call it Gryphon.

Mrs. RIDEOUT: Gryphon—sorry. I do not quite know how to ask you this, and I hope I am not asking you something I should not, but who really owns this company? Is it owned by the three people or is it owned by—

Mr. COOK: Yes; there are three major Canadian shareholders.

Mrs. RIDEOUT: And they are all Canadians?

Mr. COOK: Yes.

Mrs. RIDEOUT: Would you say that you have a monopoly on industry across Canada?

Mr. COOK: That we have?

Mrs. RIDEOUT: Yes, that you could keep the other companies with your—

Mr. COOK: Oh, yes, we have a general line of pharmaceuticals, over a hundred different products.

Mrs. RIDEOUT: So there is no competition, then in your particular field.

Mr. COOK: Yes, there is competition in all pharmaceuticals to a great extent, probably 90 per cent. There are 2,000 or 3,000 beneficial pharmaceutical drugs on the market, and I think what is causing the problem is not the aspirin, is not the barbiturate, is not the triple sulpha or the ammonium chlorides or ferrous sulphate. These are not the drugs that are causing people to ask questions. There are only a very few drugs causing people to ask questions, and these drugs almost to a one are covered by patent.

Mrs. RIDEOUT: Which protects them?

Mr. COOK: Yes, which protects them.

Mrs. RIDEOUT: Mr. Cook, your three associates which are Canadian owned, are these drug orientated companies, I mean people in these three organizations?

Mr. COOK: Are you talking about the shareholders or the management?

Mrs. RIDEOUT: I would say the three principal shareholders in Micro, Paul Maney and—

Mr. COOK: Well for myself, I am a chartered accountant. Mr. Miller has been in the drug industry at the selling and distributing end for well over 20 years. Our third director, Mr. Heintzman, is our financial director.

Mrs. RIDEOUT: Is that the man from Heintzman pianos?

Mr. COOK: Yes, that is one of them.

Mrs. RIDEOUT: The reason I ask is that you gave a very comprehensive picture of the facilities you have, and the way you carry out your operational end of it, and I wondered if you had at the same time competent people looking after your production end of your business.

Mr. COOK: We very definitely do.

Mrs. RIDEOUT: Do you have one person in charge of these three, or is it—

Mr. COOK: No, we have two separate plants, as mentioned. The man in charge of our chemical plant is a Ph.D., in chemical engineering. Underneath him is a chemical engineer who acts as production manager, and under him are the various technical men. Our finishing plant is under the control of a qualified pharmacist, who is a production man. He has been in this business for 20 years or so and has had a lot of experience. In addition to him, we have two other qualified chemists who are acting in the control capacity; under them technicians who have been for many years in the drug industry. In addition to this we have a research organic chemist who is a Ph.D., as well, and who does development work and special projects.

Mrs. RIDEOUT: Is Mr. Gadsby employed in your company?

Mr. COOK: Mr. Gadsby? No, he is not employed. He is acting as a consultant.

Mrs. RIDEOUT: In other words, you take advantage of the service he has to offer?

Mr. COOK: Yes.

The CHAIRMAN: Who is Mr. Gadsby?

Mrs. RIDEOUT: Well, I guess he was working with the Ontario Government, was he not?

Mr. COOK: Yes he was.

The CHAIRMAN: As a consultant. But I am sorry I lost your question there; I do not think the name comes up in the brief anywhere.

Mrs. RIDEOUT: It is G-a-d-s-b-y?

Mr. COOK: Yes.

Mrs. RIDEOUT: Did you get it all right? I think he was a purchasing agent for the department of health in the—

Mr. COOK: Some years ago, yes.

Mrs. RIDEOUT: And he is now a consultant with your firm?

Mr. COOK: Yes.

Mrs. RIDEOUT: I think that is all.

Mr. BRAND: I would like to clear a little something up here that you were talking about, Mr. Cook. You were referring to the products that were tested, the comparative testing of the quality of the drugs, and the base, and that. This is the implication I get from what you said, I would like you to correct me if I am wrong. You implied that your products were not tested, only Gilbert's, and therefore that you were suffering from guilt by association. Is this correct?

Mr. COOK: The way it read to me, the independent testing, there is no doubt that Smith Kline & French tested our products; I think they said so themselves. I am talking about the independent testing that was done. It was not clear to me whether it was done on our products, Gilbert's products or both of us.

Mr. BRAND: If I were to show you some figures to indicate that in fact they did test your products and they did not come up to standard, what then?

Mr. COOK: At this point I would have to say that your figures were wrong.

Mr. BRAND: Oh, not my figures, those of the independent company, Warnock Hersey.

Mr. COOK: That is correct.

Mr. BRAND: You would say they are wrong?

Mr. COOK: Yes. We are in a very fortunate position that we have not Mr. Bethel on our staff and he is on Smith, Kline and French's.

Mr. BRAND: I am not talking about Mr. Bethel. I am talking about Warnock Hersey which is the independent group we are talking about.

Mr. COOK: I would think that he would approve of their work.

Mr. BRAND: Of whose work?

Mr. COOK: Of Warnock Hersey, or else he would not have produced it along with his information.

Mr. BRAND: We spent a lot of time on triflurin. I wonder if we could get away from triflurin for a change. We are all getting a little tired of tranquilization in the Committee, because on this Committee it is producing a lot of ulcers and some of the members must go to one of the tablets that are used to treat ulcers. You put out a product, pro-pantheline bromide, under the trade name of Banlin tablets. Is that correct?

Mr. COOK: Yes.

Mr. BRAND: I have before me a letter from Ninfa Redmond, Master of Science, Pharmaceutical Analysis Laboratories of the Warnock Hersey Company Limited and the comparison of tests done on the Pro-Banthine tablet which is a trade name of the Searle Company. It is important to mention Searle because there is something in the paper today about the birth control pill, and they are the first ones who brought it out so we can give them a little boost on that.

The assay was done here by the U.S. P. method and by the B.P. method. If I may just read from the B.P. method at the moment—that is the determination of the bromide in the tablet: Searle unaged tablets showed up at 99.5 per cent and the aged tablets at 95.5 per cent, both within the B.P. limits.

Banlin tablets, unaged 100.89 per cent and 100.3 per cent, which is very good. The aged tablets, however, show 91.75 and 91.9 These are below the B.P. limits. What do you think of those statements?

Mr. COOK: There is no specification in the B.P. for assaying aged tablets.

Mr. BRAND: Would you agree that it is a method of finding out whether the tablets will stand up under shelf life and other conditions?

Mr. COOK: It is if they are taken at comparable times from date of manufacture.

Mr. BRAND: Yes, I believe these were.

Mr. COOK: These were?

Mr. BRAND: Yes, to the best of my knowledge.

Mr. COOK: How would they know our date of manufacture?

Mr. BRAND: Well, I understand, and you have put it out in your brief, that you have lot numbers so that you know this, do you not? I believe you stated

that in your brief. In fact, you made a point of it. I will point it out to you if you like. You made quite a point of this toward the end of your brief. It says on page 44 that:

> It should be noted that the labels in actual use show the proper lot numbers for identification purposes.

Which I presume are used to determine the age of the tablet.

Mr. COOK: No, they are not.

Mr. BRAND: What are they for then, just to show the lot number?

Mr. COOK: Yes, so that you can track this product back to its original sources of material.

Mr. BRAND: Then, let us go on a little bit further and we will come back to that later.

I must underline what some of the other members of the Committee have said about the breakdown of the manufacturing dollar. You made quite a point of ticking off this Committee on page 12 about straying outside our terms of reference. I think, in view of that, it is only fair that we should get back to the costs of drugs and prices. You state that we stray outside of this and go into the matter of quality of drugs and then you spend your whole brief talking about quality. Are you intimating by your statement on page 12 that you can separate the cost and price of drugs from quality control?

Mr. COOK: No.

Mr. BRAND: Yet you intimate that we are outside our terms of reference.

Mr. MACKASEY: Mr. Chairman, Dr. Brand will have to speak for himself on this. I do not draw that inference from reading section 5, page 12.

Mr. BRAND: Well, let us read it into the record because I drew that inference.

> While the terms of reference to this Committee relate to the cost of drugs and their prices several members of the Committee have expressed concern over the importance of maintaining the quality of the drugs referred to and the safety of their use by the public.

I think that seems quite clear.

Mr. MACKASEY: Mr. Chairman, on a point of order, I think this is just a factual statement in the brief. Many members have expressed their concern. I do not consider this as Micro Chemicals ticking off the Committee for straying outside the terms of reference. It is an observation.

Mr. BRAND: This is a subjective thing, of course.

Mr. MACKASEY: That is right.

Mr. BRAND: I think I am entitled to my subjective approach to this.

Mr. MACKASEY: Yes, exactly.

Mr. BRAND: I wanted to find out, of course, if this is indeed what you meant in the brief. I am asking that question and I presume from your previous answer you did not mean this; it was merely a straying of the pen.

Mr. COOK: No.

Mr. BRAND: Are you going to be prepared then to give us a breakdown of your manufacturing dollar and the other material that has been asked for relating to the financial structure of the company? I am interested in the profit your company is making.

Mr. COOK: I would say that we would be prepared to submit data comparable to that of other firms in the pharmaceutical industry.

Mr. BRAND: Do you have the material from the other firms?

Mr. COOK: No, but if the Committee could—I would be prepared—

Mr. BRAND: You would be prepared if other firms did it, that is all?

Mr. COOK: Yes, we would be prepared to go on the same basis that other firms would be prepared to submit that information.

Mr. BRAND: I think this is most important because constant reference has been made to the high profit margins of the other firms. I think we must have comparisons here, as Mrs. Rideout pointed out. I take it since you have begun manufacturing triflurin tablets that you have not changed you method of manufacture at all. You did not improve it after the initial surveys came out done, for example by SKF which you are taking great exception to? You did not improve the quality to bring it up to—

Mr. COOK: We are not getting any different results. I do not know what technical changes could have been made, but we have to make our products stand up to certain specifications and we have.

Mr. BRAND: With regard to the selling price per kilogram of active ingredient of triflurin, for example, do you think around $10,000 would be accurate?

Mr. COOK: Depending on the product mix, yes.

Mr. BRAND: What do you mean?

Mr. COOK: They make more money, if you talk in terms of the active ingredient, on a 1 milligram tablet, than on a 10 milligram tablet.

Mr. BRAND: Let us say, that is a valid figure for one of the methods of manufacture. Do you have any breakdown figures with you now as to the manufacturing costs of raw materials and others, what you use in the way of medical information, promotion and such?

Mr. COOK: On our organization as a whole?

Mr. BRAND: No. For example, on triflurin.

Mr. COOK: It is very difficult to break this down on one product. I think the large companies have the same difficulty.

Mr. BRAND: I will give you a breakdown of the SKF. Do you think you can match it up with that?

Mr. COOK: All right.

Mr. BRAND: Let us say the selling price per kilogram is $13,565 for SKF for stelazine and yours would be $10,852. Would that be accurate, comparatively speaking?

Mr. COOK: What was the first figure of SKF?

Mr. BRAND: Thirteen thousand five hundred and sixty-five dollars, which is about 20 per cent higher than your figures.

Mr. COOK: It might not be.

Mr. BRAND: You were saying a while ago that your selling cost of these tablets was between 20 and 30 per cent lower?

Mr. COOK: Yes, but we also have an example in this brief that shows that in one case of a large sale we were 50 per cent less or better. It is very difficult to strike an average on a product that you are just beginning to market.

Mr. BRAND: I would like to go on, since I do not want to put you on the spot in that regard. You have made a statement here. I believe, about 12 per cent in research and development. What research are you working on now? I did not see in your brief any comment on research so I was a little surprised to hear this very high figure.

Mr. COOK: We classify research and development in two major phases because there is no Canadian-owned basic manufacturing company engaged in research and development. This is a fact, but you have to start some place. It is quite obvious that outside of the large corporations you are going to have to start at the bottom. The bottom in our opinion is technical development and technical techniques.

Mr. BRAND: Yes; you went through that before, but what about pure research? Are you doing any?

Mr. COOK: Yes, we are doing some investigation work on one or two products.

Mr. BRAND: You mean clinical investigation or molecular manipulation or what?

Mr. COOK: Yes; we have one under primary evaluation and we have one that is now under a new drug application with the Food and Drug Directorate.

Mr. BRAND: It is a brand new product?

Mr. COOK: In terms of products, yes.

Mr. BRAND: A result of molecular manipulations?

Mr. COOK: In one case it would be: in the other case it would not be.

Mr. BRAND: You cannot give us the per cent for doing the pure research then? The average of the industry is around 6 per cent I believe and Ayerst, McKenna and Harrison were running about 9 per cent. Have you any idea what yours would be?

Mr. COOK: No, I have not.

Mr. BRAND: If one has difficulty with any of your drugs, and this is a hypothetical question, to whom may the doctor turn? Where may he turn to find out information about your drug? Do you have a medical information branch which supplies this? Do you have doctors on staff?

Mr. COOK: We have a consulting physician.

Mr. BRAND: A physician? What are his qualifications?

Mr. COOK: He is a doctor, a qualified general practitioner.

Mr. BRAND: A general practitioner. He is not a pharmacologist, or a doctor of internal medicine?

Mr. COOK: He is doing a lot of pharmacology work.

Mr. BRAND: Do you know where he is doing this? I am interested in his qualifications, naturally.

Mr. COOK: No, I do not.

Mr. BRAND: Is he a shareholder in the company?

Mr. COOK: No.

Mr. BRAND: I was wondering. We have piano players who are manufacturers, in it. What medical information do you supply with your products to the medical profession?

Mr. COOK: We supply brochures and index cards with our products.

Mr. BRAND: Yes. Is there any reason for the small amount of information available in the Vademecum by your company. I will take triflurin as an example, as compared to SKF.

Mr. COOK: No. The Vademecum is a commercial publication.

Mr. BRAND: To which you subscribe.

Mr. COOK: That is right. That information has been approved by the Food and Drug Directorate.

Mr. BRAND: Do you think it is adequate?

Mr. COOK: Yes, we do.

Mr. BRAND: Do you think that the amount that SKF puts in on the triflurin and stelazine drugs is just excessive and not necessary?

Mr. COOK: I have no opinion on that.

Mr. BRAND: Is there anybody in your firm who has an opinion on it?

Mr. COOK: I do not think it is of concern to us how much money they spend or what they put into a publication such as the Vademecum.

Mr. ORLIKOW: May I just interject a question? Are you saying that the company which puts it in pays according to the amount that they put in?

Mr. COOK: Oh, yes.

Mr. ORLIKOW: This is very interesting. I had the impression throughout all the weeks and months of inquiries that this was an independent objective report. I did not realize that this is really paid advertising. You could put in 15 pages or 20 pages or 50 pages about each drug provided you wanted to pay for it and then you could say, "we put in ten times as much as the other company, therefore, our product must be ten times as good". I did not realize that until now.

Mr. BRAND: I think that is an unfair comparison. That is not what I am referring to. I am referring to some specific matters in the toxicology and the dangerous use of a drug as potent as triflurin. I have here the 1967 Vademecum, that is the new one. You say it is a commercial publication. Are you intimating that it is really of no value?

Mr. COOK: I think all literature is of value.

Mr. BRAND: I am in favour of motherhood, too, but do you think this is used much by the medical profession? This point has been brought up before, as you know in this Committee, and I am interested in hearing—

Mr. COOK: I probably think it is used a great deal by more doctors than say a firm like Hoffmann-LaRoche who decided not to put anything in it at all.

Mr. BRAND: I am afraid I do not get the meaning of that.

Mr. COOK: As I say, this to me is a commercial publication in which you decide whether or not you are going to put anything in, and how much you are going to put in, but if you do not put anything in I do not think it should be held against you.

Mr. BRAND: I am not holding it against anybody for not putting it in or otherwise. I am wondering if it is not misleading to a certain degree to leave certain things out, contraindications, and side effects, and such. That is the point I am getting at.

Mr. COOK: I would have to say no because we have had this literature reviewed by the Food and Drug Directorate under the terms of the Hilliard committee.

Mr. BRAND: One thing that I think is of great importance, since the thalidomide tragedy, is the question of whether or not these drugs are safe to be used at the time of pregnancy. I notice nothing in your little short half column brochure on triflurin here to indicate whether or not it is safe for use in pregnancy so I took the trouble to look up the Smith Kline & French one here and it is certainly mentioned in the six columns which are devoted to discussing stelazine, their brand name. It is certainly mentioned in here. May I read it to you:

> While it is now recognized that caution should always be observed when prescribing for the pregnant patient, if the physician considers that the mental disorder or emisis must be controlled, then 'Stelazine' is indicated.

Certainly it alerts the physician who use the Vademecum and I can assure you as a physician that a lot of them do. Practically the great majority of them do. It alerts them to some of the dangers in the use of the drug, but I see no mention in yours about this and I am certainly not going to go into it to show you all the different things that you do not have that they do have.

Mr. COOK: But this is coming down to a matter of opinion.

Mr. BRAND: Coming down to a matter of cost as Mr. Orlikow pointed out, is it not? If it costs you less to put in half a column, then your costs are going to be lower than that of Smith Kline & French who have put in six columns, or seven columns.

Mr. COOK: In that particular book, yes.

Mr. BRAND: Yes, this is one only.

Mr. COOK: Well then, I would say that Hoffmann-La Roche has made a handsome profit on that book to date.

Mr. BRAND: I am not talking about Hoffmann-La Roche. I am talking about your product and Smith Kline & French's stelazine.

Mr. COOK: But the reasoning is essentially the same, Dr. Brand.

Mr. BRAND: I am asking about a specific drug which we have been talking about. Let us not get off on any side issues. I shall go into Hoffmann-La Roche later, if you like. At the moment I would appreciate it if you could confine yourself to what we are talking about. You say you produce triflurin tablets for 20 per cent less than Smith Kline & French and you say they are of equal value, and so on—perhaps they are. However, my point is, why do the others sell at a higher cost? This is what I am trying to get at. I think this is a valid question and I think the Chairman will bear me out when I point out that there are methods used and things done by the other firm which your firm does not do, and this may account for some of the increased costs of the other firm. If these are useful and valuable adjuncts to the physician in his treatment of the patient, then I think it is a valid increase in cost. This is the only point I am trying to make. Would you agree with this? That is what I want to know.

Mr. COOK: At this point I do not know what I am to agree with.

Mr. BRAND: Well, I think everyone else gets the point. We will go on the another question. You have mentioned you have a physician, and it is in your brief of course, who is available for consultation on certain things with your firm. A great deal has been said by some of the larger manufacturers, including Smith Kline & French and, incidentally, including Hoffmann-La Roche, about the medical and pharmacological teams which are used in the firms to provide information for physicians and so, and in the use of the drugs. Now, if you have difficulty with any of your drugs, and let us say you have had in the past, what would you do then if you have only one consulting general practitioner to turn to. Let us say a firm writes to you—one of these large mental hospitals that you are talking about—and says they have had a little difficulty with the drug. What would you do to provide them with some help as to side effects and such of the drug?

Mr. COOK: First of all, we would investigate the cause of the trouble and then we would have to take appropriate action. This action might be the use of a medical man; it might entail the Food and Drug Directorate; it might entail many things.

Mr. BRAND: Would you ever go to the people from whom you have the compulsory licence to obtain this information?

Mr. COOK: I think if the case warranted it we would.

Mr. BRAND: In other words, you would take advantage of the money they are spending in their firm producing the same drug as you are producing under compulsory licence? They are spending a lot more money to keep these people on hand to provide this information and you would go to them for it? Is this right? In other words, you are selling cheaper to a certain degree because you do not have these people on staff. It is certainly part of the cost,—I am not saying how much—is it not?

Mr. COOK: You could say it is part of the cost.

Mr. BRAND: Yes, that is exactly what I am saying. For example, you evidently supplied chlorpromazine—and I have forgotten your trade name for chlorpromazine—to the Essendale Mental Hospital in British Columbia and a problem of pigmentation arose in the patients who were using the drug.

Mr. COOK: Yes.

Mr. BRAND: Where did you get help on this problem?

Mr. COOK: There was already clinical data available publicly on this problem prior to this.

Mr. BRAND: Did you not go to the general manager of Poulenc who held the original patented drug to obtain help from them?

Mr. COOK: No.

Mr. BRAND: I have your sworn statement before Mr. Jacques Foussard of the town of Mount Royal in the province of Quebec, which I am quite willing to put on the record if the members would like to have it. The intimation here is that he was used for the purpose of helping to investigate the problems that went on.

Mr. COOK: Directly by us?

Mr. BRAND: No; they could not get any help from you, according to this, because you did not have any full time medical advisers and therefore the people at the Essendale Mental Hospital went directly to Smith Kline & French. This is correct, is it not?

Mr. MACKASEY: May I have the date of that, Mr. Brand?

Mr. BRAND: Yes, 1965, I believe.

Mr. MACKASEY: Would you permit me one supplementary question?

Mr. BRAND: Yes.

Mr. MACKASEY: Is this particular mental hospital still numbered amongst your customers or clients?

Mr. COOK: We have been selling this hospital for approximately six years.

Mr. MACKASEY: But have you sold them since this date?

Mr. COOK: Yes, since that date we have been selling to them.

Mr. MACKASEY: In other words, it has not materially affected your relationship with the hospital.

Mr. COOK: It did at the time.

Mr. MACKASEY: But it has been restored? You have regained their confidence?

Mr. COOK: We did after this. We sent—

Mr. MACKASEY: At the present moment you are a legitimate source of supply? Today you are a legitimate or potential source of supply for that hospital? I think the judge gets my point. Are your relationships with this particular hospital now on good terms?

Mr. COOK: No, they are not.

Mr. MACKASEY: You are not selling them yet, even today?

Mr. COOK: We are selling them other products but we are not selling them chlorpromazine.

Mr. MACKASEY: But you are selling other products?

Mr. COOK: Yes.

Mr. ORLIKOW: Mr. Chairman, I wonder if Dr. Brand could very briefly tell us what this pigmentation problem was.

Mr. BRAND: Well, this they do not know and I do not think they have solved it as yet.

Mr. ORLIKOW: Well, what was the problem?

Mr. BRAND: The problem was pigmentation of the patients—a pigmentation in the skin which resulted from the use of chlorpromazine from various sources, one of which was Micro Chemicals and Paul Maney Laboratories. I do not think it has been solved as yet. They are still working on it—I know Smith Kline & French are still working on this problem. The point I was trying to make—

The CHAIRMAN: Yes, I was going to say that I think I missed the point of view indroducing this evidence.

Mr. BRAND: The point I am trying to make should, I think, be obvious. It is this. There has obvisouly been presented before this Committee a discrepancy in prices between the two firms. The Paul Maney Laboratories sell a particular drug, say, from 20 up to 50 per cent lower than the other company. There must be reasons for this and I am wondering if some of these matters like the provision for full time advisory help do not add to the cost of drugs with the other firms. This is the point I am trying to make, Mr Chairman. If you do not have any advisers or too many detailmen, on your staff and I know you have some on yours, and you do not have the medical information available, or the provision of medical information through papers which may be published in the various journals, your costs are going to be a lot less than those of the other firm which does provide this service. This is the only point I am trying to make.

Mr. COOK: No, not necessarily, because we do know there are fixed costs, and there are variable costs, and a large corporation which would have the benefit of the initial marketing of a product can absorb this type of charge and still not charge the prices they are charging.

Mr. BRAND: So you do not think it is valid to say that if they hold the patent for this drug, which Smith Kline & French does hold, and it is an original drug brought out by Smith Kline & French, I believe,—

Mr. ORLIKOW: No, that is not true. Did they not get the licence from the European manufacturer?

Mr. BRAND: Well, I was going on the basis of what you presented as evidence a few minutes ago, Mr. Orlikow, from the New York *Times*, which made that statement.

Mr. ORLIKOW: Well, they are the American patent holders as they are the Canadian patent holders. I think it is pretty—

Mr. COOK: No, Mr. Orlikow. I think you will find that Smith Kline & French are the licence holders of chlorpromazine in the United States, but it is an original patent, but for trifluoperazine this is a Smith Kline & French patent, an original patent.

Mr. BRAND: But not for chlorpromazine?

Mr. COOK: Not for chlorpromazine.

Mr. BRAND: No, do not mix us up. You made the statement, of course, that you have not had any difficulties with any of your drugs and I accept this, of course. Has there not been some question raised quite recently about the therapeutic behaviour of some of your products from some of the British Columbia mental hospitals?

Mr. COOK: Yes, there has.

Mr. BRAND: Could you tell us what they have been?

Mr. COOK: We were notified that there was indication there was not the therapeutic effectiveness desirable from our chlorpromazine which they have been using for over six years, and as a result of this they would not place our name on the tender list until this had been thoroughly investigated. However, when we were sent to investigate we were asked by one of the key doctors not to be unduly alarmed, to take our time in our investigation and would we please not make a large amount of noise about this. I have had information subsequent to this. The Food and Drug Directorate have sent one of their special representatives there and it would be interesting to find his evaluation.

Mr. BRAND: Is this not also true for the Manitoba mental hospitals, particularly in Selkirk or Brandon, about trifluoperazine?

Mr. COOK: The hospital at Brandon has not lodged an official complaint with us.

Mr. BRAND: You do not know anything about the Food and Drug taking some of your products, trifluoperazine for example, for assay at the moment?

Mr. COOK: We have heard.

Mr. BRAND: There are some problems in dissolution time, I believe.

Mr. COOK: We have not heard about problems; we have heard about their taking the drug.

Mr. BRAND: Why do you think they would take the drug if they were not worried about it?

Mr. COOK: That is a very interesting question. I am starting to wonder why they took the drug away, too.

Mr. BRAND: Certainly. While we are on that subject, do you think the Food and Drug regulations are adequate and that their staff is adequate to look after the pharmaceutical industry and the safety of drugs?

Mr. COOK: I have no knowledge of the adequacy of the Food and Drug Directorate, but I do know that they are a very conscientious and hard-working group of people.

Mr. BRAND: Yes, and I do not doubt this at all, but do you think they have sufficient staff?

Mr. COOK: I think that under the circumstances they have, yes.

Mr. BRAND: You make quite a point about qualifying under 74GP1B, the more recent and very restrictive legislation, for which I congratulate your firm. Do you agree with the officials who administer this, that drugs should be brought into this country encapsulated, let us say, or in tablet form and that the firms who produced them should not be subject to any of the conditions under

74-GP-1B, and yet they obtain this rating and sell these drugs directly to hospitals through purchase by the Department of Defence Production. Do you think that is the way it should be? Do you think that Canadian firms, or subsidiaries of other firms that are in Canada, should be subject to these very stringent rules and others which bring in already compounded drugs are not, apparently, subject to the stringent rules of 74-GP-1B? Do you think this is right?

Mr. COOK: I just want to clarify your question. What you are saying is that it is possible to bring in a finished product?

Mr. BRAND: Yes, we have evidence before this Committee to the effect that finished products have been brought in from overseas firms—they have been sold through one who sells tractors and a few other things, like Colonial Agencies—and sent directly to veterans' hospitals, and such. And yet the methods of manufacture of these firms and their quality control have not been looked into by the officials of the Food and Drug Directorate or the Department of Defence Production.

Mr. COOK: Well, I would have to agree with you that finished products should be regulated on the same basis, regardless of their source.

Mr. BRAND: Thank you. Now, one last question at this time. You have made quite a point of saying you are not a generic firm. Do you have something against generic firms?

Mr. COOK: No, we do not.

Mr. BRAND: What would be the difference between your firm which is not an innovator—and yet it may be, according to your recent testimony owing to this new drug application—and the generic firms?

Mr. COOK: I think everybody has a pretty difficult time in trying to pin down what a generic firm is. I would say that a firm that largely sells by trade name is not a type of firm that you are referring to as a generic firm. I just cannot define it myself, but my impression of a generic firm is a firm that will sell nearly all of its products by their chemical names.

Mr. BRAND: Since you sell by trade name would you be in favour of doctors prescribing everything by generic name? This has certainly been suggested to us many times.

Mr. COOK: I have no opinion on that. I feel, though, that it goes against our whole way of life. We keep putting special names on everything from cars to Cheerios. I just can not imagine the implication. I could not visualize what would change if this happened. To me it would be very drastic.

Mr. BRAND: That is fine for now.

Mr. LAIDLAW: Mr. Chairman, several questions come to mind. The first one is directed to Mr. Cook. During the presentation of his evidence—and Mrs. Rideout also is anxious to find out about this problem—Mr. Cook several times used the expression "open competition". You felt that open competition is the answer in bringing down drug costs and prices. Take, for example, the larger manufacturers. They are all in open competition, or do you mean competition of a different kind? As I understand it, there is intense competition within the industry itself at the moment. What do you mean by "open competition"?

Mr. COOK: I mean competition on a monopolistic drug; on a drug per se; on the individual items.

Mr. LAIDLAW: On the individual items. As long as a drug is under patent monopoly and if section 41(3) did not exist it would be impossible, then, to introduce competition until after the term expired?

Mr. COOK: I would assume so, yes.

Mr. LAIDLAW: My second question, Mr. Cook, is: As I understand it, your compulsory licences cover only very important drugs, the so-called "winners", the patentable drugs, and it is easily understood, I think, that the use of section 41(3) will inevitably bring the price of those particular drugs down. How are you going to bring down the prices of, say, patentable drugs down. How are not have any interest, because the market was too small, for example?

Mr. COOK: I do not think the market is ever too small on any product. I think the principle here is that if the price is already fair—and this is something that is a very difficult thing to come by—there will be no interest in anyone obtaining a licence through section 41(3) of the Patent Act. In my opinion it applies to any drug that gets into a position where it is priced too high.

Mr. LAIDLAW: The fact, then, is that there have been very few compulsory licences issued. I take your answer to mean that, in effect, for most drugs the prices are fair and reasonable. In other words, apparently nobody is interested in literally hundreds of patented drugs because even if they were able to obtain compulsory licences for each of them they would not be able to reduce the price?

Mr. COOK: I would say this is a hypothetical question, but I would have to agree, yes; it is a normal business reaction to attack something that has a large margin of profit in it.

Mr. LAIDLAW: I think this is an interesting observation. I would just like to add another question in attempting to determine your attitude about reducing profits, generally speaking. Would you be satisfied if section 41(3) could be expanded to include the licensing of imports provided, of course, that those imports were cleared through the Food and Drug Directorate?

Mr. COOK: I would have to say that our position is that we cannot go against competitive principles and that we would have to agree with this, except our own opinion is that this would not be a controllable situation, that the safety factor and the policing of imports coming into this country, which is already a difficult matter, would make it a very hazardous move. This is just my opinion.

Mr. LAIDLAW: That may be, but assuming that that safety factor could be introduced, though, would it not only introduce more of this so-called open competition we are talking about?

Mr. COOK: It certainly would introduce open competition.

Mr. LAIDLAW: And increase efficiency in drug firms, generally speaking, including your own?

Mr. COOK: Possibly, yes.

Mr. LAIDLAW: My final question I would like to direct to Mr. Thorson. This relates, Mr. Thorson, to some evidence given earlier before the Committee dealing with section 41(3), and two suggestions were made. One of the large

drug manufacturers complained, perhaps properly, that compulsory licences were applied for almost a day after the patent was issued. If the Commissioner of Patents grants a compulsory licence immediately, then it would seem to indicate that the patentee was unable to recoup his research costs. Do you think that it would be effective in any way if section 41(3) were amended so that a compulsory licence, for example, could not be obtained for, say, a period of three years after the patent issue? In other words, to give some relief to the additional expense incurred by the patentee.

Mr. THORSON: I do not think there could be any objection to such a requirement. I look at it in this way, that if the owner of the Canadian patent had three years in which he was completely free from an application for a licence under section 41(3) of the Patent Act he would have three years in which to keep up his prices, including research charges made against him by his parent for research that he has not done. But it might be a desirable amendment to provide that no licence should be issued until after three years from the date of the issue of the Canadian patent. I cannot see any objection to that.

Mr. LAIDLAW: It was thought at the time that there would be a better balance between the patentee who becomes the licenser and the compulsory licencee. My last question, Mr. Thorson, is this: Do you believe it advisable to amend section 41(3) to make it mandatory that the Commissioner of Patents receive the approval of the Food and Drug Directorate prior to the issuing of a compulsory licence? At the moment the present commissioner is following the recommendations of the Haley report and no compulsory licences are issued, as you know, unless the Food and Drug Directorate approves. This, however, is not in the statute. Commissioners come and go. A commissioner might, because he has wide authority, decide not to consult the Food and Drug Directorate. What are your views with respect to that?

Mr. THORSON: I think that an amendment of that sort would be quite desirable, and I think that some credit should go to Mrs. Jones for the representation that she made to parliament, because as a result of her representations the Minister of National Health and Welfare appointed a special committee under Dr. Hilliard. Dr. Hilliard made a report, and one of his recommendations was the one that you referred to. I think it would be highly desirable that that should be put into statutory form. The result has been that there has been the closest cooperation between the commissioner and the Food and Drug Directorate, and I think it would be desirable that that should be put into statutory form. If that were to happen I think some of the credit for the move would be coming to Mrs. Jones for raising the question when she did.

Mr. LAIDLAW: Thank you, Mr. Thorson. Those are all my questions.

Mr. HOWE (*Wellington-Huron*): In the reference to page 24, it is rather disturbing the number of times it is mentioned that the big drug companies are getting excessive prices. Are you intimating that the big drug companies are ruthless, are pirates, rooking the public by charging excessive prices for drugs?

Mr. COOK: I would not like to use such terms as those.

Mr. HOWE (*Wellington-Huron*): But you keep saying "excessive". This word "excessive" is a pretty strong word.

Mr. COOK: The problem is that they have a monopoly and that they are entitled under this monopoly to do what they feel they want to do. It is up to people to take advantage of section 41 (3) to put them back in line.

Mr. HOWE (*Wellington-Huron*): What people?

Mr. COOK: People such as ourselves—and we are not the only ones who are paying compulsory licences. But as long as section 41 (3) is there, there will be at least the wherewithal to control the price of drugs if they get out of line, and the only way that we know they get out of line is because someone attacks them.

Mr. HOWE (*Wellington-Huron*): You stated that a certain product that you were producing was selling in the marketplace at 20 per cent less than some of these others. Are you intimating that the purchasing agencies for these hospitals just do not know what they are doing; that they are not using public funds fairly, and that they are paying more than they should for these drugs. You mentioned quite a few institutions that are buying drugs from both of your firms. Why did they buy the other firms' drugs? Are they better salesmen, or do they give more services than you do? There must be some reason. I do not think that the people who are buying for these big hospitals are stupid.

Mr. COOK: No, but there is a certain amount of psychological power in promotion and advertising.

Mr. HOWE (*Wellington-Huron*): And service.

Mr. COOK: And service as well.

Mr. HOWE (*Wellington-Huron*): Therefore, these prices are not as excessive as you might make out in some cases because special services are being provided by the other company.

Mr. COOK: We are not attacking the prices per se; we are attacking the result and we claim that the result of the operations of these firms are producing profits that are excessive.

Mr. HOWE (*Welling-Huron*): Well how do they sell their products? If someone else has as good a product at a much less price, is the general public stupid for buying these products and continuing to pay excessive prices for them?

Mr. COOK: I think that people pay more for things in any line and this is just human nature. No one gets 100 per cent of a market when there is an open competition. I have not the answer for you on that—I have not the answer on any product—because someone can always sell a certain percentage of the market for the simple reason that the people that he deals with think differently.

The CHAIRMAN: Perhaps I should point out that in this case the public do not buy the drugs that we are talking about; they are either purchased through a hospital or they are written up as a prescription by the doctor. The public does not actually buy the drug.

Mr. HOWE (*Wellington-Huron*): I am not Dr. Howe; I am just an ordinary layman.

Mr. COOK: I am sorry.

Mr. HOWE (*Wellington-Huron*): But as I say, whether the public buys it or not, or whether the hospitals buy it, surely they are businessmen enough to

know that if there is another product on the market for less money they would not buy this expensive one. It is disturbing to me that there are people acting as purchasing agents for these institutions who are being bamboozled, so to speak. The term "excessive" is used many times here. And "excessive" means unjust or unfair, but this other firm is still selling their product.

Mr. COOK: Unfortunately this is our opinion and, as I say, every person you deal with has a different opinion. It is a question that I just cannot answer.

Mr. MACLEAN (*Queens*): On page 22 you make the statement:

> In this part of the submission to the Committee the associated companies show:
>
> 1. That the costs of patented drugs are too high and that the prices charged by the patentees for them are, in many cases, excessive.

Now you have not said anything about the products of copiers or products sold under licence. Does this mean to imply that the prices for licensed drugs are never excessive, that they are just right?

Mr. COOK: They are as right as competition can make them.

Mr. MACLEAN (*Queens*): This leads me to the conclusion then that there is no point in having one licensee in the case of a patented drug. You are trying to make the point, in the case of a patented drug that where a patentee has a patented drug he has a monopoly and he can charge whatever the market will bear or whatever his conscience permits him to charge. But in the case where there is only one licensee, what is to prevent him from charging prices that are just a bit less excessive than the prices of the patentee?

Mr. COOK: This is happening in some cases. It could be that we have not had enough time for any retaliatory moves of the opposition. This is a very good point, because if we have a case such as this and time lapses and both these people seem to be still on the high side, a third man might come in and obtain a licence, or try to force a licence, to bring the other two down even further. I think this works on an automatic basis. It is a common-sense sort of thing that they will not stay there very long. Actually, I think the situation at present is very real. We have chlordiazepoxide, which has a compulsory licence against it. There is very little difference between a licensee and a licensor. At present we have before the commissioner an application for a compulsory licence for chlordiazepoxide and although w know very well that there are two people already on the market with it, we feel that there is still room for us to come into the market.

Mr. MACLEAN (*Queens*): Well, your statement leaves the implication that it may not be justified. You say that the cost of patented drugs are too high and that prices charged by the patentees in many cases are excessive. You imply that it is not necessarily so that the price of manufactures under licence is not excessive.

Mr. COOK: No, but what we have done is put into motion a mechanism of human instinct. Prices might not come down earth-shatteringly overnight, but in the long run competition will prevail.

Mr. MACLEAN (*Queens*): There may be a period though—

Mr. COOK: Oh, there may be a period yes.

Mr. MacLean (Queens): —when this licensee is also making an excessive profit.

Mr. Cook: I would not say that. You have to also realize that a man who obtains a compulsory licence has certain things that he must recoup: his development, his initial marketing, his plant and so on. Therefore he is in a position where he must charge prices to recoup initial expenses that might not be recurring on that particular item. At the same time I think our chlorpromazine situation has shown that there is a general downward trend, that the prices we started out with in our application to the Commissioner are not the prices that we are using today. In other words, we did not go and say to the Commissioner: "Mr. Commissioner, we can make this for X price less for the Canadian public", and then just sit there and charge those prices forever and a day. Our prices are much lower than that now. We have had to balance; when we make a price adjustment downward, we have to consider very seriously a lot of the same fundamental problems that the originator had: How are we getting our money back on this product? How are we making a profit? And so on.

Mr. MacLean (*Queens*): I agree with that, but these same factors would also apply in the case of the patentee in the manufacturing and marketing of a product and they have to charge a higher price to begin with to liquidate special costs in connection with the production of the drug. Are you saying that holders of patents of drugs never lower their prices?

Mr. Cook: Yes, I think essentially experience has shown that they just do not bring their price down over a period of years. This is a relative thing; I mean it is your opinion on how long you are going to have to wait for this to happen, especially when you see the usage of the product increasing at an astounding rate.

Mr. MacLean (*Queens*): I believe this is a matter of opinion with regard to the ethical conduct of one group as opposed to another and their opinion of their own standard of ethics, rather than anything you can substantiate very accurately statistically.

Mr. Cook: No, I think that this puts it in a light where the competitive urge will take over. I like to equate this thing in terms of what a person would logically do. All you have to do is confront him with a problem and he will do something. Up until now, if there is no voluntary licence, the man has no problems and he has no motivation. Now the motivations may not be the best, but I think the motivations in this case are at least more acceptable than the entire monopoly as a system.

Mr. MacLean (*Queens*): I want to refer to a specific thing in the evidence which was given before the Committee by the representatives of Hoffman-La Roche on October 20. On page 774 of the transcript of evidence they make this statement:

> (68) In order to stress the contradictions, Roche pointed out, in a further submission to the Commissioner, that
>
> (a) Micro was apparently admitting that its manufacturing costs would be around $460 per kilo
>
> (b) Micro was now proposing compensation to Roche of $69 per kilo

(c) Micro was claiming that its profits would be about 17.08 per cent of its average selling price of $3,400 or $578 per kilo.

Then they point out that the sum of a, b and c, the cost to manufacture, the royalty on the drug and the profit, amounted to $1,107 per kilo, and they leave the question as follows:

(e) there was thus a completely unexplained gap of no less than $2,293 in its selling price, though it must cover distribution among other costs.

If you accept these figures would you enlighten the Committee on to what these costs totalling $2,293 per kilo would be applied?

Mr. COOK: I do not have the figures before me, but I think the figures probably are not an important factor. You want to know what happened to the money in between. I think this is your point.

We do have distribution costs and we do have administration just like any other company. By and large, this would take up a portion of this amount. Now, I am not saying that it is this amount, but ultimately you can take the cost of your bare material and your selling price and break out as a percentage exactly what every segment is. Every drug is a little different. Some drugs have higher selling costs than others; some have higher manufacturing and packaging costs than others. It is a pretty complicated thing.

Mr. MACLEAN (*Queens*): Yes, I realize that; but I would think that someone who, by implication, seems to imply that they are in a segment of the business which is more virtuous than the patented drug manufacturers, would be prepared to substantiate their cost and demonstrate to the Committee that the cost of the drugs which they are manufacturing is as low as is reasonable to expect.

In connection with this—and I do not mean to imply any reflection on your company—we have repeatedly been given profits on various drugs in the form of mark-up on the drug itself; in this case, 17.08 per cent.

Is it not possible that under certain circumstances figures of this type are really pretty meaningless? Surely the profit that a company makes should not be judged simply by the mark-up of profit—in that sense, on the product—but rather on the return on the capital investment.

Mr. COOK: This is reasonable, but it also stands to reason that you have to start from some place. Those figures are all predicated on the future. We do not know what the product mix will be at the various levels. You can estimate. You can only shoot for a certain area, and this is what we have to do; because through experience with other drugs that we have handled, through experience with other licences that we have obtained, it is a matter of our judgment.

Mr. MACLEAN (*Queens*): Based on past experience would you agree that a more valid assessment of profit would be related to capital investment rather than to mark-up on the product.

Mr. COOK: I think this is something which you should consider, but I do not know how valid it is under any given circumstances.

Mr. MACKASEY: Mr. Cook, I have only one or two short questions. On page 33 you start a series of tables, and you have comparative figures showing the reduction in prices of a particular product put out by Poulenc and also now

marketed by Micro. One premise that I would like to challenge—and not because I know the answer—is that the price of Poulenc drugs—we will take as an example, the 25 milligrams for $10.50—was brought down to $8.90 strictly as a result of Micro Chemicals' entrance into the market between 1960 to 1965. Are we right in presuming this? Is there not the possibility that competitive products from other big companies have caused this?

Mr. COOK: No; I would not say that we have competitive products. We do not believe that other drugs are competitive products to particular—

Mr. MACKASEY: But your whole statement on page 33 and 34 is based on the presumption that the only factor that caused the drop of the Poulenc price from $10.50 to $8.90 over a period of five years was the existence of Micro Chemicals' product. What is this product? Is it a tranquillizer?

Mr. COOK: Yes, it is a tranquillizer.

Mr. MACKASEY: Have there been many tranquillizers come on to the market during this period? Did Librium come on to the market around this time?

Mr. COOK: Yes.

Mr. MACKASEY: Would this not have had an effect on Poulenc's prices?

Mr. COOK: No; because if you look at who uses the products and where they are used, their use is generally very specific. We have gone to mental hospitals where very little Librium is used.

Mr. MACKASEY: Yes.

Mr. COOK: But chlorpromazine has been used, and there has been an increase in its use. In other words, someone has not come in and taken a slice out of it.

Mr. MACKASEY: I understand this phenomenon takes place even between countries; that you can have one country where something does not sell, but in Germany, for example, it will sell.

I am a little surprised at the conception that only the existence of a copier can control the innovator, because, by your own figures, I think, you point out that at least 60 per cent of your sales are to hospitals. Are not these the prices over a drug counter in individual prescription?

Mr. COOK: It has been our assessment that this drug is used more in hospital cases than over the counter. Although the over-the-counter business is substantial it might be a smaller percentage.

Mr. MACKASEY: But these are the prices of the drug store, are they not. These are the prices which, according to your declaration on pages 33 and 34, have been reduced. In other words, you are building up your case for the application of 41(3), and, this is supposed to be a tangible example for examination?

Mr. COOK: Yes.

Mr. MAKASEY: I have an open mind on this, but I have the thought that possibly there are other factors which have reduced this price.

Mr. COOK: There might be; but it is our contention that this is the main factor.

Mr. MACKASEY: What reduced your price?

Mr. COOK: Rhone Poulenc reduced our price.

Mr. MACKASEY: If it could be reduced from $6.00 to $4.20 why was it not $4.20 in the beginning?

Mr. COOK: Because we were recouping initial expenses.

Mr. MACKASEY: Were not Poulenc recouping certain expenses when they were selling it—

Mr. COOK: It was quite a number of years before 1960.

Mr. MACKASEY: How many years before?

Mr. COOK: Probably about eight years before that.

Mr. MACKASEY: To me, theoretically at least, Poulenc's reduction from $10.50 to $8.90 is not really a big one. Could not this have been done because at some stage they decided that they had recouped certain basic expenses?

Mr. COOK: It could, but it is highly improbable, if they go along for from 8 to 10 years without this ever occurring to them, and when their largest increase in usage was in that period.

Mr. MACKASEY: You chose a particular product here. I think Mr. MacLean made the point—and I would do the same I am sure—that it is on what we might call the "best seller" list—it is a very desirable product. These firms like Poulenc have to recoup research, although it is debatable where they should do it. I think Mr. Justice Abbott suggested the parent company, but not necessarily the subsidiaries; but are there not other factors? How would a demand for this particular drug develop once it was put on the market by Poulenc?

Mr. COOK: You are asking me, and I am going to give you my opinion on this thing. It is basically because the drug is a good drug. If you get something that is good and it works, this is the best selling agent you can have.

Mr. MACKASEY: Could we stop there for just a moment. Obviously, one of the charges that keep coming up—and, I think, with justification—is that there are thousands of drugs and that probably we could cure all present illnesses with 500 of them. Despite the quality of the discovery—it is not unlike somebody with oil in his back yard, if he does not know it is there—surely to goodness the mere fact that it is a very desirable product is not sufficient to create the demand? No doctor that I know of has so much time at his disposal that he can search day in and day out for this elixir, if we may call it that?

Mr. COOK: No; but there again we are in the same situation as are the large companies. You have to contact the doctor. In my opinion, doctors are pretty aware of things that are new.

Mr. MACKASEY: How are they made aware?

Mr. COOK: I know a lot of doctors who do a lot of reading; you might call it a busman's holiday, or something like that.

Mr. MACKASEY: Reading what?

Mr. COOK: Medical journals and scientific publications. Some of them are very interested, especially if they are in a highly classified line of work.

Mr. MACKASEY: You say "some." Would you like to hazard a guess at what percentage of doctors receive their information only through this very desirable source?

Mr. COOK: It is not their only information; but I think it is part of their natural tendency to investigate the area in which they are working.

Mr. MACKASEY: You have been very honest with us today, and I think you will have to agree that not only must a company discover a desirable drug but that it has to make it and its concentrated effects known to the medical profession as fast as possible. Is this a fair assumption?

Mr. COOK: Yes.

Mr. MACKASEY: Therefore, do you not think that when compulsory licences are granted the royalties are rather meagre? I think perhaps Mr. Justice Thorson should answer that one.

Mr. THORSON: They are very small.

Mr. MACKASEY: Do you think they are realistic?

Mr. THORSON: The patentees have described them as pittances and that is really what they are.

Mr. MACKASEY: You have so described them, too.

Mr. THORSON: The Supreme Court describes them that way.

Mr. MACKASEY: Yes; but that does not make it right, does it?

Mr. THORSON: That is the law, as found by the Supreme Courts.

Mr. MACKASEY: You are a very learned gentleman. Do you think they are adequate?

Mr. THORSON: This is not for me to say.

Mr. MACKASEY: This is why you have earned your reputation for being learned. You fielded the question.

Earlier in your testimony you mentioned that when Mr. Justice Abbott brought down a ruling it created a bombshell. That is the phraseology you used.

Mr. THORSON: The decision threw a bombshell into the pharmaceutical camp. Let us put it that way.

Mr. MACKASEY: Was this because it was an unexpected decision?

Mr. THORSON: Well, to some extent, yes.

Mr. MACKASEY: Why was it so unexpected?

Mr. THORSON: They had been building up a great plea that the royalty should be consistent with the maintenance of research, the importance of subject matter and so on. This was "shot" by the Supreme Court in the case to which I refer, and the "shooting" surprised them.

Mr. MACKASEY: I imagine it did. By your own description the royalty is a pittance.

Mr. THORSON: Oh, it is.

Mr. MACKASEY: My own personal observation, if it is permitted by the chairman, is that it is rather unfair; that it is not a very realistic appraisal.

Mr. THORSON: No, I do not think so. This appears in the brief. In most of these cases the Canadian companies are subsidiaries of companies that are owned outside of Canada, and they are really merely distributing bodies. They do not contribute anything in the way of research. They are merely distributors, and under the circumstances why should they get anything?

Mr. MACKASEY: Well, you are on to my favourite subject.

Mr. THORSON: They do not do any research.

Mr. MACKASEY: Are you of the opinion that no research is done in Canada by the pharmaceutical industry?

Mr. THORSON: I think there is one company.

Mr. MACKASEY: Do you mean Ayerst McKenna?

Mr. THORSON: Yes. I believe that is about the only one.

There is some minimal research being done, but not research leading to the discovery of these very, very valuable and wonderful drugs.

Mr. MACKASEY: Would you agree with me that there should be more research done in Canada?

Mr. THORSON: Oh, by all means.

Mr. MACKASEY: If more research were done in Canada do you feel that that would be time for the government or the courts to make a more realistic appraisal of royalties?

Mr. THORSON: Well, I do not know. This is a matter of policy, I think, to be considered by the government. But I think that Mr. Justice Abbot's judgment in the Supreme Court is really carrying out the legislative policy that lay at the back of the enactment of section 41(3).

Mr. MACKASEY: You are the judge, and I agree with you; but do you not think that the Hilliard Report has, perhaps, underlined the fact that we tend, in making these judgments, to be very narrow—as a judge should be—that we are reading the Patent Act and nothing else, and that not enough consideration has been given to the Food and Drug Directorate?

Mr. THORSON: No; I think that this judgment is in line with the policy that underlay the enactment of the section; and where people do not contribute anything to research and are not the inventors why should they get any reward?

Mr. MACKASEY: You have just said "where people do not contribute anything to research". I think this is a very valid point and does strengthen section 41(3). Suppose that situation were to change tomorrow and that legitimate, basic research were being done in Canada?

Mr. THORSON: I think that if you had a patentee who was in that situation then I think his royalties would be substantially raised.

Mr. MACKASEY: In other words, if you were the patentee, or were identified with some of these firms, you would want to take a look in this direction and start doing some research in Canada?

Mr. THORSON: No; it might be an economic matter. It might be more beneficial to have the research done in the big Swiss laboratories, or the French

laboratories, or the English laboratories, or the American laboratories, and just use the Canadian subsidiaries as distributors.

Mr. MACKASEY: Beneficial for the firm, but certainly not beneficial for Canada and Canadians.

Mr. THORSON: No, no.

Mr. MACKASEY: Do you use detailmen, Mr. Cook?

Mr. COOK: Yes.

Mr. MACKASEY: What are their academic backgrounds, in general?

Mr. COOK: By and large, we do not employ pharmacists as detailmen, but we do have pharmacists in charge of our sectional areas.

Mr. MACKASEY: What do you use if you do not use pharmacists?

Mr. COOK: We screen out applicants through advertising, or something of this nature, and then they are given a program inside the plant; after that they are put under the supervision of one of our capable men. In other words, you train the men.

Mr. MACKASEY: How long does this period of training go on?

Mr. COOK: For him to become familiar with the entire procedure might take from six months to a year, keeping him under supervision.

Mr. MACKASEY: But during that period of six months to a year is he actually out in the field doing his job?

Mr. COOK: In conjunction with other detailmen.

Mr. MACKASEY: I have been for three years on this Committee and still cannot pronounce the words. I am just wondering how they get by. I have got a very poor opinion of detailmen in Canada, in general—not of the people but of our standards. By skirting around the question you have left me with the impression, rightly or wrongly—and perhaps you would like to elaborate—that the qualifications of your detailmen are less than those, for instance, of the PMAC firms who have been here.

Mr. COOK: No; I would say they are not.

Mr. MACKASEY: Well, at least one firm mentioned specifically that they were all university graduates, or that a percentage of them were. How many detailmen do you have?

Mr. COOK: We have approximately 12.

Mr. MACKASEY: That is a small number. Probably you can recall from memory their backgrounds, or academic qualifications. Could you describe them generally?

Mr. COOK: Well, most of them we have are high school graduates.

Mr. MACKASEY: Are there some that are not?

Mr. COOK: Well, some of them are college graduates.

Mr. MACKASEY: Yes, of course; and they also went to high school. I am sorry.

Mr. COOK: As I say this is a minimal type of thing. You must remember,

also, that from time to time you do employ detailmen who have come from other pharmaceutical sources.

Mr. MACKASEY: Which may not make them any better.

Mr. COOK: No. It is just that they are oriented to this type of work.

Mr. MACKASEY: Do you feel that they are capable of going into a doctor's office and imparting information to a doctor?

Mr. COOK: The role of the detailman is only to make the information available.

Mr. MACKASEY: How does he make it available in your case. Does he present something?

Mr. COOK: He would present literature on what we call our detail card or brochure. If the doctor, is interested in this type of medication, or is interested at all, he might request samples. If he wanted other literature he would ask the detailman who, in turn would write.

Mr. MACKASEY: Perhaps I should have helped you by saying that I am interested now in the individual doctor rather than in hospital purchases. How are your detailmen paid?

Mr. COOK: It depends; largely on a salary plus incentive basis; but we do have situations where they are on commissions.

Mr. MACKASEY: Do you think that this is desirable?

Mr. COOK: I cannot see any better way.

Mr. MACKASEY: I did get, I think, from, I think, the president—or perhaps he is the vice-president—of PMAC an assurance that henceforth, as a result of my representations on this Committee, they would eliminate any situation within their membership where detailmen were on commission.

I think the reason is obvious. A commission salesman can be very "sloppy" in his presentation, because his prime objective is to reach his objective at the end of a week or a month. He has, perhaps, to misrepresent, or force upon a doctor an abnormal quantity of drugs, and so on. Do you not think that there is a built in danger in the commission system?

Mr. COOK: There might be. As I say, there is only one instance that I can think of where this happens in our experience.

Mr. MACKASEY: What do you mean? Is there only one man in this field?

Mr. COOK: That is on a commission arrangement.

Mr. MACKASEY: Is this of his choosing or of yours?

Mr. COOK: I would certainly seriously consider this.

Mr. MACKASEY: I am hoping to make it a recommendation of the Committee that detailmen in Canada be taken off this basis. I understand that in Europe the detailman is treated much more seriously. In many countries I suppose he is a medical man. Am I right? Do you know whether this is so?

Mr. COOK: I am not familiar with this, no.

Mr. MACKASEY: I believe that there are countries where the detailman must be an M.D.

Mr. COOK: I think that you have a valid point.

Mr. MACKASEY: In other words, you would agree to putting your commission man on a salary?

Mr. COOK: Yes.

Mr. MACKASEY: Thank you, Mr. Chairman.

The CHAIRMAN: Dr. Brand?

Mr. BRAND: On that point may I say that I have not been altogether of the opinion, as a practising physician that they have a low calibre of detailmen. I must take exception to that.

Mr. MACKASEY: I assume you are speaking about my comments. I am generalizing. I have to repeat my statement—and I think it is based on the evidence here—that if a man is selling drugs on commission I do not regard him as anything different from the Fuller Brush man, or the man selling the Encyclopaedia Britannica. He has to sell so much a month to live. This does not fit in with the ethical appearance of an industry dealing with people's health. I would rather see the doctor visited by a man whose prime objective is to impart information and not to sell drugs.

Mr. BRAND: I think it should be made clear to the Committee, Mr. Chairman, that in the majority of instances they are not there to sell drugs to the doctor. This is the impression which has been left, and it is, of course, incorrect.

Perhaps you Mr. Cook, could substantiate, or deny that they have more to do with sales to hospitals and to wholesale houses and things of this nature? Do you deal through them?

Mr. COOK: Yes.

Mr. BRAND: It seems to me to be this rather than sale directly to doctors. I think this is quite wrong. I think, Mr. Cook, you stated that the idea of coming to the doctor was to provide the information and to provide samples if he so requested?

Mr. COOK: Exactly.

Mr. BRAND: It is that rather than the actual sale of drugs.

Is it not a fact that even if you do away with the commissions, which you appear to have agreed to do, it would be quite easy for any company to insist, as a condition of employment that a certain amount of a certain drug be sold in a certain area? This would get around the problem and create a very interesting situation from the viewpoint of the salesman, even though in fact you have done away with the commission. Can you honestly state that doing away with the commission would serve any useful purpose?

Mr. COOK: Well, as I pointed out at the beginning, this is a difficult area and we certainly welcome any comments on it. I think it is a valid point to consider. Whether it is right or wrong, I do not think we are in a position to know yet.

Mr. MACKASEY: Mr. Cook, I do know of countries in Europe where the state does intervene in this particular area. They feel that safety is a factor and that this is a link in the whole chain. If a man, by your definition, does not have to be a pharmacist—that he should have high school level but not necessarily better—I

have visions, for instance, of a man shifting from a bakery, or a dairy, or from being a book salesman, and moving into the selling of drugs.

Mr. Brand has pointed out that his job is not to sell drugs. If that is so it is pretty hard to evaluate what his commission should be. I still insist that if you are going to pay a man a commission there has got to be some direct correlation with his sales level.

Mr. BRAND: Perhaps, Mr. Cook, you could comment on whether, by doing away with commission, you might cut down on the competition among the various firms which approach hospitals. Do you feel that the effect would be also to diminish the incentive to sell vigorously which has an effect in lowering the price of drugs?

Mr. COOK: I think that in this whole area, as you have pointed out, there are so many devices used, or that could be used, to take the place of the commission, that if we did away with commissions somewhere along the line there has to be an evaluation of a man and his job and his worth. Even if he is on salary, at some point someone is going to say: "Listen; this man is not worth his money," or "He is worth his money."

Now we come back to setting a salary for him. You find that the hospital business is not increasing, or that it is decreasing in an area. You try to find out why. Your prices are all right, and you used to get this business. It could be the man.

You find that your wholesale business is not what it should be.

The next thing you know you have him in the office and you are saying to him: "What seems to be the problem?" The pressure is back on this man to sell again. The pressure is not economic from a commission point of view, but it is if he loses his job. I know what you are trying to eliminate, but how to eliminate it is a very difficult situation. In the drug industry there are such things as quotas that some companies use as a yardstick or a measuring device, but this does not apply in our organization. A man cannot work for a company which is in business to make a profit and not be expected to be measured in some way, and this is extremely difficult.

Mr. MACKASEY: May I intervene again, Dr. Brand, because this is important to me. You have again strengthened by misgivings because all through the hearings the pharmaceutical industry in general has always tended to create the impression that these detailmen are not salesmen, that they are only legitimate sources of information to doctors. Therefore, whether they ever sold a drug should not be important. It should be important that that detailmen tell the busy doctor if he turned around, as Dr. Brand mentioned about the vademecum, that everything being equal, stelazine or your product should not be taken by a wife or a lady in time of pregnancy. This is important. But if the sale of that particular drug could be jeopardized by that information not being volunteered by the detailman, and that detailman is on commission, the tendency could very well be for him to ignore that little fact simply because it was not asked. There is the threat to safety that commissions pose. If he is not a salesman why should there be any relationship to the sales volume in his particular area?

Mr. COOK: It is extremely difficult.

Mr. MACKASEY: Is there a better way of imparting information?

Mr. COOK: I know I would have to give it a great deal of thought. It would be extremely difficult to find a solution.

Mr. BRAND: I will ask a few very brief questions. Are you planning on increasing your detailman staff across the country in order to increase the sale of your products through drug stores?

Mr. COOK: Yes.

Mr. BRAND: Do you think this will increase your costs?

Mr. COOK: It might initially, but we are used to keeping a very sharp eye on our costs.

Mr. BRAND: But it is bound to increase something, surely, if you hire more men. Let us be reasonable.

Mr. COOK: Yes, and we have taken this into consideration.

Mr. BRAND: Do you use "gimmicks" to sell?

Mr. COOK: What do you term "gimmicks"?

Mr. BRAND: For example, the round thing that goes on telephones advertising "Triflurin—Paul Maney, Limited" so that the short-sighted doctor can see the numbers on the telephone easier.

Mr. COOK: Yes, actually we do; and we find that we have doctors saying that they have a lot of very aged patients who cannot see very well, and can we supply them with some more for their patients, and we do.

Mr. BRAND: I am glad to hear that. I did not know you would supply any more. I could use a couple myself. However, I am arguing about the validity of gimmicks. There was quite an argument here some time ago about whether the use of gimmicks was putting up the price of drugs. Do you agree with this?

Mr. COOK: No, I do not agree that this puts up the price of drugs.

Mr. BRAND: Not at all?

Mr. COOK: No.

Mr. BRAND: Are you planning on putting out any further information to doctors about your drugs? I have had a recent experience with one of your detail men, and I was not altogether impressed with the amount of information he provided me with. In your brief you point out that a lot of the additional information which you do not have in the vademecum is provided in the trade-sized packages; I would point out to you that doctors do not see trade-sized packages, but the druggist does. We do not get this additional information, and we certainly do not get it on these little cards. Are you planning on increasing this at any time?

Mr. COOK: We probably will.

Mr. BRAND: Will this increase your costs?

Mr. COOK: I do not think it will increase the costs because this is a controllable variable to your sales.

Mr. BRAND: There has been a great deal of discussion as to what variable cost means in the transportation bill, and I am sure it has no more meaning to any members of this Committee than it has to the Transport Committee.

Mr. MACKASEY: I have to disagree. I am a firm believer in the fixed and variable system.

Mr. BRAND: Perhaps you can explain it to me sometime, Mr. Mackasey.

Mr. MACKASEY: It can be explained by graph very easily.

Mr. BRAND: I have one other point. You made a statement, of course, that Hoffmann-La Roche was no longer in the vademecum and expressed great surprise at this. Is it not a fact that they now produce their own because they felt that there was not sufficient room in the vademecum to put all the information they would like to put about their products?

Mr. COOK: I do not know whether this is a fact, but the point that I was trying to make is that there are alternate sources exactly like this. A doctor is not lost because he has not a vademecum.

Mr. BRAND: I would argue that point.

Mr. COOK: If he wants information he can get it.

Mr. BRAND: Where would I get it immediately as a practising physician when I use one of your products and I run into a problem?

Mr. COOK: Well, you could have the information already in your office by reason of detail men leaving information with you—and this brings up the desirability of the compendium which we know is being produced right now. There probably is a need for a central type of reference.

Mr. BRAND: What are we going to do right at this moment?

Mr. COOK: I think you will have to do exactly what you have been doing up to now until something better comes along. I hope this compendium will provide a better answer.

Mr. BRAND: Do you mind telling me what I do now?

Mr. COOK: You take the issue of *Current Therapy* off your shelf.

Mr. BRAND: Yes, that is one way I do it.

Mr. COOK: I am quite sure that you practice very efficiently now.

Mr. BRAND: Is it not right that I may go to the same product produced by another firm that has much more information?

Mr. COOK: You might.

Mr. BRAND: Yes, this is a fact.

Mr. COOK: This would be your prerogative. As I say, you would do exactly what you are doing now.

Mr. BRAND: Which would indicate, therefore, that your company is, to a degree, taking advantage of the additional information provided by the patentee, if that is the correct term.

Mr. COOK: This is a matter of opinion, and we do not believe that we are.

Mr. MACKASEY: Mr. Chairman, could I ask Judge Thorson a question. When is the last time you appeared before a parliamentary committee?

Mr. THORSON: This is the first time I have appeared before a parliamentary committee. I have been a member of parliamentary committees many times years and years ago.

Mr. MACKASEY: A long time ago.

Mr. THORSON: About 40 years ago.

Mr. BRAND: Perhaps we can ask Judge Thorson if committees are any more efficient now than they used to be.

Mr. THORSON: Much.

Mr. BRAND: Do you notice any change in them from years ago—

Mr. THORSON: Not much.

Mr. BRAND: —or are they just as inefficient as ever?

Mr. THORSON: It is rather a novel experience for me, I must say.

The CHAIRMAN: We hope that the government will pay more attention to our reports than they sometimes have in the past. Are there any other questions?

Mr. THORSON: It is a very interesting experience. I am crazy enough to wish that I were back in the House.

The CHAIRMAN: We thank the gentlemen who appeared today for their brief and for their time. The meeting is adjourned until next Tuesday, January 17, at 9.30 a.m. when Prescription Services Incorporated will be before us. Their brief has been in your hands for over a month.

APPENDIX "A"

Submission

of

Micro Chemicals Limited, Gryphon Laboratories Limited

and Paul Maney Laboratories Canada Limited

to

The Special Committee

of

The House of Commons of Canada

on

Drug Costs and Prices

January 12, 1967.

INTRODUCTION

This submission to the Special Committee of the House of Commons on Drug Costs and Prices is made by Micro Chemicals Limited, Gryphon Laboratories Limited and Paul Maney Laboratories Canada Limited. Each of these companies is incorporated under the laws of Ontario and is, of course, a separate legal entity and performs a specific function. The three companies are associated with one another under common ownership and direction.

While the invitation to appear before the Committee in order to rebut the charges made by Smith Kline & French Inter-American Corporation when it appeared before the Committee on October 27, 1966, was extended specifically to Paul Maney Laboratories Canada Limited, the charges affect the other companies as well and they respectfully accept the invitation as if it also extended to them as they believe it was intended to do.

The associated companies deeply appreciate the opportunity of rebutting the charges made by Smith Kline & French. They will be able to show that they are false and submit that they are simply an example of the ruthless and unscrupulous attacks which Smith Kline & French have made against Micro Chemicals Limited and its associates in an effort to stave off the competition which Micro Chemicals Limited will provide against it in the operation of the licence, under Canadian Patent No. 612,204, to manufacture and sell trifluoperazine which was granted to it by the Commissioner of Patents under section 41(3) of the Patent Act with its resulting reduction in the price of trifluoperazine and the consequent reduction of the excessive profits which Smith Kline & French has been making from its sale.

While the associated companies welcome the opportunity of rebutting the charges made by Smith Kline & French, they also believe that they can be of assistance to the Committee in answering the specific question referred to it, namely: How can the cost and the price of drugs be reduced?

With a view to making this submission as useful as possible for the purposes for which it is made it is divided into four parts:

1. Part I describes the respective functions of each of the associated companies and sets out their manufacturing, production, distribution and quality control facilities.
2. Part II expresses the opinion of the associated companies on some of the causes of the high cost prices of drugs, sets out the importance of section 41(3) of the Patent Act as a statement of national policy that the foods and medicines to which it applies, including drugs, should be made available to the public at the lowest possible prices, subject to the condition specified in the section, and gives proof that licences under the section granted by the Commissioner of Patents acting in close co-operation with the Food and Drug Directorate of the Department of Health and Welfare have been effective in reducing the prices of the drugs in respect of which the licences were granted.
3. Part III is primarily concerned with the rebuttal of the false charges made by Smith Kline & French and the safety to the public in the use of the trifluoperazine tablets made from the trifluoperazine manufactured by Micro Chemicals Limited under its licence.
4. Part IV enumerates the recommendations of the associated companies for the reduction of drug costs and prices.

PART I

In this part of the submission to the Committee the associated companies show:

1. The historical background of the respective companies and their place in the Canadian pharmaceutical industry.
2. The manufacturing, production and distribution facilities of the respective companies.
3. The personnel of the companies.
4. The range of manufacture, production and distribution of the respective companies.
5. The quality control facilities and practices of the respective companies.
6. The acceptability of the manufacturing and quality control facilities of the respective companies.

HISTORICAL BACKGROUND

Paul Maney Laboratories Canada Limited has been operating as a distributor of pharmaceutical products for approximately eighteen years, having been incorporated in 1948. It was originally operated as a subsidiary of an American pharmaceutical company, known as Barlow Maney Laboratories Incorporated, of Cedar Rapids, Iowa. This company was closely associated with the State University of Iowa in the development of specialty pharmaceutical products bearing its trade names. Its products were formulated, compounded, manufactured and

shipped as finished products to its Canadian subsidiary for distribution in Canada.

About twelve years ago the Company was sold to the persons who were operating it at that time, and became wholly Canadian owned.

Shortly thereafter it was decided that there must be an expansion of activities. It had become apparent that the distribution of pharmaceutical products by small companies was being made increasingly difficult in the fact of the growing power of the subsidiary pharmaceutical companies in Canada that were wholly owned by the foreign pharmaceutical giants and the indications that they would force the small companies either to sell or cease operations.

It was, therefore, decided to broaden the base of operations. With that in mind the owners purchased Standard Tabletting Limited, which later became Standard Tabletting Company Limited, which provided an existing business of manufacturing finished pharmaceutical products in Canada with a plant, equipment and personnel suitable for the purpose. This led to the incorporation in 1957 of Gryphon Laboratories Limited which has been producing finished pharmaceutical products not only for distribution by Paul Maney Laboratories Canada Limited but also for other pharmaceutical houses for sale under their own labels.

As the development of the production company in association with the distributing company proceeded it appeared that the pressure on small companies was more severe than had been anticipated and it became necessary to re-assess the position. Experience had shown that the large foreign owned drug companies were selling their specialty products covered by patents at very high prices without any reduction of them and at the same time selling products similar to those being distributed by the small companies at very low prices that throttled them with the implied threat of the possibility of being forced out of business. It was then considered that if the production and distribution companies were to survive they had to be in a position to compete with the large companies in dealing with the new drugs in respect of which patents had been issued.

This led to the advisability of recourse to section 41(3) of the Patent Act. Micro Chemicals Limited was then incorporated in 1959. It made its first application for a licence under section 41(3) of the Patent Act on July 21, 1960. This was for a licence under Canadian Patent No. 519,525, owned by Societe des Usines Chimiques Rhone-Poulenc, now Rhone-Poulenc S.A., to manufacture and sell chlorpromazine hydrochloride. This licence was granted on September 7, 1961. A second application was made on February 7, 1961, and the licence granted on May 17, 1963. This was a licence to manufacture and sell bisacodyl under Canadian Patents Nos. 543,125 and 602,496, owned by Dr. Karl Thomas G.m.b.H. Recently, on June 21, 1966, a licence to manufacture and sell trifluoperazine under Canadian Patent No. 612,204, owned by Smith Kline & French Inter-American Corporation, was granted to Micro Chemicals Limited, based on its application, dated March 30, 1965. More recently Micro Chemicals has negotiated a licence from Rhone-Poulenc S.A. to manufacture and sell prochlorperazine. And Micro Chemicals Limited has outstanding applications for the manufacture and sale of chlordiazepoxide under patents owned by Hoffmann-La Roche Limited and for the manufacture and sale of chlorothiazide under patents owned by Merck Sharp & Dohme of Canada Limited.

Thus the respective operations of the associated companies, of which particulars are given later, extend from the manufacture of bulk active chemical materials by Micro Chemicals Limited, the production of pharmaceutical products in pharmaceutical dosage form by Gryphon Laboratories Limited and the distribution of pharmaceutical products by Paul Maney Laboratories Canada Limited.

2. Manufacturing, production and distribution facilities

The associated companies carry out their operations in their own plants and areas respectively. Micro Chemicals Limited manufactures bulk active chemical materials in its chemical plant situated in Cooksville, Ontario. Gryphon Laboratories produces the bulk active chemical materials that it obtains from Micro Chemicals Limited and from other sources in pharmaceutical dosage form in its plant situated in Etobicoke, Ontario. And Paul Maney Laboratories Canada Limited distributes its pharmaceutical products from premises located in the plant at Etobicoke. While each company is, of course, a separate legal entity they are associated with one another, the shares of each company being owned by the same persons and each company having its head office at 20 Advance Road, Toronto 18, Ontario.

(a) *Manufacturing facilities of Micro Chemicals Limited*

Micro Chemicals Limited, hereinafter called simply Micro Chemicals, operates its modern, up-to-date chemical manufacturing plant, with a floor space of 8,000 square feet, at Cooksville, Ontario. Up to the present this plant has involved an outlay of approximately $250,000 and further investment is under way for the expansion of its facilities.

The plant was designed specifically for the manufacture of pharmaceutical chemicals. Its equipment is explosion proof throughout with special features for handling the most delicate and dangerous synthesis in safety, such as non-sparking floor surfaces, full-length floor drains, double scored windows for explosion proof venting and explosion proof lighting. The plant has a fully automatic 3½ million BTU high pressure steam boiler and a 1 million BTU Dow Therm unit for high temperature heating for use as may be required.

The main facilities of the plant, so far as reactor capacity is concerned, range from 100 gallon glass lined, stainless steel reactors to 500 gallon and 750 gallon glass lined, stainless steel reactors, making for the possibility of increasing the batch size as the market for pharmaceutical products expands. This represents a tremendous plant capacity for the manufacture of pharmaceutical chemicals.

In addition to the reactors the plant is equipped with pressure filtering systems, filtering tanks, vacuum filters, vacuum ovens, centrifuges, a distillation apparatus, including high vacuum distillation, and gas absorption units. Transfer systems are by explosion proof pump or vacuum for volatile liquids.

The equipment design and installation has been made in such a manner as to provide the plant with the utmost versatility for the handling of a wide range of chemical reactions. The transfer systems and the equipment modifications are of such a nature that the plant can switch from the manufacture of one chemical material to that of another with a minimum of time and expense.

The plant is regularly inspected by government departments and has been found to be an excellent installation.

(b) *Production facilities of Gryphon Laboratories Limited*

Gryphon Laboratories Limited, hereinafter called simply Gryphon Laboratories, produces pharmaceutical products in pharmaceutical dosage form in a building, with a floor space of 15,000 square feet, at Etobicoke, Ontario. Its capabilities range from the production of tablets to capsule filling, liquid manufacturing, suppositories and the like, but the production of tablets represents its major item of operation. The plant has up-to-date granulators, comminuting machines, blenders and dryers. Its tabletting equipment consists of rotary machines, single punch machines and coating pans. In order to eliminate contamination of its products all production areas are separated from one another by glass windowed walls and all machines are separated from one another. High capacity dust extraction units are used and the plant is completely air conditioned and closed to the outside at all times. All raw material areas, including quarantine areas, are physically wired off to ensure maximum control over raw materials coming into or going from the plant. Raw materials and finished products are subject to a continuous inventory system and the usual laboratory control procedures and their accompanying stickers for quarantine, holding and release of materials and products.

The packaging department is complete with electronic table counters, weighing equipment and fillers. All bottles, caps, labels and the like are subject to the same control procedures as in the case of the production division. All labels are kept in a locked area under strict supervision.

The plant was one of the first plants to be inspected under the new rules adopted a few years ago for acceptability for Government tenders. It was one of the first plants to be approved under 74 GP 1 (a) and has since then passed inspection for continued approval of it.

(c) *Distribution facilities of Paul Maney Laboratories Canada Limited*

Paul Maney Laboratories Canada Limited, hereinafter called simply Paul Maney Laboratories, is a sales and distributing company with extensive facilities for the distribution of pharmaceutical products. It has been operating for approximately eighteen years as a distributor of brand name ethical pharmaceutical products to members of the medical profession, hospitals, clinics, pharmacies and government institutions throughout Canada. Its distribution operations extend from coast to coast in Canada and it has offices and stocks in Montreal, Toronto, Calgary and Vancouver. An area in the plant at Etobicoke has been set aside for it from which it distributes its products efficiently and rapidly. For example, a call for its products from Vancouver can be put on a plane at Malton Airport and reach its destination within a few hours from the placing of the order.

3. *Personnel*

The associated companies employ between thirty and forty persons. The production personnel at the technical level are all highly experienced persons, most of them having had from ten to twenty years in the pharmaceutical manufacturing business. The supervisory and administrative staff includes two persons with Ph.D. degrees in chemistry, three chemists (one a chemical engineer and two organic chemists), a pharmacist and a consulting physician on call when required.

4. *Range of manufacture, production and distribution*

(a) The range of bulk active chemical materials manufactured by Micro Chemicals in its chemical plant is extensive. It manufactures chlorpromazine hydrochloride, bisacodyl, and trifluoperazine hydrochloride under compulsory licences thus far granted to it by the Commissioner of Patents on applications made by it under section 41(3) of the Patent Act. Recently, Rhone-Poulenc S.A. has granted it a licence to manufacture and sell prochlorperazine. Micro Chemicals has also applied under section 41(3) of the Patent Act for licences to manufacture chlordiazepoxide and chlorothiazide. The proceedings in these applications have been closed and Micro Chemicals is awaiting the decision of the Commissioner of Patents in respect of them.

While the manufacture of bulk active chemical materials under compulsory licences granted under section 41(3) of the Patent Act is a very important part of Micro Chemicals' manufacturing operations, they are not restricted to such manufacture. In addition to the said bulk active chemical materials Micro Chemicals manufactures other pharmaceutical chemical compounds, such as promazine hydrochloride, a tranquillizer, aluminum glyconate, a buffering agent, and calcium benzoyl P.A.S., an anti-tubercular drug. It also has several other products in the development stages for future manufacture. The design of the plant, its equipment and personnel are such as to permit the manufacture of a very wide range of pharmaceutical chemical compounds. It has great hopes that many pharmaceutical materials and allied products, heretofore imported into Canada or controlled by foreign companies, will be manufactured successfully in its plants and enable it to become an important segment of the pharmaceutical manufacturing industry in Canada.

(b) Gryphon Laboratories puts into finished pharmaceutical dosage form the bulk active chemical materials that it has obtained from Micro Chemicals. These include not only the bulk active chemical materials which Micro Chemicals has manufactured under the licences under section 41(3) of the Patent Act which the Commissioner of Patents has granted to it and will manufacture under its licence in respect of prochlorperazine, but also the other pharmaceutical chemical compounds manufactured by Micro Chemicals to which reference has been made.

The production done by Gryphon Laboratories is not confined to the production in pharmaceutical dosage form of the bulk active chemical materials and other pharmaceutical chemical compounds that it has obtained from Micro Chemicals. It also puts into pharmaceutical dosage form materials and compounds that it has obtained from sources other than Micro Chemicals.

(c) Paul Maney Laboratories distributes a very wide range of pharmaceutical products, including those produced by Gryphon Laboratories from the bulk active chemical materials and other pharmaceutical chemical compounds manufactured by Micro Chemicals.

Paul Maney Laboratories has handled many potent and dangerous drugs and has complied in all cases with the requirements of the Regulations of the Food and Drug Directorate of the Department of National Health and Welfare. The extent of its distribution will, of course, increase as the demand for the drugs in respect of which Micro Chemicals has obtained or will obtain licences increases.

5. *Quality control facilities and practice*

While the terms of reference to this Committee relate to the cost of drugs and their prices several members of the Committee have expressed concern over the importance of maintaining the quality of the drugs referred to and the safety of their use by the public.

The associated companies are in complete accord with this concern. They submit that the pharmaceutical products distributed by Paul Maney Laboratories have been subjected to the most careful quality control at every stage of their manufacture, production and distribution that has been humanly possible and is equal to that exercised by any other pharmaceutical products company.

The associated companies have the benefit of a quality control laboratory located in the premises of the plant at Etobicoke. This is a modern, up-to-date control laboratory, equipped with all the necessary means for analysis and control of the pharmaceutical products distributed by Paul Maney Laboratories at every state of manufacture of the bulk active chemical materials by Micro Chemicals, production of such materials in pharmaceutical dosage form by Gryphon Laboratories and distribution of the finished pharmaceutical products by Paul Maney Laboratories. This equipment includes ultra violet and infra red spectrophotometers, non-aqueous titration equipment, potentiometers, melting point apparatus, moisture content analysis equipment, a high temperature furnace and, generally, all the equipment required for chemical analysis including that required for vitamins, hormones and the like. The personnel of the quality control laboratory consists of two chemists, including the Chief Quality Control Chemist, and two highly qualified technicians.

It is the duty of the quality control laboratory to check all incoming raw materials, all manufacture and production at various stages, test finished products, perform stability studies and conduct shelf life tests and ensure that all the requirements of the Food and Drug Directorate and the recommendations of 74 GP 1 (a) and (b) have been complied with.

In the belief that it will be of interest to the Committee the companies set out, by way of example, the various steps taken to ensure that the drug trifluoperazine is of the highest possible quality and is safe for use by the public. This is the drug covered by Canadian Patent No. 612,204, owned by Smith Kline & French Inter-American Corporation, hereinafter called simply Smith Kline & French, a wholly owned subsidiary of Smith Kline & French Laboratories of Philadelphia, in respect of which the Commissioner of Patents granted a licence to Micro Chemicals Limited on June 21, 1966, and in respect of which Smith Kline & French made its charges.

The steps taken for the control of the bulk active chemical material manufactured by Micro Chemicals are enumerated in their chronological order as follows, namely:

(1) The raw materials, being the component chemicals from which trifluoperazine is synthetized, are received either in the plant of Micro Chemicals or in that of Gryphon Laboratories and are immediately placed in quarantine and labelled with appropriate stickers.

(2) A quality control chemist checks the quarantined materials and takes samples of them.

(3) The quality control chemist performs all the tests on the said samples required by the Pharmacopeia or the House Standard that are necessary for the identification of the materials and the ascertainment of their purity.

(4) After these tests have been satisfied the materials are released from quarantine and go to general stock at Micro Chemicals' chemical plant for manufacturing by it.

(5) The materials are then synthetized into their bulk active chemical form by the Chief Chemical Engineer and his technicians.

(6) At various stages of the process of manufacturing samples of the synthetized materials are taken and brought to the quality control laboratory for analysis in order to ensure that the chemical compounds have been correctly developed according to the House Standard and the teachings of the specification of Canadian Patent No. 612,204.

(7) The completed active bulk chemical material is again quarantined at Micro Chemicals' plant and a complete analysis is done on samples of it at the quality control laboratory in order to ensure that it meets all the requirements of the British Pharmacopoeia for triffuoperazine.

(8) If the bulk active chemical material meets the requirements a certificate of analysis is issued and kept on file in the records and the material is then delivered to Gryphon Laboratories' plant.

The steps in the quality control of the material taken while it is in this plant are enumerated in their chronological order as follows, namely:

(1) The material is quarantined, a quality control chemist takes samples of it and performs all the tests required by the Pharmacopoeia or the House Standard for the identification of the material and the ascertainment of its purity and if these tests are met the material is released to the general goods area.

(2) The Pharmacist then supervises and checks the weight of the active material and the other components, such as binding material, all of which have gone through similar quarantine, checking and releasing procedure, according to a master formulation sheet for the product, a copy of which has been sent to the control laboratory.

(3) The materials are then granulated and blended.

(4) The control laboratory checks the potency of the blended material and notifies the Pharmacist on the advisable tablet weights.

(5) The blended material is then released for compressing into tablets.

(6) During the compressing period the control laboratory takes samples of the blended material every hour and checks them for weight variation and assays them for active potency.

(7) The tablets are then released for coating.

(8) The tablets are then coated according to the general art of coating and brought to the specified size and colour.

(9) The tablets are then quarantined and samples are carefully checked in order to ensure that they meet the requirements of the Pharmacopoeia and the House Standard.

(10) The tablets are then released for packaging.

(11) The tablets are packaged in bottles, pursuant to work orders, under the supervision of the control laboratory which is responsible for the allotment of bottles, caps, labels and other packaging material.

(12) The finished product in bottles, properly labelled, are further checked by the control laboratory and released for distribution.

(13) The bottles containing the tablets are then placed in the area allotted to Paul Maney Laboratories.

The delivery of the bottles to the Paul Maney Laboratories' area in the plant does not end the quality control exercised in respect of the finished product.

(1) Stability studies are done on it in order to ensure its continuing potency during its shelf life.

(2) Assays of it are made from time to time.

(3) All bottles are correctly labelled so that the product can be identified with certainty and a complete recall system by lot numbers is kept in accordance with the Food and Drug Regulations for maximum safety and protection of the public.

In addition to the tests that have been enumerated the control laboratory keeps additional records for its own information and makes tests in addition to those required by either the Pharmacopeia or the Food and Drug Regulations. Several assays are done on every batch of the bulk active chemical material and also on the finished product.

The completeness of the control exercised in respect of trifluoperazine warranted the statement made by Micro Chemicals in the course of the proceedings on its application under section 41(3) of the Patent Act for a licence to manufacture and sell trifluoperazine in paragraph 8 (5) of its Reply to the Counterstatement filed by Smith Kline & French, as follows:

> "(5) If the licence applied for is granted, every person who buys the applicant's trifluoperazine may rest assured that, notwithstanding its lower price as compared with that of the patentee's Stelazine, it will be manufactured under as safe and controlled conditions as those of the patentee's Stelazine, that it will have as wide a margin of safety as that of the patentee's Stelazine and that its quality will in every respect be equal to that of the patentee's Stelazine".

This statement is repeated to the Committee in the firm belief that it is true.

The associated companies extend an invitation to the Committee to visit the plants referred to and check the manufacturing, production and distribution facilities referred to and see the manner in which the quality control referred to is exercised.

6. *Acceptability of manufacturing and control facilities*

The manufacturing and control facilities of the associated companies have been approved by the Food and Drug Directorate and the Commissioner of Patents.

The following facts support this statement:

(1) The Report of the "special Ad Hoc Committee Studying Matters Involving the Patent Licensing of Drug Manufacturers", known as the

Hilliard Committee, appointed by the Minister of National Health and Welfare, which report was made to the Minister on July 8, 1965, contained, *inter alia*, the following recommendation:

"A compulsory licence for the preparation or production by chemical or fermentation processes of substances intended for subsequent use in medicines should not be granted unless there is first furnished to the Commissioner of Patents a favourable report or certification by the Director of the Food and Drug Directorate on the competency of the applicant for such licence to manufacture or produce such substance, including adequacy of manufacturing facilities and controls as required by the Food and Drug Regulations".

(2) The Commissioner of Patents, in pursuance of the close co-operation which exists between him and the Food and Drug Directorate, having before him the application of Micro Chemicals for a licence under section 41(3) of the Patent Act to manufacture and sell trifluoperazine, requested on May 31, 1966, a report from the Food and Drug Directorate on the competency of Micro Chemicals for the licence applied for and the adequacy of its manufacturing and control facilities.

(3) On June 6, 1966, R. A. Chapman, the Director-General of the Food and Drug Directorate, made the following report to the Commissioner of Patents:

"

Tunney's Pasture,
Ottawa 3, Ontario.
June 6, 1966.

Mr. J. W. T. Michel,
Commissioner of Patents,
Patent and Copyright Office,
Department of Secretary of State,
Canadian Building,
Ottawa, Ontario.

Dear Mr. Michel:

Re: Application by Micro Chemicals Limited under Section 41(3) of the Patent Act for the grant of a Licence under Canadian Patent No. 612,204—Smith Kline and French Inter-American Corporation

Relative to the above subject and your enquiry of May 31st, we offer the following comments.

The firm Micro Chemicals Limited manufacture the chemical trifluoperazine and supply it to Gryphon Laboratories Limited, who in turn use the chemical in manufacture of the finished drug referred to as "Triflurin Tablets". The firm Paul Maney Laboratories markets the product and it is understood that the three companies have a common ownership.

On the basis of our knowledge, these firms have adequate manufacturing facilities and controls and comply with section C.01.052 of the Food and Drug Regulations.

Yours sincerely,
(signed) R. A. Chapman,
Director General".

(4) This report was made after a careful analysis of the tablets containing the active trifluoperazine manufactured by Micro Chemicals Liited and an inspection of the manufacturing and control facilities of the associated companies.

(5) On June 21, 1966, the Commissioner of Patents granted to Micro Chemicals the licence to manufacture and sell trifluoperazine for which it had applied.

It is also brought to the Committee's attention that the Regulations of the Canadian Government Specifications Board setting the "Standard for Manufacture, Control and Distribution of Drugs" for the supply of drugs to agencies of the Government of Canada, known as 74-GP-1a of February 7, 1964, superseded by 74-GP-1b of October 7, 1966, have been complied with.

Since the grant of the licence to Micro Chemicals, Paul Maney Laboratories has submitted tenders for the supply of trifluoperazine in the form of "Triflurin" tablets to several hospitals of the Department of Veterans Affairs and its tenders for such supply have been accepted and deliveries of the supplies have been made accordingly.

It is also brought to the attention of the Committee that "Triflurin" tablets, supplied to the Brandon and Selkirk Mental Hospitals in Manitoba on a no-charge basis, have been subjected to clinical tests and found highly satisfactory, with the result that after the grant of the licence the tender of Paul Maney Laboratories for the supply of trifluoperazine tablets to the two hospitals was accepted in preference to the competing bid of Smith Kline & French and the said tablets were supplied accordingly.

Moreover, the trifluoperazine tablets distributed by Paul Maney Laboratories under the name "Triflurin", put into pharmaceutical dosage form by Gryphon Laboratories from bulk active trifluoperazine manufactured by Micro Chemicals have been subjected to careful analysis by the Food and Drug Directorate and no complaint has been received from it.

The quality control facilities of the associated companies are dealt with further in Part III of the submission rebutting the false charges made by Smith Kline & French.

PART II

In this part of the submission to the Committee the associated companies show:

1. That the costs of patented drugs are too high and that the prices charged by the patentees for them are, in many cases, excessive.

2. That section 41(3) of the Patent Act provides an important means for protecting the public against excessive prices charged by the large drug companies, through their subsidiaries in Canada, for the drugs covered by the Canadian patents which the subsidiaries have obtained for them.

3. That Micro Chemicals and its associates have given convincing proof of the importance of section 41(3) of the Patent Act and the efficacy of licences under it in reducing the prices of patented drugs.

4. That there is need for competent licensees under section 41(3) of the Patent Act in order to carry out the national purpose that Parliament had in mind when it enacted the section.

5. That, in view of the close co-operation that now exists between the Food and Drug Directorate and the Commissioner of Patents before an application under section 41(3) of the Patent Act is granted, the Food and Drug Directorate may be relied upon for ensuring that the applicant for the licence has the necessary manufacturing and quality control facilities for maintaining the high quality of the drug covered by the patent in respect of which the licence is sought and the safety of its use by the public.

6. That it is in the public interest that section 41(3) of the Patent Act be retained so that the national purpose for which it was enacted may continue to be served.

7. That it is in the public interest to have an organization such as that of the associated companies as an agency that can be relied upon as a source for the manufacture and distribution of the patented drugs in respect of which licences under section 41(3) of the Patent Act have been granted so that the public may have the benefit of their valuable therapeutic qualities at prices substantially lower than those charged for them by the owners of the patents for them.

1. *The Excessive Costs and Prices of Patented Drugs*

It is submitted that the situation with regard to the costs and prices of patented drugs is not the same as that with regard to other drugs. With respect to the latter there are many drugs in respect of which competition has driven their prices down to acceptable levels. The situation is different with regard to the costs and prices of the drugs in respect of which patents have been granted in Canada to subsidiaries of the great drug companies. These subsidiaries are wholly owned by their foreign parents and are in, the main, merely distributors in Canada of the drugs discovered elsewhere and have not made any contribution to the research leading to such discovery.

The great drug companies spend large sums in research, frequently resulting in failures, but occasionally resulting in "winners", such as "Librium", the trade name under which Hoffmann-La Roche sells its "chlordiazepoxide" and "Stelazine", the trade name under which Smith Kline & French sells the trifluoperazine. They then put the prices of the "winners" at all that the traffic will stand and continue to charge such prices. They carry this policy into effect, through their subsidiaries, in the various countries in which their subsidiaries have acquired patents, including subsidiaries in Canada who have acquired Canadian patents for the inventions that were made abroad.

The associated companies have no hesitation in stating that, in many cases, the prices charged for such drugs as those specifically referred to are excessive. This is a matter of deep concern to the members of the public who are dependent on such drugs for the benefit of their valuable therapeutic qualities for the relief of their illnesses.

It is obviously difficult to present a detailed review of all the cases in which the prices charged for patented drugs are excessive. The associated companies, therefore, select a case, in respect of which they have particular knowledge, as

an illustration of the excessive prices charged by the big drug companies, through their wholly owned subsidiaries in Canada, for the drugs covered by their Canadian patents.

The particular case to which the associated companies refer, by way of illustration, is that of the excessive prices charged by Smith Kline & French Inter-American Corporation under its Canadian Patent No. 612,204 for trifluoperazine, which it sells under the trade name "Stelazine".

In its application under section 41(3) of the Patent Act, under Canadian Patent No. 612,204, for a licence to manufacture and sell trifluoperazine, Micro Chemicals stated, as one of the grounds for its application, that the retail selling prices for "Stelazine" tablets recommended by Smith Kline & French were too high. In the course of the proceedings under the application several facts in support of the statement were disclosed. They are enumerated as follows:

(1) Smith Kline & French put their cost of manufacturing Stelazine tablets in Canada at $1,480 per kilogram, which amount included $1,039 for synthesis, compounding and packaging and $441 as return on manufacturing investment. There were three facts that showed that this alleged cost was much too high:

(a) It was proved in the Hoffmann-La Roche v. Bell Craig case that the total cost of putting chlordiazepoxide (Librium) into usable dosage form was only $460 per kilogram, and it was submitted that it was inconceivable that the corresponding cost for trifluoperazine (Stelazine) should be more than three times as high.

(b) It was also a fact that an Italian firm had made a public offering of trifluoperazine for sale at $270 per kilogram and had made a profit at such price.

(c) Micro Chemicals estimated that its production costs for trifluoperazine would be less than $500 per kilogram.

It is interesting to note that in its submission to the Commissioner on the amount of royalty payable by the licensee it was admitted that the cost of manufacturing the bulk active trifluoperazine in salt form was within the range of $100 to $150 per kilogram.

(2) Smith Kline & French put the cost of research and product investigation and return on research investment in Canada, as an item of its trifluoperazine costs, at $3,113 per kilogram, notwithstanding the fact that it had not made any research leading to the invention of trifluoperazine or any contribution to such research.

(3) Smith Kline & French put the cost of medical information and return on medical information investment in Canada, as an item of its trifluoperazine costs, at $5,455 per kilogram, which works out at over 40 per cent of its net selling price, which it put at $12,639 per kilogram. Micro Chemicals pointed out two objections to this amount:

(a) It included advertising and promotion costs incurred by Smith Kline & French solely for the purpose of increasing its profits from the sale of trifluoperazine and the description of them under the heading of Essential Drug Services or Medical Information was a misdescription.

(b) Moreover, the amount of $5,455, representing more than 40 per cent of the net selling price, was excessive as compared with the average

of 25 per cent for the 27 firms from which information had been obtained on "Expenditures of Selected Firms on Advertising, Research and Quality Control", as shown at page 115 of Appendix Q to the Report of the Restrictive Trade Practices Commission concerning the Manufacture, Distribution and Sale of Drugs, made to the Minister of Justice on January 24, 1963.

Costs of the kinds enumerated make for excessive prices of drugs such as trifluoperazine.

Coupled with these facts there is the clearly established fact that the United States parent of Smith Kline & French has one of the highest net profit ratios in the drug industry. Smith Kline & French disputed the accuracy of the statement made by Micro Chemicals but proof of its truth was given:

(a) The statement of costs made by Smith Kline & French to which reference has been made itself indicates that the charge levelled against the parent lies against its subsidiaries as well.

(b) In each of the years 1961 to 1964 inclusive the United States parent of Smith Kline & French realized net profits on its sales before taxes, ranging from 37 per cent in 1961, 36 per cent in 1962, 35.3 per cent in 1963 to 35.1 per cent in 1964. These figures appear on page 2050 of the 1965 Standard Listed Stock Reports of Standard & Poor's Corporation of August 23, 1965. These reports are based on information supplied by the corporation in respect of which the reports are made. The percentages of profits referred to are by way of contrast to the average net profits before taxes of 17.08 per cent made by the 28 firms that reported such profits as shown at page 147 of the Appendix Q previously referred to.

Thus it was conclusively shown that the profit ratio of the parent Smith Kline & French was more than twice as high as the average of the profit ratios of the 28 firms referred to.

Moreover, an analysis of the costs submitted by Smith Kline & French showed a net profit before taxes of 27.1 per cent, or 10 per cent higher than the average net profit before taxes of the 28 firms referred to.

It is not surprising, therefore, in view of the excessive prices charged by Smith Kline & French for its trifluoperazine, that the Commissioner of Patents granted to Micro Chemicals the licence for which it had applied, particularly after the Food and Drug Directorate had approved its manufacturing and quality control facilities, as shown by its letter to the Commissioner of Patents, dated June 6, 1966, set out on page 19 of this submission.

2. *Importance of Section 41(3) of the Patent Act*

The associated companies submit that section 41(3) of the Patent Act provides an important means for protecting the public against excessive prices charged by the large drug companies, through their subsidiaries in Canada, for the drugs covered by the Canadian patents which they have obtained for them by the authorization in the section to the Commissioner of Patents to grant licences under the patents "unless he sees good reason to the contrary" in order that the licensees may provide competition with the patentees and pull down the prices charged for their drugs.

It is not surprising, therefore, that the drug companies that have appeared before the Committee have complained about section 41(3) of the Patent Act, for it stands in the way of their maintaining their prices for the drugs covered by their patents and making the profits from their sale of them that they could make from their patent monopoly if the protection provided by the section were abolished.

It is submitted that it is desirable to set out the legislative policy underlying section 41(3) of the Patent Act and the national purpose which Parliament had in mind for its enactment. This can best be done by setting out the terms of the section and referring to the important decisions of the Supreme Court of Canada relating to it.

Section 41(3) of the Patent Act, R.S.C. 1952, Chap. 203 provides 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".

Section 41(3) has been an important provision of Canadian patent law ever since 1923. It is, threefore, of interest to note that it is only comparatively recently that advantage has been taken of the protection to the public that it provides.

The legislative policy underlying the section and the national purpose for its enactment have been the subject of important judicial decisions.

It was established by the Supreme Court of Canada in Parke, Davis & Co. v. Fine Chemicals of Canada Ltd. (1959) S.C.R. 219 that the legislative policy underlying section 41(3) was that the new substances to which it applies "are, in the public interest, to be free from legalized monopoly". In that case Mr. Justice Rand said, at page 222:

> "The legislative policy underlying the subsection to be gathered from its special terms is obvious: all new substances, apart and as distinguished from processes, are, in the public interest, to be free from legalized monopoly".

This was a clear statement that when the public interest so demands the ordinary monopoly granted by a patent should not apply in the case of patents for food or medicine.

It is also clear from the language of the section that it is mandatory that the Commissioner of Patents shall grant a licence of the kind contemplated by the section to any person applying for the same "unless he sees good reason to the contrary" and the Supreme Court of Canada made it clear in the case referred to that Parliament has entrusted the decision on whether any particular licence, for which an application has been made, should be granted to the Commissioner of

Patents. In that case, Mr. Justice Martland, speaking for Mr. Justice Locke and Mr. Justice Cartwright as well as for himself, said, at page 228:

> "The wording in question is "the Commissioner shall, unless he sees good reason to the contrary, grant to any person applying for the same...". In this case the Commissioner did not see such good reason. The decision is his to make and it cannot be said, on the evidence, that his decision was manifestly wrong, having in mind that one of the main considerations before him is that of the public interest".

The national purpose for which the section was enacted was authoritatively stated by the Supreme Court of Canada in Hoffman-LaRoche Limited v. Bell-Craig Pharmaceuticals Division of L.D. Craig Limited (1966) S.C.R. 313. In that case Mr. Justice Abbott, delivering the unanimous judgment of the Court, said at page 319:

> "In my view the purpose of s. 41(3) is clear. Shortly stated it is this: No absolute monopoly can be obtained in a process for the production of food or medicine. On the contrary Parliament intended that, in the public interest, there should be competition in the production and marketing of such products produced by a patented process, in order that as the section states, they may 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".

This is a clear statement that the purpose of section 41(3) is to provide competition with the owner of the patent in order to make the food or medicine to which it applies, which includes drugs, available to the public at the lowest possible price, subject to the condition specified in the section, namely, that such lowest price should be "consistent with giving to the inventor due reward for the research leading to the invention". The meaning of this condition was the subject of controversy until the decision in the case referred to. The controversy was settled by Mr. Justice Abbott. He made it clear that the reward referred to meant reward to "the inventor—not the patentee—". This threw a bombshell into the big drug companies' camp for it meant, in effect, that in settling the amount of royalty or other consideration payable by a licensee the Commissioner should not include in the base for fixing the royalty any amount by way of reward in a case where the owner of the patent is not the inventor of the invention covered by the patent and has not made any research leading to it. The decision means that in such a case the condition referred to does not apply. It follows that in a case where the owner of the patent is not the inventor of the invention covered by the patent and has not made any research leading to the invention the Commissioner should have regard to the desirability of making the food or medicine available to the public at the lowest possible price, without regard to the condition referred to, since it does not apply in such a case.

In view of the fact that in the case of every Canadian patent owned by a subsidiary in Canada of a foreign parent the subsidiary is not the inventor of the invention covered by the patent and has not made any research leading to the invention, it is not surprising that the big drug companies, through their subsidiaries in Canada, have become frantic in their submissions to the Committee in their protests against section 41(3) of the Patent Act. They realize that it

provides a means for the release of the strangle hold in the matter of patented drug prices which they have been able to put on the public.

It is, of course essential to the release of this strangle hold that there should be competent applicants for licences under the patents who will provide, if the licences applied for by them are granted, effective competition with the patentees and pull down the prices of the patented drugs.

3. *Proof of the efficacy of licences under Section 41(3) of the Patent Act in reducing the prices of patented drugs*

Micro Chemicals Limited and its associates have been convincing proof of the importance of section 41(3) of the Patent Act as a provision for the protection of the public against the excessive prices of patented drugs and the efficacy of licences under the section in reducing the prices of such drugs.

Micro Chemicals made its application for a licence to manufacture and sell chlorpromazine hydrochloride on July 21, 1960, but its licence was not granted until May 31, 1962, and, subsequently, there was a variation in its terms.

The history of the operation under the licence is a striking illustration of the effectiveness of the competition with the patentee which Micro Chemicals and its associates have provided and the substantial reduction in the prices of chlorpromazine which has resulted from the competition.

In its application for a licence for Canadian Patent No. 519,525 Micro Chemicals set out the list prices which Rhone Poulenc, the owner of the patent, recommended for its chlorpromazine, which it sold under the trade name "Largactil", and the list prices proposed by Micro Chemicals if its licence should be granted.

The associated companies now set out, as Table I, these two sets of prices, side by side with one another, showing the prices of the various strengths of the chlorpromazine per 100 tablets:

TABLE I

1960 List Prices

Rhone Poulenc	Micro Chemicals
25 mg $10.50	$ 6.00
50 mg $15.00	$10.00
100 mg $25.00	$15.00

These prices proposed by Micro Chemicals represented only the beginning of the competition that took place. After the licence to Micro Chemicals was granted the chlorpromazine which it has manufactured and which Gryphon Laboratories had put into pharmaceutical dosage form was distributed by Paul Maney Laboratories under the name "Chlor Promanyl".

The extent of the competition provided by Micro Chemicals and its associates, so far as volume is concerned, has been substantial. The average sales of chlorpromazine made by Rhone Poulenc have been approximately 1,100 kilo-

grams per year. The sales made by Paul Maney Laboratories of chlorpromazine manufactured by Micro Chemicals have been as follows:

In the year 1963	910 kilograms
In the year 1964	640 kilograms
In the year 1965	675 kilograms
In the year 1966	680 kilograms

As the years went by the prices of chlorpromazine tablets were substantially reduced. The associated companies now set out, as Table II, the present list prices of "Largactil" and "Chlor Promanyl", side by side with one another, showing the prices of the various strengths of chlorpromazine per 100 tablets:

TABLE II

Largactil (Rhone Poulenc)	Chlor Promanyl (Paul Maney)
25 mg $ 8.90	$4.20
50 mg $12.80	$7.26
100 mg $21.30	$9.50

The associated companies now set out, as Table III, the recommended list prices of Rhone Poulenc in 1960 and the present recommended list prices of Paul Maney Laboratories, side by side with one another, showing the prices of the various strengths per 100 tablets:

TABLE III

Largactil (Rhone Poulenc)	Chlor Promanyl (Paul Maney)
25 mg $10.50	$4.20
50 mg $15.00	$7.26
100 mg $25.00	$9.50

Thus the present recommended list prices of the chlorpromazine tablets made from chlorpromazine manufactured by Micro Chemicals under its licence are less than those recommended by Rhone Poulenc for its tablets in 1960 in the following percentages:

25 mg	40%
50 mg	48%
100 mg	38%

It follows that individual patients who are advised by their physicians to use chlorpromazine may now buy their necessary requirements of the drug at the reduced prices indicated as compared with the prices that they would have been obliged to pay for it before Micro Chemicals obtained its licence.

While the reduction in the price of chlorpromazine to users of the drug resulting from the competition with the patentee which Micro Chemicals and its associates have provided is substantial, the reduction in the price at which Governments may buy their requirements of chlorpromazine is even greater. This is demonstrated by two sets of figures. In 1960 Rhone Poulenc submitted a

tender to the Government of Ontario for the supply of its requirements of chlorpromazine tablets for six months at the following prices per thousand tablets for the various strengths of the product:

"25 mg,	2,071,000 at $21.00	$43,491.00
50 mg,	785,000 at $43.00	$33,755.00
100 mg,	560,000 at $53.00	$29,680.00
Total		$106,926.00"

Recently, Paul Maney Laboratories supplied the Government of British Columbia with its requirements of Chlor Promanyl in lots of 250,000 tablets at the following prices per thousand tablets for the various strengths of the product:

"Sept. 7, 1966 — 25 mg at $ 5.40
Nov. 11, 1966 — 50 mg at $ 8.10
Oct. 19, 1966 — 100 mg at $13.45"

This shows reductions in prices as compared with those charged by Rhone Poulenc in 1960. Put in terms of percentages of the present prices of "Chlor Promanyl" as compared with those of "Largactil" in 1960 they are as follows:

" 25 mg tablets — 25.7%
50 mg tablets — 18.8%
100 mg tablets — 24.1%"

It may reasonably be stated that if the quantities of Chlor Promanyl supplied by Paul Maney Laboratories had been greater the prices charged by it would have been less.

It is too early to give complete proof of the effectiveness of the competition which Micro Chemicals and its associates will provide against Smith Kline & French in the sale of trifluoperazine in respect of which Micro Chemicals obtained its licence under section 41(3) of the Patent Act on June 21, 1966.

In its application for a licence under Canadian Patent No. 612,204, owned by Smith Kline & French Inter-American Corporation, Micro Chemicals set out the list prices which Smith Kline & French recommended for its trifluoperazine which it sold under the trade name "Stelazine" and the list prices proposed by Micro Chemicals, if its licence should be granted.

The associated companies now set out as Table IV these two sets of prices, side by side with one another, showing the prices of the various strengths per 50 tablets:

"TABLE IV

	1965 List Prices Smith Kline & French	Micro Chemicals
1 mg	$ 4.75	$3.80
2 mg	$ 6.25	$5.00
5 mg	$ 8.80	$7.05
10 mg	$11.70	$8.80"

This table shows a proposed reduction of 20 per cent.

Recently, shortly after Micro Chemicals obtained its licence, Paul Maney Laboratories obtained a contract from the Province of Manitoba for the sale of trifluoperazine tablets, made from trifluoperazine manufactured by Micro Chemicals under its licence, for approximately $66,000 against the competing bid made by Smith Kline & French which is believed to have been approximately $130,000. This contract was awarded to Paul Maney Laboratories after thousands of trifluoperazine tablets, which Paul Maney Laboratories sells under the name "Triflurin", had been supplied to the Government of Manitoba on a no charge basis for clinical testing in the Brandon and Selkirk Mental Hospitals and had been found eminently effective.

While it is not possible to forecast how far the prices of trifluoperazine will be reduced the associated companies submit that they will provide as effective competition with Smith Kline & French in the sale of trifluoperazine as they have provided with Rhone Poulenc in the sale of chlorpromazine. The prices will be brought down to the levels established as the result of the competition contemplated by Parliament when it enacted section 41(3) of the Patent Act.

4. *Need for competent licencees under section 41(3) of the Patent Act*

The associated companies submit that when the Commissioner of Patents has granted a licence under section 41(3) of the Patent Act it is because the owner of the patent has brought the licence on his own head by his conduct under the monopoly which his patent has given to him.

The owners of Canadian patents covering drugs need not have any fear of licences under their patents in cases where their prices for the patented drugs are fairly competitive. This is implied in the national purpose for which section 41(3) was enacted.

But when the owner of the patent steps outside the limits implied in the section and charges excessive prices for his patented drug and makes an unreasonable profit from its sale, as in the case, for example, of Smith Kline & French, he opens himself up to an application for a licence under section 41(3) and the competition which the licensee will provide with the resulting reduction in price that the force of competition will compel.

The justification for the competition contemplated by Parliament when it enacted section 41(3) of the Patent Act in 1923, more than 43 years ago, was well expressed by President Jackett of the Exchequer Court of Canada when he said in Hoffmann-La Roche Limited v. Bell-Craig Pharmaceuticals Division of L. D. Craig Limited (1965) 2 Ex. C.R. 266, at page 282:

> "Section 41(3) was passed because, in the field to which it applies, 'the specific public interest in free competition' was deemed to be more important than the maintenance of the patentee's monopoly rights".

Under the circumstances, it is essential to the fulfilment of the purpose which Parliament had in mind when it enacted section 41(3) that there should be, in a proper case, determined by the Commissioner of Patents, acting in close co-operation with the Food and Drug Directorate, a competent licensee who has the equipment and the necessary manufacturing and quality control facilities to provide the competition contemplated by the section and who can be relied upon to pull down the prices charged by the patentee.

5. *Importance of Existing co-operation between Food and Drug Directorate and Commissioner of Patents*

The associated companies submit that the importance of the co-operation that exists between the Food and Drug Directorate and the Commissioner of Patents before he grants an application for a licence under section 41(3) of the Patent Act cannot be too strongly stressed. There was, as already stated, a clear illustration of this co-operation before the Commissioner of Patents granted to Micro Chemicals the licence to manufacture and sell trifluoperazine for which it had applied.

It is further submitted that the Food and Drug Directorate may be relied upon for ensuring, before a licence is granted, that the applicant for the licence has the manufacturing and quality control facilities that are necessary for the maintenance of the high quality of the drug covered by the patent in respect of which the licence is sought and the safety of its use by the public.

6. *Retention of Section 41(3) of the Patent Act Essential*

The associated companies submit, notwithstanding the attacks made on section 41(3) of the Patent Act by the large drug companies, that it is in the public interest that the section be retained in order that the national purpose for which it was enacted may continue to be served.

Finally, the associated companies submit that it is in the public interest to have an agency that can be relied upon as a source for the manufacture, production and distribution of the patented drugs in respect of which licences under section 41(3) of the Patent Act have been granted so that the public may have the benefit of their valuable therapeutic qualities at prices substantially lower than those charged for them by the owners of the patents for them.

And the associated companies sincerely believe that they can be such an agency and perform this important function.

While it is, strictly speaking, not relevant to the specific reference to the Committee, the associated companies bring to its attention that they are developing a research program within their means and have several important projects under way that will materially assist them in performing the functions on which they have embarked and for which, as they have proved, they are well fitted.

Part III

In this part of the submission to the Committee the associated companies rebut the charges made against Paul Maney Laboratories by Smith Kline & French on October 27, 1966.

They sincerely thank the Committee for the invitation extended to the President of Paul Maney Laboratories, conveyed by the Clerk of the Committee in her letter of November 17, 1966.

In passing, they draw the Committee's attention to the fact that Paul Many Laboratories is not a generic firm as suggested in the letter. It is a distributor of brand name pharmaceutical products.

The charge to which the associated companies particularly object was made when Smith Kline & French appeared before the Committee on October 27, 1966.

It appears on page 44 of the Smith Kline & French brief, as set out on page 961 of the transcript of the evidence befofe the Committee, as follows:

> "Paul Maney, in a notice published earlier this year, referred to its product as being of B.P. standard. However, tablets sold by Paul Maney have assayed across a considerable range of potencies from the lower limit of the B.P. standard to the upper limit of our own—that is, from 92 per cent of B.P. standard to 120 per cent. A patient taking Paul Maney trifluoperazine tablets may thus suddently receive a 20 per cent increase or decrease in dosage, besides receiving on average 16 per cent less of the drug than if he were taking 'Stelazine' ".

The statement that "a patient taking Paul Maney fluoperazine tablets may suddenly receive a 20 per cent increase or decrease in dosage, besides receiving on average 16 per cent less of the drug than if he were taking Stelazine" was false. Smith Kline & French has taken advantage of the privileged nature of its submission to the Committee to make a statement which it must have known to be false.

The associated companies challenge Smith Kline & French to have an independent person buy Stelazine in bottles of 1 mg, 2 mg, 5 mg and 10 mg tablets and also buy Triflurin tablets in bottles of 1 mg, 2 mg, 5 mg and 10 mg tablets and have them both analyzed by an independent laboratory acceptable to both Smith Kline & French and the associated companies. It would then be found that there is no difference between the potency of Triflurin tablets and that of Stelazine tablets. The analysis would show that there is the same amount of the active trifluoperazine base in a Trifluorin tablet of a given strength as there is in a Stelazine tablet of similar strength.

It is significant that Smith Kline & French did not report to the Food and Drug Directorate the result of the test alleged by Mr. Ross F. Bethel to have been made last May on two lots of Paul Maney Laboratories. If it had done so and satisfied the Food and Drug Directorate of the truth of the tests it is highly unlikely that the Food and Drug Directorate would have given the associated companies the approval set out in the letter of June 6, 1966, to the Commissioner of Patents to which reference has been made.

It is also significant that the evidence given by Mr. Allmark of the Food and Drug Directorate did not support Mr. Bethel's statement.

In Mr. Bethel's inter-office memorandum, dated December 12, 1966, which Mr. R. F. Daily, the Vice President and General Manager of Smith Kline & French enclosed with his letter to the Chairman of the Committee dated December 12, 1966, it is admitted that the labels on the bottles containing Stelazine tablets of Smith Kline & French now read

> "Stelazine
> tablets
> trifluorazine
> tablets B.P."

and, of course, indicate the strength of the tablets in the bottle, for example, 1 mg, 2 mg, 5 mg or 10 mg, as the case may be. Moreover, the label shows, in the case, for example, of 1 mg tablets, that each tablet contains 1 mg of the active

trifluoperazine base. Mr. Bethel's memorandum also contained the following statement:

> "The B.P. monograph does not state what the strength must be—only that the tablets contain trifluoperazine hydrochloride which, of course, ours do. It is the only form of the chemical practical to use for this particular dosage form—which is the whole crux of the matter".

In other words, trifluoperazine hydrochloride being the salt form of the chemical is the form best suited for making trifluoperazine tablets.

It follows, of course, that if a tablet is to contain, for example, 1 mg of the active trifluoperazine base, which is the denominator of its potency, the weight of the tablet, since it is made from the salt form of the chemical, namely, trifluoperazine hydrochloride, must be greater than 1 mg.

This fact is recognized and plainly stated in the labels of the bottles containing "Triflurin" tablets. Attached hereto as Appendix "A" to this part of the submission is a reproduction of labels of the kind used by Paul Maney Laboratories on its bottles containing its "Triflurin" tablets in its several strengths of 1 mg, 2 mg, 5 mg and 10 mg. These show in each case the weight of the active trifluoperazine base in the tablet and the weight of the trifluoperazine hydrochloride contained in the tablet as the equivalent of the active trifluoperazine base. The information shown on the labels is put in a table as follows:

"Label	Amount of active trifluoperazine base in each tablet	Amount of trifluoperazine hydrochloride contained in each tablet
1. Triflurin " 1"	1 mg	1.18 mg
2. Triflurin " 2"	2 mg	2.36 mg
3. Triflurin " 5"	5 mg	5.90 mg
4. Triflurin "10"	10 mg	11.79 mg"

It should be noted that the labels in actual use show the proper lot numbers for identification purposes.

The labels used by Smith Kline & French on their bottles of Stelazine tablets in its several strengths of 1 mg, 2 mg, 5 mg and 10 mg show in each case the weight of the active trifluoperazine base in the tablet but make no reference to the weight of the trifluoperazine hydrochloride contained in the tablet. Attached hereto as Appendix "B" to this part is a reproduction of labels actually taken from bottles containing Stelazine tablets. It is noted that the label for the 2 mg tablets does not state that the tablets are B.P. tablets. This indicates that the label was one that was in use before the Food and Drug Directorate required Smith Kline & French to make the change.

Thus it is clear, so far as the labels go, that there is no difference between the manner in which the potency of Triflurin tablets is claimed from that in which the potency of Stelazine tablets is claimed. Both claim the potency in terms of the weight of the active trifluoperazine base contained in the tablet. The only difference is that Paul Maney Laboratories sets out the weight of the trifluoperazine hydrochloride in the tablets whereas Smith Kline & French does not.

Recently, assays were made on lots of Triflurin tablets and also on lots of Stelazine tablets. The assays showed the percentages in the tablets of the active trifluoperazine base claimed in the labels. The assays on the Triflurin tablets were as follows:

'Lot number	Percentage of claimed base
Triflurin "1" Lot 738	100.9%
Triflurin "1" Lot 819	99.2%
Triflurin "2" Lot 792	100.4%
Triflurin "2" Lot 807	101.3%
Triflurin "5" Lot 724	97.4%
Triflurin "5" Lot 790	98.1%
Triflurin '5" Lot 791	100.8%
Triflurin "5" Lot 809	100.2%
Triflurin "5" Lot 816	100.6%
Triflurin "10" Lot 793	97.6%
Triflurin "10" Lot 811	98.3%
Triflurin "10" Lot 817	98.5%"

The assays on the Stelazine tablets were as follows:

"Lot number	Percentage of claimed base
Stelazine 1 mg Lot F-6397	99.1%
Stelazine 2 mg Lot I-5508	97.9%
Stelazine 5 mg Lot F-6362	96.1%
Stelazine 10 mg Lot D-6250	98.0%"

These assays prove two facts, namely,

(1) That there is no difference between the potency of the Trifluring tablets and that of the stelazine tablets.

(2) That the variations in potency are well within the limits of 92½ per cent to 107½ per cent of the British Pharmacopoeia and also within the limits of 95 per cent to 105 per cent claimed by Smith Kline & French as stated by Mr. Bethel, on October 23, 1966, as appears on page 906 of the transcript of the evidence.

The associated companies inform the Committee that a complete report on these assays was sent to the Food and Drug Directorate.

Moreover, the Food and Drug Directorate has done a great deal of testing of Triflurin tablets and has not made any complaint with regard to them.

The associated companies again remind the Committee that before Paul Maney Laboratories' tender for the supply of trifluoperazine to the Government of Manitoba for use by the Brandon and Selkirk Mental Hospitals was accepted

extensive clinical tests of the tablets were made and were found to be very effective.

So far as the associated companies are aware, there have not been any ill effects from the use of Triflurin tablets. On the contrary, their effects have been very beneficial.

Under the circumstances, the associated companies submit that there is no substance in the charges made by Smith Kline & French and that they should not be believed.

Pr 1000 tablets SCT 7162

TRIFLURIN "1"

TRIFLUOPERAZINE TABLETS B.P.
1 mg. (Base)

PAUL MANEY LABORATORIES TORONTO CANADA

Each tablet contains:—
Trifluoperazine Hydrochloride B.P. 1.18 mg
(Equivalent to 1 mg of the base)

Lot No

Dose:—Adults. In psychiatric states, 2 to 30 mg. daily, in divided doses. As an antiemetic, 1 to 6 mg. daily. Or as directed by a physician.

Keep in a cool dry place.

Pr 1000 tablets SCT 7163

TRIFLURIN "2"

TRIFLUOPERAZINE TABLETS B.P.
2 mg. (Base)

PAUL MANEY LABORATORIES TORONTO CANADA

Each tablet contains:—
Trifluoperazine Hydrochloride B.P. 2.36 mg
(Equivalent to 2 mg of the base)

Lot No.

Dose:—Adults. In psychiatric states, 2 to 30 mg. daily, in divided doses. As an antiemetic, 1 to 6 mg. daily. Or as directed by a physician.

Keep in a cool dry place.

Pr 1000 tablets SCT 7164

TRIFLURIN "5"

TRIFLUOPERAZINE TABLETS B.P.
5 mg. (Base)

PAUL MANEY LABORATORIES TORONTO CANADA

Each tablet contains:—
Trifluoperazine Hydrochloride B.P. 5.90 mg
(Equivalent to 5 mg of the base)

Lot No.

Dose:—Adults. In psychiatric states, 2 to 30 mg. daily, in divided doses. As an antiemetic, 1 to 6 mg. daily. Or as directed by a physician.

Keep in a cool dry place.

Pr 100 tablets SCT 7165

TRIFLURIN "10"

TRIFLUOPERAZINE TABLETS B.P.
10 mg. (Base)

PAUL MANEY LABORATORIES TORONTO CANADA

Each tablet contains:—
Trifluoperazine Hydrochloride B.P. ..... 11.79 mg
(Equivalent to 10 mg of the base)

Lot No.

Dose:—Adults. In psychiatric states, 2 to 30 mg. daily, in divided doses. As an antiemetic, 1 to 6 mg. daily. Or as directed by a physician.

Keep in a cool dry place.

Each tablet contains trifluoperazine, 1 mg. (10-[3-(4-methyl-4-piperazinyl) propyl]-2-trifluoromethylphenothiazine) as the dihydrochloride.
Dosage as directed by a physician.
50 Tablets
1 mg.
Stelazine*
tablets
trifluoperazine
tablets B.P.
*Reg. Can. T.M. Off.
Smith Kline & French I.A.C., Montreal 9, Que.
KEEP IN A COOL DRY PLACE
Pat. 1961 No. 612,204
CI Lot F.6397

Each tablet contains trifluoperazine, 2 mg. (10-[3-(1-methyl-4-piperazinyl) propyl] -2-trifluoromethylphenothiazine) as the dihydrochloride.
Dosage as directed by a physician.
50 Tablets
2 mg.
Stelazine*
trifluoperazine
tablets
*Reg. Can. T.M. Off.
Smith Kline & French I.A.C., Montreal, Que.
KEEP IN A COOL DRY PLACE
Pat. 1961 No. 612,204
CF Lot J.3508

Each tablet contains trifluoperazine 5 mg. (10-[3-(1-methyl-4-piperazinyl) propyl] -2-trifluoromethylphenothiazine) as the dihydrochloride.
Dosage as directed by a physician.
50 Tablets
5 mg.
Stelazine*
tablets
trifluoperazine
tablets B.P.
*Reg. Can. T.M. Off.
Smith Kline & French I.A.C., Montreal 9, Que.
KEEP IN A COOL DRY PLACE
Pat. 1961 No. 612,204
CF Lot F.6362

Each tablet contains trifluoperazine, 10 mg. (10- [3- (1 -methyl-4 piperazinyl) propyl) - 2- trifluoromethylphenothiazine) as the dihydrochloride.
Dosage as directed by a physician.
50 Tablets
10 mg.
Stelazine*
tablets
trifluoperazine tablets B.P.
*Reg. Can. T.M. Off.
Smith Kline & French I.A.C., Montreal 9, Que.
KEEP IN A COOL DRY PLACE
Pat. 1961 - No. 612,204
CD Lot D.6250

PART IV

The associated companies believe that the most useful recommendations that they can make to the Committee for the reduction of the prices of patented drugs, consistent with ensuring their quality and the safety of their use, are:

1. That section 41(3) of the Patent Act should be retained.
2. That the power vested in the Commissioner of Patents to grant licences under section 41(3) of the Patent Act, "unless he sees good reason to the contrary", should continue to be vested in him.
3. That the co-operation that now exists between the Food and Drug Directorate and the Commissioner of Patents before the Commissioner grants a licence under section 41(3) of the Patent Act should be continued.

Respectfully submitted.

Ottawa, January 12, 1967.

APPENDIX "B"

Dr. Harry C. Harley, M.P.
House of Commons
Parliament Buildings
Ottawa
Canada

Dear Dr. Harley:

The brief submitted to your Committee by Mr. Jules Gilbert makes certain allegations regarding the position taken by Smith, Kline & French in our appearance before you. I feel it necessary to answer these allegations, and at the same time to set straight some of the misconceptions in Mr. Gilbert's brief.

With regard to the technical issues raised by Mr. Gilbert—notably, the development of B.P. standards and the procedure we follow in labelling—I enclose a memorandum prepared by Mr. Ross Bethel, our Technical Department Manager. This clearly illustrates, I believe, a fundamental fallacy behind Mr. Gilbert's argument, the assumption that the standards set out for trifluoperazine in the British Pharmacopoeia can be equated with those established several years earlier by this company, standards on which the worldwide medical acceptance of trifluoperazine has been based.

However, Mr. Gilbert's position in this matter is, itself, ambivalent. While his brief appears to defend the absolute validity of the B.P. standards, his latest price list for his product carries the legend: "All strengths are calculated as the base equivalent", and thereby seeks to measure up to the SK&F standards.

I would only add that, as we stated in our brief, assays of Mr. Gilbert's tablets have demonstrated both variations in potency and a generally lower level of potency than 'Stelazine'. Most of these assays have already been submitted to you. For convenience, a summary of them, conducted by both Warnock Hersey and our own company, is attached to Mr. Bethel's paper.

Mr. Gilbert claims that we have misrepresented the relative prices of our products. Our statement that "selling prices appear to be only slightly below those of our product" was based on the reported price 5 mg. tablets paid by a provincial government hospital. According to our information, this price was $41.80 per thousand plus shipping; the comparable price for "Stelazine", purchased in quantity, comes to $43.20 per thousand including shipping.

Mr. Gilbert considers it a matter of gravest importance that we made representations to the Food and Drug Directorate asking that the recommendations of the Hilliard Committee be implemented with regard to trifluoperazine. Certainly, we believe that these recommendations, made by responsible and informed medical scientists, should be fully implemented. In particular, the Directorate ought to extend the safety provisions of the "New Drug" regulations to a subsequent manufacturer of a potent drug until chemical, pharmaceutical and clinical equivalence has been established by generally accepted methods, and also when new or serious side effects have developed with extended usage. In fact, it was concern about the implications of multiple manufacturing and distribution if trifluoperazine which prompted Dr. Eloise Jones

to raise the problem in Parliament, an action which led to the establishment of the Hilliard Committee. We would be happy to have the Directorate submit to your Committee the correspondence exchanged on this subject.

Yours sincerely,

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

Enc.

INTER-OFFICE MEMORANDUM

SMITH KLINE & FRENCH I.A.C.—MONTREAL

December 12, 1966

To: Mr. R. F. Daily,

From: R. F. Bethl,

Subject: *Comments in the technical aspects of the submission of Jules R. Gilbert to the Special Committee.*

The following comments reply to allegations in the paragraphs referred to:

Paragraph 4.3.1.

"Since the product trifluoperazine was innovated by SK&F, they undoubtedly wrote the standards or supplied the information for the standards to the British Pharmacopoeia Committee. Under the circumstances, we believe that SK&F would set these standards as high as possible."

SK&F did not write the B.P. standards, and, in fact, have always taken exception to them. The B.P. monogram appears to ignore the standards established by 'Stelazine' during the several years that 'Stelazine' was on the market prior to the B.P. publication. For reasons unknown, the Committee preferred the present misleading statement of potency. The B.P. limits of 92.5 per cent to 107.5 per cent of label claim are less stringent than ours of 95 per cent to 105 per cent. There is now some indication that the B.P. has recognized the need for standardized expressions of potency as evidenced by a statement by Mr. Johnson of the British Pharmacopoeial Commission, appearing in the Pharmaceutical Journal, p. 316, April 2nd, 1966, as follows:

"It was hoped that drug dosages would be quoted in the B.P. in terms of the active moiety and that manufacturers would co-operate in expressing dosage forms in that way."

On this subject I have additional information indicating the shortcomings of expression of drug product potencies in the salt forms rather than the common denominator of the base.

Paragraph 4.3.1.

"Further, since the product has been described in thed in the B.P. in both its chemical and tablet form, it follows that it has been sold long enough and in sufficient quantity so that a "new drug" status is no longer necessary."

This statement is without any backing, and represents a very dangerous generalization. We are informed that appearance in a recognized compendium such as B.P. is one of the points considered by the Food & Drug Directorate in the determination of new drug status, but it is only one of these considerations, and one which is obviously at variance with the recommendations of the Hilliard Committee.

Paragraph 4.3.1.

"The objection of SK&F is not as to the purity of the Gilbert product trifluoperazine, since this aspect is not questioned."

As we are all aware, the SK&F objection is that this product purports to be the equivalent of 'Stelazine' tablets and is in fact not, since (1) its potency is considerably below the SK&F standard; (2) no clinical work to our knowledge has been submitted to prove equivalency; and (3) by Mr. Gilbert's admission, knowledge is lacking as to the mode of manufacture of the basic chemical.

I attach a summary of the test results of the Gilbert product in support of the above statements.

Paragraph 4.3.2.

"We know further that they (SK&F) have instigated investigations by the Directorate to check our quality and label."

No such requests have been made.

Paragraph 4.3.2.

"We now find that 'Stelazine', the SK&F product, has been misbranded and is still improperly labelled."

Our 'Stelazine' labelling over the years has consistently met Food & Drug requirements. Our present label reads as per attached copy. As shown above, 'Stelazine' tablets were being used and established proper potency and effectiveness levels and expressions well before the B.P. The appearance of the B.P. monograph confused the picture, but, as shown above, this is now recognized, and future monographs will probably follow the present policy of expressing all potency levels in terms of the base. Our labels have always and consistently expressed this.

The B.P. monograph does not state what the strength must be—only that the tablets contain trifluoperazine hydrochloride which, of course, ours do. It is the only form of the chemical practical to use for this *particular* dosage form—which is the whole crux of the matter. To produce a good pharmaceutical product a formulator will use the chemical

form best suited to each dosage form, so that in tablets he might use a salt form such as the hydrochloride, in suppositories he might use the base, in liquids he might use another salt form, say the maleate. But so that the physician might correlate the potency and dosage from different dosage forms, a common denominator of expression *must* be used. This common denominator is the active moiety of each form, that is, the base.

It is perhaps significant that Jules R. Gilbert Ltd. does not offer a complete trifluoperazine product line, but only the most profitable items, those which do not require a New Drug Submission. It is interesting to speculate on the dilemma which the Gilbert philosophy on potency would pose if a full line were in fact offered, since one salt form is not appropriate for all dosage forms.

We have some time ago advised the F.D.D. that we intend to remove the B.P. designation from our labels. The reason is obvious. Gilbert has come along and completely, and perhaps deliberately, clouded the whole matter. His inference is that his product is of the same potency as 'Stelazine' tablets, (of course, by formulating to 18-20 per cent lower than the 'Stelazine' standard, the batch yield is very considerably increased).

In view of the stong position advanced by Mr. Gilbert for the salt potency stand, it is surprising that in his most recent literature on Triperazine he states that he is now formulating in terms of the base. This means that a patient receiving the Gilbert tablets of intermittently old and new formulation could receive as much as 20%-30% swings in potency.

Paragraph 4.3.7.

"We really try hard to emulate."

"We already have plans for individually identifying each tablet with our own mark so that there can be no mistake as to the source of the product."

We can only agree with the first statement. If the statement of intention is also true, it will represent the first time there has been any indication of this change of heart. We can only hope Mr. Gilbert will also change the colour and/or size and shape of his product to ensure that there is no mistake as to the source.

R. F. Bethel.

Each tablet contains trifluoperazine, 2 mg. (10-[3-(1-methyl-4 piperazinyl) propyl] -2-trifluoromethylphenothiazine) as the dihydrochloride.
Dosage as directed by a physician.
50 Tablets
2 mg.
Stelazine*
trifluoperazine
tablets
*Reg. Can. T.M. Off.
Smith Kline & French I.A.C., Montreal, Que.
KEEP IN A COOL DRY PLACE
Pat. 1961 No. 612,304
CF Lot B.5093

Each tablet contains trifluoperazine 2 mg. (10-[3-(1-methyl-4 piperazinyl) propyl] -2-trifluoromethylphenothiazine) as the dihydrochloride.
Dosage as directed by a physician.
50 Tablets
2 mg.
Stelazine*
tablets
trifluoperazine
tablets B.P.
*Reg. Can. T.M. Off.
Smith Kline & French I.A.C., Montreal 9, Que.
KEEP IN A COOL DRY PLACE
Pat. 1961 No. 612,304
CG Lot

TRIFLUOPERAZINE TABLETS—GILBERT

Summary of Laboratory Examinations

Lot K154 — 5 mg.
From Nova Scotia Hospital, Dartmouth, N.S.

SK & F test:	Average 88.8% trifluoperazine
	Range 82.0-91.9 — 10 assays
Warnock Hersey test:	Average 83.5% trifluoperazine
	Range 76.5-87.7 — 10 assays

Very similar to SK & F 'Stelazine' tablets in appearance and colour, no monogram

Lot 605 — 2 mg. — bottle of 50 tablets
From Toronto

SK & F test:	Average 75.8% trifluoperazine
	Range 65.3-91.3 — 11 assays
Warnock Hersey test:	Average 87.9% trifluoperazine
	Range 83.4-96.9 — 10 assays

Colour and appearance very similar to SK & F 'Stelazine' tablets, no monogram

Lot 605 — 2 mg. — bottle of 100 tablets
From Vancouver

SK & F test:	Average 78.4% trifluoperazine
	Range 66.8-89.5 — 10 assays
Warnock Hersey test:	Average 80.6% trifluoperazine
	Range 70.4-92.2 — 10 assays

Colour and appearance very similar to SK & F 'Stelazine' tablets, no monogram

Gilbert mail piece, copy attached, indicates potency claim calculated on the base. Our tests and those of Warnock-Hersey, calculated on the base, therefore indicate a product well below acceptable limits.

December 9th, 1966

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966-67

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 28

TUESDAY, JANUARY 17, 1967

WITNESSES:

Representing Prescription Services Inc.: Mr. W. A. Wilkinson, President, and Mr. Richard R. Walker, Q.C., Legal Counsel, both of Windsor, Ont.

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

25516—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

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

and

Mr. Brand,	Mr. Howe (*Wellington-Huron*),	Mr. O'Keefe,
Mr. Clancy,	Mr. Hymmen,	Mr. Orlikow,
Mr. Côté (*Dorchester*),	Mr. Isabelle,	Mrs. Rideout,
Mr. Enns,	Mr. Johnston,	Mr. Roxburgh,
Mr. Forrestall,	Mr. MacDonald (*Prince*),	Mr. Rynard,
Mr. Goyer,	Mr. Mackasey,	Mr. Tardif,
Mr. Howe (*Hamilton South*),	Mr. MacLean (*Queens*),	Mr. Whelan,
		Mr. Yanakis—24.

(Quorum 10)

Gabrielle Savard,
Clerk of the Committee.

MINUTES OF PROCEEDINGS

TUESDAY, January 17, 1967.
(38)

The Special Committee on Drug Costs and Prices met this day at 10.00 o'clock a.m. The Chairman, Mr. H. C. Harley, presided.

Members present: Mrs. Rideout, and Messrs. Brand, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), Isabelle, Orlikow, Rynard, Tardif, Whelan (10).

In attendance: Mr. W. A. Wilkinson, President of Prescription Services Inc. and Mr. Richard R. Walker, Q.C., Legal Counsel, both of Windsor, (Ontario).

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

The Chairman introduced Mr. Wilkinson who, in turn, introduced Mr. Walker.

The Committee proceeded to the consideration of the brief of Prescription Services Inc. and of the memorandum presented this day to supplement the brief.

Mr. Wilkinson made preliminary comments.

Agreed,—That the brief and the memorandum be printed as an appendix to this day's proceedings (*See Appendix "A"*).

Mr. Wilkinson and Mr. Walker were questioned.

The Chairman informed the Committee that a Notice of Motion received from Mr. Orlikow will be considered by the Steering Committee.

On behalf of the Committee, the Chairman thanked the witnesses for their presentation, and at 11.40 a.m. the Committee adjourned to 3.00 p.m., Monday, January 23, 1967.

Gabrielle Savard,
Clerk of the Committee.

25516—1½

EVIDENCE

(Recorded by Electronic Apparatus)

TUESDAY, January 17, 1967.

The CHAIRMAN: Ladies and gentlemen, we will proceed with our meeting.

There is some correspondence and other matters that I think perhaps should be dealt with, at the next meeting. We will proceed first with the witnesses we have before us this morning. We will discuss various things, one of which is a motion Mr. Orlikow wishes to put before the Committee, at a later time today when we have a quorum.

We have before us this morning the brief of the Prescription Services Inc., as represented by the President of the organization, Mr. Wilkinson. I will ask him to make an opening statement and to introduce himself and the other gentlemen with him. Mr. Wilkinson.

Mr. W. A. WILKINSON (*President, Prescription Services Inc., Windsor*): Thank you, Mr. Chairman. Mr. Chairman and members of the Committee, my name is William A. Wilkinson and I am the President of Prescription Services Inc., the operators of the Green Shield Prescription Plan. With me is the general counsel of the corporation, Mr. Richard R. Walker, Q.C. Mr. Walker has acted for the corporation since its incorporation and he represents many pharmacists and physicians in their business and personal affairs. Over the years Mr. Walker has made a special study of the Ontario Pharmacy Act. Because of his close association with the Green Shield Plan and with pharmacy, he is conversant with most of the matters concerning prepaid prescription plans and I would hope that Mr. Walker will be able to answer some of the question you might ask.

I would like, if I may, to make several preliminary comments in connection with the brief which we have submitted. In the first place, let me say that we who operate the Green Shield Prescription Plan are equally as concerned with the costs of drugs as this Committee. It is clear that as the cost of drugs increase or decrease, the cost of benefits paid through this plan will increase or decrease in the same proportion. Where we may differ, however, is in determining the ultimate goal and whether an effective program to reduce drug costs is possible. So far as actually instituting a program to reduce drug costs, may I point out to the Committee that during the period in which this Committee has been sitting and reviewing the matter the cost of prescription drugs has risen. I can give the Committee several examples of these increases if you wish. My main point, however, is that notwithstanding the publicity that has been given to the issue by the establishment of your Committee and by the testimony of the witnesses who have come before you, nevertheless the price of drugs has, in fact, increased. For that matter, the price of drugs has been increased by the act of the government itself in increasing the federal sales tax. Thus I say that I have grave doubts as to whether or not it is possible to effect a drug cost reduction program.

However, we at Green Shield feel that the real issue lies not with the cost of drugs alone. If, in fact, some member of the public is unable to afford the purchase of a drug, a reduction in cost of that drug will not make him better able to purchase that drug unless it is a significant reduction, say, as much as 25 per cent or 50 per cent. An over-all drug cost reduction of this significance is, I suggest, not realistic and, perhaps, cannot be effected. This being the case, what solution can be provided for those persons who by the nature of their illness are required to purchase drugs over a long-term basis, and what program can be devised for those who are required to purchase a great deal of drugs through a short-term period? It is to answer these particular questions that the Green Shield Plan has been developed. It is our view, and we suggest that the record of our plan supports that view, that the prepaid prescription plan is an answer to these problems of heavy short-term and long-term drug requirements and, thus meet the fundamental public problem.

I believe that some testimony was given before this Committee concerning cystic fibrosis patients and I think that the Committee might be interested to know that there is no exclusion under our plan working against the subscriber or their dependents who suffer from this disease. I quote this as a matter of interest and, as a specific example: A child in south western Ontario who is a cystic fibrosis patient, during the period between August 8, 1966 and December 31, 1966, which is a period of five months, received benefits from the Green Shield Plan, in the form of prescriptions dispensed for this child, in the amount of $834.11 while for the same period, the premiums collected for the child were 65¢ a month for five months or a total of $3.25. Again, I suggest that this is an example of how a prepaid prescription plan works to resolve these fundamental public problems.

I would like, if I may, to call your attention to a typographical error on page 11 of our brief, line 5 on the right hand side; *$2.55* should read *$3.12*.

Mr. Chairman, that is my opening statement.

The CHAIRMAN: Thank you, Mr. Wilkinson. Is it agreed that the brief and the memorandum of today be printed as part of today's record?

Some hon. MEMBERS: Agreed.

The CHAIRMAN: As a side attraction this morning for any of those who have or have not seen these—and I know Mr. Wilkinson is very active and very interested in this—this is a new childproof bottle which is designed in such a way that it is very difficult for a child to open, and for some adults. They are here if anybody wishes to see them. You open them by palming them and turning the top.

The meeting is open for questioning.

Mr. RYNARD: Mr. Chairman, on the second page of Prescription Service Inc.'s brief, I see down on the centre of the page the following statement:

> Green Shield pays for these on prescription. P.S.I., W.M.S., Blue Cross does *not*.

I am wondering if Mr. Wilkinson could tell us to what extent they pay for doctors' services. I know of cases where people who are insured go to a doctor with a runny nose or a cold and request a prescription. There is a charge of $3 or $4 for the call; then they go to the drug store and you people pick up the tab on

it. Does this sort of thing increase your costs markedly? There must be a percentage of people, at least, who go to the doctor and say that they are not going to pay for this; they request a prescription from the doctor, and then you have a doctor's fee as well as the fee for the drug to pay. Others may slip down to the drugstore and gets their benadryl and that is the end of it.

Mr. WILKINSON: If I understand your question, Dr. Rynard, I think what you are asking is in the case of a physician's plan where the patient has free access to the physician and may go at any time he chooses,—

Mr. RYNARD: That is right.

Mr. WILKINSON: —and has access to medicine as the result of a prescription, does this increase the utilization.

Mr. RYNARD: That is right. That is much better put.

Mr. WILKINSON: And if the increase of this utilization is real use or abuse?

Mr. RYNARD: That is right.

Mr. WILKINSON: I think perhaps that this problem is more apparent than real. There are, of course, hypochondriacs and there are those persons who just do not feel that they have filled out their week properly unless they have gone and sat in a doctor's office. These people have always been with us and they are always going to be with us. As to whether this is abuse, every medical plan whether it be the hospital plan, a physicians' plan or a medicine plan—a prescription plan—depends at its initial stage on the integrity of the physician; without physician integrity we can have no plan. If this patient did not need this medication, he should have been told so and a prescription should not have been written. In our experience this is the case. I could say that a study of utilization within the Green Shield Plan, in our own case, indicates that there is a greater per capita utilization than what, say, the DBS says is the normal per capita utilization. I do not believe, though that it is that much that it is a real problem.

Mr. RYNARD: I am very glad to hear this. In defence of the physician, may I say that it is pretty hard for the physician to control somebody who comes in, says he has a bad cold and has been accustomed to taking certain medication for it. The doctor who looks the person over may be in a hurry but he realizes the patient has a cold and for the sake of good doctor-patient relations he gives the prescription. This is the point that I am making. However, you have already said that this is a very small percentage of your total.

I think that if you revert to the New Zealand figures, you will note it made a substantial difference there. I remember being in a doctor's office in New Zealand one night when somebody called up on the telephone. This person had to come down to the doctor's office, the doctor wrote out a prescription, and for writing the prescription he received a fee of $1.50. The patient then went to the pharmacist and there was a fee there of 25¢. I do not think the actual drug cost one-third of that. This is the point I was trying to make.

Mr. WILKINSON: I think, doctor, there is also this factor in far more cases, I might say, than those which you cite; the patient, in using a prescription plan, is acquiring bona fide required medication that he would not normally have been able to get. I agree that there are bound to be abuses. I could quote a figure if it would ease your mind at all. Our per capita consumption of prescriptions over

the 12 month period ending October 31, is .3171 prescriptions per person per month. If you multiply this by 12 you will find that this is just under four prescriptions per person per year. This is not too far out of line with what the DBS says the per capita is at the moment. It is more an apparent problem than it is real.

Mr. RYNARD: Thank you.

The CHAIRMAN: Dr. Isabelle.

Mr. ISABELLE: Can any druggist become a member of your organization?

Mr. WILKINSON: Yes, sir. Pharmacists may become members of the Green Shield Prescription Plan or Prescription Services which is the parent organization provided those who make application are registered pharmacists within their own jurisdiction?

Mr. ISABELLE: Is that the only requirement?

Mr. WILKINSON: That is the only requirement. No money even changes hands for a membership.

Mr. ISABELLE: You are paying the pharmacist's fee on a professional basis?

Mr. WILKINSON: Yes, sir.

Mr. ISABELLE: Do you have any fixed fee for the pharmacist?

Mr. WILKINSON: Yes, sir.

Mr. ISABELLE: Is it $1.65?

Mr. WILKINSON: The fee figures out as a net of $1.65, but I would like to take a moment to explain how we arrived at this. Our formula is based on the cost of the ingredients and the cost of the ingredients is defined as the manufacturer's suggested list price less 40 per cent; or in a case where there is no list price, the wholesale price as published in the manufacturer's catalogue becomes the cost price. It is a standard, arbitrarily fixed price by our corporation; it has been done so in order that we could computerize. To this we add a fee of $1.70. The pharmacists collect 35 cents from the patient at the time the prescription is filled, so now we are at cost plus $2.05. When we pay the bill to each pharmacist we deduct 40 cents a prescription from him, which is approximately 10 per cent of the average price of the average prescription. This brings the $2.05 back down to $1.65. So when the dust has settled, our pharmacist is being paid cost, by definition, plus $1.65.

Mr. ISABELLE: Is the only criteria for a druggist belonging to your organization that he must be a registered pharmacist?

Mr. WILKINSON: That is the criteria, but once he has agreed to this he signs a contract with us.

Mr. ISABELLE: Oh, well, that is it.

Mr. WILKINSON: But this contract can be cancelled by either side on 30 days notice.

Mr. WALKER: The one additional thing, of course, is that the pharmacists agree to accept the cost plus $1.65 net fee arrangement. Otherwise we would have no way of controlling the cost of benefits.

Mr. ISABELLE: Well I must agree with you on this plan. I must say that I was amazed when I first heard of it. A few patients around Ottawa who had this plan came to my office and they were very, very satisfied. As a matter of fact, I think this is a real plan for large families because apparently they do not have to pay too much and it is on a yearly basis.

Mr. WILKINSON: We are not very big in Ottawa. We have only 384 families and they are principally in the dairies. I do not know whether you want to know what dairies they are.

Mr. ISABELLE: We have so many?

Mr. WILKINSON: Well, there is Borden's, Clark's, Pleasantview and Producer's. There is also the branch plant of the Drug Trading Company in Ottawa. We are not very strong in Ottawa. We do have 270 other groups in the plan and I have brought with me a list of these groups.

Mr. ISABELLE: Do you limit yourself only to Ontario?

Mr. WILKINSON: No, sir. We operate from coast to coast and we have subscribers all the way from Moncton to Burnaby. We have almost the whole town of Lynn Lake, Manitoba at the Sherritt-Gordon mine there; International Nickel has just negotiated Green Shield into their most recent contract at Thompson, which becomes effective on the 1st of March. We operate across Canada. In actual fact, if it might be interesting to you, Mr. Chairman, during the 12 month period which has just ended October of 1966—these are the last available figures—we processed 338,613 prescriptions during the year for a premium collection of $1,408,000. We paid out to druggists $1,179,000 for medicine. I think that any time that a single organization is buying $1¼ million worth of drugs in a single year it is a plan which is in successful operation.

Mr. HOWE (*Wellington-Huron*): This is an interesting brief. You bring out what we have found in the meetings we have had, that deciding what to do about the cost of drugs is a pretty difficult thing. You state at the bottom of page 3 a few areas in which you do feel there might be something done. It says:

> (g) That drugs have been overpriced as a consequence of profiteering and if so by whom?

Now, do you think this is happening?

Mr. WALKER: I do not think that we were trying to suggest that, sir. What we were trying to point out is the difficulty in getting the point of reference: On what basis are you judging whether drug costs are high, low or indifferent? We simply put it up as an example. We are not suggesting anybody is profiteering; we are simply saying that presumably if one could establish that that would be a point of reference on which you could say that drug costs were too high.

Mr. HOWE (*Wellington-Huron*): There have been some outstanding examples which some of the members have brought up where there has been a tremendous difference in the cost of the same drug at different drugstores. But do you agree this is not the general rule?

Mr. WILKINSON: I agree.

Mr. HOWE (*Wellington-Huron*): These are the exceptions?

Mr. WILKINSON: It would seem to me that they are the exceptions. As you probably know, I am a pharmacist. I have spent 34 years as a practicing

pharmacist and until two years ago I spent full-time at it. I still keep a very close association with my drug store for the simple reason that my partner, who is a new purchaser, has a very substantial mortgage in my favour, so I keep a very close tab on the retail drug trade. I would agree with you, Mr. Howe, that where there appears to be this great differential in price it is the exception.

Mr. HOWE (*Wellington-Huron*): You also mention that drugs have been overpriced because of the application of taxes. Then you go on to say that when this is all broken down over the whole cost of drugs it does not mean too much in the individual case. Is that not true?

Mr. WILKINSON: Could I come back, Mr. Howe, to the top of page 3, the last sentence in the first paragraph, where we say:

> For example, when one talks of the cost of drugs being high what in fact is really meant?

We are asking a question.

> Does it mean that:

—and then we list these as questions as opposed to statements.

Mr. HOWE (*Wellington-Huron*): And do you not go on pretty well to answer them in subsequent paragraphs?

Mr. WALKER: What we attempted to do, though, was to simply point out that when you raise the question in the first instance you get into complications in the answers. For example, if you took item A and say that one drug is more expensive than another, it depends, of course, on whether you need it. For example, in a very personal sort of way, I am quite satisfied that my wife would not be alive today if it were not for antibiotics. So what does it matter what the cost is so long as you get the drugs, and this is a complication in trying to determine whether that is a high or low cost. It depends on what your need is at the time. So what we are really saying in the Green Shield plan is this: that we must deal with the facts at the market place; we live in a market economy; there are drugs that are sold; there are drugs that are required, and we have attempted to develop a plan which will give the public the opportunity to budget their cost against illnesses they know are going to occur, because unfortunately they will, and budget their costs against a heavy short-term cost or a heavy long-term cost.

Mr. HOWE (*Wellington-Huron*): There was one other thing you pointed out on page 13 that I think is quite significant, namely, that there is probably too much money spent on advertising. You suggested that advertising and promotion costs to manufacturers should be restricted to 15 per cent of their gross sales. Then further on down you indicate that that might mean 30 cents a prescription for people who are buying drugs, if we got the advertising down from 28 or 29 to 15 per cent. So is it not true that in the individual drug costs it is pretty difficult to pinpoint how you get these costs out?

Mr. WILKINSON: If I could make one correction, Mr. Howe, that 30 cents is the total figure. Assuming a reduction in selling cost—

Mr. HOWE (*Wellington-Huron*): Oh yes, sales tax, too.

Mr. WILKINSON: —down to 15 per cent and assuming a total remission of the sales tax, this only comes to 30 cents a prescription. So this is in itself not a great

deal of money on a prescription basis; and if you spread it over on a per capita basis it would come to less than 9 cents per month per person over 20 million people in Canada.

Mr. WALKER: Another way of looking at it is if the drug costs $5 and its price is reduced by 30 cents, if you could not afford to pay $5 you could not afford to pay $4.70 either. So again reducing the price on that individual drug does not answer the problem.

Mr. HOWE (*Wellington-Huron*): This is what I have felt all along. How do you promote your plan? Do you send material out to doctors or druggists?

Mr. WILKINSON: We have a salesman who operates a sales agency on this. Since we only deal with groups of individuals in employment pictures then our problem is to sell industry and to sell labour. This must be done in such a way that the major effort in any individual case takes place just prior to labour negotiations for that company. We hope that we have been sufficiently successful in our sales talk to labour and management that the Green Shield plan will be included in the amendments of the new collective bargaining agreement, that it will be bargained into the agreement as a fringe benefit and that it will become effective as a fringe benefit. Now there is no other way of selling this plan other than the normal effort that can be made in receiving invitations to speak to groups, various service clubs and making appearances in various places of this nature. I do a great deal of that and our Mr. Featherston works almost entirely within the labour movement.

Mr. HOWE (*Wellington-Huron*): Is it just available to groups, not to individuals?

Mr. WILKINSON: Yes, it is only available to groups.

Mr. HOWE (*Wellington-Huron*): Are any of the civil organizations in any of the provinces or in the federal civil service in your organization?

Mr. WILKINSON: No. The civil servants, as you know, have their own plan which is a major medical type of plan, which I understand is administered by one of the insurance companies and is underwritten by a syndicate of some 19 insurance companies. It is quite a different plan, it covers hospitalization, medical, major medical and certain prescriptions with deductible and co-insurance factors in the contract—and it is a reimbursement plan as opposed to a prepaid plan.

Mr. HOWE (*Wellington-Huron*): Do you have any municipalities' organizations?

Mr. WILKINSON: Yes, we have police associations in municipalities and a number of utilities commission in various communities.

Mr. HOWE (*Wellington-Huron*): Any retail travellers associations or anything like that?

Mr. WILKINSON: We do not have a retail travellers association but it would be possible.

Mr. HOWE (*Wellington-Huron*): Commercial travellers, I mean.

Mr. WILKINSON: It would be possible. If they were interested we could make it applicable.

Mr. RYNARD: Mr. Chairman, I have a supplementary to that question. Under this plan could you take in a whole township, headed up with a reeve and council, as a group?

Mr. WALKER: You mean the municipal authority?

Mr. RYNARD: That is right.

Mr. WILKINSON: We have that.

Mr. WALKER: Yes, if it formed a group.

Mr. RYNARD: The ratepayers?

Mr. WILKINSON: No, not the ratepayers.

Mr. RYNARD: Why not?

Mr. WILKINSON: Well we could if this were to arise, yes. We would have no objection to taking in all of the ratepayers provided someone could guarantee that this could become a condition of living within this township.

Mr. WALKER: And someone would have to undertake the collection of the premiums so that you would know you had a constant situation.

Mr. RYNARD: Well the municipality could do that itself; they have the machinery to collect them with the taxes.

Mr. WALKER: Yes but legally they would not be authorized to do it—not in the province of Ontario at the present time, anway. You could not add it to a tax bill.

Mr. RYNARD: They could not add it to a tax bill?

Mr. WALKER: No.

Mr. RYNARD: I doubt if they could add anything to a tax bill the way they have gone up.

Mr. ISABELLE: Could you give us a rough figure of what it could cost a family of four: the father, the mother and two children about 10 years of age?

Mr. WILKINSON: Dr. Isabelle, if you will open this green folder at paragraph 15 you will find the rates. They are not calculated for you so I will do it. It is $1.90 for a single person; $3.80 for a man and his wife; $4.45 for a man, wife and one child; $5.10 for a man, his wife and two children and $5.75 for a man, his wife and three or more children.

Mr. ISABELLE: In other words it comes up to about $70 a year.

Mr. WILKINSON: Yes, if you have a maximum family. To put it another way, doctor, over the same period which I read a few moments ago, on a per person per month, basis—which is the only way you can gather data on a prepaid plan—we achieve a premium of $1.313 per person per month for every man, woman and child within the plan.

Mr. HOWE *(Hamilton South)*: Mr. Chairman, a couple of questions have come to my mind. You say, cost plus $1.65?

Mr. WILKINSON: Yes.

Mr. HOWE *(Hamilton South)*: In other words, the druggist gets $1.65 for dispensing his prescription.

Mr. WILKINSON: Yes; he achieves this on every prescription.

Mr. HOWE *(Hamilton South)*: Does he suffer any average loss by so doing over what he nets now with his retail price plus his dispensing fee, whatever it is, in the particular area in which he is working?

Mr. WALKER: To start off with, Dr. Howe, you would have to know what each individual druggist's volume was and what fee or gross profit method he was using and measure it in each case. It would be very difficult to come up with any kind of an opinion on this question.

Mr. HOWE *(Hamilton South)*: But the thing is this: if anybody is taking any kind of loss on this it would be the retail druggist, not the manufacturer. I said "if" anybody is taking a loss.

Mr. WALKER: Yes, because we are working on the manufacturer—

Mr. HOWE *(Hamilton South)*: It does not hit the manufacturer at all; it hits only the retail druggist.

Mr. WALKER: We are working on the manufacturer's list price.

Mr. HOWE *(Hamilton South)*: Yes. Although that does not change, the druggist's retail price could vary.

Mr. WALKER: Yes.

Mr. HOWE *(Hamilton South)*: Now, just to hit this from the opposite angle, this cost seems to be an extremely variable thing. You are allowing cost as being list less 40 per cent. You accept that, and yet we found out in the investigation of librium, for example, that if it is bought in 5,000 lots the druggist gets it for $4.68, whereas at list less 40 per cent it would be $7.20, so he would, therefore, be making approximately another $2.50 over and above the $1.65 if he were buying it in 5,000 lots.

Mr. WILKINSON: This is true, doctor. This prevails in many other items besides librium.

Mr. HOWE *(Hamilton South)*: I am aware of that. I only exemplified this because I happen to know these particular figures, but there are many others where they are allowed 40 plus 10 plus another percentage on quantity buying, are there not?

Mr. WILKINSON: Yes. As I stated before, it is necessary for the plan to have a standard set definition of cost or we cannot go into the monster—the computer —to do automatic pricing or pricing by projection. The usual cost to the pharmacist is list less 40 per cent, with the exception of special deals such as you mention, and with the exception of cases where the pharmacist is required, in getting dribs and drabs, to go to the wholesale and accept a price from the wholesale which, in effect would work out to be list less 25 per cent or 28 per cent.

There are a great many of these cases, especially among the small community pharmacists, where they have to deal with the wholesaler and where they are unable to exercise any leverage as the result of bulk purchasing. We have found by experience that we can live with the pharmacist and the pharmacist can live with us if we give him a straight list less 40 per cent across the board, let him accept the little additional profit he makes by buying his deal in quantity, and let

him lose some of that on some of the other items where he must fill in from his wholesaler. I will be the first one to agree that this is not a precise way of establishing cost. On the other hand, it is a very practical way and it is a way that has been accepted, and it permits us to operate.

Mr. HOWE (*Hamilton South*): Of course, I will not accept the premise of the word "little". Two dollars and fifty cents extra over and above $1.65 is more than 100 per cent of the profit that should have been made, so it is not a little item in many instances.

Mr. WALKER: I think you are making an assumption there, doctor, that every pharmacy is in a position to engage in bulk buying in the way that you describe. Our point is that we must establish a cost in order that we can regulate it and computerize it. There is no point in trying to establish a cost based upon the buying power of the largest pharmacy chain in the country, because that would simply reduce the cost as far as the small individual community pharmacy is concerned and he would be put out of business.

Mr. HOWE (*Hamilton South*): Therefore your big druggist is going to be making more money, so this is no special deal; this is actually penalizing your small man.

Mr. WALKER: Again doctor, dealing with the facts at the market place, that has not changed a bit. That prevails in any form of commercial enterprise in this country; those who sell more of something get larger discounts. We do not control that; we are simply saying that is the market place, we live with it.

Mr. HOWE (*Hamilton South*): That does not mean that I have to like it.

Mr. WALKER: Oh, no. It does not mean that we have to like it either, but we have to live with it. That is the difference.

Mr. HOWE (*Hamilton South*): I hope that this Committee will prove that we do not have to, because I think this is very unfair. This happens in doctors' offices with injectables, too. If you buy one you get a certain price; if you buy 3 you get another 10 per cent; if you buy 6 you get one free; and if you buy 12 you get 3 free and another 10 per cent off. And this, to me, is penalizing the small doctor the same as this is penalizing the small druggist. He is making less money because he is unable to buy in large quantities, and yet he is doing the same work and putting out the same prescription with the same degree of effort—and perhaps more—and making less. I am not criticizing you. I am making a general comment on the economics of this country.

Mr. WALKER: In reply to your general comment, if you can succeed in reducing that cost, that is fine with us because our price will go down automatically. We are only suggesting that you may not be able to achieve a significant reduction.

Mr. HOWE (*Hamilton South*): This is likely true, but still we bat our heads against this brick wall in an attempt to do something, do we not? By the way, I was not criticizing you and I do not want you to think I was. It is a system I do not like; I have not liked it for many years because I still think that what we are doing is penalizing the small man by our system. This is all I was commenting on.

Do you have any restrictions on the type of drugs that can be prescribed? Do you have a formulary?

Mr. WILKINSON: No, we do not believe in formularies for reasons which, if you want to go into it, I will explain, but we do have exceptions, and these exceptions are contained on page 10 of this pamphlet. They fall principally into four or five categories. They are prosthetic devices and first aid supplies—and you may think it is unusual that we should put prosthetic devices in there. I am sure that in some cases there are physicians—and no reflection intended—who will prescribe a trip to Florida and write it on a prescription. We have had prescriptions for wooden legs, a wooden arms, braces and all kinds of things which are not really medicines. We do not pay for vitamins. The vitamin business is one of its own, and if we were to include vitamins—and I think the vitamin business in Canda today is roughly $40 million—we would really have the situation that Dr. Rynard was talking about; the doctors' offices would be flooded with patients who just wanted their monthly supply of vitamins.

We do not pay for proprietary or patent medicines which have a patent number on them for obvious reasons. In the first place, physicians do not precribe them; in the second place, it is not a prescription.

We do not pay for medications which, although they may be on the open market, are normally sold in places other than drug stores. I am thinking in terms of mouth washes. You can name half a dozen of these television commercials that you are seeing today. We do not pay for these even though they are written by a doctor and signed as a prescription.

We will not pay for birth control pills. We do not pay for any injectable medicine of any nature, insulin included.

Other than these, we pay for almost everything in the compendium. It runs about 94 per cent of the prescriptions that are written. In spot checks that we have done there are about 6 per cent that turn out to be items in these four or five categories—this is prior to birth control pills, I should say.

We have some control over the quantities that the plan is willing to pay for. This is not to say that we wish to dictate in any way what the physician may prescribe. We will pay for the smallest treatment package—sometimes called the smallest treatment package—and in this case I am thinking of such things as 16 achromycin, 24 prostaphlin, 2-ounce bottle of bicillin, this type of thing that is packaged in a normal treatment. We will pay for this on any one prescription or, where there is not a small treatment package, we will pay for 34 days continuous use or whatever the doctor ordered, or whichever is the least of those three. We are always in hot water on this because somehow or other we get accused of trying to dictate the practice of medicine, and I go to great lengths to point out that we are not attempting to dictate, in any of these regulations, what the physician in his own judgment may decide that that patient needs. All we are saying is that in accordance with our premiums paid we are willing to pick up a tab for that much of it.

Mr. HOWE (*Hamilton South*): You say that it is limited to 34 days. You were talking earlier about cases of cystic fibrosis and I am sure that this medication is continuous.

Mr. WILKINSON: It is limited to 34 days on one prescription, doctor. Then he can get the prescription again.

Mr. WALKER: But he must go back to the doctor to have the prescription repeated.

Mr. HOWE (*Hamilton South*): Oh, I see your point. You will allow the doctor to write one prescription for a 34-day treatment—say 100 tablets at the rate of three times a day which, in round figures, is 34 days—and then he must go back again.

Mr. WILKINSON: Or the physician must authorize it in some legal way.

Mr. HOWE (*Hamilton South*): In other words, a renewal of a prescription by the druggist phoning, say, in the case of tranquillizers or some such thing as this, is allowed?

Mr. WILKINSON: Yes, if it is a legal repeat. If it is a substance which according to the Food and Drugs Act, or the Narcotics Act, or the Control Drug Act that you may repeat by giving your permission on the telephone, we accept this.

Mr. WALKER: In other words, as long as the doctor re-exercises the discretion; it is up to the doctor to say. "I want the patient to have this."

Mr. HOWE (*Hamilton South*): Is there any limitation as to any make or brand?

Mr. WILKINSON: Just what the doctor ordered.

Mr. HOWE (*Hamilton South*): It is strictly what the doctor ordered. There is no restriction; in other words, that some drugs must be generic brands or anything like this?

Mr. WILKINSON: No, sir. We refuse to get involved in the generic versus trade names controversy.

Mr. HOWE (*Hamilton South*): I was not trying to get you involved in a controversy; I was trying to get you to save money in some instances if this were possible. But then you would run up against the objections of the doctors in some instances.

Mr. WALKER: The single point is this: If the doctor writes the prescription, what he puts down is what is dispensed, as it is dispensed in any other drug store or any other pharmacy on any other program.

Mr. HOWE (*Hamilton South*): I will not impinge on some questions that I think are going to be asked.

Mr. ORLIKOW: I am not going to ask too many questions, Mr. Chairman.

From what I have read of the brief and what I have heard of the testimony this is a good insurance plan as far as it goes. It works, I gather, in much the same way as non-profit medical insurance plans like P.S.I. in Ontario or the Manitoba Medical Service in Manitoba. I can understand why the plan says that in order to participate a person has to be part of an occupational group in some plant or some organization where the monthly premiums can be collected. I can understand the difficulties that you indicated in answer to Dr. Rynard's question in respect of enrolling a whole municipality because if a municipality cannot, and I am sure it cannot by law require every person to pay three or four dollars a month, then, or course, they cannot make the payments and you could not finance it. I am favourably impressed by what you are doing on a voluntary basis.

At the same time I am a little concerned with what I detected as a note of defence of parts of the industry with which you are not really concerned. I think

it was Mr. Walker who said that if his wife had not had antibiotics she would not be alive and therefore the price was not too important. That is true up to a point but if a person has to take a drug regularly—and there are many people who have to take cortisones, tranquillizers and in some cases antibiotics, and they have to take them for a long period of time, if not for life—then the question of what they pay becomes very important. I was looking at some testimony given before the Kefauver Committee a few years ago, Mr. Chairman. I am just going to give one example. Before that Committee, McKessons and Robbins, which is a big company in the United States, testified that a person taking prednisone, which is one of the important forms of cortisones, and buying a hundred a month of their product from a retail druggist, would pay about $3.50 a month; if they used one of the brand names put out by Schering or Upjohn or Merck they would be paying $27 a month. The difference between $3.50 and $27 a month to most people, and particularly to the kind of people that your organization services, the wage earners, that is a very substantial amount of money. I am not saying it is your fault. All I am saying is that this question of whether drugs can be supplied to the consumer at lower prices is very important. I can understand your point of view and as an ex-druggist I can understand the retail druggist's point of view, that it is not for him to substitute a generic brand when the doctor prescribes a brand name; that is something that the doctor has to do. I can understand that, but I am a little concerned when you, as I listened to your testimony, seemed to indicate that these things were not important.

Mr. WALKER: If I may be so frank, I think you put some intent into some of my wording that was not there. When I made the reference to the antibiotics for my wife I simply tried to pose the difficulty that arises when you discuss that question. For example, you put the problem very neatly because on the one side you have the problem that if the drug is required, the cost of it does not matter, if that is what is going to keep you alive. On the other hand, the ever difficult aspect of the same question is, what are you going to do if you are going to have to spend the rest of your life on it, which is the point you made. I was simply making the point that that question is extremely difficult to decide. I am not arguing the subject in defence of anybody. In our view what we have said is that the real issue is to provide to the public those drugs which they require, whether they require them for a short term or a long term period, and permit them to budget their cost so that they are not concerned with the individual cost on a per dosage basis. That is what the plan does. We are not here in defence of anything; we are here to show you how, in fact, we resolve that very problem, and in effect, what I am saying is that I agree with you that the real key question is, how can you provide the drug for somebody who has to have it over a long period of time. Once you put this plan into operation and again, being frank, the issue of the cost per dosage fades away. The man who is paying his premium does not concern himself with the cost on an individual basis any more than I who am a subscriber to the Windsor Medical Service, a prepaid medical plan, have any interest at all in what the doctor charges for the service he provides. What I am concerned with is the amount of my monthly payment.

Mr. ORLIKOW: Well, I agree completely and to the extent that you have control, and to the extent that people belong to your plan, the threat of fantastic costs because of major illnesses, difficult illnesses and prolonged illnesses is

lessened and it is evened out, and for this I think you deserve a great deal of credit. But I suggest to you that if the drug companies are making too much money, or if the patent system produces a situation whereby Canadians pay more for prescription drugs than anybody else, or if the cost of getting the information to the doctors who write the prescriptions is to be reduced from the 30 per cent, which the drug companies have testified it is roughly, to something much lower and much more manageable so that the cost of the prescriptions would go down, as a result of which your premiums could go down, then not only would the ordinary citizen who does not belong to your plan benefit but even your members would benefit because if the cost were reduced by a third then your premiums would go down, obviously. Is that not correct?

Mr. WALKER: If the cost were reduced by a third, yes.

Mr. ORLIKOW: I am not going to belabour this because there is not much point of my debating with you drug costs which are attributable to the manufacturer. You are the servicer—I am not saying this in a critical sense—and at the level you are working I think you are doing a good job; if you were not you would not get the co-operation of management and labour which you are. I know, for example, that your plan is going into operation at Thompson. I know the steelworkers organization there very well. They are very tough hardheaded negotiators and I am sure that before they agreed to including your plan as part of their package in their most recent agreement, they looked at it very carefully. I am not being critical of that at all. If I took something you said out of context, I am sorry, but I want to nail down that the larger questions of cost are really not within your purview. This is the important point I want to make.

Mr. WILKINSON: If I might just nail that down, Mr. Chairman, the official view of prescription services is simply that as a fiscal agent for both the pharmacists and the patient, we are most interested in being able to provide for him whatever the doctor orders at the least possible price; and we are as concerned, or more concerned than the members of this Committee that there is a great disparity in prices in certain items, as you mentioned. We are more concerned, I say, because we actually are paying the money out of the bank while perhaps you gentlemen are not concerned, except with your own private purchases. We are spending something in the order of $125,000 a month for pharmaceuticals and we would be delighted if we knew of some way in which we could reduce the cost of the ingredient that goes into the prescription without resorting, as we have been so often asked, to a formulary, which I believe to be interference with the practising physician, without insistence on generic terms which I believe to be outright interference with the physician. On these two matters alone we could easily pass a regulation within our organization and say that we will only pay on the basis of generics. We could easily pass a regulation and say that we will only pay for such things as are listed in this compendium. We do not feel that this is the right thing for the plan. We do not feel that this gives the people freedom of choice and we feel that it is an outright interference with the medical profession. We would hope that you ladies and gentlemen would be able to find some way in which the disparity of prices in the future can be brought down. We are actually looking toward you and to you in the hope that your recommendations will at least get the 12 per cent sales tax off so that we will not have to raise premiums.

Mr. ORLIKOW: Mr. Chairman, I think we at least have an understanding of both sides. I can understand the feeling of this organization, that it is not for them to dictate to the doctor. Not only would it be resented by the doctor, but I am sure it would lead to difficulty between the patient and the doctor if the patient had to go to the doctor and say, "Look, the prescription that you wrote cannot be filled and paid for by the plan to which I belong." I think that there is some question of what drug is used, and I think this has to remain with the doctor. If this Committee or the department feels that generics should be more commonly used, that is something which we will have to apply ourselves to accomplishing; but I did want it on the record and I am satisfied to have on the record my feeling that the question of the cost which lies with the manufacturer is something which we still have to examine very carefully.

Mr. BRAND: Mr. Wilkinson, I have a few brief questions here. At page 15 you say, "we might say that the Green Shield plan is unique." I am a little curious then why you continue comparing yourself to the Windsor Medical Services, Blue Cross and all this sort of thing if you are the only one.

Mr. WILKINSON: We are the only prescription plan on the North American continent on a prepayment basis. We are modelled after the general administrative organization of Windsor Medical and P.S.I.

Mr. BRAND: You say that no plan for the prepayment of prescription drugs exists upon the North American continent with the exception of Green Shield. Is that correct?

Mr. WILKINSON: Prepayment, yes.

Mr. WALKER: The Windsor medical does now offer a prescription side, but we are saying that this is the only prepaid prescription plan per se.

Mr. BRAND: I am afraid you lost me.

Mr. WALKER: There are other plans in terms of medical services which provide for prescriptions, and Blue Cross is one of these; Windsor Medical does provide an area. But the only thing that this plan is concerned with is the field of prescriptions alone. The other plans are essentially medical service plans, originally.

Mr. BRAND: But do they not provide prepayment as well?

Mr. WALKER: No. It depends; Windsor Medical happens to be prepaid, but Blue Cross, as you know, is a reimbursement program.

Mr. BRAND: So there are a few others than yourself?

Mr. WILKINSON: If I might say, Windsor Medical is a prepayment plan. Their extended health care, as far as pharmacy benefits is concerned, is an extended health care plan with a very large deductible of $50 a person, which must be overcome first.

Mr. BRAND: Do you think the setting up of this plan has resulted in the lowering of costs for the average subscriber to your scheme?

Mr. WALKER: We have no way of judging that. All I can tell you is that a single man pays $1.90 per month, which is $18.00 a year; the maximum family runs something on the order of $68 per year, and in between lie the other various families.

Mr. BRAND: I think there is a way of judging it from the Canadian Pharmaceutical Association figures of the average cost of prescriptions; but you say that as a result of the methods you were using throughout your scheme that the average cost of prescriptions per capita is lower than the average, say, in Ontario or other provinces where you are operating.

Mr. WALKER: The only problem with that, Dr. Brand, is that this presumes we are comparing apples with apples.

Mr. BRAND: But there are different kinds of apples.

Mr. WALKER: Yes, but we have found, when for instance we were trying to compare this program with other surveys, that they have not necessarily been on the same premises, the same assumptions; we are just saying that statistically we cannot prove it one way or the other. What we have attempted to give to you has been supported by statistical evidence which has been very carefully compiled. On what we have not compiled we do not want to say that we will give you an expert opinion that it will be this or that or something else; we just do not know.

Mr. BRAND: What is the average cost of a prescription as paid for by P.S.I.?

Mr. WILKINSON: It is $3.438 plus 35 cents that the pharmacist gets.

Mr. BRAND: And $3.43 plus 35 is about $3.80.

Mr. WILKINSON: It is $3.79.

Mr. BRAND: The average across Canada would be somewhere in the nature of $3.56, so you are actually higher.

Mr. WILKINSON: On the basis of those figures, if that were the end of it, we are probably 18 or 19 cents higher. This leads us back to Dr. Rynard's question of what happens to your utilization prescriptions per person per month and what happens to the size of the prescription that the physician writes for the patients who are on the Green Shield Plan on continuing medication. So immediately you introduce those two variables, the most important of which is the size of the prescription. It is general practice in areas where Green Shield is widespread, such as in Essex, Kent and Lambton counties where we have about 1 out of every 3 people in the plan, that wherever a person is on continued medication, the physician knows that this patient is on continued medication and will write a full month or three months' prescription—in other words, one month and two repeats. They will give the full 34 days. I am speaking now of such things as hypertensives, the cardiac-insufficiency medications, thyroids, diuretics and so on. So the size of the prescription, instead of being what the patient can pay for in two weeks becomes a month's supply; a $4.00 prescription now becomes an $8.00 prescription. We have no way of knowing what the effect of this is and, frankly, although this has been asked of us now at every one of five inquiries that I have appeared before—and we could spend a lot of money in researching this—our board can see no useful purpose in us doing it, as far as we are concerned, and spending $30,000 to research this, because it would be of no benefit to us. I cannot answer your question because of the variables, but we are very close together in spite of it.

Mr. BRAND: From what you have said, would you say it would be true that there was some degree of over-utilization as a result of this prepayment plan?

Mr. WILKINSON: I do not like the word "over-utilization", doctor.

Mr. BRAND: I will change the word. Let us say that there is a much greater tendency toward ordering more prescriptions when they are all going to be paid for.

Mr. WALKER: If you said, if there is an "increased" utilization, yes.

Mr. BRAND: All right, but I think there is as a result of this.

Mr. WALKER: Who is going to judge whether there is over-utilization?

Mr. BRAND: I do not argue that; "increased utilization" is a much better term.

Mr. WILKINSON: Yes there is, in the same way as you have an increased utilization in hospital beds and an increased number of people sitting in the waiting rooms since OMSIP.

Mr. BRAND: You made a point of mentioning the fact that you covered cystic fibrosis cases, and Dr. Howe opened the door on this. I was a little surprised to note that when you were talking about injectables, you excluded all insulin substitutes.

Mr. WILKINSON: Yes.

Mr. BRAND: I am a bit curious about this, because surely the idea of such a plan as yours is to help overcome the continuing costs, particularly the large costs, and you use those who do not use as many prescriptions to make up for those who use a lot. Certainly in maturity onset diabetes where oral insulin—and that is a bad term to use for them—substitutes are prescribed, it would seem to me that this would be a very real field that you should be covering. Frankly, I am very amazed that you are not covering it.

Mr. WILKINSON: May I say in answer to that, Dr. Brand, that the Green Shield plan is not a perfect plan; it has a number of imperfections. The premium structure was devised prior to the introduction of the oral hypoglycemic agents. They were not invented when we "struck" this premium. We suddenly found ourselves faced with $13 per hundred if we permitted this on 100 a month on a continuing basis.

Mr. BRAND: Does this mean that if any newer things come out worth this sort of money that they will be excluded as well because of this? Is this not what you are suggesting?

Mr. WILKINSON: Could I just finish my thought?

Mr. BRAND: Sorry.

Mr. WILKINSON: We wanted to cover these in the worst way and we were able to do a year's test run in a plant at Sarnia. We supplied the oral hypoglycemic agents to all of the subscribers in the Prestolite factory in Sarnia for one solid year, and then we put the results through a machine. We found that in order to supply those people with the oral hypoglycemic agents at today's prices, it would require an increase in premium of 4.6 cents per person. There is not 4.6 cents per person in our surplus structure at the moment. There will be an increase in premium as time goes on—I am certain there will be an increase in these premiums—and we would hope to be able to include the oral hypoglycemic agents in the next premium rise to answer this particular need.

Mr. WALKER: You might be interested to know that we have agreed to maintain the premium structure for a fixed period of time. That is why it will be taken into the next premium structure review.

Mr. BRAND: Would it not have been better in your memorandum to say that, rather than to have said:

> (b) Less than 2 per cent of the population are diabetics and less than 1 per cent use insulin. Since it is not prescribed but bought on a continuing basis over the counter—

And incidentally this is news to me; maybe it is true in Ontario but it certainly is not in my province.

> —the abuse and trafficking in this product require it to remain out of the plan.

This is your statement.

Mr. WILKINSON: We are speaking now of injectable insulin, not the oral hypoglycemic agents.

Mr. BRAND: I was not aware that abuses and trafficking were going on and I am rather curious about this.

Mr. WILKINSON: Here again, I say I spent 34 years handcuffed to a dispensing counter, and I can assure you that if there is any way of person A enrolled in the plan obtaining insulin without any doctor's order, simply on a continuing basis over the counter for Aunt Sarah or Aunt Mabel or the lady next door, it will be done.

Mr. BRAND: It is certainly not true that you can buy oral hypoglycemic agents across the counter.

Mr. WILKINSON: I was not speaking of that; I was speaking strictly of insulin.

Mr. BRAND: In your memorandum you make the statement that "the use and cost are consequently impossible to control" with reference to injectables administered by a physician. Is it not possible that if a certain injectable prescription was given for them to the patient and purchased from the pharmacy that the use and cost of such would be very easy to control under that basis and that this cannot be the only reason why you do not wish to cover them?

Mr. WILKINSON: They are administered, in most cases, by a doctor, and I might say, Dr. Brand, that this is one of the places in the early stages of the plan where it almost hung up. I sought the advice of the executive of the Essex County Medical Society on it. It was their considered view at that time that we would be very wise to exclude injectables, and although it would work a hardship in some cases, that in most cases it would be impossible to control; and since the plan is in no position to pay a physician, because he is not a pharmacist and we do not pay physicians, there was no way of paying for this medicine administered by the physician. It was upon the advice of the executive of the Essex County Medical Society that this was left out. In my view it was wise advice that was given to us.

Mr. BRAND: In other words, it would have cost far too much money.

Mr. WILKINSON: Dr. Brand, we can design a premium for anything. The point is, where are you going to price yourself out of the market? The more benefits you put in, then the higher you build the premium—and this can be done actuarially. We can put anything you want in there, including a trip to Florida, but when you have done this, you have your premium to a point where neither management nor labour will consider it as a fringe benefit, and your work has been in vain. We have discovered that we can provide a plan which is far from perfect but, on the other hand, it will handle something in the order of 94 to 95 per cent of all of the drugs that a physician normally prescribes and average the cost of these over time and over the population for the subscribers.

Mr. BRAND: Thank you very much for that answer. Are you a non-profit organization?

Mr. WILKINSON: We are a non-profit organization.

Mr. WALKER: A corporation without shared capital under Ontario law.

Mr. BRAND: What you have been pointing out more or less in the last few minutes, and correct me if I am wrong is the drastic cost that would result if all drugs were covered under some sort of a scheme.

Mr. WILKINSON: I think this follows.

Mr. BRAND: Is that not a very important point to make? As you said, you can price yourself out of the market if you covered everything. There have been proposals put before us, and we have all heard them, about paying for all the cost of prescription drugs such as in the United Kingdom. With your experience as a non-profit organization, and with the experience in the spiraling of costs, the more you add, could you envisage financial difficulties with such a scheme, if everything was covered? Is that a fair question?

Mr. WALKER: I do not think that is quite what we are saying. What we are saying is this: We can create a premium structure which will incorporate all of these but people, and after all that is who we are dealing with, will not pay that premium. In any management-labour bargaining there is always a consideration of cost. Particularly when management undertakes to pay the Green Shield premium as a fringe benefit, it is quite concerned with cost. So is labour because they know if the cost of the package is too much they cannot get management to buy it. We are simply saying that the premium structure has to be related to the capacity of people to undertake them.

Mr. BRAND: It has to be realistic.

Mr. WALKER: Realistic, right. We did not feel, if we built in these other provisions, that it would be realistic.

Mr. BRAND: You have chosen a method of payment from the pharmacist: cost plus dispensing fee. Do you find that the pharmacists are satisfied with the $1.65 they receive?

Mr. WILKINSON: I do not know quite how to answer that, Dr. Brand. It depends on the volume of business that the pharmacist is doing. I am not trying to hedge your question at all. We in Essex county, as I said, have one in three. We have one store, for instance, that last month filled 1,343 Green Shield prescriptions and this was about one-third of his business. Now he is delighted with $1.65 on top of his cost and the extra work in filling out the pharmacist's

charge card, which is an IBM card requiring a copy of the prescription and other data, is no problem to him at all. However, if you go to some other district where we have very few subscribers and the pharmacist does anything from one to 25 prescriptions a month in the plant, it is a beastly nuisance; he does not like filling in the forms and he does not remember from one filling to another how to fill them in, and he is the very fellow who gets a Librium prescription which he could get $12 for, but for which he can get only $8.70 from us. Automatically, he is pretty annoyed about it and lets us know in no uncertain terms.

To answer your specific question, I do not know of any pharmacist anywhere who is happy with $1.65. They want much more than this because they feel they are entitled to much more than this, and perhaps they are. I am sure that if we offered them cost plus $5 they would gladly take it. On the other hand, depending on the volume they are doing, they are well satisfied to reasonably well satisfied to not so satisfied to just plain angry.

Mr. WALKER: To turn it around another way: in areas where the plan has heavy membership, we do not find any member pharmacies withdrawing from the plan.

Mr. BRAND: This was the point I was wondering about. You mentioned you had covered completely one town in Manitoba.

Mr. WALKER: Yes, Lynn Lake.

Mr. WILKINSON: We have everybody who works for the mine there.

Mr. BRAND: Is there a druggist there?

Mr. WILKINSON: One druggist.

Mr. BRAND: Is he making a living at it?

Mr. WILKINSON: If you hand me that blue book I can tell you what his month's account is. I do not know whether it should go in the record.

Mr. BRAND: I do not really think we should put it in the record.

Mr. WILKINSON: If you are asking, is he making a living; he is making a very fine living.

Mr. BRAND: Of course that is the one point I wanted to make. So on $1.65 it seems they can make—

Mr. WALKER: Excuse me. Remember this, though—and we have no control over this: If another druggist moves into Lynn Lake he can become a member of the plan. There is no restriction on membership. Presumably he does rather well because of the fact he is the only druggist there, but if three other druggists move in and they all become members of the plan, then presumably it would be a different matter.

Mr. BRAND: I am willing to accept that. However, we have had evidence that some of the druggists who have had a great deal of difficulty making a living are those in the smaller towns; so naturally if I find one in a small town who through some particular scheme is making a very particular good living naturally I am pleased—particularly when the Canadian Pharmaceutical Association came before us and said it was tough on some of these in the small towns.

Mr. WALKER: Of course this is purely a matter of opinion, I would have thought that those in the larger urban areas would have the greater difficulty

because they face much more competitive pricing. Certainly that is the experience amongst my clients.

Mr. BRAND: Well it certainly is not the experience from the evidence before this committee, particularly when you see variations between $1.98 for 25 10 milligram Librium all the way across to $5.95 for the same prescription. It would seem to me that this really is not too valid. This brings me, incidentally, to another question. You have worked out this method of cost plus dispensing fee and I know it is used in a few other places, in small areas.

The CHAIRMAN: Toronto is not a small area.

Mr. BRAND: Is it used all over Toronto?

The CHAIRMAN: Pretty well now, I think.

Mr. BRAND: Well I would be very happy to put on the record some of the prices out of Toronto, Mr. Chairman, if you would like, and they certainly do not build that up. It cannot be true all across Toronto.

Mr. WALKER: Do not forget, doctor, when you say cost plus professional fee, we are establishing under our system a method of cost but someone else is using the professional fee basis. Also, it depends on two things; first of all, the amount of the professional fee and, second, the manner in which he calculates cost.

Mr. BRAND: Oh.

Mr. WALKER: His calculation of cost could be different from ours.

Mr. BRAND: Give me some examples.

Mr. WILKINSON: Well there is very heavy pressure on me right now to change our cost from list less 40 to list less 33-1/3 because the pharmacist feels that in cases where he has to buy from wholesale houses he gets considerably less than a 40 per cent discount and that on these particular cases he is losing, and that he should not lose but the patient should pay. I came from a meeting in Toronto yesterday where every second person I spoke to is rather critical of what they consider to be our rather high-handed and arbitrary way of assigning list less 40 as a cost.

Mr. WALKER: Of course the other thing is that it depends on what the professional fee is. Now this ranges from perhaps $1 to $2.50 and, of course, I think there perhaps are some who use a combination of the gross profit system and the fee. So it depends on what premise you are working. But I believe that the use of the professional fee has received, we will say, the general approval of the College of Pharmacy. Right?

Mr. WILKINSON: Oh yes.

Mr. WALKER: It was Professor Fuller who first developed the concept.

Mr. BRAND: Well that, of course, leads to my question. You mentioned that you could not think of anyway you could reduce the cost of drugs, much as you would like to. Certainly that is the dilemma we are all in. Do you think the general cost of drugs would be reduced by utilization of some method of cost plus a professional component?

Mr. WALKER: If you were able to develop a method within—

Mr. BRAND: Let us say the method proposed.

Mr. WALKER: —the existing framework of law which was enforceable to determine or regulate, if I could use that word, the cost. In other words, if cost goes down under our program inevitably the premium cost would go down or would maintain its level, but the question is: how do you regulate cost?

Mr. BRAND: Surely the pharmaceutical profession can regulate its own self. I mean if you came to an agreement in the Canadian Pharmaceutical Association, for example, on a method of determining cost which would be acceptable to a majority of the members, and a professional fee which would—

Mr. WALKER: I believe, doctor, that some of the gentlemen in Ottawa from the Restrictive Trade Practices Commission might be chasing us. All we would be doing is sitting down together and agreeing to fix prices. I believe the government does not like this.

Mr. ORLIKOW: It is also against the law.

Mr. WALKER: Yes.

Mr. BRAND: So you do not think this is feasible then?

Mr. WALKER: No.

Mr. BRAND: The pharmaceutical association has suggested it, so I am a little surprised.

Mr. WALKER: Well we do not always agree with the pharmaceutical association.

Mr. BRAND: You see they are not really fixing prices there because they have decided on different professional components across the country, depending on the areas, as you will see in their brief.

Mr. WILKINSON: I think it should be made clear here that although I am a pharmacist I do not speak for any pharmacy association. Although I am a member of the CPHA I am not speaking for the CPHA.

Mr. BRAND: I am not asking you to do so; I am merely asking for your opinion as head of what is, apparently, a very successful and very worthwhile organization. You surely must have some idea with regard to this area.

Mr. WILKINSON: We are speaking from the point of view of administrators of a prepaid plan and in some cases this cuts right across what the CPHA think to be their best interests right across what the OPA think to be their best interest and I think in some cases it cuts right across what the manufacturers believe to be their best interest. But we are trying to give you the benefit of our several years of experience in a unique plan where we believe that under certain conditions certain things can be done.

Mr. BRAND: By the way, have you been visited by any officials of government? I notice you are fixing prices in that you have them sign an agreement to accept a certain type of thing?

Mr. WALKER: Yes, the restrictive trade practices.

Mr. WILKINSON: Mr. MacGregor of the restrictive trade practices visited us at the time of the inquiry. He visited our office and went completely through our pricing arrangements.

Mr. BRAND: He did not think you were fixing prices?

Mr. WILKINSON: There was nothing further. We were not called and we were not cited.

Mr. BRAND: So really the statement about worrying about the whole thing is not really too valid then?

Mr. WILKINSON: No, because we are not fixing prices in collusion with anyone else. We simply say: If you wish to dispense within this plan—and there is no compulsion for you to dispense in this plan—these are the conditions under which you shall. Now if we got together with Blue Cross, with PSI, Pharmacare or any other organization which may come along in the future, and agreed upon a price, I am afraid we would be violating the law.

Mr. BRAND: Thank you very much.

Mr. HOWE (*Wellington-Huron*): On page 11, two-thirds down the page, it states:

Portion of 35 cents direct payment—

on each month. How do you arrive at the 11 cents in this situation with a standard industrial group?

Mr. WILKINSON: What we are trying to do in that column under Standard Industrial Group is to give you a breakdown of that $1.44. If I could give it to you from the top it is: 66 cents paid to the pharmacist for ingredients; 41 cents paid to him as a dispensing fee and that 41 cents is that portion of a prescription that a patient gets a month. If you will recall earlier, I said that the utilization is .3171 of a prescription per person per month. So if you divide his $1.65 fee by .3171 you get the 41 cents. Now since the patient says 35 cents at the time of the filling of the prescription but he only gets .3171 of a prescription each month, then to get this into person month coverage again you must divide the 35 cents by .3171, which comes out to 11 cents.

The CHAIRMAN: I am sure that is clear.

Mr. WILKINSON: The key to all utilization data has to be on the basis of person month of coverage.

Mr. WALKER: What we are talking about is this. You end up with .3 of a prescription and it is 35 cents for each prescription, so the 11 cents represents roughly .3 of 35 cents, and that is all.

Mr. ISABELLE: Say I prescribe two tablets of morphine will the patient have to pay 35 cents to the druggist?

Mr. WILKINSON: Yes sir.

Mr. ISABELLE: And the druggist will receive a professional fee of $1.65?

Mr. WILKINSON: Yes sir.

Mr. ISABELLE: And the total prescription will cost about 28 cents?

Mr. WILKINSON: Yes sir. If you are wondering about the justification of this, take the other end of the scale: for a $22 prescription he still only gets the $1.65.

Mr. WALKER: We felt, for instance, if you were to work it on a sliding tariff related to cost that you mix two things. First of all, we are taking about a professional fee for a professional service. But the second thing is that you would, in effect, penalize the person who requires the expensive drug by hitting

him with a whacking fee; so, in effect, the $1.65 is an averaging in cost of the whole spectrum of it.

Mr. ISABELLE: I think, Mr. Chairman, that the manufacturers must be very satisfied with this plan, also the pharmacists, the people and, of course, the doctors are delighted. It is not because it is the only one; it is the best one.

The CHAIRMAN: Are there any other questions?

Mr. WILKINSON: Could I just say, in response to Dr. Isabelle, that we have received no support in anyway, shape, or form—lip service or otherwise—from the pharmaceutical manufacturers. It is impossible to get an appointment with them to go before their board to even explain the plan. I can only take it from this that they are not too happy with our plan, and that perhaps they may see in this type of plan a growing threat to their own enlightened self-interest.

Mr. BRAND: You had better explain that one.

Mr. WALKER: Well, I think it would be better perhaps if we restricted it to this: since they do not seem to want to talk to us, presumably it must mean they do not approve of the plan.

Mr. BRAND: That is pure presumption.

Mr. WALKER: Actually I think that we might better put it this way: this plan was developed mainly by the pharmacists in Essex County; it was a self-help, pull-it-up-by-the-boot-straps operation; they got no support from anybody except pharmacists and, I might add, they did not seek any support from anybody—and oddly enough, they are not today seeking any support from the government, which seems to be where everybody seeks support. We did not ask for any aid, and we did not get any aid.

Mr. BRAND: For the life of me I cannot see how this could harm any enlightening self-interest, as you put it, of the manufacturers. How can this possibly relate at all to them? They are getting their money; they are selling their products.

Mr. WILKINSON: I rather wish I had not said that.

Mr. WALKER: I was going to suggest, Mr. Wilkinson, on the advice of counsel that you should get out of this. But let us put it this way: that is really a matter of opinion as to the situation of the Pharmaceutical Manufacturers' Association. What we have tried to do is talk about stuff we know about; the rest of it is simply a matter of conjecture, which would be better off the record.

Mr. BRAND: Well if this is something you do know about, why did you want to see them in the first place?

Mr. WALKER: Oh, because it is new, and to explain the plan; we have been talking about it to a great many people over the last 10 years.

Mr. BRAND: What advantage would there be? Were you looking for some cheaper prices from the manufacturers?

Mr. WALKER: I think, originally, we perhaps were looking for a little financial support.

Mr. BRAND: I see.

Mr. WALKER: You see, at the outset we received financial support from the Essex County Pharmacists, each of whom put up $150 on a 10 year repayment program without interest. Then we received additional financial support from the Ontario Pharmacists' Association, and we would have welcomed some support from the Pharmaceutical manufacturers. In all cases, by the way, this is support without any strings; we are not interested in having anybody take over the plan.

Mr. BRAND: In retrospect, do you not think, that it was better you did not receive support?

Mr. WILKINSON: We are delighted.

Mr. BRAND: Then there was no suggestion that there would be any tie-in with the manufacturing group, and you are very much better off the way you are.

Mr. WALKER: We agree with you, based on hindsight. Let me put it this way: Mr. Wilkinson worked, ostensibly, as the paid president of this plan on a part time basis at $100 a month for eight years, so we could have used some financial support.

Mr. WILKINSON: We are glad we did not.

The CHAIRMAN: For the record, did the plan not operate at a loss for some period of time?

Mr. WALKER: Oh yes.

Mr. BRAND: Well, all the more power to you.

Mr. ORLIKOW: At a loss to whom?

Mr. WALKER: In effect, a loss to the pharmacists who put up the original support loan. In other words, each pharmacist in Essex County—88 of them, I believe it was—put up $150 each; that is where the loss was. By the way, we were always in a position to pay the benefits; they would have come out of the pharmacists' hide.

Mr. ORLIKOW: Have you repayed that money to the pharmacists?

Mr. WALKER: No, but it will be repayed this year. It is due in August of 1967.

Mr. WILKINSON: These repayments are due in 1967 and early 1968 and these monies will be repayed. There is a natural tendency for people or organizations who are perhaps in the same discipline but in different phases of it, to be suspicious or to have a certain fear of the growth, and with the growth, the power of another organization. I refer to our present policy of being utterly opposed to formularies and generic prescribing *per se*; I think that it would be quite in order for other disciplines of pharmacy to be a little worried as to whether we will change our view on this, and perhaps cause some embarrassment.

Mr. WALKER: All of which, summed up, means that this program has disturbed the status quo of the various members of the pharmaceutical discipline over a period of years.

Mr. BRAND: Not of the subscribers?

Mr. WALKER: No; the subscribers enjoy the plan.

The CHAIRMAN: I would say in conclusion that if some of your words regarding other organizations and their intentions have been misinterpreted by yourselves, I am sure you will hear about it in the near future. The proceedings of these meetings are fairly well attended by various parties.

Are there any other questions? If not, we would like to thank Mr. Wilkinson and Mr. Walker for appearing before us today.

Before we adjourn the meeting, there are several things I would like to mention. First of all, there is no meeting any day during this week. At the next meeting we will have a return visit by officials from the Canadian Pharmaceutical Association; they are bringing drug store representatives from as far away as Halifax, and the president of their organization from Vancouver will be here. We are holding that meeting after orders of the day at approximately 3 o'clock or 3.30 this coming Monday, and also at 8 o'clock that night, if necessary.

Mr. BRAND: Will Mr. Lawson be here.

The CHAIRMAN: Mr. Lawson is from Halifax. However, there will be a meeting of the steering Committee this week; Mr. Orlikow has sent a notice of motion to the Chairman of the Committee—a motion which he could not present this morning—dealing with the request to some of the companies for financial information. Both Dr. Rynard and Mrs. Rideout have asked the Chairman if we would consider having Dr. Hilliard come before the Committee; his report has been discussed many times and Dr. Rynard, Mrs. Rideout—

Mr. BRAND: You can add my name to that list.

The CHAIRMAN: —and Dr. Brand, and I think most members of the Committee would like to have the opportunity to talk to Dr. Hilliard about this.

Mr. BRAND: He is my old chief; I should talk to him.

The CHAIRMAN: Even though we graduated, at different times I also was a student under Dr. Hilliard.

The meeting is adjourned until next Monday, except for the steering Committee which will meet later this week.

APPENDIX "A"

BRIEF
TO THE SPECIAL COMMITTEE ON DRUG
COSTS AND PRICES
by
PRESCRIPTION SERVICES INC.

(*Operating the Green Shield Prescription Plan*)

1.1 The purpose of this Brief is to suggest and enlarge upon the following ideas:

(a) We suggest to the Special Committee that without an adequate definition of "The Cost of Drugs" it is difficult, if not almost impossible to develop an effective program to reduce the price of drugs.

(b) The impact of the 11 per cent Federal Sales Tax upon the cost of drugs has been an area of special concern to the Committee. We have set out herein an appraisal of this effect from our own statistical records.

(c) We suggest that whatever economies may be effected, the reduction in the cost of drugs will not in itself be significant. We further suggest that any such reduction, when spread over the whole population would be expressed in pennies per month of savings. We make these suggestions assuming the implementation that all of the economies that have been suggested to this Special Committee and to other similar Commissions and Inquiries concerned with the problem over the past 10 years.

(d) Based upon our actual operating experience we should like to outline to the Special Committee our view that the people of Canada are most concerned about two aspects of the problem of drug costs.

These are:

(1) In the first place, people are concerned with the unevenness of the burden of drug costs, (whether they are expensive or in-expensive per dosage), as those costs relate to certain persons or categories of persons in our population:

(2) In the second place, people are concerned with the unevenness of the burden of drug costs to those who are required to undertake that burden for sudden illnesses or short term therapy or when drugs are required over extended periods of time in the treatment of chronic sickness or chronic illness.

(e) We wish to outline to the Special Committee, the manner in which the Green Shield Prescription Plan works and how it has been effective as a resolution to the foregoing areas of public concern.

2.1 It is a platitude to suggest that the question of "The Cost of Drugs" is an extraordinarily complex one. However, the fact that it is an unresolved problem will explain why all of the various Committees on Drug Costs, such as the

Ontario Committee, the Restrictive Trade Practices Committee, the Royal Commission on Health Services, the Ontario Medical Insurance Inquiry and the Ontario Legislative Committee on the Aging and other similar Committees and Commissions have not yet been able to define the problem much less produce effective answers to it. It is our view that one cannot ascertain whether the cost of drugs is HIGH unless one can determine what those costs are high in relation to. To discuss the issue effectively, there must be an adequate definition of the meaning of the phrase "Cost of Drugs". For example, when ont talks of the cost of drugs being HIGH what in fact is really meant? Does it mean that:

(a) One drug is more expensive than another? or

(b) That one category of drugs is more expensive than others? or

(c) That drugs are more expensive than other commodities? or

(d) That drugs are more costly when compared to the results obtained from the usage? or

(e) That drugs are costly in relation to their expenses of manufacturing and distribution? or

(f) That drugs are costly as a percentage of the Gross National Product or as a percentage of personal income? or

(g) That drugs have been overpriced as a consequence of profiteering and if so by whom? or

(h) That drugs have been overpriced because of the application of taxes?

It will not be particularly useful for us to make detailed comment on all of the foregoing categories but several examples will pose the nature of the problem that underlies each one.

(a) For example in category (a) it is true that Cortico-stearoids and hormone products are many times the cost of phenobarbital and other chemicals. Notwithstanding this difference in cost, it is also true that their need is equal when they are prescribed for a properly diagnosed condition.

(b) In category (b) it is also true that within the same category of drugs, one drug may be more expensive than another; thus some antibiotics cost more than others. Penbritin or Lincocin cost more than Tetracycline, which in turn costs more than Penicillin V and Penicillin G. The cost comparison however, is not relvant if one or the other of these drugs is in fact required for medication. Additionally, it is worth observing that the more recent the drug discovery, the higher its cost but in turn, the longer the drug is upon the market the less its cost. Penicillin when first marketed was so expensive that it was far beyond the financial reach of the public but today, penicillin is marketed at a fraction of the cost for each dose and this reduction has occurred within a period of approximately 25 years.

(c) Within category (c) it is quite true that some drugs may be more expensive than other commodities. However, drug costs on a long term basis form interesting comparisons with the long term usage of other commodities. A patient on sustaining therapy for arthritis, taking Butazolidin will spend approximately $10.00 a month. Another person smoking 1 package of cigarettes a day, will spend

$12.00 a month. In these circumstances, it is difficult to say that the use of Butazolidin as a medication to relieve pain is truly more expensive than the luxury of cigarette smoking with its attendant health hazards. Similar comparisons can be made with other commodities such as liquor, gasoline, newspapers, air-conditioning, househeating, etc.

2.2 Similar points with respect to each of the above mentioned categories could be identified. However, this list of references and the supplementary remarks in no way exhausts the possibilities of the various references within which the subject of the cost of drugs could be considered. However, to our minds the continuing search for an adequate reference point or an adequate definition by the various Commissions and Inquiries through the past 10 years has not been a fruitful one. To our knowledge, not one of the Commissions or Inquiries has been able to develop an effective or acceptable program to reduce drug costs.

2.3 An unvarnished fact is that sickness is an undesirable condition and that medicine in consequence is a highly unpopular purchase. Its unpopularity is further increased by the traditional lack of communication which exists between the physician and the pharmacist on the one hand and the patient on the other in the prescribing and dispensing of a prescription through the use of medical Latin, a language known only to the prescriber and the dispenser. In consequence, the ultimate consumer of the medication, the patient, is called upon to purchase a commodity whose content and purpose he little understands but does know that it relates to an illness that he could well do without. In these circumstances, it is hardly extraordinary that the public have a natural resentment to the price of drugs whatever the price may be. However, even if we accept as normal this patient resentment to a forced purchase prescribed in a dead language it still does not lead to a definition of the cost of drugs or the establishment of an adequate framework of reference nor does it offer any relief from the prices presently being charged whether they are high or not. We suggest to the Committee—and it is borne out in the operation of the Green Shield Prescription Plan—that to the public the real area of concern is the unevenness of the burden of drug costs when required suddenly for short term therapy or when required over long periods of time in relation to chronic illnesses—and thus as it relates to the cost of drugs the public is most concerned with the establishment of an effective program to permit them to budget—in much the same way as in the field of Medical and Hospital Plans—against the cost of drugs whenever required to be used.

3.1 There seems to have been a considerable body of conflicting testimoney given to the Special Committee concerning the 11 per cent Federal Sales Tax and its application and its measurement. The testimony suggest that the 11 per cent Federal Sales Tax represents anywhere from 3.7 per cent to 18.9 per cent on the consumer price of the total number of prescriptions dispensed and about the only figure or calculation upon which any agreement was reached was that the total Federal Sales Tax collected by the Federal Government during the year 1964 approximated $14,000,000.00.

3.2 Under the Green Shield Prescription Plan the Member Pharmacists are paid for dispensing prescriptions for our subscribers upon a Cost-Plus dispensing fee method of payment and consequently, from our own data, we are of the view that we can accurately estimate the effect of the 11 per cent Sales Tax.

3.3 As the Special Committee is aware the 11 per cent Federal Sales Tax is applied upon the manufacturer's list price, reduced by 40 per cent initially and by a further 15½ per cent of that remainder. Therefore, the formula is:

11 per cent x mfg. List Price less 40 per cent less 15½ per cent = Sales Tax

or phrased in another way, for every $10.00 of list price the Sales Tax will equal 11 per cent of $5.07, that is to say, 55.77 cents.

3.4 An analysis of 308,191 prescriptions processed by the Green Shield Prescription Plan, during the period from September 1, 1965 to August 31, 1966 revealed that the average cost of ingredients was $2.12, while the manufacturer's list price for those ingredients was $3.51. Upon the basis of each $10.00 of list price the 11 per cent Federal Sales Tax would be:

$$\frac{3.51 \times 55.77}{10} = 19.7 \text{ cents for each prescription}$$

Using this calculation the Sales Tax collected by the Federal Government for those 308,191 prescriptions, dispensed from September 1, 1965 to August 31 1966 would equal $60,097.20.

3.5 This Sales Tax calculation can be extrapolated and projected for 20 million persons by reference to the average enrolment in the Green Shield Plan for the period from September 1, 1965 to August 31, 1966, which was 82,763 persons or 1/242 of the approximate 20 million Canadian population. In addition, if we assume three (3) factors namely:

(a) Cost-Plus fee system of payment used by Green Shield;

(b) The Green Shield Prescription Plan actual utilization data;

(c) The actual Green Shield Plan average cost of ingredients we can then extrapolate and project to Canada's estimated population of 20 million by the following calculations:

$60,097.20 x 242 = $14,543,522.40 of Federal Sales Tax being paid annually.

3.6 We would suggest to the Special Committee that the close relationship of this extrapolated figure to the amount of Sales Tax actually recovered by the Federal Government during 1964 would indicate a verification of our calculations as set out above.

3.7 Previous testimony before your Committee and questions from the Committee have related to the "pyramiding" of the Federal Sales Tax. Additionally, some concern has been expressed as to whether if the Federal Sales Tax was remitted entirely there would be an actual reduction in price to ultimate consumer, the public, at the retail level. We suggest that where the gross profit system of retail pricing is employed it is inevitable that a "pyramiding" of the

Federal Sales Tax will result. If for example we apply the figures above set out which assume that with relation to $10.00 of list price, the Federal Sales Tax is 55.77 cents, then the price by the manufacturer to the retailer will be $6.00. This $6.00 will be made up of approximately $5.45 cost of ingredients and 55 cents Sales Tax. This same $6.00 marked-up at the retail level at 40 per cent will result in a selling price of $10.00. Of that $10.00 retail price then $9.10 relates to the cost of ingredients marked-up from manufacturer's list and .90 cents relates to the Federal Sales Tax, also marked-up. This aspect of "pyramiding" is fairly apparent and will be applied in the gross profits system of pricing whatever the retail price of drugs may be. However, it is not possible in our opinion to calculate in actual dollars and cents, the ultimate effect of "pyramiding" unless a prescription by prescription study was made with a sufficient sampling of those prescriptions to permit an accurate projection over the whole population.

3.8 We suggest however, that the "pyramiding" question could be eliminated and the complete remission of the Federal Sales Tax passed on to the consumer, if retail pharmacy employed the cost of ingredients plus fee system of payment. We add that this has been the system adopted by the Green Shield Prescription Plan. Under this system any reduction in the cost of ingredients at the manufacturing or distribution level must ultimately be passed on to the consumer. Under this system the retail pharmacist is being paid for his professional services, which is a fee related to the professional service offered and unrelated to the cost of the ingredients sold.

3.9 We have suggested to the Special Committee that it is unlikely that any reduction in the cost of drugs will in itself be significant and that when spread over the whole population of Canada, would be expressed in pennies per month. In this respect we would like to refer not only to the probable effect of the remission of the existing Federal Sales Tax but also to observe the results of other price reductions if they were effected. We propose to examine such reductions as they will effect a reduction on a monthly basis of the premium in a Prepaid Prescription Plan, such as the Green Shield Prescription Plan.

4.1 To relate price reductions to premiums per month, it is necessary to develop the following statistical information for the Special Committee, which is taken in part from a twelve month study of the utilization data of the population of the Green Shield Prescription Plan (comprising 950,094 persons/per/months coverage) in the Standard Industrial Groups representaing all segments of the population and a five-year study comprising 30.220 person/per/months of retirees, isolated from the utilization data of the Standard Industrial Groups. From this information we find the following:

Item	Standard Industrial Group	Retiree Group
Average Prescription Price to the Plan	$3.40	$3.88
Average No. of Rxs per/person/per/month	.315	.633
Total Cost of Operation of the Plan	$1.44 per/person/per/month	$3.12

The total cost of operation of the Plan, for both the Standard and Retiree Group is made up as follows:

Item	Standard Industrial Group	Retiree Group
Paid to Pharmacist for ingredients	.66¢	$1.69
Paid to Pharmacist as dispensing fee	.41¢	.86¢
Average burden for administration	.20¢	.20¢
Required for financial reserves (5%)	.06¢	.15¢
Portion of .35¢ direct payment in each month	.11¢	.22¢
Total	$1.44	$3.12

(NOTE): Portion of .35¢ direct payment is calculated in the Standard Industrial Group as .35¢ x .315 (the average number of prescriptions per/person/per/month) and in the case of retirees as (.35¢ x .633).

4.2 To indicate the cost per/person/per/month for the Canadian population as a whole and assuming that the population of Canada is 20 million with all persons enrolled and the demographic composition of the enrollees remains the same as the present standard Green Shield Prescription Plan Industrial Group the minimum cost would be:

$1.44 x 20,000,000 x 12 months
or $345,600,000.00 yearly.

By the same token, if the demographic composition of the Plan changed so that it had a heavier composition of retirees and the heavy users of drugs who are within the 44 to 60 age bracket, then the cost could increase to the maximum $3.12 per/person/month, which would result in $3.12 x 20,000,000 x 12 or $748,800,000.00 yearly. As a passing note, we might observe that these estimates are in the same range as those made by us to the Royal Commission on Health Services at a time when the Green Shield Plan was much smaller and the amount of available data was consequently smaller.

4.3 Using the foregoing information however, one can now view the impact of a reduction in the cost of drugs. For example, assuming that the Sales Tax were entirely remitted and the total cost passed to the consumer, there would be a reduction, according to the foregoing information of about $14,000,000 yearly, which when reduced to a prescription basis, results in a reduction of less than .20¢ a prescription. Assuming the average person uses .315 prescription per/-month or 3.77 prescription per/year this would result in a reduction per/-person of population of about .75¢ a year, a relatively nominal saving. If the population became burdened with retirees and heavy users and the annual cost rose to $748,800,000 a year, the reduction per prescription would be about 23 cents a prescription or $1.81 which again represents a relatively nominal reduction.

4.4 Various suggestions have been made to this Special Committee and to other Commissions as to how price reduction can be effected. We do not propose

to comment on the usefulness of these suggestions because in all frankness we are unable to think of any area in our present market economy where a truly feasible program of real price reduction can be effected. However, it has been suggested that advertising and promotional costs of manufacturers should be restricted to 15 per cent of their gross sales. Others have suggested that the Federal Sales Tax should be remitted entirely. If we assume that both of these programs were put into effect—and if we also assume that these reductions were passed along to the consumer—these two reductions together, would mean a reduction in the overall price of drugs by about .30 cents a prescription. Thus if for the sake of argument we concede a reduction of .30 cents a prescription we can examine the consequent dollar reduction. Based upon the utilization data of the Green Shield Prescription Plan Standard Industrial Group the dollar reduction would be about $22,680,000 a year or about $1.14 per/person/per/year *or* about .09c per month. We suggest to the Committee that a price reduction .09¢ per/person/per/month is relatively nominal result. This reduction can be expressed in another way. If a premium of $1.44 per/person/per/month would cover the Canadian population, under existing conditions and with the utilization data of the Green Shield Plan then these reductions in costs of these two areas would permit the Plan to operate for $1.35 per/person/per/month or about a .09¢ a month reduction in premium costs.

Thus we have seen the impact of a significant percentage reduction in drug costs and find it is not significant in actual dollars. And again we suggest that these reductions would not provide answers to what we find to be the major areas of public concern. We suggest that the only way to resolve the problems is through a soundly based prescription plan providing a budgetary system. There may well be other programs to be devised for this purpose but one that in our opinion does provide an answer is the prepaid prescription plan, such as the Green Shield Prescription Plan.

5.1 The Green Shield Plan, is a voluntary prepaid plan whereby Prescription Services Inc., acts as a fiscal agent, on behalf of subscribers drawn from the public, and on behalf of pharmacies that have become members of the Corporation. Under the Green Shield Plan, agreements are made with individual pharmacies or pharmaceutical corporations operating retail pharmacies, under which Green Shield agrees to reimburse the member pharmacy for drugs compounded or dispensed by the member pharmacy to subscribers and their dependents upon a cost-plus fee schedule as predetermined by Green Shield, subject to a deduction (now 10 per cent) from the allowed price of prescriptions to be applied for administration costs and subject to further deduction in the event of the Plan operating at less than cost. Green Shield Prescription Plan also offers to the subscriber upon a group prepayment basis, without medical requirements, the right upon the payment of the premium fixed by the Corporation to have prescriptions issued by a lawfully qualified medical or dental practitioner to the subscriber of his dependents, dispensed by a member pharmacy of their choice without cost to the subscriber except for a monthly specified premium payment and a fixed .35¢ charge payable in respect to each prescription dispensed, paid direct to the pharmacy dispensing the prescription.

5.2 Under the Green Shield Plan the pharmacist is reimbursed for the cost of the ingredients sold plus a professional fee. The cost of ingredients is calculated

according to a stipulated schedule developed by the Corporation to which the member pharmacists agree—and must adhere. The professional fee is presently fixed at $1.65 for each prescription.

5.3 We might say that the Green Shield Plan is unique. No plan for the prepayment of prescription drugs exists upon the North American Continent with the exception of the Green Shield Plan. The Special Committee will no doubt be interested to know that in May 1962, the Green Shield Plan made a submission to the Royal Commission on Health Services and at that time was a Plan in a pilot stage providing services for approximately 1,500 people. Two years later, the Plan prepared a report for the Ontario Medical Insurance Inquiry, and at that time the Plan was providing its services for approximately 8,000 people. One year ago, in the case of the Ontario Select Committee on the Aging, a further report was prepared by the Plan at which time it was offering its services to more than 60,000 persons in excess of 300 communities throughout Ontario through the services of some 1300 member pharmacies and at that time had extended its services beyond Ontario throughout Canada from Moncton in the East to Burnaby in the West. Today, one year later, the Green Shield Plan is offering its services to more than 105,000 people, (an increase of 45,000 people in the one year) who reside in communities throughout Ontario and in Canada and are serviced by some 1800 pharmacies. The Green Shield Plan presently serves 250 industrial plants, whose management and employees have written the Green Shield Plan into their collective agreements during the course of labour negotiations. We are glad to say that the Green Shield Plan has the support of a large segment of organized labour.

5.4 The foregoing is, of course, a brief description only of the operation of the Plan but the Canadian Pharmaceutical Journal in its January 1966 issue devoted four (4) pages to a discussion of the Plan and its operation and a copy of this article is attached as an appendix to this Brief. In addition, the President of the Corporation, Mr. William A. Wilkinson, will be glad to answer in detail any questions that any member of the Special Committee may care to ask concerning the Plan and its studies in the field of prepaid prescriptions.

5.5 We are glad to say that the Green Shield Plan has had an extraordinary growth. We are also equally glad to say that the Green Shield Plan has established its fiscal soundness and has proved that such a Plan can be operated on a self-sustaining basis in the private sector of the economy. It has risen from a pilot plan stage to an active growing full-fledged Prepaid Prescription Plan. It has also shown that a prepayment plan upon a Group basis, offering prescription drugs can be provided upon a sound financial basis. At the same time—and more importantly—it has shown that the public can avail themselves of a wide range of prescription drugs at a relatively low constant and even cost. From the substantial and rapidly growing public particpation in this Plan we feel that our opinion in this regard is substantiated.

Respectfully submitted
Prescription Services Inc.
by
William A. Wilkinson—President

Board of Directors
W. A. Wilkinson Phm.B.
T. W. Moffat Phm.B.
K. J. Wiley Phm.B.
J. R. McGaffey Phm.B.
G. J. Alexander B.Sc. Phm.B.

Advisory Board
J. D. Geller
Geo. Burt
Henri Breault, M.D.
A. C. Scales Phm.B.

MEMORANDUM

December 7, 1966

A RECAP OF THE EXTENT OF PRESCRIPTION BENEFITS OBTAINABLE UNDER THE GREEN SHIELD PRESCRIPTION PLAN

The term Medicine in its broadest sense is often used as a synonym for prescription and a prescription is often thought of as any order for medicine originated by a physician or dentist. In fact it is much more complicated than that as is shown by the following definitions and comparisons.

Under the term "Medicine" we have several categories.

1. *Proprietary or Patent Medicines*

These are formulations of drugs whose formula is registered with the Department of Health & Welfare. They are packaged for sale under trade names and are almost never prescribed by a physician. They are such items as Lysol, Listerine, Exlax, Pepto-Bismol, Dristan and hundreds of others. Where a doctor would want a person to use such an item he would order it verbally or write it as an unsigned note. Green Shield does not pay for such an order—neither does Physicians Services Inc., Windsor Medical Services or Blue Cross.

2. *Household Drugs*

These are such items as Castor Oil, Epsom Salts, Boracic Acid and the like normally found in a medicine chest. They are never prescribed and .35¢ would buy a sufficient quantity. No plan pays for these.

3. *Over the Counter Ethicals (O.T.C.)*

These are drug formulations packaged under trade names and promoted both to the public at large through the drug store and to the physician for prescription purposes. They differ from patent medicines in that their formula is published on the label and most of them had their origin as a prescription item which by now has become well enough known to have an "over the counter" demand. Such items would be Benadryl, Pyribenzamine, Amphojel, Maalox, Robitussin, Benylin, etc. This is a large and ever growing category of medicine which is very much a part of the physicians' arm amentarium and are widely prescribed. They are not considered hazardous, poisonous, dangerous or narcotic drugs under any Act of Canada and a prescription is not required by law to obtain them.

Green Shield pays for these on prescription. P.S.I., W.M.S., Blue Cross does not.

4. *Physicians Special Formulations*

These are a diminishing category but still form a substantial number of prescriptions written. They are private formulas used by certain physicians wherein the pharmacist is required to start from scratch with the raw bulk chemicals and compound the capsule, powder, suppository or liquid, etc. The reason for mentioning these is that unless one of the ingredients is legislated against P.S.I. W.M.S., or Blue Cross would not pay for it, because although you need a prescription to get it a prescription is not required by law. This requirement is specifically stated in the regulations of P.S.I., W.M.S., and Blue Cross plans for prescriptions.

5. *Pharmaceutical Specialties*

By far the greatest number of prescriptions, some 6,000 items are drawn from this group. It is also the most confusing, for it is composed of several categories as is shown below. It should be emphasized that specialties in this group are not packaged for over the counter sale, are not advertised to the public, are promoted only to the physician and dentist and you do need a prescription to acquire the medicine at least initially, and in some, but not the majority of cases, a prescription is required by law each time you get the medicine. This depends of course on the degree of danger of the drug and to what degree it is legislated against.

CATEGORIES

(a) *Legend Drugs* (about 35 per cent of total)

(1) *Narcotic Drugs*

These are designated with an (N) in the Compendium of Pharmaceutical specialties, and a prescription is required by law. e.g., Codeine, Morphine, Demerol and combinations, etc.

(2) *Controlled Drugs*

These are designated with a (C) and a prescription is required by law. e.g., Phenobarbital, Amphetamines and combinations.

(3) *Prescription Required Drugs*

These are designated with a (Pr) and are not considered habit forming as (1) and (2) above but still require a prescription by law as they are judged to be dangerous. e.g., Cortico-Steroids, antibiotics and combinations with other drugs.

These above mentioned categories comprise about 35 per cent of the listings in the Compendium and would be paid for by all prescription plans.

(b) *Non Legend Drugs*

These comprise about 65 per cent of the listings in the Compendium. They are not legislated against by the Food and Drug Directorate; their sale is restricted in most cases to a pharmacy and it would certainly be necessary to have a prescription to first acquire them for a diagnosed condition. If required for continued use a physician could specify the required number of repeats. In other words, a prescription is needed in

order to inform the pharmacist regarding the drug, its proper strength and the dosage for the patient. A prescription is NOT required by law.

These include such commonly used drugs as: Digitalis, Digoxin and Nitroglycerin for the heart. Most eye drops, ear drops, nose drops. Most antihistamines for hayfever and colds. Nearly all stomach antacids and ulcer medicines, almost all skin ointments except cortisone types and many many others routinely prescribed by a physician.

By definition, P.S.I., W.M.S., or Blue Cross would not knowingly pay for any of these prescriptions.

In fairness to all concerned it should be stated here that the categories of exempted medicine are drawn mainly from this group for Green Shield, e.g., vitamins and the like. It should also be stated that although this group comprises 65 per cent of all the specialties in the Compendium, individual prescribing habits, as well as the specialty of the physician will govern the percentage of this group found in a sampling of typical prescriptions.

The Green Shield Plan is the only Prescription Plan which will pay for this group of prescriptions subject to the limitations shown below.

The Green Shield Plan does however have some excepted medications and those are defined on page 10 of the Service Agreement.

(a) First aid supplies.
(b) Vitamins and other dietary supplements.
(c) Contraceptives (These are elective).
(d) Proprietary and patent medicines (see above).
(e) Medications generally sold in non drug outlets.
(f) Prescriptions dispensed by a physician.
(g) Prescriptions while in hospital (OHSC).
(h) Injectibles of any kind, insulin and oral insulin substitutes.
    (a) It should be noted that most injectibles are administered by a physician in his office from stock bottles. The use and cost are consequently impossible to control.
    (b) Less than 2 per cent of the population are diabetics and less than 1 per cent use insulin. Since it is not prescribed but bought on a continuing basis over the counter, the abuse and trafficking in this product require it to remain out of the plan.
(i) *Quantity Limitations*

The quantity of any one prescription is limited only to the standard treatment size package in the case of specialties of 34 days continued use in the case of ongoing treatment.

We are convinced of the fairness and reasonableness of the benefits and restrictions and this is borne out by the almost unanimous acceptance of the regulations by over 110,000 persons presently in the plan. Complaints regarding either the service or the restrictions are few indeed and all cases which have so far arisen have been amicably resolved. This is in stark contrast to the great degree of dissatisfaction reaching this office from subscribers to the other plans as well as from their Union Executives, who appeal to us to help them resolve the ever growing number of complaints regarding unpaid claims.

There is in addition the one great advantage which no other plan possesses and that is the prepayment feature, it is the only known way to acquire the prescriptions when they are needed. This is most appreciated and widely recognized by those on limited incomes or those who have been suddenly struck by a huge prescription bill in-between pay days. Reimbursement, however, it is done, still requires the subscriber to finance his purchases and seek relief at a later date—deductibles only aggravate the condition.

An indication of the widespread availability of prescriptions under the Green Shield Plan can be seen from the following example.

We were recently informed of the new premium rates for the Blue Cross Plan which will come into effect on January 1, 1967, as well as the premium structure of a new plan which they proposed to introduce.

When these rates were applied to the present enrolment of the Green Shield Plan, it was found that the total amount of premiums in each case, if applied over a 12 month period—September 1, 1965 to August 31, 1966 would be less than the amount of benefits actually paid out by Green Shield over the same period of time.

In summary then, it can be said that the Blue Cross Plan, Windsor Medical Extended Health Benefits and Physicians' Services Inc., Extended Health Plan, will not knowingly reimburse a subscriber for any prescription unless it is an injectible or it is listed as a legend drug in the Compendium, i.e. (N) (C) (Pr) and then only after the deductible features of the plan have been complied with. The Green Shield Plan covers all of these legend drugs and many, many more as has been shown above.

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966-67

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 29

MONDAY, JANUARY 23, 1967

WITNESSES:

Representing the *Canadian Pharmaceutical Association, Inc.:* Mr. D. A. Denholm, B.S.P. of Vancouver, President; Mr. J. K. Lawton, Ph.C. of Halifax; Mr. R. E. Wilton, Phm.B. of London, Ontario; Mr. D. M. Cameron, B.Sc. Pharm. of Edmonton, Registrar of the Alberta Pharmaceutical Association; and Mr. J. C. Turnbull, B.S.P. of Toronto, Executive Director.

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

25518—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

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

and

Mr. Brand,
Mr. Clancy,
Mr. Côté (*Dorchester*),
Mr. Enns,
Mr. Forrestall,
Mr. Goyer,
Mr. Howe (*Hamilton South*),
Mr. Howe (*Wellington-Huron*),
Mr. Hymmen,
Mr. Isabelle,
Mr. Johnston,
Mr. MacDonald (*Prince*),
Mr. Mackasey,
Mr. MacLean (*Queens*),
Mr. O'Keefe,
Mr. Orlikow,
Mrs. Rideout,
Mr. Roxburgh,
Mr. Rynard,
Mr. Tardif,
Mr. Whelan,
Mr. Yanakis—24.

(Quorum 10)

Gabrielle Savard,
Clerk of the Committee.

MINUTES OF PROCEEDINGS

MONDAY, January 23, 1967.
(39)

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

Members present: Mrs. Rideout, and Messrs. Harley, Isabelle, MacDonald (*Prince*), Mackasey, MacLean (*Queens*), O'Keefe, Yanakis.

In attendance: Representing the Canadian Pharmaceutical Association Inc.: Mr. D. A. Denholm, B.S.P. of Vancouver, President; Mr. J. K. Lawton, Ph.C. of Halifax; Mr. R. E. Wilton, Phm.B. of London, Ontario; Mr. D. M. Cameron, B.Sc. Pharm. of Edmonton, Registrar of the Alberta Pharmaceutical Association, and Mr. J. C. Turnbull, B.S.P. of Toronto, Executive Director.

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

The Chairman introduced Mr. Denholm who, in turn, introduced his associates.

The Committee proceeded to consider the Supplementary Brief submitted by the Canadian Pharmaceutical Association, Inc.

Agreed,—That the above brief be printed as part of today's proceedings (*see Appendix A*).

Mr. Denholm summarized the first two sections of the brief; Mr. Turnbull went briefly through section 3.

At 4.00 o'clock p.m. the Members' presence being requested in the House, the Committee adjourned until 7.00 o'clock p.m.

EVENING SITTING
(40)

The Special Committee on Drug Costs and Prices reconvened at 7.10 p.m. The Chairman, Mr. Harry C. Harley, presiding.

Members present: Mrs. Rideout and Messrs. Forrestall, Goyer, Harley, Hymmen, Johnston, Mackasey, MacLean (*Queens*), O'Keefe, Orlikow, Yanakis—(11).

In attendance: Same as at afternoon sitting.

The Committee resumed consideration of the brief of the Canadian Pharmaceutical Association, Inc.

25518—1½

Mr. Denholm reviewed the recommendations and observations contained in section 4. During the course of his remarks, Mr. Denholm tabled, for the information of the Members, a Report on Survey of Dispensing Costs prepared in October 1965 on behalf of The Pharmaceutical Association of the Province of British Columbia by Mr. Walter W. Fee, F.P.I.A., R.I.A., of Vancouver, Management Accountant and Consultant.

The witnesses were questioned by the Members, the Counsel and the Accountant.

On behalf of the Committee, the Chairman thanked the members of the Association for appearing again before the Committee.

At 9.50 o'clock p.m. the Committee adjourned to 11.00 o'clock a.m., Thursday, January 26, 1967.

Gabrielle Savard,
Clerk of the Committee.

EVIDENCE

(Recorded by Electronic Apparatus)

MONDAY, January 23, 1967.

The CHAIRMAN: Ladies and gentlemen, I think we should start today's meeting. As we all are aware transportation problems are being discussed in the House today; and some members have experienced difficulty in getting to the Committee because of bad weather. We are very pleased that the Canadian Pharmaceutical Association were able to get here. I think they are here because they arrived yesterday.

Mr. Denholm is going to make a brief statement and then we will hear evidence. First of all, is it agreed that the supplementary brief of the Canadian Pharmaceutical Association be printed as part of today's record?

Some hon. MEMBERS: Agreed.

Mr. D. A. DENHOLM (*President of the Canadian Pharmaceutical Association*): Thank you, Mr. Chairman. Mrs. Rideout and gentlemen, it is a great pleasure for the Canadian Pharmaceutical Association to have this opportunity to make a supplementary presentation to you in the hopes of being of some further assistance to the Committee in its deliberations. I must apologize for the fact that we were unable to place this written material in your hands prior to today to enable you to peruse it in advance, but time just did not permit it; that being the case, we would like to run through and summarize briefly some of the items contained in the brief.

Firstly, Mr. Chairman, may I introduce to the Committee the members of the Association who are present with me today. Mr. Don Cameron, on my extreme right, is the registrar of the Alberta Pharaceutical Association and is here in his capacity of chief administrative officer of the provincial licensing body. Next is Mr. R. E. Wilton of London, Ontario. Mr. Wilton is a retail pharmacist and operates two retail pharmacies in London. Then there is Mr. J. K. Lawton of Haifax who, as a retail pharmacist in that city, operates five pharmacies there. Next, of course is Mr. John Turnbull, our executive director, who needs little introduction to you since you have met him before.

The brief that we have prepared, Mr. Chairman, is in four parts. I think it is necessary that we run through them briefly, because we were not able to get them to you in advance. Part 1 of the brief is a summarization of the original submission to the Committee and this goes from pages 1 to 7 inclusive. It is not my intention to deal with that to any extent at this time since this is merely a summarization of the most important points that were in the original submission to you to refresh your memory of that submission.

Section 2 consists of a number of pieces of additional information and statistics which we have endeavoured to gather together to be of some further assistance over and above the original submission to you. In paragraph 2.1 we

make some statements with reference to our relation to the Pharmaceutical Manufacturing Industry; in 2.2 the Wholesale Drug Industry; in 2.3 the hospital pharmacy group and you have already heard from the representative body of that group, the Canadian Society of Hospital Pharmacists.

In paragraph 2.4 we make some comments on academic training and with your permission, Mr. Chairman, I would like to read that one in detail in view of the fact that some evidence has been placed before you concerning the matter of academic training. At the bottom of page 9 we say:

> Academic training, offered in eight degree-granting universities in Canada, enables the pharmacist to assume the role discussed above. The curriculum provides specialized training while educating the student in the broader phases of professional life by providing, in its four years: (1) an extensive background in the basic sciences; (2) advanced study of newer developments; (3) an emphasis on pharmacology to assist in evaluating claims and the judging of the efficacy and safety of new or competing medicines; (4) specialization in particular fields of interest; and (5) a rounded general education. Other statements to the contrary, the profession does not believe that anything less would provide adequate preparation for assumption of the full safeguarding and consultant responsibilities which are to be expected ot the pharmacist.

Again we would draw paragraph 2.5 specifically to your attention, Mr. Chairman, since it outlines an activity that we are currently undertaking that has a bearing on the academic training of the pharmacist. We say:

> Pharmacist manpower and utilization is the subject of a study in depth to be undertaken by a commission on pharmaceutical services sponsored by our Canadian Pharmaceutical Association, in keeping with a recommendation received from the Canadian conference of pharmaceutical faculties. This commission, which will include authorities on occupational studies, one of whom may be its chairman, will initiate its two-year task in the immediate future leading to a report on (1) the occupational role of the pharmacist; (2) structural and manpower needs of the profession; (3) student recruitment, selection and academic performance vs professional performance; and (4) translation of concept and fact into practical reality.

The purpose of this commission, of course, is to evaluate the academic training that is presently being given and with a view to the future to evaluate the needs with respect to academic training.

We next come to a portion of Section 2, retail pharmacists in which we have gathered together some statistics over and above our original presentation which we feel may be of some assistance to the Committee and with your permission, Mr. Chairman, I will ask Mr. Turnbull to pick up at this point and discuss with you the statistics and material that are presented on page 11 and subsequently.

Mr. J. C. TURNBULL (*Executive Director of the Association*): Mr. Chairman, and members, one of the questions asked of us when we appeared before the Committee previously was a set of statistics which would relate to the purchasing of the retail pharmacists on a direct from manufacturer basis as opposed to wholesalers and the ratio quantities, and what have you. I regret that we are not yet in a position to provide that type of statistics to the Committee but if it is

deemed important to the Committee's deliberations we will continue to attempt to get it to you.

On page 11 we have updated previously submitted statistics which are directly extracted from the blue pages appendix attached to the brief and which I presume Mr. Chairman, will not, as previously it did not, appear, in the transcript of the meeting, although you did indicate it is quite an undertaking for the Queen's Printer to duplicate it. This would be done at your pleasure.

The first set of statistics, of course, relates to what we have chosen to call the total drug store dollar; that is the distribution and apportionment of the dollar realized in sales in the retail pharmacy with which most of the members are possibly most familiar. We then turned our attention to an up dating of statistics, which we had previously presented, to depict the distribution of the pharmaceutical dollar by bringing to these pages figures that include the prescription dollar and yet do not relate to a great variety of merchandise in the retail drugstore. These figures show a breakdown of that dollar and we can come back to those if you so wish. This is followed by an indication of the net profits coming from various types of pharmacies, the first being 5.6 cents on the dollar and 6.4 cents on the consumer dollar. The highest noted in the complete suvey in these various categories is 7.7 cents only as net profit before deductions for income tax, and what have you.

We refer briefly to the prescription only statistics, which you will note on page 13, arising from a study conducted in British Columbia relative to 1964 figures. These were compiled by a firm of management accountants and consultants. At the bottom of page 13 we have summarized the average prescription price which in 1965 was shown to be $3.32 in Canada, just one cent above the 1964 figure. Per capitawise this works out to $10.22 in Canada where the usage rate had increased quite substantially to 3.07 prescriptions per individual. Also on that page we present comparative figures of the United States experience in the average prescription as opposed to that in Canada and here we would point out that experience, as tabulated since 1955, has shown that the American average prescription price has been consistently higher than that which is available from the retail pharmacies of Canada.

Page 15 presens in a very brief form a spot check of randomly selected pharmaceutical preparations marketed in Canada, and you will note that over the space of some 13 years, 47 of 99 that were checked showed no change in price, 37 showed a gradual increase in prices, and 16 a gradual decrease in prices.

On page 16 we have attempted to clarify any misinterpretations that might have been placed upon Canadian pharmacies long-standing statement relative to multi-pricing policies which they have referred to on many previous occasions. We quote a statement from our presentation of October 1961 to the Restrictive Trade Practices Commission and for sake of clarity I would re-state the association's position.

> The Canadian Pharmaceutical Association is of the opinion that the principle of equal price for equal quantity and equal quality, provided that there is a reasonable and equitable relationship between quantity price levels, is the only principle which should guide pricing policies in the distribution of drugs to all purchasing levels.

This is elaborated upon in those pages and then on the following page we state our belief as to the effect of the establishment of such like price for like quantity and that is that

> A single price policy with the only differences being due to economies realized through volume of purchase would result in an institutional price which would be somewhat higher and the price to retail pharmacies would be substantially lower.

We say this in our true belief that the retail pharmacist is, in fact, faced with competition from all individuals, institutions and agencies who make drugs available, with or without, attendant safeguarding procedures, to the ambulatory patient.

You will find also on that page a brief statement concerning the ownership of retail pharmacies which is in keeping with our true belief that it is in the best interest of all that the control and ownership of pharmacies rest in the hands of pharmacists. We carry this further with the statement on page 18, related to the joint practice of medicine and pharmacy, and draw the Committee's attention to the new Hart bill of the United States Congress which in brief prohibits a physician from owning, either directly of indirectly, an interest in a pharmacy and also prohibits physicians, generally, from dispensing drugs and devices.

We refer again in this brief to the subject of sales tax which is quite a favourite subject, I know, before this Committee, and without any attempt to bring forth statistics, we do draw the Committee's attention to a statement of recent correspondence from the Minister of Finance in reply to our plea that this new levy, moving up from 11 to 12 per cent, be not applied to drugs. The Minister in his reply gave an indication that our—

> request that drugs be relieved of the additional one percentage point in the rate of sales tax will be given careful consideration before the Excise Tax Act amendment comes up for debate in the House of Commons.

We would respectfully urge the members of this Committee to support our request.

The CHAIRMAN: Mr. Turnbull, before you go any further I understand that the members' presence is requested in the House. As I mentioned, there are some problems in the house. As members are aware, there is no vote taken between six and eight, would it be convenient to adjourn until seven o'clock?

Mrs. RIDEOUT: Mr. Chairman, I know that it is the usual procedure not to vote between six and eight but sometimes votes are taken.

The CHAIRMAN: Not usually. If ten members stand and say that it not be counted, then there usually is not a vote If it is convenient for the members of the Association, and the Committee members, we could have a bite of dinner and start again at seven o'clock, and at least we could go for a solid hour, I would think, without any interruption.

Mrs. RIDEOUT: Would there be any hope of meeting in the railway committee room so that we would be near the Chamber?

The CHAIRMAN: We have checked that and apparently not. We do not have the proper facilities for recording the proceedings there.

The meeting will adjourn until seven o'clock this evening.

EVENING SITTING

The CHAIRMAN: Gentlemen, we will resume our meeting which was interrupted this afternoon. At that time we were considering the supplementary brief of the Canadian Pharmaceutical Association. Mr. Denholm, will you proceed.

Mr. DENHOLM: Mr. Chairman, and particularly those who were not here this afternoon, we indicated our pleasure at having the opportunity to appear again before you and perhaps offering something by way of assistance to your deliberations and the problems before you. We also apologize for not having had the opportunity of getting this supplementry brief into your hands prior to the hearing to give you an opportunity to peruse it before we met today.

We indicated that the brief was divided into four parts. We had dealt with the first two and Mr. Turnbull was in the process of discussing the third section of the brief, he was at page 18 at the time we adjourned. With your permission, Mr. Chairman, I suggest we resume at that point.

The CHAIRMAN: We had just finished speaking about federal sales tax.

Mr. DENHOLM: Yes, paragraph 3.2 on page 18.

Mr. TURNBULL: Leaving the sales tax statement, we present in the brief a comment relative to some of the press reports concerning certain studies that have apparently been made in which there has been brought to public attention certain variations in retail pharmacy prices. Of course we have indicated in our brief that it is impossible to comment on the published stories until such time as we have a certain awareness of the manner in which the studies were carried out and the circumstances under which the pricing was sought.

On the following page, under the topic of "Counting and pouring", which has been popularly discussed on several occasions, we respectfully draw the Committee's attention to the appendices of the brief and in particular to one that relates the process of counting and pouring; as possibly seen by the public, to some of the less apparent procedures that are involved in such a prescription and the rendering of pharmaceutical service.

Mr. Chairman, drug information and its dissemination is an important part of pharmaceutical life. We are pleased to be able to tell your Committee that our Compendium of Pharmaceuticals and Specialties is now very close to being off the press and within a short time will be distributed free of charge to all physicians, pharmacies and hospitals in Canada. I have obtained from the printers a mocked up copy in case any members of the Committee are interested in seeing the material which is presented in this book. Although it is not the final copy, it will give you an idea, if you wish to have a look at it. We look forward to sending out copies as soon as it is off the press.

These then are the general observations on Canadian Pharmaceutical Association's brief today, following up our initial presentations last June and early July, which leads us to the point where we feel that we can make certain recommendations to the Committee.

Mr. DENHOLM: Mr. Chairman, just before going on to the recommendations I would draw your attention back to page 13 where Mr. Turnbull referred to a survey of dispensing costs conducted in the province of British Columbia. The

report of that survey is available. I have a copy for you, Mr. Chairman, and should you wish copies made for the members of the Committee, these are available at your pleasure, sir.

The recommendations begin at page 20:

> Although the Canadian Pharmaceutical Association does not believe that the Committee has been presented with evidence to permit it to concur with the statement in its terms of reference which are to the effect that "drug costs are too high", it is of the opinion that certain steps can be taken without delay which will directly influence an immediate lowering of the price at which drugs are manufactured, distributed and sold and/or which will indirectly exert a stabilizing effect on the many components of cost and, hence, continue to maintain expenditures for pharmaceutical services as an extremely small part of the consumer dollar.

To this end, we respectfully submit the following recommendations.

> 1. We recommend that the Excise Tax Act and/or other pertinent legislation be amended to provide for the abolition of the application of Federal Sales Tax to medicinal preparations and therapeutic appliances.
>
> 2. We recommend that the Income Tax Act be amended to provide personal income tax relief on the total of personal expenditures for prescribed pharmaceutical services provided by pharmacists and all other professionally rendered health care services by the removal of its present "3 per cent of net income" clause.
>
> 3. We recommend that every possible action be undertaken to influence and promote the establishment of recognisable procedures whereby the prices at which the community retail pharmacist purchases his drugs bear a fair and equitable relationship to those which are offered to other individuals in the health professions, to hospitals and related health services institutions and to governments and their agencies.
>
> 4. We recommend that, through its report and the public influence of its members, the Committee support the advancement of public drug insurance and/or prepayment plans which are service programs sponsored by pharmacists and financially guaranteed by all levels of pharmaceutical endeavour.
>
> 5. We recommend that our governments give immediate attention to granting tangible financial assistance to individuals within defined illness categories to enable them to obtain first class pharmaceutical services from local, private pharmacies.
>
> 6. We recommend that the Compendium of Pharmaceuticals and Specialities be endorsed as a valuable, comprehensive information tool worthy of both professional and governmental support through editorial involvement and financial assistance, particularly as such may permit enhancement of its related information capabilities.
>
> 7. We recommend the development of better and more consistent methods of gathering, recording and publishing statistics related to the manufacture, distribution and sale of drugs and in relation to the provision of pharmaceutical services.

8. We recommend support of Pharmacy's moves toward establishing an equitable professional fee-for-service system which is not directly related to the cost of the drug ingredients of a prescription.

9. We recommend that every committee, commission, agency or other body charged with the responsibility of investigating and/or reviewing matters pertaining to, or related to drugs and/or pharmaceutical services, be such responsibilities of a policy or administrative nature, be required to avail itself of the consultant services of one or more pharmacists knowledgeable in the subject who shall be retained either full or part time for such purpose.

Mr. Chairman, a number of subsidiary notes have been attached to each of these recommendations. Although I have not read them, I left them for the private perusal of members of the Committee or for questioning, as you see fit. This concludes the summarization of this supplementary brief to this Committee. Once again, I regret that we were not able to place it before you in full in advance. We have skipped over it fairly lightly. With respect, sir, we would invite any questions that the members of the Committee may have.

The CHAIRMAN: The meeting is open for questioning. Because of the limited time that we might have, would members come to the point rapidly. Perhaps you would allow me to judge the time that each member should be given.

Mr. MACKASEY: Mr. Chairman, on page 13 you have shown two types of prescription, non-welfare and welfare. Why is there a difference in the average ingredient cost?

Mr. DENHOLM: I think I can answer your question directly since I am from British Columbia and was involved in setting up this survey. The difference here is that almost invariably the quantity prescribed in welfare drugs is higher than for general prescription service.

Mr. MACKASEY: Why is that?

Mr. DENHOLM: I would have to rely on medical authorities for the real reason, sir, but the average quantity prescribed for welfare patients is higher than for general prescription service.

Mr. MACKASEY: I believe you, but why does a welfare patient need more material than one who is not a welfare patient.

Mr. CAMERON: Perhaps I can make a relevant comment, Mr. Chairman. It is our experience that, by and large, many of these people are chronically ill, and that is why they are under the welfare program.

Mr. MACKASEY: As I understand, from what is contained on this page, the druggist loses money on every welfare prescription that he fills.

Mr. DENHOLM: Yes. I might mention that the provincial association is in negotiation at the moment with the provincial government to correct this matter.

Mr. MACKASEY: Apart from humanitarian reasons, just how many welfare prescriptions can you afford to fill if you are losing money on every one?

Mr. DENHOLM: Not too many, sir.

Mr. MACKASEY: Why do you do it?

Mr. DENHOLM: The pharmacist has a responsibility to the community to fill prescriptions that come to him. Let us step out of welfare altogether: there are occasions when persons come to a pharmacy who do not have the benefit of welfare coverage and yet are unable to pay for their prescriptions. I know of no pharmacist in British Columbia who would refuse to fill that prescription, so this is part of that over-all picture. I am not trying to intimate to you that this is a great humanitarian act, but I am suggesting to you that the pharmacists are prepared to accept their professional responsibilities to the community by accepting a lesser return to the point of a loss in contributing to welfare prescription services.

Mr. MACKASEY: The point I am getting at is that the community, in a sense, has a responsibility to the druggist and he should not have to bear it.

Mr. DENHOLM: I appreciate that.

Mr. MACKASEY: How do you distinguish in British Columbia between a welfare prescription and a non-welfare prescription?

Mr. DENHOLM: The welfare program in British Columbia calls for the submission to the pharmacist of a duplicate prescription on a form which is provided to the physician by the department; the patient has a medical identity number, and so on, and the benefits are within the prescribed limits of the drug benefit list.

Mr. MACKASEY: Perhaps I should have asked you how the price is arrived at, which is more pertinent.

Mr. DENHOLM: It is arrived at on the basis of a contract agreement between the provincial association and the department of social welfare.

Mr. MACKASEY: So the real reason for your getting less for the welfare prescription is because the government has set these prices rather than for humanitarian reasons. The $2.86 is what you are entitled to by law.

Mr. DENHOLM: I do not think that is at all accurate because there is no law involved here. This is an agreement between the provincial association and the Department of Welfare; although I am not at liberty to discuss the brief that is before the government of British Columbia because it is still before them, we have pointed out to them among other things that this arrangement was negotiated some 12 years ago and has not been amended since that time. That is one of the reasons that it is low.

Mr. MACKASEY: To finalize this particular point, you have now found after detailed study that the agreement is not realistic and that you lose money on every prescription.

Mr. DENHOLM: Precisely.

Mr. MACKASEY: I believe you mention elsewhere that this loss in a sense is, therefore, borne by the general public indirectly who have to pay a little more for their prescriptions because of this loss.

Mr. DENHOLM: This might be said, sir.

Mr. MACKASEY: Then if this is adjusted in British Columbia through agreement, can we hope for a lowering of the other prescription costs?

Mr. DENHOLM: Well, the loss is really being borne by the pharmacist today, and there have been no adjustments in his general over-all prescription pricing patterns to the general public as the result of this loss.

Mr. MACKASEY: Without looking at the blue section—the Chairman pointed out that time is of the essence—what is the net return in British Columbia as compared with other provinces before taxes?

Mr. DENHOLM: I believe it is 3.2 per cent.

Mr. TURNBULL: It is 4.0 per cent in the medium range. Table No. 7 combines all of them but you have a range there of 125,000 to 150,000 sales gross, and it shows 4.0 per cent. If you go over into the more numerous group it comes into the 3.4 per cent net profit before taxes.

Mr. MACKASEY: How does that compare with other provinces?

Mr. DENHOLM: Table No. 2 shows 3.7 per cent for British Columbia; and going from left to right in this table it shows 6.1 per cent for Alberta; 3.7 for British Columbia; 5.3 per cent for Manitoba; 8.3 per cent and so on. We are the lowest in the country, sir.

Mr. MACKASEY: In view of these figures, I can hardly blame you if you do not pass it on.

Mr. DENHOLM: It is the lowest in the country.

Mr. MACKASEY: This could be one of the contributing factors, in other words.

Your observations on patent legislation on page 5 are of interest to me. You suggest that the period of protection should not exceed three years. Would you care to explain why you have come to this conclusion?

Mr. TURNBULL: You will recall possibly, Mr. Mackasey, the discussions of the original brief and this appeared on page 21; we have merely brought this forward into this brief as well. The same type of statement was made at that time that we feel it is in the interests of the innovator and the inventor to protect them with certain patent rights in Canada. We are of the belief that because of the manner in which drugs are being improved day after day in modern life the active existence of a drug is quite short today compared with several years ago. Therefore, we are suggesting that possibly protection not exceeding three years —unless, of course, it be produced in Canadian based facilities—is quite ample, and in providing this protection it will encourage the production of this drug in Canada.

Mr. MACKASEY: You have not given me any reason why it should be 3 years rather than 4 years, 6 years or 5 years. I am persistent in this because this is one of the conclusions the Committee is trying to come to, and we value your opinion in this matter.

Mr. TURNBULL: We are of the opinion that 3 years is adequate except relative to drugs of a particular nature which might require an extension of this due to their marketability or certain problems in establishing Canadian-based facilities.

Mr. MACKASEY: Mr. Turnbull, on what did you base your opinion?

Mr. TURNBULL: At this particular moment I cannot provide an adequate answer to this. This is something that we have worked on; it is not something

new. This goes back several years and is identical with the submission we made before the Hall commission.

Mr. MACKASEY: Do you have this study available?

Mr. TURNBULL: Yes.

Mr. MACKASEY: Could you put it at the disposal of the Committee—not tonight, of course.

Mr. TURNBULL: By all means.

Mr. MACKASEY: On the same page on the topic of quality, you say:

> The Association does not share the belief of some witnesses that the Food and Drug Directorate should be a certifying body which tests each and every batch of a drug preparation and, indeed, such would be financially impractical and physically impossible. Where a reputable industry exists, it should not be necessary.

Do you mean where a reputable manufacturer exists, or are you using the word "industry" collectively?

Mr. TURNBULL: Individually or collectively, sir, I believe was the intent here. If our industry in Canada enjoys an excellent reputation we do not believe that a government agency should be charged with the responsibility of certifying what they themselves should be doing.

Mr. MACKASEY: I could agree with the statement in its entirety, Mr. Turnbull, if you were to say, "where a reputable manufacturer exists", because the word "industry" to me includes everybody who contributes to that industry. What bothers me is the existence of different importers in Canada who have nothing more than an office here; the point is: why should they escape the law?

Mr. TURNBULL: I think we could sum it up by saying that if there are individuals, who cannot be considered reputable, making drugs available in Canada—and this might be a little bit different than other industries—they should not be allowed to distribute them in Canada.

Mr. MACKASEY: We agree. The point is, however, that they do come under the collective term "industry". This is why I raised the question.

Mr. TURNBULL: I would suggest that they should not be termed "industry" in Canada as they are now.

Mr. MACKASEY: My next question is on page 6, which I think is very important.

> In view of the administrative controls possible under the Food and Drugs Act, the Association does not believe that a separate Standard, 74-GP-1b, establishing a list of manufacturers 'qualified' to sell to the Government is necessary. Indirectly, the latter influences an increase in the price of drugs and it may well create situations which, in the future, will work contrary to the interest of the private medical and pharmaceutical practitioner and those whom they serve.

Would you care to elaborate on that?

Mr. TURNBULL: I think this relates to our previous conversation and I do not think anyone would argue with our premise that if there is a certain established list of manufacturers who through some circumstance or other are adjudicated

as the only ones qualified to sell to the government of Canada, then we are of the opinion that those who are not so qualified should not be allowed to market their products to the citizens of Canada.

Mr. MACKASEY: In other words, I think we agree again that this standard should apply not only to those selling to the government, but to everybody.

Mr. ORLIKOW: Mr. Chairman, I am not quite clear as to who is going to set this standard. On page 5 it is suggested that the Food and Drug Directorate does not need to check anything. Who is going to set the standard?

Mr. TURNBULL: Is it necessary to set such a standard if the drugs that are being marketed by a company do indeed meet the standards specified in the Food and Drugs Act and its regulations?

Mr. DENHOLM: I wonder if I could answer that, Mr. Chairman. I think the point here is that this is a standard which, while having virtues, is not applied to all persons and all companies and that is why we object to it. This is a standard which applies to only certain people and because there is in existence another standard, which may or may not be up to the level we would desire, this creates a situation where there is a double standard. This is the principle to which we object, sir.

Mr. MACKASEY: Is it more logical that the one standard be equal to the top standard?

Mr. DENHOLM: Across the board, sir.

Mr. MACKASEY: In other words, the 74-GP standard should be the standard that the Food and Drug Directorate use in all their inspections regardless of whether or not these manufacturers are selling to the government.

Mr. DENHOLM: And in saying that we would add that 74-GP-1 as a minimum be established across the board.

Mr. MACKASEY: Regardless of what they sell through the different channels.

Mr. DENHOLM: Yes, sir.

Mr. MACKASEY: For information purposes, you are publishing Compendium of Pharmaceuticals and Specialties. How will this Compendium differ from the Vademecum?

Mr. DENHOLM: This is pretty easy to answer, sir. I do not know whether you were here this afternoon when the mock-up copy of the Compendium was passed around, but with all due respect to the Vademecum and its publishers, the Vademecum is a limited publication of a promotional nature; this is a comprehensive publication of an informative nature, so the concept is different to start with. To give you some indication of the difference in the scope of the two magazines, I shall ask Mr. Turnbull to give you some figures we have with relation to the number of monographs of prescription specialties on the market in Canada which appear in the two publications.

Mr. TURNBULL: I think it should be understood that we are not in competition with the Vademecum. Presumably, it has its role. We have been publishing this type of thing for several years. The Compendium is edited under professional and unbiased circumstances utilizing as much assistance as can be ob-

tained from the public literature relative to the various drug preparations. Our rough calculation give or take a few figures, would indicate that the most recent edition of Vademecum International contains 1,701 monographs of the products of some 96 companies. We have not been able to do a count of the actual monographs that will be contained in the Compendium, but the circumstances under which our monographs are written are somewhat different. There will be well in excess of 5,000 monographs. Possibly the best comparison—and we chose this one because it is at the beginning of the Vademecum where it lists according to company—is that whereas the average company publishes 46 monographs of 20 brand name products on 19½ pages in the Vademecum the Compendium publishes full monographs, 122 monographs of 122 Abbott trade names which are presented to the professions in approximately 500 dosage forms.

Mr. MACKASEY: May I ask you a question, Mr. Turnbull. How is the book financed?

Mr. TURNBULL: The book is financed by the association and we hope to obtain a certain amount of money through the sale of it. We have appended a copy of our advertisement to the book.

Mr. MACKASEY: Do the manufacturers contribute in any way?

Mr. TURNBULL: The manufacturers are not financially involved other than in the therapeutic index section which we made available to them through their free choice, subject to editorial review in order to assist us in its distribution, free of charge, to the medical profession, the retail pharmacies and each hospital in Canada.

Mr. MACKASEY: The one complaint I have had of the Vademecum, of course, is that the companies pay by the square inch. Do you charge on the same basis?

Mr. TURNBULL: No, definitely not. They are not involved in the editorial portion of the book whatsoever. The companies were invited to participate through the therapeutic listing of products which they wish to appear there. This was extended to every pharmaceutical drug manufacturer in Canada.

Mr. MACKASEY: Mr. Turnbull, it states on page 6, under "Brands and generic names":

> Possibly less than one third of all prescriptions could be written in generic terminology.

And then:

> Drug preparations having the same generic name, with or without an added brand name, are not necessarily therapeutic equivalent.

Would you like to eleborate on that?

Mr. TURNBULL: The first is a statement which sums up at least three studies that have been conducted in this regard and that indicate that less than one third of all preparations, not the dollar value of the research, could be written in generic terminology. This has shown up in at least three if not four of the studies that were made on the available preparations on the market.

Mr. MACKASEY: In other words, if the doctors were schooled to prescribe generically they could only do so in only one third of the cases?

Mr. TURNBULL: Yes.

Mr. MACKASEY: What are the impediments to prescribing for the other two thirds?

Mr. TURNBULL: In two thirds of the cases the products are prescription specialties which are specific to a company. They are combinations of drugs or individual drugs which are produced only by that company.

Mr. ORLIKOW: I have one supplementary question, Mr. Chairman. Is it true that in the third that could be written with generic names are included a very large percentage of the drugs which are (a) used more frequently and (b) used extensively? I am thinking of tranquillizers and antibiotics.

Mr. DENHOLM: Mr. Chairman, with respect to this third, the third varies from any one year to another because those in the manufacturing field who choose to distribute their products under generic name only, and this is their choice, do so in those fields which involve, as you mention, volume drugs only. This field varies tremendously. In one year this third might be made up of X group of drugs and in another year half the group might change because some groups are no longer volume drugs, s the generic name houses, if we can use that term, are then dropped out of the field. I think Mr. Turnbull has some figures in this regard.

Mr. MACKASEY: With respect to your last statement, did you say that generic firms would drop the field when volume is no longer important?

Mr. DENHOLM: That is right, sir.

Mr. MACKASEY: Who keeps the drug available if it is needed in isolated cases?

Mr. DENHOLM: The initiating manufacturers who have put the drug on the market in the first place.

Mr. MACKASEY: They assume this moral responsibility to make it available.

Mr. DENHOLM: That is right.

Mr. MACKASEY: And the generics withdraw.

Mr. DENHOLM: That is right. They are involved in the volume market only.

Mr. ORLIKOW: Are you suggesting that they do it as a service to the public and that they are not interesed in a profit?

Mr. DENHOLM: I suggest that any business concern in Canada which is not interested in profit, sir, is going to be out of business very quickly. I also suggest that they recognize their responsibility in providing a range of products, some of which, quite frankly, may not be profitable in themselves.

Mr. MACKASEY: In other words, when the profit is no longer available through volume, the generics cease to be interested.

Mr. DENHOLM: That is correct, sir.

The CHAIRMAN: Do you have any figures in this regard, Mr. Turnbull?

Mr. TURNBULL: No, I do not have any up to date figures, Mr. Chairman. I think what Mr. Orlikow is saying is quite true, in that the sedative and the fast moving lines are the lines in which this type of preparation is normally found available.

Mr. ORLIKOW: Would it make a substantial difference to the individual patients, institutions, hospitals or provincial hospitals whether they buy chlorpromazine, for instance with the brand name or whether they buy one of the generics?

Mr. TURNBULL: I do not know the comparative price levels of the institutions. I was commenting only on the fact that phenobarbitol, thyroid and A.S.A. compounds are the first compounds and that sulpha drugs and what not are quite popularly available in generic terminology.

Mr. ORLIKOW: Could this make a substantial difference even at the retail level?

Mr. TURNBULL: I presume it could with very cautious buying, sir, all things being equal with respect to the products and the desire of the physician of course.

Mr. MACLEAN (*Queens*): On page 17 you say that the ownership of retail pharmacies rests, in the majority of cases, with the individual pharmacists. Bearing that in mind, I would like a further explanation of the breakdown of the sales dollar as pointed out on page 11. In this regard I would say that the 18½ cents paid for salaries to local resident employees would include the proprietor's salary.

Mr. DENHOLM: Yes indeed, sir.

Mr. TURNBULL: My officers caught me on this point too, sir. The employees here that is, the man who is self-employed is certainly, shall we say, his own employee.

Mr. MACLEAN (*Queens*): What are the circumstances that decide how much he is going to pay himself? How much of his gross income comes through profits and how much through salary paid to himself? Is he completely free to pay himself whatever salary he likes or is there a scale of fees that determines this?

Mr. TURNBULL: There is certainly no scale of fees other than logic and business practice. Possibly the gentlemen who are owners of retail pharmacies would care to comment.

Mr. DENHOLM: Possibly we might ask Mr. Lawton to comment on this questions Mr. Chairman. He is involved in this.

Mr. MACLEAN (*Queens*): Yes. If I might go on, I will ask a subsidiary question now and perhaps the whole matter could be dealt with at once. Turning to table 2, the blue table at the back, which lists the various costs and so on by provinces, it strikes me as rather strange that in a province like Alberta where the average income is quite high that the total income for the pharmacists there is $15,209 whereas in a province like Newfoundland or New Brunswick where the average income is considerably lower, I would think than in Alberta the income is $25,553 in one case and $24,368 in the other. In addition to that the profits vary widely from province to province. Other income also varies widely, for instance from $40 in the case of Newfoundland to $1,748 in the case of British Columbia. Generally speaking the proprietors' salaries seem to be in reverse proportion to the average salary in the province concerned.

Mr. DENHOLM: Mr. Chairman, Mr. MacLean asked a number of questions. Perhaps we could ask Mr. Lawton to answer the first one which, as I recall it, was: What system is used to apportion the owner's income between salary and net profit.

Mr. LAWTON: Mr. Chairman, the store owner who is self-employed, has an attitude toward his salary and he believes that he should pay himself the

normal going rate that he would pay another pharmacist. However, since he is his own employee, he has the privilege of adjusting his salary up or down, possibly in most cases due to income tax considerations. There is no set scale of fees for owner-pharmacists; certainly in the case of employed pharmacists it is the going rate, and again there is no set scale. I believe that in table 2 you compared the return to pharmacists in Newfoundland and I think that you have to realize that in Newfoundland only three stores responded to this survey, and they might have been three large volume stores. In Alberta it showed up very clearly that the average sales were $101,000; in Newfoundland the three stores had average sales of $150,000 and this throws the comparison off quite a lot.

You also mentioned other income. Other income includes many things: the income from post office and stamp machines, vending machines, this type of thing and of course in many areas there are not large numbers of these; in some areas, a post office particularly in small towns, is not involved in drug store operations at all.

Mr. MacLean (*Queens*): Comparing Newfoundland and British Columbia, the net profit of the stores shown in British Columbia is approximately $7,000, whereas in Newfoundland it was $15,000. I suppose that is to some extent in proportion to the total sales.

Mr. Denholm: Mr. Chairman, other than indicating that perhaps I, who come from British Columbia, should move to Newfoundland, perhaps Mr. Turnbull might have something to say on this.

Mr. Turnbull: I think it unfortunate, sir, that you make reference to the Newfoundland chart and possibly, in view of the many interests in this particular table, it is unfortunate that this does indeed appear in here. The summary in this survey is conducted by a source which is independent of our association office, and when the time came to publish these tables we were contacted with the suggestion that if the results of the three pharmacies that happened to voluntarily participate in this program, were published, it would encourage other pharmacies in Newfoundland to participate in the future. This is the only reason that this particular table, which represents four per cent of the pharmacies in Newfoundland, did indeed appear what is basically an association publication.

Mr. MacLean (*Queens*): I see. Perhaps it would be fairer to compare New Brunswick and British Columbia, for example. But to go on with my question, I notice that in the sample given here, in New Brunswick the net profit is much higher than in British Columbia; the proprietor's salaries are the same in those two cases, but in some of these cases the profits are high and the salaries low and vice versa. Is there any provincial tax law or anything of this sort that would influence the druggist, depending on what province he is in, to show more of his income as salary and less of it as profit and vice versa.

Mr. Denholm: There may be, but not to our knowledge.

Mr. MacLean (*Queens*): Is it not correct that the figures here in table two are just a sample and are not necessarily very representative of the total in any of these provinces.

Mr. Denholm: In some of the provinces, Mr. MacLean, they are most representative and I think from an actuarial point of view it depends entirely on

how many have reported; it has been indicated that the 109 pharmacies reporting in British Columbia, for example, represent 22 per cent of the pharmacies, which I think most actuaries would accept as a representative sample, whereas the 3 per cent from Newfoundland is not a representative sample and there is variation between these two figures, sir.

Mr. MacLean (*Queens*): Thank you.

Mrs. Rideout: Mr. Chairman, I was interested on page 4 in the "Dollar effect of the legislation", where you state that

> —place a very costly, hidden, financial burden on the pharmacist. He must follow strict procedures—

and then you go on to say:

> Regrettably, and quite improperly, too many of these Regulations do not pertain to the other professions who may legally handle drugs.

I wonder if you would mind elaborating a bit.

Mr. Denholm: Yes; by way of example, the provisions of the Narcotic Control Act and Part III of the Food and Drug Act, which regulate the sale and distribution of controlled drugs, impose a great many regulatory provisions on the pharmacist in the distribution of these drugs by way of recording purchase, sale and receipt of properly constituted medical authority for dispensing these drugs. This is a costly adminstrative procedure for the pharmacist.

Mrs. Rideout: Are you suggesting that other people do not have to follow these procedures?

Mr. Denholm: In some cases they have a lesser requirement in this respect, Mrs. Rideout, yes.

Mrs. Rideout: But the same procedures of safety are observed, I would think.

Mr. Denholm: If the procedures of safety, which are required of the pharmacist, are necessary in the interests of safety, and we believe they are, then the same degree of safety is not provided.

Mr. Rideout: It certainly should be.

Mr. Denholm: Agreed.

Mrs. Rideout: What about the hospitals where certainly a large amount of drugs are dispensed. I would expect in hospitals that the same degree of safety and precautions would be taken.

Mr. Denholm: There are certain requirements in the hospitals, and of more particular concern at the moment are the requirements in the nursing homes which become near-hospitals. Perhaps we might ask Mr. Cameron to comment on this from his point of view because he is a provincial officer of a pharmaceutical association, and I am sure that he is concerned with the degree of control exerted at these various levels. We were referring here not only to the hospital situation but, quite frankly, to the degree of requirement on physicians for recording, as opposed to the degree of requirements on pharmacists; there is considerable variation, a quite improper degree of variation, in our view. Mr. Cameron will comment with respect to the hospital situation.

Mr. D. M. CAMERON B.Sc. Pharm., Edmonton (*Registrar of the Alberta Pharmaceutical Association*): Mr. Chairman, with specific reference to nursing homes, we recently have had an exposure to situations which we believe to be not in the public interest, by virtue of the rather significant amount of drugs being distributed and an almost complete lack of records pertaining thereto. We have taken this up with the provincial government of the province of Alberta and explained to them our concern, and they have agreed we believe. The regulations that were supposed to have been in effect are going to have to be stringently observed by them just as they are by the pharmacist. With specific reference to the nursing homes, it has in fact, I think, been established that they are not hospitals in the province of Alberta, will not conduct themselves as such and will make a proper accounting of the drugs distributed through their resources; in future they are going to have to secure these drugs from licensed pharmacies in the province of Alberta.

There are also some variations between those records required of a pharmacist and those required of a hospital. By and large, I think, most people do not find a wide discrepancy between pharmacy practice and hospital practice by virtue of the fact that you have in active treatment hospitals immediate access to physicians who exercise a good control over hospitals by virtue of stop-order programs and other things of this nature. Because of what I have said, there is probably not the same concern between these two particular institutions; but it is of some concern and of some administrative cost, I might add, that records required of hospitals are not the equivalent of records required from pharmacists.

Mrs. RIDEOUT: I have great concern for the consumer because he or she must have complete trust in the doctor and the druggist. It concerns me that you suggest there are places where the same restrictions are not properly adhered to. I would think that the same people who check the pharmacies to see that proper safeguards are carried out would also be checking these other institutions.

Mr. DENHOLM: Mrs. Rideout, our reference here of course is not to the level of safety and the level of restrictions; our reference here is to the fact that the number of the regulations and, shall we say, restrictions, are greater in the case of their application to the retail pharmacist than to the others.

Mrs. RIDEOUT: In other words it is more costly.

Mr. DENHOLM: This is placing a more costly burden. By the way these are the procedures that we listed in our first brief on page 62 of the transcript of the third hearing and you will recall that we, facetiously, made the *s* of *special* look like a dollar sign.

Mrs. RIDEOUT: Mr. Chairman, if I may have one more minute, I would like to put a question to Mr. Lawton of Halifax, a retail pharmacist and owner of a small drug chain. I am interested in the small druggist; it is going to be more difficult for them because they are going to run into the same competition now as the corner grocery store did when the supermarket came along. However, as we all are well aware, competition is good and it builds up sales. How are you going to be able to keep the price of your drugs on the same level as the large retail outlets which can sell much cheaper.

Mr. LAWTON: Mrs. Rideout, in our area, as of October 1, the larger outfits cannot sell drugs—the more expensive drugs particularly, very much cheaper than we can, and still stay in business.

Mrs. RIDEOUT: By "more expensive", do you mean the patent drugs.

Mr. LAWTON: No, any high priced drug, because we now have in existence a pricing method, which I think you have heard about; it is the cost plus a professional fee method.

Mrs. RIDEOUT: Right across Canada.

Mr. LAWTON: It is not right across Canada, but in some provinces its use is as high as 70 per cent. We have in the Halifax metropolitan area about 65 stores and I believe that around 50 or 51 are using this system, in effect, it reduces the difference between the discount price of a large operator and the regular retail drugstore. It does not matter what the ingredient cost is, we still make $2.00 on it, and the larger store cannot do much better than that and stay in business. The difference is getting smaller all the time.

Mrs. RIDEOUT: So competition will not actually reduce the price of drugs?

Mr. LAWTON: As far as we are concerned they cannot be reduced much more in retail pharmacies.

Mrs. RIDEOUT: Thank you very much.

Mr. O'KEEFE: Mr. Chairman, the questions I had in mind, particularly about the Newfoundland appendix, have been asked by Mr. MacLean and Mrs. Rideout has very thoroughly cut the ground under a few other questions I had.

I notice under "dispensing cost" on page 13 that in respect of non-welfare prescriptions the dispensing cost is $1.75 and you make the magnificent profit of 2 cents. On welfare prescriptions the average ingredient cost is $1.72; dispensing cost, $1.75, and your loss is 61 cents on every prescription. What does that $1.75 suggest?

Mr. DENHOLM: I wonder if I could have the copy back that I gave you, Dr. Howe. Thank you. This survey was conducted in British Columbia by a management consultant, together with the advice of the provincial association's consulting actuary, and the various costs in the pharmacy are broken down into direct costs and indirect costs. They are apportioned as follows: direct costs, consisting of salaries and these include the salaries, as was indicated earlier, of the owner-manager, in addition to the employed pharmacists and the lay help: the cost of containers, labels, prescription pads, and so on, and everything that directly contributed and could be directly attributed to the provision of the prescription service. The indirect costs are those which are indirectly concerned with the dispensing of prescriptions and apply to such matters as accounting and collection, advertising and promotion, bank charges, insurance, laundry, heat, rent, repairs, telephone, unemployment insurance, welfare plans, and this sort of thing.

Mr. O'KEEFE: Would you agree that that could not be very accurate?

Mr. DENHOLM: This was drawn up by a management consultant firm which indicated that it was accurate in that the total of the indirect costs for each respondent pharmacy were applied to the build-up of the dispensing cost, based on the ratio of prescription sales to gross dollar sales.

Mr. O'KEEFE: Just in British Columbia?

Mr. DENHOLM: That is correct, sir. Then, to check this figure out, the indirect costs were apportioned on the basis of floor space to see if this made any difference, and it made .1 per cent difference which, in the view of our actuary, constituted an accurate presumption that this should be proportioned to prescription sales. The aggregate figure for indirect costs was 27.7 per cent. The balance were direct costs, made up primarily of salaries to the professional help in the pharmacy. I can give you the actual break down of that figure. I am sorry you do not have this chart before you, sir. As I indicated earlier, I will make it available to you in sufficient numbers so that it may be distributed.

The division between direct costs and indirect costs was $1.48 for direct costs, and this is salary and containers and labels and dispensary equipment, all the matters which you can reasonably direct to the dispensing function, and the indirect costs were 27 cents, for a total of $1.75. You asked a moment ago if this apportionatement of indirect costs was accurate. We think it is accurate, sir, but even if it is out slightly, the fact is that it only costs you 27 cents out of the $1.75, which is a very small portion of the dispensing cost. The major part of the dispensing cost is the direct cost, which you can, with certitude, apply directly to the dispensing function.

Mr. O'KEEFE: Just one more question, Mr. Chairman. On page 3 of appendix A you say:

> Similarly, if the amount and frequency of an anticholinergic medication is not adequate, the peptic ulcer patient runs the risk of a perforated ulcer.

Now, this is the important part:

> It is recognized that improper prescribing habits have greatly contributed to the emergence of drug-resistant bacteria.

Whose improper prescribing habits?

Mr. DENHOLM: The quotation was:

> It is recognized that improper prescribing habits have greatly contributed to the emergence of drug resistant bacteria.

And, as I undersand it, the question was: improper prescribing habits such as what?

Mr. O'KEEFE: Who has any improper prescribing habits?

The CHAIRMAN: You mean the medical profession's prescribing habits, Mr. O'Keefe?

Mr. O'KEEFE: I am asking the witness. Do they apply only to British Columbia?

The CHAIRMAN: That is a terrible thing to ask an Ontario chairman!

Mr. O'KEEFE: I suggest, Mr. Chairman, this is a rather serious question.

The CHAIRMAN: I should say, when it comes to dispensing, that the responsibility is on the medical profession; the pharmacist merely fills the written prescription.

Mr. MACKASEY: I have been trying to trace my ulcer, Mr. Chairman, for six months now.

Mr. O'KEEFE: But surely, Mr. Chairman, as the witness has presented Appendix A, and I asked a question on it, I am entitled to an answer, or is my question out of order?

The CHAIRMAN: No, it is not. I am answering it for you. The improper prescribing habits are the responsibility of the medical profession.

Mr. O'KEEFE: You agree—

The CHAIRMAN: You are asking where they got the basis for the statement they have made?

Mr. O'KEEFE: Yes.

Mr. TURNBULL: If I may reply, Mr. Chairman, this statement arises from the many published medical and pharmaceutical accounts of some of the difficulties that have been encountered with some drugs, due to the fact that drug-resistant bacteria have emerged from extended therapy or in some cases, inadequate therapy, and this type of thing. You will notice that the next sentence refers to a recently published survey in which the medical profession have very fully co-operated.

Mr. O'KEEFE: This is the American Pharmaceutical Association and I am interested in the Canadian association.

Mr. TURNBULL: Well, of course, the effect of drugs is the same whether they happen to be prescribed for an American or a Canadian, shall we say.

Mr. O'KEEFE: That might not always be so, sir. You suggest that the American prices are higher, so the drugs might be different.

Mr. TURNBULL: Well, this statement, of course, does not relate in any respect whatsoever to prices.

Mr. O'KEEFE: I realize that.

Mr. TURNBULL: This statement is made on the basis of medical evidence. This is not casting reflection upon one or another; it is a fact of life. It has developed as experience is gained with many drugs.

Mr. MACKASEY: May I ask a supplementary question? In other words, what you are saying, Mr. Turnbull, is that the druggists have a professional responsibility, even beyond that of a doctor, to make certain that the patient is protected?

Mr. TURNBULL: True, sir.

Mr. MACKASEY: This is fundamentally why this appendix is in here?

Mr. TURNBULL: And at every opportunity they have to apply it. They must provide that extra safeguarding procedure.

Mr. MACKASEY: Are you legally responsible if the doctor makes the prescription out incorrectly?

Mr. DENHOLM: Not legally, sir.

Mr. TURNBULL: Morally responsible and presumably partly legally responsible.

Mr. MACKASEY: If the doctor prescribes the wrong dosage, perhaps enough to kill a patient, have you any legal responsibility not to fill that prescription?

Mr. TURNBULL: Yes, I believe the pharmacist has a legal responsibility and, indeed, this is one of the reasons for the occasional telephone call to double check on the actual prescription as written by the prescribing physician.

Mr. MACKASEY: Thank you.

Mr. O'KEEFE: Thank you, Mr. Chairman.

Mr. FORRESTALL: My questioning will be very brief. It may involve perhaps two questions which I will direct to the panel in general. I go to your blue appendix in which you set forth very nicely a lot of detail on the operation of the Canadian retail pharmacy in Canada in 1965. I think it would take something short of a staff of accountants to separate drugs from—as I think was suggested at one time—tires and rubber gloves and candy and cigarettes. The average cost of drugs in Canada in 1965 was set at $3.32 and it may be my own shortcoming, but do you set forth anywhere in the various tables that follow the average cost of drugs by province or region or geographic area?

Mr. TURNBULL: Yes, sir. You will find that at line 7 from the bottom of each table.

Mr. DENHOLM: The average price per prescription, listed by province, sir.

Mr. TURNBULL: You will see, for example, in Nova Scotia the average price is $3 per prescription.

Mr. FORRESTALL: It says, "Average Price per Rx". That is prescription, I presume. I see, fine. That takes care of that. My question was prompted by the fact that we hear a great deal in the committee to the effect that my particular area is one of the highest drug price areas in Canada and I wanted to refute it. Just a quick glance across that line shows me that indeed that is not true.

Getting into something a little more relevant, then, you put forward several recommendations to the committee, and to those who are following these events, for lowering the cost of drugs to the people of Canada in general. If all these nine recommendations were implemented, have you made any calculations and come up with an estimate of how much you could lower the $3.32 average price per prescription across Canada?

Mr. DENHOLM: Well, Mr. Chairman, I do not know whether the question was rhetorical or not but—

Mr. FORRESTALL: It was not rhetorical. It was a very direct question. You make a lot of meaningful recommendations. I will put it more directly to you. You made a lot of statements and recommendations but I notice not one of them takes a nickel out of your pocket. That is what I am after.

Mr. DENHOLM: If I might suggest, Mr. Chairman, it would be absolutely impossible, actuarially, to attach a precise figure—

Mr. FORRESTALL: I did not asking you for a precise figure. I asked if you had done any work on it. Yes or no?

Mr. DENHOLM: —which would be affected by each of these recommendations. In fact, on the first recommendation, which seems a fairly tangible one, with respect to the removal of the sales tax, you have had witnesses before this committee, Mr. Chairman, some of them expert witnesses from government departments, and the range of—

Mr. FORRESTALL: You spelled that one out yourself.

Mr. DENHOLM: —"guesstimate" has been something out of this world. Certainly we are not prepared to—

Mr. FORRESTALL: That is all I am asking, whether you have done any work on it or not.

Mr. DENHOLM: We have gone a good deal of work on it but we have not been able to come up with any precise figure, sir.

Mr. FORRESTALL: Would you care to guesstimate?

Mr. TURNBULL: We can only guesstimate, sir, on the possible effect of the elimination by the government of the sales tax, which is actually about the only single tangible item here. The effect on the public purse in Canada of any delay in abolishing this tax would be to insist that the public contribute approximately $14 to $15 million a year for the drugs which they purchase, due solely to the effect of the 11 per cent sales tax.

Mr. FORRESTALL: Yes, that is good. In short, the recommendations are here and they stand as submitted. Mind you, I am not being critical of the recommendations. I was curious whether or not you had done any such work. I was not asking a rhetorical question.

Mr. TURNBULL: I can assure you—

Mr. FORRESTALL: I have more to do with my time here than ask rhetorical questions. Let us deal specifically with your number 8 recommendation. Mr. Lawton is quite familiar with this one and seems to think it is working very well in Halifax. I talked to him privately about this. This is in—

> support of pharmacy's moves toward establishing an equitable professional fee-for-service system which is not directly related to the cost of the drug ingredients of a prescription.

This is one recommendation that has enjoyed and continues to enjoy increasing support among pharmacists in Canada. It has been suggested to us that a move like this has a particularly adverse effect on the lower-costing drugs by driving the price of them up.

Mr. DENHOLM: Certainly the basic concept of the system, Mr. Chairman, is that the cost of providing the dispensing service as calculated by one means or another, whether by a provincial organization, as indicated in this survey, or by an individual practitioner, is spread directly across the prescription volume so that the same cost is apportioned to each prescription and subsequently the return to the pharmacist on the high priced drugs is less and the return to the pharmacist on the lower priced drugs is lower. So, in relation to the status quo, the low cost prescription comes up in price. Certainly in many instances—and I will call on Mr. Wilton and Mr. Lawton to respond to this further from their practical experience—where the patient is on a low cost chronic medication over a long period of time, and this might effect a hardship, I know that many pharmacists enter into consultation with the patient's physician to ascertain whether or not he approves of the patient having a larger quantity in order to spread that cost out over a longer period of time, thereby not costing the patient any more.

Mr. FORRESTALL: I am aware of this.

Mr. DENHOLM: You are technically correct, the low cost ones are up and the high cost ones are down. The proportion is different and pharmacists are taking these measures to ease up on this for the benefit of the chronic patient.

Mr. FORRESTALL: This is very interesting. Could I ask a supplementary question, if Mr. Lawton or Mr. Wilton would follow through. You say that 84 per

cent of your prescriptions are for $5 or under, and I am curious to know what percentage of that 84 per cent, from the cost of ingredients point of view, would be under $2?

Mr. LAWTON: Mr. Forrestall if I can refer to a small survey that I made in the first two weeks of January we examined, I think, 3200 prescriptions and we examined them with regard to their price. We found that 42.2 per cent were under $3, another 42.2 per cent were between $3 and $5, and I think 14 per cent were over $5 and 1.4 per cent were over $10. So, 42.2 per cent were under $3 and 42.2 per cent were between $3 and $5.

Mr. FORRESTALL: That is 42.2 per cent between $3 and $5. Is that right?

Mr. LAWTON: That is right.

The CHAIRMAN: As a point of clarification, does that include the $2 prescription fee? Has that been charged on all those prescriptions?

Mr. LAWTON: Yes.

The CHAIRMAN: In other words, the cost of the ingredients was actually under $1?

Mr. LAWTON: May I clarify this? In the survey that we did certain contraceptive prescriptions were also included and there is a difference in the profit on this type of prescription as compared to the regular ones, so it throws the figures out a little bit. They were not all based on a $2 fee, sir.

Mr. TURNBULL: Could we give you the national figures on this?

Mr. FORRESTALL: Yes, you can.

Mr. TURNBULL: With the first brief we included a prescription study involving 223,000 prescriptions. This was a survey made in November, 1964. It showed that 25 per cent of the prescriptions were dispensed at what had been established as the break-even cost figure at that time of $1.93. This survey had quite an extensive table. It also showed that 84.3 per cent of all prescriptions were dispensed at less than $5 and 1.4 per cent were over $10. The finer breakdown is in these tables.

Mr. FORRESTALL: What I want to get from you—and it is a little clearer now but I am not quite prepared to accept it—is your assurance that this particular recommendation for which you are soliciting our support is, indeed, not going to drive up the cost of so great a proportion of the lower cost drugs that the person or family that has to come in and buy these drugs is going to have to pay more for the drugs than if some other equally equitable system were introduced. If I pay $25,000 for something I expect the salesman is going to get a higher commission than if I pay 25 cents. I am concerned about that principle of whether or not the safeguard is build into the average.

Mr. LAWTON: Mr. Forrestall, the fee is completely divorced from the price of the ingredients. However, let me point out that the casual prescription—the man who has to get a prescription filled for a cough once or twice a year—is not terribly affected by this if it is a low priced drug. If it is a chronic or a catastrophic type of illness over a long period of time the patient can arrange, in consultation with the physician, to buy larger quantities and he gets all this

extra medication for the same fee. I can give you some very good examples, I think, but possibly this is not the time to do it.

Mr. MacLEAN (*Queens*): May I ask a supplementary question? Is there any relationship between this proposed $2 fee and the cost of dispensing a prescription, as listed in the third item from the bottom of table no. 2?

Mr. TURNBULL: That is his basis of calculation, sir, yes.

Mr. MacLEAN (*Queens*): Well, what does this figure on the table represent?

Mr. TURNBULL: This is table no. 2?

Mr. MacLEAN (*Queens*): Yes. I want to know if it represents the same thing. The cost now varies from $1.10 per prescription in Prince Edward Island to $1.44 in Quebec—

Mr. TURNBULL: You will appreciate, sir, this study is related to the many different types of prescription pricing that exists today in Canada. This is related, for example, using table 1, to the national averages where it shows $1.32 as the cost of dispensing a prescription, and it is in relation to the complete mix which established $3.32 as the average price of a prescription in Canada. It is not directly related to that $2 fee or the fee system.

Mr. MacLEAN (*Queens*): That is what I wanted to make clear.

Mr. TURNBULL: That comes up in individual studies, such as the one which was conducted in British Columbia for a specific purpose. The British Columbia study, because it is reasonably up to date, was included in our brief, although it is specific to a province rather than at the national level.

Mr. DENHOLM: Mr. Chairman, it should also be pointed out that while we seem to be using this figure of $2 as the professional fee in our discussion of this system, based on studies conducted in different areas this varies. In some areas it may be $2.10 and in others $1.85, but we are using the $2 figure as a basis of discussion.

Mr. MacLEAN (*Queens*): Yes, but the point I am trying to make is that that $2 is not comparable. It is not the same figure as the $1.32 that appears in the cost of—

Mr. DENHOLM: Right, sir.

Mr. TURNBULL: And if perchance this were established by an individual pharmacy, such as Mr. Wilton's or Mr. Lawton's, présumably the $2 would also include a calculation of their required profit, which would be over and above the actual bare cost.

Mr. FORRESTALL: I just have one final question which I will perhaps direct to all of you, and you can answer it very briefly with a yes or no. You can elaborate on it if you wish. It does not matter very much. Even if I have asked rhetorical questions, this one is not rhetorical. Do you think the cost of drugs in Canada is too high?

Mr. DENHOLM: We indicate "no" at page 20, sir. We do not believe there is evidence to indicate that drug costs are too high. We do agree, because of the increased utilization of drugs, that the total drug bill to Canadians has increased

but this is a measure of utilization rather than cost. No, sir, we do not believe that drug costs are too high.

Mr. FORRESTALL: Do all of you, as individuals, believe that?

Mr. TURNBULL: There is no evidence that drug costs are high in relation to the Canadian economy.

Mr. FORRESTALL: I tend to agree with you. I do not think I pay too much for drugs. I certainly think there are areas, such as the chronically ill, and so on and so forth, where the cost of drugs is unbearable to certain individuals due to particular circumstances. I like to throw that in once in a while just to see what people say. We get some surprising answers.

Mr. DENHOLM: Mr. Chairman, I think we agree wholeheartedly—as we have stated on many occasions—with Mr. Forrestall, and while we do not believe the cost of drugs is too high, we do agree that the burden of drug costs to certain categories of the population is virtually unbearable.

The CHAIRMAN: Perhaps as Chairman I might be allowed to ask a very simple question, and one which we have talked about many times. I think you have already given us the answer to this once before, but we would like to have the assurance of the Canadian Pharmaceutical Association that if the federal sales tax is removed all the pharmacists are willing to pass this saving on to the consumer?

Mr. DENHOLM: Mr. Chairman—

The CHAIRMAN: Whatever the amount may be.

Mr. DENHOLM: Certainly you have that assurance. This sales tax is levied at the manufacturing level and presumably the manufacturers would decrease their prices by an amount equivalent to the sales tax reduction, and as the retail pharmacist's calculation of his charge to the consumer is based on his cost from the manufacturer, it would be passed on to the consumer, yes sir.

Mr. MACKASEY: May I ask a supplementary question? You say based on the cost from the manufacturer. Do you mean the cost including federal sales tax?

Mr. DENHOLM: Yes, that is correct, sir. The invoice cost to the pharmacist includes the federal sales tax, whether it be 11 per cent or zero.

The CHAIRMAN: Fine. Did you have a supplementary question Mr. Laidlaw?

Mr. LAIDLAW (*Legal Counsel to the Committee*): Yes, Mr. Chairman, arising out of Mr. Forrestall's last question, if I may. I am very puzzled indeed about the last paragraph on page 7 of the brief, where it is stated:

> The suggestion that drug costs have increased 'out of all proportion' to prices of other commodities and services is completely erroneous, as illustrated by D.B.S. statistics which show that prices in general increased some 36.8 per cent between 1949 and 1964, while drugs increased by only 20.7 per cent.

In their previous submission this association gave a list of the average prices of prescriptions to the consumer. In 1949 the average price was $1.38; in 1965—as you have heard tonight—the average price was $3.32. If my arithmetic is correct, that is an increase in the average prescription price of 140 per cent. I

am not able to distinguish that argument from the argument which you advance on page 7 that the increase in the average general cost of living from 1949 to 1965 was approximately 40 per cent.

I would like some explanation in order to ascertain why there has been an increase of 140 per cent in drugs in that period of time.

Mr. DENHOLM: Mr. Chairman, I think it should firstly be pointed out that the increase in the average prescription price is not directly related to an increase in drug costs because there is no relationship here to the number of prescriptions. Secondly, there is no relation to the quantity or the type of medication.

This particular paragraph in our submission, as it was in section 1, was a direct referral back to our original submission, and I would like to ask Mr. Turnbull to give you the statistics on which this statement is made.

Mr. TURNBULL: The statistics quoted on page 7 are those that were quoted on page 17 of our first brief. They are the statistics produced by DBS, where one office preparad one set of statistics on two subjects. The added prescription price bears no relationship whatsoever to this. As Mr. Denholm pointed out, there are so many things that affect the prescription price: the quantity of the prescription; the ingredients of the prescription; whether it is of a chronic nature or not; or, if you wish to refer to the type of medication, if it is symptomatic as opposed to specific. There are many, many variables that enter into what is termed "the average prescription price".

Mr. LAIDLAW: This is true, Mr. Turnbull, but it is extremely important, it seems to me, that the consumer in 1965 is presumably paying 140 per cent more for his prescriptions than he did in 1949.

Mr. TURNBULL: He is not if he received the same prescription in 1966 as he received in 1949. I cannot equate the two sets of figures, but presumably in the eyes of DBS his 1949 prescription would, if he were to present the identical prescription today, cost him an increase of 20.7 per cent.

Mr. LAIDLAW: Do you know how many drugs were used by DBS in ascertaining this percentage of 20.7?

Mr. TURNBULL: I am familiar with the fact that the drugs used in the sampling by DBS today are not the drugs that were used in 1949, yes, but they are in similar categories. I presume that an office such as DBS has equated some weighting, and what have you, to its production of this figure.

Mr. LAIDLAW: Then this figure of 20.7 per cent is not necessarily a correct figure?

Mr. TURNBULL: I would not argue with DBS, sir. I would like to. This is why we make the very positive recommendation that there is a great need for the various statistics-gathering agencies to get together and come up with some type of co-operative undertaking whereby the sets of figures have some relationship to one another.

Mr. LAIDLAW: May I ask one more question, Mr. Chairman?

The CHAIRMAN: Yes.

Mr. LAIDLAW: This question also arises from a statement that I believe you made, Mr. Turnbull. I do not want to put words into your mouth, but it arose earlier when Mr. Mackasey was talking about the term of patents. Your suggestion was that three years would be sufficient, in your view, for the term. I think, however, you added words like these: unless a new drug was produced in this country and manufactured here, in which case that drug manufacturer or inventor would get the required 17 year term.

Mr. TURNBULL: No, I am sorry, Mr. Laidlaw, I did not make a statement which was in any way similar to that. I said that unless, due to the nature of the drug and the particular problems related to its manufacture and distribution in Canada, it were such as to cause that three year period to be changed.

Mr. LAIDLAW: Then you have different terms in view for patent protection, depending on the nature of the drug or where it is made. You do not make this three year term apply right across the board, whether the invention takes place in Canada or in a foreign country?

Mr. TURNBULL: We make the very definite statement here that we do believe the inventor should indeed receive patent protection, or is entitled to patent protection. At the same time, we believe that such patent protection should take the Canadian scene into account, and this is why we have suggested the period of such protection need not exceed three years, or some other suitable period of time which is made necessary by the particular nature of the drug, or unless it be produced in Canadian-based manufacturing facilities. In other words, the three year period—and we have indicated we will attempt to produce our studies on this—is thought to be reasonable in the light of the changing nature of drug therapy today. It is a period in which a foreign invention should be produced in Canada—at least production begun—and if, indeed, it is not, then other steps should be taken. In the light of particular problems in relation to a particular invention or drug, this period of time may have to be changed, but the individuals responsible for the legislation would determine this.

Mr. LAIDLAW: If I may particularize, Mr. Turnbull, because I think this is an important point, if the drug was invented in Canada and produced in Canada, are you inclined to favour the view that the patent term should be, say, 17 years and not three, as opposed to an invention made outside the country?

Mr. TURNBULL: I presume that if a Canadian invention is properly acknowledged in other countries—perhaps this is not answering your question—then we should extend the same privileges to another country. I do not know whether 17 years is a fit and proper period; it does seem an unnecessarily long period for an innovator to recap the financial outlay on his invention. I would be inclined to say that if it is a wholly Canadian invention the patent protection of a Canadian citizen could be considered for a longer period, yes.

Mr. LAIDLAW: Thank you, Mr. Turnbull.

Mr. YANAKIS: May I ask a supplementary question?

The CHAIRMAN: Yes, Mr. Yanakis.

Mr. YANAKIS: Concerning this patent legislation, can you tell me, Mr. Turnbull, how long the prednisone tablet has been on the market?

Mr. TURNBULL: No, sir, I am not familiar with this.

Mr. YANAKIS: Can anyone of you gentlemen tell us?

Mr. TURNBULL: It goes back to 1948 or 1949.

Mr. MACKASEY: From 1948 or 1949.

An hon. MEMBER: Would it be in this book here?

Mr. TURNBULL: No. In the light of my own personal experience in pharmacy it is 1948 or 1949.

Mr. YANAKIS: I understand that the Frosst manufacturing distributors and the Schering manufacturers are members of your association?

Mr. TURNBULL: No, sir; the Canadian Pharmaceutical Association is an organization representing the pharmacists of Canada, the profession of Canada. Individual pharmacists may be employed by companies, but we have no company membership whatsoever in the association.

Mr. YANAKIS: Is it possible that one of these two industries is producing the prednisone tablet on the patent rights?

Mr. TURNBULL: I do not have that knowledge.

Mr. YANAKIS: I was discussing the matter with a local pharmacist the other day and he showed me a prescription by a doctor for such a tablet, and the prescription read Schering prednisone tablet, 5 milligram. The patient could not buy this prescription because it was too expensive. Schering is retailing this 5 milligram prednisone tablet at 100 tablets for $22.70. Frosst has the same 100 tablets for $4.20; so you can just imagnie the difference. If they are producing on the patent rights, I think it is an abuse of these rights to allow them to run so long if they take so much advantage of it.

Mr. TURNBULL: We can only assume, sir—and I do not know that I am qualified to comment on this—that the people who are marketing prednisone in Canada are doing so legally, and that if they are not there is litigation either underway or contemplated, or something, to, shall we say, prevent it. In commenting on the prices, we can only also presume that the prices charged by the individual manufacturer have, in the eyes of that individual manufacturer, some sound basis. While they may vary—as you have indicated—from $4.20 a hundred to $22.70 a hundred, there is some reasonable and logical answer in the eyes of the individual company.

Mr. YANAKIS: I could not believe that. Could the pharmacists open the price index and show me the prices that are suggested by the company?

Mr. TURNBULL: Yes, I have them here.

The CHAIRMAN: As far as the pharmacists are concerned, if it was written for the Schering product they would have no alternative but to dispense it, whether it cost $22 or $4. If it was written in the generic form, then they could dispense either one, according to their own discretion.

Mr. TURNBULL: If he was fully confident in his own mind he would assume his professional responsibility to dispense the product which he felt would meet the needs of that patient, if it was not specified by the physician, and presumably, in keeping with his knowledge of the patient's financial resources, would act accordingly.

Mr. YANAKIS: Yes, according to his opinion. He could not give the patient the other brand name if the doctor specifies the Schering tablet.

Mr. DENHOLM: No, if the prescription is outlined as you have described it, sir, the pharmacist has no option but to supply that.

The CHAIRMAN: Except in the province of Alberta. In all the other provinces this is correct. In the province of Alberta he would have been able to do this. In the rest of the provinces the law says that he must prescribe it as it is written.

Mr. TURNBULL: The pharmacist must assume that the physician has some reason for selecting the product of a particular company when he prescribes that particular company's product, and it would be determined on many factors, based on his personal experience with the treatment of an ambulatory patient as to the type of response, and that type of thing, that he is actually looking for.

Mr. MACKASEY: I have a supplementary question, Mr. Chairman. I think, Mr. Turnbull, somewhere in your brief you state quite categorically that no two drugs are identical.

Mr. TURNBULL: Not necessarily; no two drugs—

Mr. MACKASEY: Therefore the Frosst and the Schering tablet may not necessarily be identical as far as the prescribing doctor is concerned.

Mr. TURNBULL: This is one reason why a physician may select one company's product as opposed to another; he has gained expericnce with that, and he does not know the type of therapeutic response to expect—

Mr. MACKASEY: Was the druggist 100 per cent correct in informing Mr. Yanakis that there were identical products?

Mr. TURNBULL: Not knowing the actual terminology used by the pharmacist, he may have informed the hon. gentleman that quantitatively they both contained 5 milligrams of prednisone.

Mr. O'KEEFE: How can you be so sure that that is right when you ascribed to him improper prescribing practices?

Mr. TURNBULL: I am sorry, sir—

Mr. O'KEEFE: How can you be so sure the doctor is right when in your brief you ascribe to the doctor improper prescribing habits?

Mr. DENHOLM: Mr. O'Keefe, I would not want that read into our brief.

Mr. O'KEEFE: It is in Appendix No. 3.

Mr. DENHOLM: It is indicated there that there are certain studies, relative to certain drugs, which would indicate that prescribing habits have contributed to the building up of drug resistance in some bacteria. This is similar to the resistance built up in an insect against DDT and that type of thing.

The certainty of the physician's prescription must be relied upon by the pharmacist except in the presence of evidence to the contrary, in which case he would undoubtedly contact the physician and discuss it with him.

Mr. O'KEEFE: Thank you.

Mr. MACLEAN (*Queens*): I have a supplementary question. It is quite possible that a doctor who had been called on by a detail man from the drug

manufacturer would not be aware of the other drugs. Are there cases where under certain circumstances, a druggist might telephone the doctor to ask if it would be all right to substitute another drug?

Mr. TURNBULL: Most definitely, yes, sir.

Mr. DENHOLM: This happens on many occasions, Mr. Chairman, particularly in those areas where he has occasion to confer frequently with the physician. It happens probably more in smaller communities, or smaller areas, than in urban areas, that he renders this type of consultative assistance which we refer to in other areas in the brief.

Mr. MACKASEY: I have been doing a little mental arithmetic on table 4 of your survey in the blue pages, entitled "297 Identical Canadian Pharmacies". First of all, is there anywhere in the brief where you break down the difference between the total sales from prescriptions and the total sales of the drug store in general.

Mr. DENHOLM: Yes; just under "Total Income", sir, you will see "Ratio of Rx Receipts to Total Receipts," about seven or eight items down.

Mr. MACKASEY: Yes, I see it.

Mr. DENHOLM: This figure across the board gives the percentage to be applied to the total sales figure at the top, as being the—

Mr. MACKASEY: Being a stupid Irishman I did it the long way. I think the figures will come out the same.

I took the average cost of prescriptions in British Columbia, since you are familiar with British Columbia, of $3.18, and I multiplied it by the figure just below it, the average number of prescriptions, which I rounded out at 13,000, and came out with a dollar value of $41,340, which is nearly 20 per cent, which would be $41,000. I then took the 13,000 for prescriptions and multiplied it by the $1.75, which is the system you are recommending, and I came up with the sum total of $22,750.

Mr. DENHOLM: I am sorry; I did not hear you.

Mr. MACKASEY: I multiplied it by $1.75.

Mr. DENHOLM: That should be $2.00.

Mr. MACKASEY: Two dollars would be worse. Let us leave it at $1.75 for the moment.

Mr. DENHOLM: The $1.75 being what?

Mr. MACKASEY: The dispensing cost.

Mr. DENHOLM: The dispensing cost in 1964, not the prescription fee—not the recommended fee.

Mr. MACKASEY: Are you recommending now that it be material plus $2.00?

Mr. DENHOLM: The B.C. Association has recommended, for 1966, cost plus $2.10.

Mr. MACKASEY: Could we round it off at $2.00, for the moment?

Mr. DENHOLM: Yes.

Mr. MACKASEY: Then the 13,000 prescriptions which were filled in 1965, if it had been done on that basis, would bring in, from the dispensing fee alone,

$26,000. I then went back to the $41,000 worth of sales and I took the figure of 68.1 per cent, which is the cost of goods sold, which, I suspect, from the evidence we have received is rather high if we are just dealing with prescriptions but we will allow that—an average of $28,000 for material. If you add the $28,000 to the $26,000 you have $54,000 income from that area; yet according to your 1965 figures you received only $41,000.

My point is that if you followed this system it would increase your sales from $41,000 to $54,000, for the same 13,000 prescriptions.

Mr. DENHOLM: I am having a little difficulty following your figures, Mr. Mackasey.

I think, in part, sir, it should be pointed out that in the year 1965 some 65 per cent of the pharmacies in British Columbia were already on a cost plus professional fee system, so that these figures incorporate the majority of pharmacies in the province already on this new system. In fairness, sir, I will say that I have no idea whatsoever what proportion of these 76 reporting pharmacies are included in that figure.

Mr. MACKASEY: I am not being critical. Let us start over again with table 4 for British Columbia and with the heading "Average Number of Prescription", 13,000.

Mr. DENHOLM: Roughly 13,000; that is right.

Mr. MACKASEY: According to your proposed plan, in filling these 13,000 prescription there would be a charge of $2.00 each plus material. Is that right?

Mr. DENHOLM: That is right.

Mr. MACKASEY: That makes a total of $26,000 for the dispensing fee. Now I would like you to add the material to this amount. What does the material cost? I can only go back to the same table, which shows that 20 per cent of the sales of $205,000, or $41,000, came from prescriptions. Am I right there? The ratio of prescriptions receipts is 20 per cent, or one-fifth, of $205,000 which is $41,000. On the next line, "Cost of Goods Sold", the relationship between the sales and the cost of the material is 68 per cent. Sixty eight per cent of $41,000 is $28,000, which is what it cost the druggist last year.

Mr. DENHOLM: Could we go back to this 68 per cent figure?

Mr. MACKASEY: Yes.

Me. DENHOLM: I did not follow this.

Mr. MACKASEY: On the second line, 68.1 per cent, "Cost of Goods Sold". Is that right?

Mr. DENHOLM: Yes.

Mr. MACKASEY: That is the material going into the $41,000 worth of sales. That works out to $28,111.

Mr. WILTON: No; the sales are $205,000.

Mr. MACKASEY: No. The $205,000 could include sales of chocolate bars. Of the $205,000 last year—

Mr. DENHOLM: This $41,000 you relate to 20 per cent of the prescription sales?

Mr. MACKASEY: Down at the bottom of the table you have 20 per cent of the $205,000 which comes from prescription sales, which is $41,000. Somewhere in that table you also point out that there were 13,000 prescriptions filled. What I am saying is that under your proposed plan the 13,000 prescriptions will bring you in $26,000 in dispensing fees; to that I add $28,000, which is for the material used last year in filling $41,000 worth of sales; I then come up with a total of $50,861 which is the figure you would have derived last year from filling prescriptions on this particular basis, rather than the old basis which gave you $41,000.

Mr. TURNBULL: Mr. Mackasey, if I may refer to the original brief and some of our discussions at that time, it is acknowledged that on the over all average, and from the survey conducted, approximately 50 per cent of today's average prescription price is the cost of ingredients; and, indeed, I note that in this study, where there were 39,700 prescriptions from British Columbia studied, the average cost of ingredients is shown at $1.65. Therefore, in that particular study the average price of a prescription was $3.29, which, as you can see, does work out to just a little bit over 50 per cent. Therefore, in using the tables, where you have taken the $2.00 fee as an example, we have average receipts of $41,450. If you divide this in half and, for the sake of convenience, make this read, shall we say, $20,500, we then come up with a gross of $46,500 spread over 13,000 prescriptions, as opposed to the survey figure of $41,450.

Mr. MACKASEY: We will stop right there, because I have used 68.1 and you are using 50, and yours could be just as accurate as mine.

Mr. TURNBULL: The 68 per cent, of course, relates to the over all operation of the pharmacy, including those items which you mentioned as being more the general merchandise in the operation, such as cigarettes, which are—

Mr. MACKASEY: What you are telling me is that the ratio between prescription sales and the material is about 50 per cent?

Mr. TURNBULL: This is directly related to prescriptions only but when we relate this to the pharmaceutical dollar the other figures which come from table 27, and which are quoted on page 12 of today's brief, definitely show that in relation to the pharmaceutical dollar—that is, over-the-counter sale of pharmaceutical preparations—it is closer to 60.5 per cent, or 60½ cents on the pharmaceutical dollar.

Mr. MACKASEY: It is not very important, except that earlier, when the PMAC were here some witness made a strong point that the relationship between the sales dollar, and the manufacture was two-thirds to one-third, which made the manufacturer's role in the over all pricing a little abnormal, and perhaps just a little unfair to them; because the relationship is not one-third to two-thirds, but 50-50.

Mr. TURNBULL: This is true; but you must keep in mind, sir, of course, that at that time the allotment of the dollar removed the sales tax and removed the effect of distribution through the wholesaler, taking it down to the bare price of the manufacturer's invoice before the application of sales tax.

Mr. MACKASEY: Mr. Turnbull, could we turn to pages 17 and 18? This is a very strong point with me. There is a statement there that. I agree with so whole heartedly that I congratulate you for putting it in here.

I do think that it is time that in Canada we introduced the equivalent of the new Hart Bill which unless there are unusual circumstances prevents doctors having a share in a drug store. One of the crying shames in the general Montreal area is doctors directing patients to particular drug stores in which they have a financial interest. Collectively or otherwise there are excellent doctors, such as our Chairman, but there are a few "bandits" in the group and I think that under normal circumstances, unless in a small, rather isolated, community a doctor should have no financial interest in a drug store. I think this is what you have emphasized here.

Mr. DENHOLM: I am sure—and I would hope you would correct me if I am wrong, Mr. Chairman—that organized medicine subscribes to the view that has just been expressed, sir. Certainly it is a view to which we subscribe. Further, it is a situation which we hope that any agency involved in the establishment of a system of medical care insurance, whether government sponsored or otherwise, would effectively correct by making it impossible for persons other than those properly qualified to own and operate a drug store.

Mr. MACKASEY: The only reason for my constantly interrupting is not because I am impatient, but the Chairman is. If he had two watches, one for my questions and one for the answers, I think I would get a better "shake".

Mr. DENHOLM: You should not ask such difficult questions.

Mr. MACKASEY: You put this in your brief because you are concerned. Let us get back to retail pharmacies. I was under the mistaken impression that you had to be a qualified pharmacist to own a drug store.

Mr. DENHOLM: Mr. Chairman, this varies from province to province. In some provinces there is legislation which currently requires that any pharmacy established must be owned in majority by a licensed pharmaceutical chemist. Even in those provinces where this exists, however, it is relatively new—and I say relatively new in terms of 15 to 20 years—and there are grandfather clauses which still permit the operation of pharmacies by non-pharmacists.

Mr. MACKASEY: Would you please elaborate on this:

> We believe it not in the best public interest that individuals who are non-pharmacists, mainly concerned with the profit-making operation of merchandising establishments, should, through ownership or substantial, direct financial involvement in any way be in a position to directly or indirectly influence the calibre of pharmaceutical service being rendered in the community.

Mr. DENHOLM: Yes, we believe that the pharmacists of Canada, by nature of their training, both academically and practical, are deeply imbued with their responsibilities to provide a safe and comprehensive pharmaceutical service, with the secondary consideration being economic—an important consideration but a secondary one. We believe that in the operation of an entity, be it a pharmacy or a corporation of any type, which is under non-pharmaceutical control the emphasis may be reversed: primarily economic and, secondly, professional.

Mr. O'KEEFE: I have a supplementary? Under the free enterprise system, how can you stop a doctor or indeed anyone else from owning a drug store provided the doctor or another person employs a qualified pharmacist?

Mr. DENHOLM: I do not think, in partial answer to the first part of the question, that there is any legislation which precludes a physician from doing this.

Mr. O'KEEFE: I thought that was the sense of your suggestion.

Mr. DENHOLM: I am saying currently there is no legislation doing so. There is legislation in some of the provinces in which non-pharmacists or non-doctors are excluded, but to my knowledge there is none in which doctors are specifically included.

Mr. O'KEEFE: Rightly or wrongly, I got the impression.

Mr. MACKASEY: That is my suggestion.

The CHAIRMAN: I am sure the medical association's code of ethics is not consistent with a doctor owning any part of a drugstore, any more than he should probably hold stock in any drug company, for obvious reasons.

Mr. MACKASEY: I would like to refer to some of the articles in *Life* and *Time* magazines. Could our Clerk be empowered to get a copy of the new Hart Bill; perhaps the steering committee could include it in its recommendations? Could I make a motion that we at least secure a copy of the bill?

The CHAIRMAN: I am sure that we can get a copy of the bill. I would think that pharmacy licensing is a prerogative of the province; this is probably something that would be handled under provincial rather than federal statute.

Mr. MACKASEY: I would still like to see a copy for the sake of curiosity.

The CHAIRMAN: We will get some copies.

Mr. MACKASEY: You have set out at the bottom of page 18 "Variations in retail pharmacy prices", which I can assure you are considerable; I do not blame you for trying to protect these variations. However, what concerns me is the insinuation that the druggist will substitute the strength of an ingredient. You say:

> ...the manner in which they were presented to enable a personal interpretation by the pharmacist, the strength of their ingredients...

What bearing has that on price?

Mr. DENHOLM: I do not think that is a consideration at all sir. From personal experience in British Columbia, we receive many comments from members of the public that they had a prescription filled in X pharmacy and had it filled again in Y pharmacy, and there was a discrepancy in price. We invariably check these out to see if the complaint has any validity and very frequently, indeed in a majority of cases, the information that the person complaining has is inaccurate as to either the identify of the drug itself or its strength—and this is what we are referring to, a half grain tablet versus a 1/4 grain tablet or its quantity. It is impossible for us to comment on specific examples of price discrepancies unless we could take the prescriptions and examine them as to strength, quantity, identity and so on.

Mr. MACKASEY: Is it not normal that there would be variation in prices?

Mr. DENHOLM: Yes sir. The cost of operation of individual pharmacies vary and, as a matter of fact, Mr. Chairman, it might be noted that on some occasions the profession or some pharmacists have been criticized in a locality because the

prices are all the same in that locality. There are hints of collusion and so on. Then of course if the prescription is taken around and the prices are all different they are criticized. It seems to me, with respect sir, it is a case of being damned if you do and being damned if you do not.

Mr. TURNBULL: Mr. Chairman, may I quote an example of the problem here. One of the studies which was published in a prominent newspaper of December 24, stated that one particular chain of pharmacies sells generic penicillin G for $2.20 for 12 tablets, but the brand name compocillin Vee-K is $5.35 for 16 tablets of less strength. There is absolutely no comparison between the two products. Compocillin Vee-K is an extremely different product than penicillin G.

Mr. MACKASEY: This is an area I do not want to get into, Mr. Turnbull, because I personally am aware of many such instances, one of which is foolproof and which I placed with Miss Savard many weeks ago in the form of a letter. The only reason that I want to get into this subject is because when it is sometimes incompletely quoted in the paper it creates the wrong impression of a very noble profession and I would rather drop it. You did mention before, Mr. Turnbull, that your pricing habits, were such as to generally double the cost from the manufacturer, in other words, the relationship between material and retail was about 50 per cent.

Mr. TURNBULL: It is not the general practice no, but that is the way it works out.

Mr. MACKASEY: You do not have to apologize for it; it is just a statement of a relationship.

Mr. TURNBULL: That is correct.

Mr. MACKASEY: When the mini budget came in and Mr. Sharp raised the tax 1 per cent, I recall the next day the Chambers of Commerce and just about every pressure group in Canada predicted that the 1 per cent would have an effect of 2 to 3 per cent on the general cost of living because of the pyramiding effect.

Mr. TURNBULL: That is right.

Mr. MACKASEY: Am I not logical in concluding, therefore, that the federal sales tax of 12 per cent on your invoice before you marked the price up had a pyramiding effect?

Mr. TURNBULL: In some respect, but as we pointed out in the first brief, the pyramid effect is less in relation to a prescription because of—

Mr. MACKASEY: The dispensing fee.

Mr. TURNBULL: —the dispensing fee. If every pharmacist in Canada was on a dispensing-fee basis, it is assumed that the percentage relationship would be very, very small. We calculate that the over-all effect, in the presence of the professional-fee-basis of pricing, would be something like 5 per cent. In other words, if the average $3.32 prescription were totally on a dispensing-fee-basis, it would be around $3.

Mr. MACKASEY: It would vary with the pricing methods depending on whether you follow the one that you are recommending or the old traditional one. Are you aware of this morning's headline in the *Globe and Mail*?

Mr. TURNBULL: Yes, sir.

Mr. MACKASEY: "Montreal M.D. links kidney disease with the abuse of headache tablets." These particular tablets are available from a druggist without a prescription.

Mr. TURNBULL: This is correct, but special precautionary statements are required on the label. I do not want to take anything away from the gentleman in question, but this is sort of catching up with some information on studies that came from Australia a few years ago which were given very serious consideration by the Food and Drug Directorate, as a result of which certain special labeling requirements are necessary on products containing phenacetin.

Mr. MACKASEY: Do you think then that these things should be put on a prescription basis?

Mr. TURNBULL: No. I am expressing an opinion of the profession when I say that except where there is very real evidence of danger due to the way in which the Canadian public is using this particular drug, it need not be on a prescription-only sale, but should be under definite supervision of the pharmacist when it is—

Mr. MACKASEY: But how could you provide that supervision if a stranger walks in—someone who is obviously on a "kick"—and buys a quantity of a particular drug. What can you do about it?

Mr. TURNBULL: I do not believe that this analgesic is normally an ingredient of those items which you suggest might be taken for a kick.

Mr. MACKASEY: Let me read this and then you tell me what they are taking it for. One fellow takes 40 a day.

The CHAIRMAN: For a headache.

Mr. MACKASEY: He may take it for a headache, but it is killing him by giving him a kidney disease. I am just trying to protect the poor man with a headache.

Mr. TURNBULL: This is an exception I believe, Mr. Mackasey.

Mr. MACKASEY: Do you think that this Dr. Gault, who is the Director of the Department of Medical Chemistry at the Queen Mary Veterans Hospital is talking about one isolated case? He describes 18 cases of kidney disease, which he directly attributes to this particular medicine or pain killer.

Mr. DENHOLM: He was talking about 18 cases, as I remember the article but in respect to 40 a day he is talking only about one. Quite frankly, if we are to legislate a control of the degree of prescription sale only on every drug which may be abused by someone, then virtually every drug on the market would be a prescription item, including aspirin which is the biggest cause of accidental poisoning in Canada.

Mr. MACKASEY: By your own argument then why cannot people walk in and buy anything else? The drugs that are on prescription or on a particular list are there to protect the people. Here is an example given by a Montreal doctor; he does not say one person took as many as 40 a day, he says here: "The mean daily intake stood at 10 tablets a day, but some had taken as many as 40 a day."

Mr. TURNBULL: I do not believe that this is a significant figure in connection with the Canadian population. However, I feel very confident that if indeed this medical evidence is sufficiently strong, the Canadian Drug Advisory Committee which works with the Food and Drug Directorate will be reviewing it.

Mr. MACKASEY: The point behind it all, Mr. Turnbull, as you know, is that I see a resemblance here to a normal drug that is efficacious, considered safe, and has been on the market for many, many years, and if used in moderation it will harm no one. But after many years, because of adequate research, we find this drug does cause harmful effects. I am thinking of a prescription drug that has been on the market for years under the classification of a new drug and then taken off and is considered to be an old drug. Suddenly some side effect is found because of better means of research, and the Hilliard Report recommends that such a drug be reclassified as a new drug. Do you approve of the Hilliard Report in its entirety?

Mr. TURNBULL: It is some time since we exposed ourselves to the various recommendations, but as I recall at that time, we wholeheartedly favoured the recommendations of Dr. Hilliard.

Mr. MACKASEY: We have a very learned judge last week who made the same wise observation. Thank you, Mr. Chairman.

The CHAIRMAN: That was a very round about way to get at that question, Mr. Mackasey. Dr. Chapman of the Food and Drug Directorate will be before the Committee on Thursday and Friday, February 2, and Dr. Hilliard himself will be before the Committee. I am sure they will both be pleased to go into that further.

Did you have a question, Mr. Blakely?

Mr. BLAKELY: Mr. Chairman, in the interest of time, I will put only a couple of questions. On page 14 you state that on average each pharmacist prescribes since 1965, 25 prescriptions per day. You described this as being "a not inconsiderable average number". Now, I had calculated the average—

The CHAIRMAN: Would you mind continuing that sentence, Mr. Blakely?

Mr. BLAKELY: No, not at all, if it is important. I did not think it was important to the question I was asking "—when combined with numerous related but intangible tasks".

The CHAIRMAN: Thank you.

Mr. BLAKELY: I calculated the average in a slightly different way, and I estimate it at 3.3 prescriptions per hour. Now, to me, this does seem to be a very low average rate.

I wonder if you would care to elaborate on why you believe it to be not inconsiderable.

Mr. DENHOLM: Well, Mr. Chairman, we might hark back to the discussion earlier this afternoon or evening—I am not sure which—wherein we indicated that the actual dispensing function was only a part of the pharmacist's function in providing a complete pharmaceutical service to the public. When viewed in this light we consider this figure to be a not inconsiderable average, when combined with numerous related and intangible tasks.

Now, in addition to the other functions that I am speaking of, and will go on further with in a moment, there are all the functions involved in the filling of a prescription that are not set forth here, and that perhaps are not well known. There are the functions of record-keeping, and these are becoming more and more considerable as there are more dangerous drugs on the market, and as the

federal requirements for record-keeping become more and more numerous. All these types of functions add to the time and therefore detract from the number of prescriptions that a pharmacist can fill in an hour.

In the provision of a complete pharmaceutical service, over and above altogether the dispensing function, the pharmacist has, as set forth by the Royal Commission on Health Services in their volume 1 at page 649, some 10 professional responsibilities which are, and can only be, provided by a trained pharmacist, and which again detract from the number of prescriptions he can fill, and, in fact, the amount of specific time he can devote to the technical or dispensing functions. The Royal Commission on health services outlines these professional responsibilities of pharmacists over and above dispensing as follows:

> Maintaining adequate supplies of drugs, even those in little demand. Standing subject to call 24 hours a day. Acting as a source of information to the physician regarding the efficacy or contra-indications of drugs—

and this is an area which is occupying an increasing amount of a pharmacist's time.

> Acting as a reminder to the customer with regard to the proper method of using the prescribed drug. Acting as a check on possible errors in the physician's prescription. Maintaining a close check on repeat prescriptions. Assuming legal responsibility for dispensing certain drugs—

and these are drugs referred to as over-the-counter drugs, which are limited to sale in pharmacies to provide an element of protection to the public.

> Making the pharmacy premises available as a place of first aid. Stocking vaccines for public health programmes. Giving customers advice on the relative merits of non-prescription products for treatment of self-diagnosed minor ailments.

I think, given time, we could add another dozen items to this list, but we are taking the list of a third party who, shall we say, could be considered an authority.

Many of these professional functions are time-consuming, and they are professional functions. It is, in our view, sir, respectfully, not proper to relate the number of prescriptions directly to the hours of the day.

Evidence has been placed before this Committee that some pharmacists can fill a hundred prescriptions a day. This is true sir, if the pharmacist stands behind a dispensing counter and takes each prescription and sells it, period; he does not receive it; he does not do the checking on it; he does not phone the doctor if it needs to be verified, or if there is any question about it; he does not do all the entering involved in it; and he does not receive the stock that is going to be used to fill the prescription. If he does not perform any of these professional functions he could fill a hundred a day. But if he is providing the full pharmaceutical service, which we consider to be the responsibility of the pharmacist, 25 a day is a not inconsiderable average number, sir.

Mr. BLAKELY: Average number.

Mr. DENHOLM: Average number; in peak periods, of course, he would fill at a rate of 50 or 60 a day. He has peak periods in the pharmacy during doctors' office hours.

Does this answer your question, sir?

Mr. BLAKELY: I am somewhat reluctant to return to this $1.75 average dispensing cost, since there has been rather frequent reference to it today, but in the calculation of this you have indicated that a very large portion of this cost is represented by salaries. Am I right in assuming that these are professional salaries?

Mr. DENHOLM: That is right, sir; it does not include lay salaries at all.

Mr. BLAKELY: Would you know what proportion of professional salaries is taken into account? Is it 100 per cent, or is it a fraction of it?

Mr. DENHOLM: Yes; 100 per cent of the professional salary is taken into account; and this is open to question from the point of view that the pharmacist is not spending 100 per cent of his time in providing this service. It is a requirement of law that the pharmacist be there all the time and that he be responsible for all these functions; and this is a part justification for it. On the other hand, there has been no consideration given to the percentage of lay salaries involved in receiving the drugs, packing them, storing them, and so on, which are also parts of this function. It was the opinion of the management consultant who did this survey that the two matters equated themselves.

Mr. BLAKELY: In the cost-plus-professional-fee method of pricing precisely what do you mean by "cost"?

Mr. DENHOLM: What do we mean by "cost"?

Mr. BLAKELY: Yes.

Mr. DENHOLM: We mean what the drug costs the pharmacist—the invoice cost to the pharmacist. Now, this will vary from area to area. In certain contractual agreements, such as welfare programmes, they have to define it as something fixed, but in normal practice it may well vary from pharmacy to pharmacy.

Mr. BLAKELY: But it is intended to be the invoice cost.

Mr. DENHOLM: It is intended to be the landed cost to the pharmacist.

Mr. BLAKELY: Is this communicated to pharmacists generally, and is it understood?

Mr. DENHOLM: No; you see, we are in an area here in which we have become involved with considerations relative to the Combines Investigation Act. In discussing the cost of the ingredient—the tangible piece of material—we are involved in commerce, and, therefore, it is, or would be, illegal for any organization to suggest to a pharmacist how he should designate the cost. Mr. Henry of the Combines Investigation Branch has indicated this to us quite clearly, although placing no limitation on our discussion, with members, of a professional fee for services rendered, or on contractual agreements with government agencies, and this sort of thing.

Mr. BLAKELY: I have one last quick question: Do you think that there are too many pharmacies per capita of population?

Mr. DENHOLM: I think, sir, that I can give you a qualified answer to that, and I think perhaps we might each give an answer.

In some areas of Canada, principally the major urban areas, it is my view that there are more pharmacies per capita than are necessary to provide pharmaceutical service to the population.

Over the whole country, however, if you tried to strike an average and to say that there are too many pharmacies in the country, you would have to predicate such a statement on the assumption that in hundreds, if not thousands, of small communities in this country there would be no pharmacies at all. Therefore, on the whole, sir, no; but in certain urban areas, yes. This is a sort of two-way answer to your question, sir.

Would you like to add anything to it, gentlemen?

Mr. TURNBULL: Well, statistics would indicate that the population ratio per pharmacy today is greater than it was a few years ago, because of many circumstances that could be mentioned. It ranges in Canada from a low of, let us say, 3,000 per pharmacy to a high of 6,700. The latter is a very high figure, but it is in a province where the population is quite wide-spread and in very small communities. The average across Canada is one pharmacy for 3,888 of the population, and presumably this includes Indians, Eskimos and everybody.

There is every evidence that Canadians have no desire for some regulation that says that they may, or may not, have the privilege of getting into an undertaking in which they can determine, in their own time, when they are going to be forced out of business.

Mr. LAWTON: Mr. Chairman I would just like to add that a recent study by the United States Department of Commerce indicated that the ratio of stores to population in the United States was just about half what it was in 1930, and normally the same situation prevails across the border. So that drug stores, per capital of the population, are certainly decreasing in number.

Mr. DENHOLM: I can certainly tell you that in British Columbia, Mr. Chairman, the number of retail pharmacies has remained static for two years, in each of which there has been a population increase in excess of 7 per cent. Therefore, the ratio is changing.

Mr. TURNBULL: In addition to being a retail pharmacist, Mr. Wilton is on the council of the licencing body in Ontario, and possibily he, from his own personal point of view, at least, could give an indication to the Committee whether he would feel it desirable to place controls on the way in which pharmacies are established in various locations.

Mr. WILTON: I have no comment, Mr. Turnbull.

There is no doubt that there is a crowding of pharmacies in some city areas, and that in smaller communities where there should be a pharmacy, often there is not one.

I cannot give you the exact figure on the ratio of druggists to population. It is in the area of 3,700 population to each pharmacy; and it is something like 2,500 to each pharmacist, I believe. This is much larger than it was 10 or 15 years ago. We are losing the fight for pharmacists. If there is a condition of overcrowding it is correcting itself.

The CHAIRMAN: In the urban areas that are over-crowded, or where we suppose that they are over-crowded, are they tending to die out in the core of the city and moving out to the suburban areas?

Mr. WILTON: Yes.

Mr. DENHOLM: Certainly this is the indication in Vancouver. One of the larger chain organizations, for example, in Vancouver has closed all its down-town operations and moved into the suburbs entirely.

Mr. MACKASEY: Mr. Chairman I have one more question, or two, if I may be permitted?

The CHAIRMAN: Mr. MacLean is first.

Mr. MACLEAN (*Queens*): I am not quite clear on one thing. I hesitate to come back to this, but I think it was contended that the proposal of a flat-rate, professional fee of, say $2.00 for each prescription would not on the average, raise the cost of prescriptions. Am I right in that?

Mr. DENHOLM: Across the board; that is correct.

Mr. MACLEAN (*Queens*): In the blue table it shows that the average cost of dispensing a prescription in 1965 was $1.32. If these contentions are all true it would mean that the dispensing fee would have to include something which is not included in the cost of dispensing a prescription, as listed here?

Mr. TURNBULL: May I ask what table you are referring to?

Mr. MACLEAN (*Queens*): It is the blue table. I think it is Table No. 1.

Mr. TURNBULL: Table No. 1?

Mr. MACLEAN (*Queens*): It states that the cost of dispensing the prescription in 1965 was $1.32. I take it that is an average?

Mr. TURNBULL: As we indicated a little earlier, this is a figure established from the great mix of prescriptions and the various methods of price-determination today, which include, in some instances, a straight commercial transaction percentage type of pricing which includes breakdown calculations; in others, plus a small professional fee; and some are on the cost plus fee for service system. It ranges, from pharmacy to pharmacy across Canada, within a $1.50 to $2.25, depending on local conditions as they may themselves determine—as Mr. Lawton may have determined a dispensing fee on which he has now settled, and as Mr. Wilton, who is on the same system, has a fee that he has established for his particular pharmacy.

The indication that it would not affect the average prescription price relates to today, not necessarily to tomorrow. It is based on the fact that if the ingredient costs, the quantity prescribed and all of these other factors in the individual, average prescription remain the same as today then the price of the prescription would remain the same. But if the ingredient costs move up or go down then the average prescription price is going to move up or down, because that one fee, which has been established on the basis of the same type of service for the aame amount of work, relates to the five cent ingredient as it does to the $10 ingredient.

Mr. MACLEAN (*Queens*): Let us put it in another way. For 1965, if the $2 professional fee had been in effect then, would the cost of the prescriptions represented here be the same?

Mr. TURNBULL: In 1965, if the cost of the ingredient was $1.32 the average price would be $3.32. But you cannot relate these figures to the average cost and the fee system. We do not know what the cost of the ingredient was in these other than the other studies which would indicate the 50 per cent mix, and that was two years ago. At $3.32 it would be $1.66. It would be $3.66 instead of $3.32, all things being equal.

Mr. MacLEAN (*Queens*): Let us turn to Table 2. I am looking at the list which happens to be for Quebec. The average price per prescription is $3.35 and the cost of dispensing a prescription is $1.44. That $1.44, I take it, is part of the $3.35?

Mr. TURNBULL: Yes, sir.

Mr. MacLEAN (*Queens*): The remainder would be the cost of the drugs to the pharmacist and to institutions such as hospitals.

Mr. TURNBULL: Who adds his return, sir. The profit would have to be added to that $1.44. This is bare cost.

Mr. MacLEAN (*Queens*): This is bare cost? Oh, I see.

Mr. TURNBULL: Bare cost of dispensing procedures.

Mr. MacLEAN (*Queens*): So that his profit, on the average, if this were a typical case, would be 56 cents? Would his professional fee of $2.00 cover $1.44 plus his profit? What I am trying to understand is the relationship between the figures.

Mr. DENHOLM: It is very difficult to create a relationship between the figures, for the reason that Mr. Turnbull has pointed out. If these figures were based on what Mr. Mackasey has referred to as 'the old system" and we were then trying to compare it to the new system, we would perhaps create a relationship. But there is a percentage of the old and a percentage of the new—the percentage not known—which muddies the water in trying to create a relationship between these figures at this time.

Mr. TURNBULL: Sir, based on the fact that we have established statistically that the ingredient cost is 50 per cent of that $3.35 prescription—let us say, $1.68 or $1.67½—and taking $1.44 as the cost of dispensing, my figure would be $3.12, There would then be a profit of 23 cents on the $3.35 prescription. In other words, it would be around seven and a half to eight per cent net profit before taxes.

Mr. MACKASEY: I would like to refer to Table No. 27 of the survey. This is a question arising out of curiosity and because of some preconceptions that I had. This is such a very elaborate and well-prepared diagnosis—if I may use that word—of cost that I am rather suprised that you have not been able to come up with a cost strictly related to the pharmaceutical end of the drug store. I think I asked that question last June.

Mr. TURNBULL: Mr. Mackasey, we feel that these last two which we quote in our brief, in which we present a breakdown of the pharmaceutical dollar, are quite factual.

Mr. MACKASEY: In Table No. 27 you compare independent druggists, chain drug stores and so on. I am intrigued about two things. One is the fact that the cost of material in the chain pharmacy should be bigher than the others. For instance, in the medical building it is only 56.9. Is that because in the medical building it is primarily pharmaceuticals?

Mr. TURNBULL: Yes, pharmaceuticals; whereas, presumably, in the shopping plaza, because of the varying—

Mr. MACKASEY: There are so many ingredients here that it makes it very difficult for the Committee really to get the information it seeks. I think you will agree with that?

Mr. TURNBULL: I think that if the Committee were to take either a medical building pharmacy, or any of the pharmacies which have prescription receipts of over 40 per cent, it would be fairly factual.

Mr. MACKASEY: Why do the chain drug stores have such a low net profit of 2.7 as compared to the medical buildings, which have 6.4 per cent, and the independent that has 6.1 per cent.

Mr. TURNBULL: Presumably they have a higher percentage of sundry sales upon which the mark-up may or may not be as high.

Perhaps Mr. Lawton might be in a better position to answer this in detail.

Mr. LAWTON: Are you talking about the gross profit or the net profit? I am sorry, I missed the first part of the question.

Mr. MACKASEY: Perhaps I could elaborate. I have been left with the impression, from previous meetings, that many of the large chain drug stores in the Montreal area are, in effect, also wholesalers who control retail chains and sell the product to other independent drug stores. At least this is what the wholesalers told us, if I recall correctly.

At first glance, when I looked at this, it puzzled me why the cost of their goods should be higher than that of the normal outlet.

Mr. WILTON: Their sale of cigarettes alone would make that difference.

Mr. MACKASEY: I have come to the conclusion that these figures are really meaningless because you have all the ingredients here as well as the drugs and pharmaceuticals.

Mr. WILTON: As Mr. Turnbull said the 21 pharmacies in medical buildings and the 89 pharmacies with prescription receipts of over 40 per cent are a truer indication.

Mr. DENHOLM: These more closely approach your problem than do any of the others.

Mr. MACKASEY: There is no use my pursuing the point. I was merely puzzled why the chain drug stores had only 2.7 per cent profit when the 89 pharmacies had 7.7 per cent.

Mr. MACLEAN (*Queens*): This is a profit on sales, is it not?

Mr. MACKASEY: They have more volume; this is quite true.

Mr. MACLEAN (*Queens*): And that turnover on sundries such as cigarettes—

Mr. TURNBULL: The survey shows, for example, that their dollar profit in total income is almost the same as that of the independent.

As a matter of fact, it is quite interesting to note that the total income figure right across those five columns is approximately the same. They all range in the 18, 19 level.

Mr. MACKASEY: And the margin of turnover is practically the same, too, which is another fallacy gone overboard.

Mr. LAWTON: Mr. Chairman, may I make a comment here? You will notice that in the gross margin it varies from, say, 35 per cent in the independents to 32 per cent in the chain pharmacies. I think it is obvious that the gross profit is lower in the chain pharmacies because they are, typically, larger stores and do a fair amount of discounting. Unfortunately, these figures muddy up the purpose of this whole meeting because they involve everything. The chain pharmacies are larger stores, but they are involved in discounting, and their proportion of total prescription receipts is not as great as that of the independents. This is quite a normal situation in these two categories.

Mr. MACKASEY: The figures are really meaningless because they involve the sale of silk stockings and everything else.

Mr. LAWTON: That is correct. They are ideal for the operation of a retail pharmacy, but not for the purpose of this meeting.

Mr. DENHOLM: With the exception of the figures in the last two columns.

The CHAIRMAN: re there any other questions? If not, I would like to thank the Canadian Pharmaceutical Association for coming before us for a second time and for bringing the additional witnesses.

The meeting is adjourned.

APPENDIX "A"

THE CANADIAN PHARMACEUTICAL ASSOCIATION INC.
PRESENTATION ON JANUARY 23, 1967

* * *

We are pleased to again present the Canadian Pharmaceutical Association before the House of Commons' Special Committee on Drug Costs and Prices. In so doing, it is our aim to complement our written presentation prepared for the Special Committee's meeting of June 14, 1966 and the discussions of that date and of July 5, 1966 as recorded in the Minutes of the Committee's Proceedings and Evidence, Numbers 3 and 7, respectively.

Our delegation, today, to the Committee is composed of Mr. D. A. Denholm, B.S.P. of Vancouver, President of the Canadian Pharmaceutical Association; Mr. J. K. Lawton, Ph.C., Halifax, a retail pharmacist and owner of a small drug chain; Mr. R. E. Wilton, Phm.B., London, Ontario, a retail pharmacist and owner of two retail pharmacies; Mr. D. M. Cameron, B.Sc. Pharm., of Edmonton, Registrar of the Alberta Pharmaceutical Association; and Mr. J. C. Turnbull, B.S.P., of Toronto, the Executive Director of the Association.

Members of the Committee will wish to direct their discussion of specific matters to one or more of these gentlemen, as such may pertain to their individual, particular endeavours. On questions which are of a general nature, the Executive Director requests permission to call upon them to assist although they may not be directly related to their personal role in pharmaceutical affairs and the manner in which drug distribution is undertaken in Canada.

The Association wishes to commend the Chairman and the Committee members for the diligent manner in which they have sought out information which will enable them to suitably report to the Parliament of Canada. Admittedly, Canadian pharmacists have been disturbed by the amount of extraneous material that has appeared from time to time in the hearings and which has, as a result, often appeared in the public press. However, we recognize that only in this way can an adequate understanding be obtained of the particular problems confronting those charged with the responsibility of ensuring that the widespread communities of Canada are provided with a comprehensive pharmaceutical service which is second to none and at fair prices.

* * *

This supplementary presentation by the Canadian Pharmaceutical Association includes a recapitulation of the Association's Brief dated June 14, 1966, an updating of its statistics, additional information pertinent to the Committee's study, observations related to statements arising from the appearance of other witnesses before the Committee, and recommendations by which the cost of providing drug services to Canadians may be advantageously influenced and by which the calibre and availability of drug therapy may be maintained at its present high level or, indeed, improved.

The C.PH.A. Brief dated June 14, 1966

1.0 The Canadian Pharmaceutical Association's presentation dated June 14, 1966 was discussed on that date by the Committee, and subsequently on July 5, 1966. To recapitulate, among its several points were:

1.1 *The retail drug business*—The demanding attributes of modern pharmaceuticals and legislation pertaining thereto make commercial endeavours relative to them markedly different from other business enterprises. Retail pharmacy is customarily seen as a composite of professional and commercial undertakings, with the latter frequently subsidizing the financial ability of the pharmacist to make a complete pharmaceutical service (involving both prescriptions and related health items) available in the community.

1.2 *Retailing and drug prices*—In 1964, revenue from the dispensing of prescriptions represented 27.4 per cent ($36,375) of the 'average' pharmacy's $131,039 in gross sales. The retail pharmacy realized a net profit before taxes of 4.8 per cent that year.

1.2.1 In 1964, too, Canadians spent $8.87 for 2.68 prescriptions obtained from retail pharmacies at an average price of $3.31.

1.3 *Pharmacy manpower utilization* may be considered poor when viewed only in relation to the narrow confines of the single act of filling prescriptions, but when placed in proper perspective and related to the standby supervision and the multitude of other activities which the pharmacist must assume in keeping with his professional, legislative and moral responsibilities, the professional staffing of pharmacies during an average 60-odd hours week cannot be criticized.

1.4 *Prescribed drugs: Prices and Expenses*—Drugs represent only the commodity portion of a comprehensive, professionally-oriented pharmaceutical service to the citizen for whom prescribed medication is being supplied or who seeks medicine for purposes of auto-therapy. A prescription is not an ordinary item of commerce or trade. It is not a merchandising commodity.

1.4.1 While it is generally acknowledged that 50 per cent of a prescription's price is represented by the tangible ingredients procured from a manufacturer/distributor, the prescription-only service cannot be divorced from the business economics of the total operation of a retail pharmacy. During 1964, retail pharmacists dispensed prescriptions valued at $171 million. Over 84 per cent were dispensed at less than $5.00 each, while those priced at over $10.00 each represented only 1.4 per cent of the $51.6 million total.

1.4.2 Statistics from pharmacies which orient their endeavours to pharmacy-related undertakings only, (say, those realizing over 40 per cent prescription revenue), indicate a breakdown of the consumer's 1964 pharmaceutical dollar to be: 62¢ paid by the pharmacist to the manufacturer/distributor; 33½ paid by the pharmacist for local services (salaries, rent, etc.); and 4½¢ retained by the pharmacist as profit *before* taxes and capital replacements.

1.5 *Federal Sales Tax*, included in the amount paid to a manufacturer/distributor, constitutes some 9¢ of the consumer's "pharmaceutical dollar". It can be calculated to represent 8.3¢ of the consumer's "prescription dollar" and, hence, in 1964, placed a $14 million burden on the ill and diseased of Canada who obtained prescription services from community retail pharmacies.

1.6 *Subsidization of prescription services* through the retail sale of non-drug items is illustrated in the statistics. Further, the retail pharmacist, and in turn, the private patient subsidizes the manner and the price at which drugs are provided to others—(1) The retail pharmacist purchases at top-dollar prices under the multiple pricing policies which place the same drug preparations at

exceedingly low prices in hospitals and similar institutions and government agencies. (2) Institutions benefit further by having purchases exempt from sales tax. (3) Welfare prescriptions granted substantial discounts by the pharmacist are indirectly subsidized by the price paid by the private patient. (4) Standby, full inventory, emergency service is expected of the pharmacist even though full utilization of his services may be adversely influenced by the diverting of popular drugs to distribution via dispensing physicians and/or the centralized dispensing to government beneficiaries (that is, veterans, armed forces, Indian hospitals); etc.

1.7 *Dollar effect of legislation*—The restrictive Regulations, all written and administered in the public interest, both federally and provincially, which pertain to Pharmacy and the distribution of drugs place a very costly, hidden, financial burden on the pharmacist. He must follow strict procedures in the purchase, storage, security, recording and dispensing of drugs. These have a very definite dollar effect on drug distribution. Regrettably, and quite improperly, too many of these Regulations do not pertain to the other professions who may legally handle drugs.

1.8 *Drug formulary systems* as used in many institutions to meet their localized day-to-day needs and situations, are not considered feasible for application at the community, private practice level where it is so necessary that all prescribers have available those drug preparations which they may individually and personally select for use in keeping with their personalized experience and expectation of the therapeutic response in individual patients who are other than under constant professional scrutiny.

1.9 *Manufacturing pharmacy* is a vital part of modern pharmaceutical endeavour. The Association strongly believes that everything possible must be done to ensure that Canadians benefit from worldwide therapeutic advances while encouraging the development of a strong, comprehensive pharmaceutical industry, including all aspects of production and research, within our boundaries.

1.9.1 *Patent legislation* should protect the innovator while providing for the enhancement of an active, self-sustaining and ever-growing industry in Canada. We believe Canada should recognize worldwide patents, but we also suggest that the period of such protection need not exceed three years, or some other suitable period of time made necessary by the particular nature of the drug, unless it be produced in Canadian-based manufacturing facilities. In modern days, patent rights on drugs extended for 17 years is deemed unnecessarily long. The right to license other producers and the compulsory licensing provisions of the Patent Act are worthy of continuance to facilitate legal production in Canada.

1.9.2 *Quality* is not something which can be "legislated into" a drug product. Quality control, properly exercised, is an expensive undertaking which should not be compromised. Adherence to the Food and Drugs Act will ensure that a manufacturer produces a drug preparation according to standards established in the public interest. The Association does not share the belief of some witnesses that the Food and Drug Directorate should be a certifying body which tests each and every batch of a drug preparation and, indeed, such would be financially impractical and physically impossible. Where a reputable Industry exists, it should not be necessary.

1.9.3 In view of the administrative controls possible under the Food and Drugs Act, the Association does not believe that a separate Standard, 74-GP-1b,

establishing a list of manufacturers 'qualified' to sell to the Government is necessary. Indirectly, the latter influences an increase in the price of drugs and it may well create situations which, in the future, will work contrary to the interest of the private medical and pharmaceutical practitioner and those whom they serve.

1.10 *Brands and generic names*—The profession of Pharmacy does not disagree with those who advocate that physicians might best prescribe drugs by their generic names, but in so stating, it emphasizes that in every instance, the pharmacist must be in a position which enables him to assume, with assurance, the responsibility of selecting the proper medication to be dispensed, be it brand named or non-branded. Possibly less than one-third of all prescriptions could be written in generic terminology. Drug preparations having the same generic name with or without an added brand name, are not necessarily therapeutic equivalents.

1.11 *Drug information*—The Association publishes a Compendium of Pharmaceuticals and Specialties, written in a manner which factually summarizes all essential, basic information about all drug preparations on the Canadian market. Use of this book permits access to information on which a practitioner may base his selection of a drug preparation best suited to the therapy to be followed in relation to the diagnosis of an individual patient's specific illness condition.

1.12 *Prescription dollars in perspective*—The Association reiterates its firm belief that the Canadian scene and way of life, its standard of living, its general economic structure, its geography, its wage and employment structure, its population characteristics and the effect of all these on the economics peculiar to the availability of drugs in Canada must be acknowledged in any debate and decisions relative to drug costs and prices. Canada does differ from other countries.

1.12.1 The suggestion that drug costs have increased 'out of all proportion' to prices of other commodities and services is completely erroneous, as illustrated by D.B.S. statistics which show that prices in general increased some 36.8% between 1949 and 1964, while drugs increased by only 20.7%. Other D.B.S. statistics show that Canadians spend less than 1¢ of their consumer dollar on drugs.

Additional information and statistics

2.0 The Canadian Pharmaceutical Association, representative of the profession and its members in all fields of endeavour in Canada, is pleased to note that the Committee has gained a deep awareness of the problems of drug distribution through the specific information it has received from various individuals, companies, agencies and organizations.

2.0.1 It is regretted that the Committee did not retain the services of a knowledgeable pharmacist who, in a private consulting capacity, might have assisted with its interpretation and assessment of the fund of material presented at its hearings.

2.1 *The pharmaceutical manufacturing industry*, its organizations and its individuals, have presented facts and figures to the Committee. The C.Ph.A as a professional association has a specific interest in industrial endeavours as such relate to the position of individual pharmacists therein and as such may exert an

influence upon the general practice of Pharmacy. From it, the basic tools of the profession are available and hence, the profession cannot divorce its interests from matters of specific concern to industrial enterprise. As stated previously, it is our strong belief that the best interests of Canada are served by the strengthening of a viable drug industry within our boundaries.

2.2 *Drug wholesalers* provide pharmacists with their essential services by maintaining quantities of drug preparations in every major centre of our vast nation. While it could be claimed that this 'middle man' procedure results in added costs, Pharmacy does not believe this to be of significance and, indeed, in no other way could complete stocks be conveniently and readily available from one large and nearby source to the many consumer outlets.

2.3 *Hospital Pharmacy* is discussed in a Brief presented by the Canadian Society of Hospital Pharmacists on November 29, 1966. Because many items classified as components of drug therapy in hospitals are not common to the drug therapy of ambulatory patients, it is difficult to tabulate comparative statistics pertaining to patient usage. However, the importance of professional responsibility being exerted in the control and handling of modern pharmaceuticals is comparable both within and outside of institutional practice. This role is summarized in the Canadian Council of Hospital Accreditation Guide No. 5 which, in part, states:

> "Because of the increase in complexity, specificity and potency of medications now available... the need for appropriate professional pharmacist service in every hospital has become more urgent."

and further that,

> "In addition to its traditional role in drug manufacturing and dispensing, the pharmacist has a collaborative role to play with the medical staff in a number of ways including the provision of a drug information service, facilitating the reporting of adverse drug reactions, and reviewing prescriptions for prevention of drug incompatability."

2.4 *Academic training*, offered in eight degree-granting universities in Canada, enables the pharmacist to assume the role discussed above. The curriculum provides specialized training while educating the student in the broader phases of professional life by providing, in its four years: (1) an extensive background in the basic sciences; (2) advanced study of newer developments; (3) an emphasis on pharmacology to assist in evaluating claims and the judging of the efficacy and safety of new or competing medicines; (4) specialization in particular fields of interest; and (5) a rounded general education. Other statements to the contrary, the profession does not believe that anything less would provide adequate preparation for assumption of the full safeguarding and consultant responsibilities which are to be expected of the pharmacist.

2.5 *Pharmacist manpower* and utilization is the subject of a study in depth to be undertaken by a Commission on Pharmaceutical Services sponsored by our C.Ph.A., in keeping with a recommendation received from the Canadian Conference of Pharmaceutical Faculties. This Commission, which will include authorities on occupational studies, one of whom may be its chairman, will initiate its two-year task in the immediate future leading to a report on (1) the occupational role of the pharmacist, (2) structural and manpower needs of the profession; (3) student recruitment, selection and academic performance *vs*

professional performance; and (4) translation of concept and fact into practical reality.

2.6 *Retail pharmacists* are most familiar to the public with whom they are in daily contact and hence, it is deemed essential that this Committee comprising the Federal representatives of the public have a full awareness of the position of the community pharmacy and matters encountered by it in its distribution of drugs and the provision of pharmaceutical services.

2.7 *The retail drug business*—The 'average' pharmacy's sales dollar (or, if you wish, the "*total drugstore dollar*") is apportioned according to the 1965 figures compiled in Table No. 1 of the Association's 24th Annual Survey of Retail Pharmacy Operations (attached hereto as an Appendix), in rounded figures:

65½¢—paid to the manufacturer/distributor
18½¢—paid for salaries to *locally* resident employees
2¾¢—paid for rent to *local* landlords
2½¢—for advertising in *local* media
—for delivery service by *local* citizens
—for repairs by *local* tradesmen
1½¢—for heat, power, telephone, taxes to *local* utilities and government
½¢—for insurance purchased from *local* agents
1½¢—for depreciation, interest and bad debts
2¢ —for miscellaneous expenses of an internal and *local* nature
5½¢—profit *before* income tax, capital replacement, etc.

This 'agerage' pharmacy, open to the public for 67 hours per week derived 28.7% of its gross income from prescriptions.

2.7.1. On the other hand, pharmacies in which prescription receipts represented over 40% of total receipts (and hence, more closely approximate a "strictly professional pharmacy practice") provide a statistical breakdown of the 1965 "*pharmaceutical dollar*" (Table 27 of the Survey) which is presented on the next page of this Brief.

	Medical Bldgs.	Other Locations
Paid to the manufacturer/distributor	57¢	60½¢
Paid for salaries to *local* employees	23¢	20½¢
Paid for rent to *local* landlords	4½¢	2¾¢
For advertising in *local* media For delivery service by *local* citizens For repairs by *local* tradesmen	3½¢	2½¢
For *local* utilities and taxes	1¢	1½¢
For insurance purchased from *local* agents	½¢	½¢
For depreciation, interest and bad debts	2¢	2¢
For *local* miscellaneous expenses	2½¢	2¢
Profit *before* taxes, capital replacement	6½¢	7¾¢
	$1.00	$1.00

While the gross sales of the above two categories of pharmacies were about equal ($113,000), those in medical buildings derived 61.7 per cent of their revenue from prescriptions and those in other locations, 52.7 per cent.

2.7.2 These three sets of statistics show net profits to be 5.6 cents, 6.4 cents and 7.7 cents, respectively, *before* deductions for income taxes and amounts set aside for capital replacement, etc.

2.8 *Prescribed drugs: Prices and Expenses*—Among the numerous studies is that completed in 1966 by a management accountant and consultant in order to establish a cost-plus-professional fee system of charging for prescription services rendered to welfare recipients under the contract negotiated with British Columbia's Department of Welfare. This study (copies of which can be provided) which takes into account direct and indirect costs of pharmacy operations in various community locations concluded that:

The average "dispensing cost" per prescription was $1.75.

NON-WELFARE PRESCRIPTIONS		
Average ingredient cost	$ 1.45	
Dispensing cost	1.75	
Total Cost	$ 3.20	
Average Prescription Price	3.22	
Profit	$ .02	

The net overall profit per prescription is very low.

WELFARE PRESCRIPTIONS		
Average ingredient cost	$ 1.72	
Dispensing cost	1.75	
Total Cost	$ 3.47	
Average Welfare Prescription Price	2.86	[Note (1)]
(Loss) per prescription	($ .61)	

It is apparent from the figures that the average-prescription dispensed to Welfare recipients is dispensed at a LOSS.

NOTE (1)—The $2.86 average Welfare prescription price was calculated from the statistics quoted in the Department of Social Welfare, Province of B.C., annual report for fiscal year ended March 31, 1964. The figures were:

$$\frac{\text{Dollar value of prescriptions } \$1{,}966{,}536.00}{\text{Number of prescriptions } 689{,}038} = \$2.86 \text{ av.}$$

The Survey itself revealed that the average selling price per Welfare prescription was $2.85.

2.8.1 From the C.Ph.A.'s 24th Annual Survey, statistics reveal the 1965 average price per prescription to be $3.32 (just one cent above the 1964 figure), per capita expenditure on prescriptions to be $10.22 ($8.88 in 1964), with a per capita usage rate of 3.07 prescriptions (up substantially from 2.68 in 1964) for prescriptions valued at $200 million.

2.8.2 It indicates, too, that on the average, each retail pharmacy dispensed 11,904 prescriptions that year. This works down to 25 prescriptions dispensed by each pharmacist per day of a 300-day year—a not inconsiderable average number when combined with numerous related, but intangible tasks.

2.8.3 Claims that, in terms of straight monetary exchange, drug prices in Canada are higher than in the United States are *not* borne out at the level of retail pharmacy prescriptions where we find that the average price in the U.S.A., determined by annual surveys published by the Lilly Digest, is consistently higher than the Canadian average:

Year	U.S.	Canadian
1965	$ 3.48	$ 3.32
1964	3.41	3.31
1963	3.39	3.20
1962	3.32	3.16
1961	3.25	3.14
1960	3.19	3.06
1959	3.09	2.98
1958	2.96	2.78
1957	2.85	2.61
1956	2.62	2.49
1955	2.46	2.26

2.8.4 One U.S.A. authority (Dr. J. Backman, Research Professor in Economics, New York University, as reported in "Drug Topics", December 26, 1966) states that, "If drug prices had risen as much as all consumer prices since 1940, consumers would have to pay $2.9 billion more than they do today." We have not attempted to calculate a projection of Canadian experience.

2.9 Stability of prices is indicated by a spot check of randomly selected preparations marketed in Canada. Starting from the December, 1966 edition of the "Price Book of Drug Store Merchandise", (a catalogue compiled from manufacturers' price lists), the 50th item on every page was traced back to May, 1953. Of the 99 pharmaceuticals traced, 29 have been available since May, 1953 or longer; 51 since November, 1958; 69 since June, 1963; and 86 since June, 1965.

— 47 showed on change in price
— 37 showed gradually increased prices
  — in years of Sales Tax increases
  — non-prescription products predominate the list
— 16 showed gradually decreased prices

2.9.1. Intrigued by the results of this check, a trace was then made of 17 pharmaceuticals on which the Brief of the Pharmaceutical Manufacturers Association of Canada of June, 1966, presented a series of worldwide calculations and comparisons. Here, we found that since their first introduction or since May, 1953, prices of four have remained unchanged, nine have decreased, and of the four which increased, two are in the non-prescription category.

Amplification of certain statements

3.0 Multiple pricing policies—The Association states its concern relative to misinterpretations of its long-standing and oft-repeated statement pertaining to

the inequalities of Industry's pricing practices (including 'deals') which cause the retail pharmacist to purchase drug preparations at prices often far exceeding those available to other purchasers. To clarify any misunderstandings, we again quote from the Association's Brief presented October 16, 1961 to the Restrictive Trade Practices Commission Inquiry into the Manufacture, Sale and Distribution of Drugs in Canada (pages 30 and 31):

> "The distribution and pricing situations outlined in the Director's Statement (the 'Green Book') are not new to the Canadian Pharmaceutical Association. The problem of multiple levels of pricing and price discount policies as such relate to the various purchasing levels, namely, governments, government institutions, hospitals and retail pharmacists, is recognized as being of vital interest to the Canadian consumer who must be assured of a high level of consumer distribution of pharmaceuticals by pharmacists in the widespread communities of this nation. It was recognized by the C.Ph.A. many years ago that eventually the problem known to them would become subject to public criticism and would possibly be voiced with a great deal of misunderstanding.
>
> The situation has not changed over the years to cause any alteration in a statement of policy made known to manufacturers early in 1955, and which has been reaffirmed by pronouncements up to, and including the present time—'the Canadian Pharmaceutical Association is of the opinion that the principle of equal price for equal quantity and equal quality, provided that there is a reasonable and equitable relationship between quantity price levels, is the only principle which should guide pricing policies in the distribution of drugs to all purchasing levels.' This statement is made in the firm belief that a policy of fair and equitable pricing should be, and can be established to the satisfaction of manufacturers, government buyers, hospitals, retail pharmacists and, of great importance, to the satisfaction of the consuming public. In consideration of quality, quantity and packaging, a policy of one fair price to all buyers should be available.
>
> Actual prices do not enter into the statement quoted above. Prices and pricing methods relate to the specific operation of the individual company and/or its distributors. Presumably, each has the ability to determine for itself the financial return it requires to provide for its expenditures and to give remuneration for its efforts in accordance with the product(s) it makes available. "Each firm undoubtedly has established price-calculation policies in keeping with its known risks, its future aspirations and its marketing integrity."

and later, on page 51, that, all things being equal and provided that sales to retail pharmacy are indeed bearing a disproportionate share of the manufacturer's fixed overhead,

> "A single price policy with the only differences being due to economies realized through volume of purchase would result in an institutional price which would be somewhat higher and the price to retail pharmacies would be substantially lower."

3.0.1. Be it direct or indirect, the retail pharmacist is, in fact, faced with competition from all individuals, institutions and agencies who make drugs

available, with or without attendant safeguarding procedures, to the ambulatory patient. Hence, Pharmacy's belief, expressed in a resolution of the Association's annual meeting of 1966, that the legality of the different prices to different purchasers who are competitors is open to question.

3.1 Ownership of retail pharmacies rests, in the majority of cases, with individual pharmacists. However, in this era of mass merchandising, the small independent finds himself at a competitive disadvantage in many ways, and as a consequence, there appears to be taking place a greater concentration of ownership into fewer and fewer hands. Many forces operating from outside rather than from inside the profession's societies exert an influence on the professional operations of a pharmacy. We believe it not in the best public interest that individuals who are non-pharmacists, mainly concerned with the profit-taking operation of merchandising establishments, should, through ownership or substantial direct financial involvement, in any way be in a position to directly or indirectly influence the calibre of pharmaceutical service being rendered in the community.

3.1.1 Except where local needs dictate, the principle of the joint practice of Medicine and Pharmacy is, in the opinion of both professions, considered to be not in the best interest of the patient. The new Hart Bill of the United States Congress, now before a Senate Sub-Committee, prohibits a physician from owning, either directly or indirectly, an interest in a pharmacy and also prohibits physicians, generally, from dispensing drugs and devices.

3.2 *Sales Tax*—Very few, if any, who have appeared before the Committee could reach agreement as to the dollars and cents effect of the application of the Federal Sales Tax to the sale of drugs. All agree that this is a highly improper tax levy on illness. In a recent reply (December 30, 1966) to our correspondence which commented on the 'Mini Budget', the Minister of Finance again stated that abolition awaits the recommendation of the Special Committee, and he promised that, "...your (our Association) requests that drugs be relieved of the additional one percentage point in the rate of sales tax will be given careful consideration before the Excise Tax Act amendment comes up for debate in the House of Commons..." We respectfully urge the members of this Special Committee to support our request.

3.3 *Variations in retail pharmacy prices*—It is logical to expect price variations in keeping with the value which the individual pharmacist finds it necessary to place upon the services rendered by his pharmacy. Extreme differences, however, are another matter, but we cannot comment upon those stated to the Committee and/or in press stories without having actual knowledge of the prescriptions themselves, the manner in which they were presented to enable a personal interpretation by the pharmacist, the strength of their ingredients, their quantities, and etc. We can only presume that normally accepted "market test" study and reporting procedures were not followed.

3.4 *Counting and pouring*—It is recognized that a busy pharmacy can handle a great number of prescriptions per day by utilizing its pharmacists on a production line basis, seemingly just counting or pouring. Such procedures are very much less than those which provide for a compresensive pharmaceutical service involving a multitude of professionally-oriented activities which are a vital part of pharmacy practice and which come within the definition of "cost of dispensing a prescription". Every procedure is important if, in some way, it

safeguards the health interest of the patient and contributes to the success of a physician's prescribed course of drug treatment. A very few seemingly routine "counting" or "pouring" prescriptions are reviewed and discussed in an article appended to this Brief. It speaks for itself (see Appendix A).

3.5 *Drug information* and ready access to it, particularly relative to each and every preparation available to meet all therapeutic requirements, is essential. To this end, the Association publishes its Compendium of Pharmaceuticals and Specialties. The completely rewritten Third Edition, now on the presses, will soon go out to every pharmacy, physician and hospital in Canada under a distribution program in which we are pleased to have the participation of several manufacturing companies. (See Appendix B) While this C.P.S. III which presents edited, unbiased information in expanded monograph form does not embody all the features we may wish, it is without comparison in Canada. (See Appendix C) These features will be incorporated in the next edition.

Recommendations and observations

4.0 Although the Canadian Pharmaceutical Association does not believe that the Committee has been presented with evidence to permit it to concur with the statement in its terms of reference which are to the effect that "drug costs are too high", it is of the opinion that certain steps can be taken without delay which will directly influence an immediate lowering of the price at which drugs are manufactured, distributed and sold and/or which will indirectly exert a stabilizing effect on the many components of cost and, hence, continue to maintain expenditures for pharmaceutical services as an extremely small part of the consumer dollar. To this end, we respectfully request favourable consideration our submissions:

4.1 (1) We recommend that the Excise Tax Act and/or other pertinent legislation be amended to provide for the abolition of the application of Federal Sales Tax to medicinal preparations and therapeutic appliances.

— all things being equal, consequent retail pricing adjustments ranging from 5 per cent to 10 per cent can be anticipated to save the consumer millions of 'drug dollars'.

(2) We recommend that the Income Tax Act be amended to provide personal income tax relief on the total of personal expenditures for prescribed pharmaceutical services provided by pharmacists and all other professionally rendered health care services by the removal of its present "3 per cent of net income" clause.

— This would provide community-wide assistance to individuals, particularly those of borderline financial means or the 'medical indigent' who must seek health care services in any one year and, indirectly, temper the price at which they were provided.

(3) We recommend that every possible action be undertaken to influence and promote the establishment of recognisable procedures whereby the prices at which the community retail pharmacist purchases his drugs bear a fair and equitable relationship to those which are offered to other individuals in the health professions, to hospitals and related health services institutions and to governments and their agencies.

— Directly, this will bring about a lowering of the cost of ingredients of the retail prescription, while the converse effect on institutional purchasing prices may be of lesser significance due to their bulk quantity

requirements. Any action taken must remove, too, the competitive inequalities at the Industry level by those who may have a "non-retail pharmacy" policy and/or whose contribution to the health care scene is solely a limited marketing function.

(4) We recommend that, through its report and the public influence of its members, the Committee support the advancement of public drug insurance and/or prepayment plans which are service programs sponsored by pharmacists and financially guaranteed by all levels of pharmaceutical endeavour.

— In themselves, such programs will not influence prices but will have the indirect benefit of spreading private costs and eliminating burdensome financial outlays by those faced with chronic or catastrophic illness situations.

(5) We recommend that our governments give immediate attention to granting tangible financial assistance to individuals within defined illness categories to enable them to obtain first class pharmaceutical services from local, private pharmacies—

— While Canadians spend a mere $10 on prescriptions, there are those of limited means or who require vast amounts of medication over extended periods of time for whom the price of prescription services is burdensome or high. Until the time when such can be given attention through voluntary insurance programs such as that proposed under Pharmacare Limited or Green Shield's prepayment plan, we believe that Canadians rightfully expect their tax dollars to brought into play to ensure that those in need of help can obtain services, as free citizens, from their choices of health practitioners.

(6) We recommend that the Compendium of Pharmaceuticals and Specialties be endorsed as a valuable, comprehensive information tool worthy of both professional and governmental support through editorial involvement and financial assistance, particularly as such may permit enhancement of its related information capabilities.

— Indirectly, "C.P.S." may influence drug costs by providing practitioners with convenient access to information on which to base their choice of drug preparations. Too, it offers the avenue through which economies can be realized in the dissemination of information to thus assist Industry in reducing expenditures which are labelled as "advertising and promotional".

(7) We recommend the development of better and more consistent methods of gathering, recording and publishing statistics related to the manufacture, distribution and sale of drugs and in relation to the provision of pharmaceutical services.

— Costly, time-consuming 'paper work' procedures will adversely affect the costs and prices of drugs and must be cautioned against in statistics-gathering procedures. Co-ordination of the efforts of the profession, the industry and governments will bring economies and produce less confusion in public interpretation of published facts.

(8) We recommend support of Pharmacy's moves toward establishing an equitable professional fee-for-service system which is not directly related to the cost of the drug ingredients of a prescription.

— Directly, the system lowers the consumer cost of expensive preparations. Indirectly, it enables the consumer to obtain prescribed drugs at prices in keeping with the comprehensiveness of service he desires or which seems to meet his individual needs.

— The "prescription dollar" is unique in the fields of commerce and professional endeavours in that it includes a multitude of safeguarding activities based on professional and legislative requirements, each of relatively minor financial significance when viewed alone, but which form a significant portion of the cost of dispensing a prescription.

— The "pharmaceutical dollar" is broader in scope than the "prescription dollar" which it includes, and while it more loosely embraces professional skills and procedures, it does encompass the application of professional judgment exercised in the public good in the distribution of drugs and health supplies, be they prescribed or offered for sale in a manner not unlike that pertaining to other commodities of commerce.

(9) We recommend that every committee, commission, agency or other body charged with the responsibility of investigating and/or reviewing matters pertaining to, or related to drugs and/or pharmaceutical services, be such responsibilities of a policy or administrative nature, be required to avail itself of the consultant services of one or more pharmacists knowledgeable in the subject who shall be retained either full or part time for such purpose.

— We recognize the great value, in their particular fields, of those whom the Committee has retained to assist it. Expertness in drug matters and the specialized knowledge of Pharmacy, privately applied, would provide for at-the-time searching out of facts and the clarification of inadequately presented statements and observations. The public of Canada is entitled to nothing less than the application of specific expertness through which it can expect a reduction of extremely expensive hours being devoted, over the years, to deliberations related to the same subject matter.

* * *

The Canadian Pharmaceutical Association has welcomed this further opportunity of working with the House of Commons' Special Committee on Drug Costs and Prices. You are assured that, in keeping with our responsibilities to the pharmacists and the public, we deem it a particular privilege and obligation to grasp every opportunity to extend our assistance, within the limits of our capabilities to you and to all representatives of the citizens of Canada.

ANNEX "A"

to C.Ph.A. Brief

"PILL COUNTING—FACT OR FALLACY?"

G. N. Rotenberg, B.Sc.Phm.,

Associate Editor, Compendium of Pharmaceuticals and Specialties

One of the qualities of pharmaceutical service which differentiates it from other transactions is that, in addition to the furnishing of a tangible commodity, there is, of necessity, a demand for a totality of knowledge which administers to and safeguards the health interest of the patient. Accordingly, the dispensing of so-called prefabricated drug preparations cannot be classified as a mechanical function. Not infrequently, the success of a physician's prescribed course of treatment hinges upon the pharmacist's ability to overcome dispensing or therapeutic problems. Let us look at but a few examples of seemingly routine "counting or pouring" prescriptions and see just how the pharmacist is involved, or may become involved.

1. Rx Tablets Digitoxin 0.2 mg.
Dispense 100.
Sig. 1 tablet three times a day.

Brief Description: A product containing a guycoside of digitalis used in the treatment of cardiac insufficiency.

The physician has prescribed an initial digitalizing dose to build up the drug concentration in the patient's system to obtain the desired therapeutic effect but has failed to indicate the necessary reduction to a daily maintenance dosage of 1 tablet after 2 or 3 days. A continued dosage of 3 tablets daily would result in severe digitalis poisoning.

2. Rx Emetrol 240 ml.
Sig. 15.0 ml. in water q. 2 h. u.d.

Brief Description: A phosphorated carbohyrate solution containing balanced amounts of levulose and dextrose in coacting association with orthophosphoric acid stabilized at a physiologically adjusted hydrogen-ion concentration used as an anti-emetic preparation.

Any dilution with water of this chemically-stabilized preparation completely destroys the hydrogen-ion concentration, thus rendering the product totally useless in the control of vomiting.

3. Rx Tetracycline Pediatric Drops 10 ml.
Sig. 10 drops q. 8 h. for earache until completed.

Brief Description: Tetracycline is a broad-spectrum antibiotic used in the treatment of infectious diseases due to a wide variety of susceptible organisms.

The pharmacist's role in clearly defining and explaining the physician's written directions is most graphically illustrated in the above example. The antibiotic is intended for oral use and if labelled strictly according to the physician's directions, the label will read "10 drops every 8 hours for earache". Insofar as the parent is concerned, the infant is suffering from earache and the pharmacist (as does happen) would well receive the complaint from the parent that the infant's ear will not hold ten drops! Similar 'tragicomical' reports of

patients taking suppositories orally or using them without removing the foil wrapper are not uncommon.

4. Rx Tabs. Parnate 10 mg. b.i.d.
Tabs Elavil 25 mg. t.i.d.
Mitte: One month's supply

Brief Description: Parnate (Tranylcypromine)—Monoamine oxidase (MAO) inhibitor

Elavil (Amitryptyline HCl)—antidepressant

The above example represents a very serious therapeutic incompatability. The concomitant usage of the two prescribed drugs could very easily lead to a severe hypertensive crisis. It should be noted that even the ingestion of common foodstuffs such as cheese, certain meat and yeast extracts, beer, alcohol, and Chianti wine may initiate severe paroxysmal hypertension and headache in patients undergoing therapy with MAO inhibitors. Therefore, the pharmacist is not only in an excellent position to detect the initial therapeutic incompatability but also in his role as an adviser on drugs, may counsel patients to avoid the above-mentioned foodstuffs in the event that the physician has neglected to bring these essential facts to their attention. In addition, since certain proprietary cold, hay fever or reducing preparations do not require a prescription, and are also contraindicated with the use of MAO inhibitors, the pharmacist realizing this, could also prevent this mishap from occurring.

5. Rx Triple Sulpha tabs. 0.5 Gm.
Dispense viii
Sig. i a.m. and h.s. for bladder infection.

Brief Description: An agent used in the treatment of infections due to sulfonamide-susceptible organisms.

Historically, the pharmacist has always advised the physician of any serious or toxic overdosage and has discharged this responsibility exceedingly well. However, underdosages to constitute an equally dangerous situation to the patient. Triple Sulpha tablets prescribed for too short a time and in extremely low dosage in a urinary tract infection, could lead to no response or a rapid relapse.

Similarly, if the amount and frequency of an anticholinergic medication is not adequate, the peptic ulcer patient runs the risk of a perforated ulcer. It is recognized that improper prescribing habits have greatly contributed to the emergence of drug-resistant bacteria. It is interesting to note that in a survey reported in the Journal of the American Pharmaceutical Association, 19.3% of all prescriptions surveyed revealed the presence of apparent underdosage, and 0.8% an apparent overdosage! Improper prescribing could well prolong the course of an illness, cause undue expense and even produce serious harm to the patient if undetected by the dispensing pharmacist.

6. Rx Tabs. Penicillin G 400,000 I.U.
Dispense xii
Sig. 1 tablet three times a day.

Brief Description: An agent used in the treatment of infections due to penicillin-susceptible organisms.

The success of an antibiotic regimen is, for the most part, dependent on the method in which the drugs are used. Unbuffered Penicillin G tablets are not very

stable in the presence of stomach acid and should therefore be administered on an empty stomach in order to effect an appreciable absorption of the drug. Similarly, the absorption of the antibiotic tetracycline is markedly retarded by the simultaneous administration of milk, antacids and other divalent compounds. Conversely, certain drugs (e.g., phenylbutazone, salicylates, etc.) should be administered with food in order to obviate any drug-induced gastric distress. Here again, the intrinsic value of the pharmacist's service augments the physician's prescribed course of medication.

Coupled with the increased complexity of pharmacodynamic activity of our modern medicinal agents is the equally diverse physical behaviour exhibited by many compounds. In fact, a recent 81-page document compiled by the Armstrong Cork Company reveals that 565 drug monographs listed in the *Pharmacopoeia of the United States XVI, National Formulary XI,* and the *American Drug Index 1964,* require storage in light-resistant containers. When we consider that these drugs, (i.e., sulphas, phenothiazine, tranquilizers, barbiturates, vitamins, etc.), are components of literally thousands of specialty preparations, the need to protect many prescriptions against photo-chemical reaction in the proper container should govern the extent of dispensing of materials "from one bottle into (*any*) other". Many drugs are also affected by such factors as temperature, moisture, and, indeed, it is mandatory that life-saving drugs such as nitroglycerin be dispensed only in amber, tightly sealed, glass containers, with a screw cap closure and liner and with extensive information relative to the use of this drug being supplied by the pharmacist.

There has been no attempt made to discuss the outstanding pharmaceutical services provided by many Canadian community and hospital pharmacists who, after consultation with their medical colleagues, have developed special ophthalmic and dermatalogical preparations which are not otherwise commercially available to meet exactly the specifications desired by the physician. Experience leads us to indicate that the "limited service" pharmacist whose interests appear to pertain solely to 'high volume-low price' endeavours invariably will not process orders for compounded medication or accept those prescriptions requiring extemporaneous compounding or involving unusual paper work.

It is readily apparent that comprehensive pharmaceutical service and practice go far beyond the mechanics of counting and pouring" medicinals. The pharmacist's extensive training, his sense of personal obligation to keep pace with progress in pharmaceutical science, his professional knowledge and skill, and his sense of public responsibility, all contribute to providing the peace of mind which must be expected in obtaining pharmaceutical services. This service does not really cost, it pays.

ANNEX "B"

to C.Ph.A. Brief

CANADA'S ONLY COMPREHENSIVE REFERENCE COMPENDIUM OF PHARMACEUTICALS AND SPECIALTIES

THIRD EDITION (1967)
A publication of the Canadian Pharmaceutical Association

NOW BEING READIED FOR FREE DISTRIBUTION TO RETAIL PHARMACIES, PHYSICIANS, HOSPITALS

Under special distribution arrangements with Provincial and National Associations and through the courtesey of those 'participating companies' who have listed their choice of products in *C.P.S. III* Therapeutic Section *(The Pink Pages)* under a participation program openly available to *all manufacturers/distributors* of prescription drug preparations in Canada, *one free copy* will be mailed to each retail pharmacy, physician and hospital.

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CALMIC
CIBA
EMPIRE
FROSST
GEIGY
GLAXO-ALLENBURYS
HOECHST
HOFFMANN-LAROCHE
LEDERLE
LILLY
LINSON
MALLINCKRODT
PAUL MANEY
McNEIL
MEAD JOHNSON
MERCK, SHARP & DOHME
NOVOPHARM
ORTHO
PARKE, DAVIS
PFIZER
PITMAN-MOORE
RIKER
ROBINS
ROERIG
ROUSSEL
SANDOZ
SCHERING
SEARLE
S K & F
SQUIBB
SYNTEX
TEXAS
WARNER-CHILCOTT
WESTWOOD
WHITE
WILL
WINTHROP
WYETH

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ANNEX "C"

COMPENDIUM OF PHARMACEUTICALS AND SPECIALTIES

Third Edition

—a reprint of an example page—

ADROYD Rx P.D. & Co.
Oxymetholone — **Anabolic Steroid**

TABLETS: 2.5 and 5 mg.
Indications: As an anabolic agent especially in post surgical, post infectious, and convalescent patients.
Administration: Orally, before or with meals for 7-21 days, up to a maximum of 90 days. Adults—5-10 mg. daily or as high as 30 mg. if indicated. For pediatric short-term anabolic stimulation: infants and children up to 6 years, 1.25-5 mg. daily; older children, 5-10 mg. As a stimulus in refractory underweight or malnutritional states, therapy may be continued for periods up to 90 days with suggested daily dosage for children up to the age of 6 years of 1.25-2.5 mg.; for children from 6 years to puberty, 2.5-5 mg., for adolescents, 5-10 mg.
Contraindications: Should not be used to stimulate growth in short, but otherwise normal and healthy, children. Prostatic carcinoma and other androgen-dependent neoplasms. Pregnant women or those of childbearing age.
Side Actions: Nausea, edema and fluid retention may occur. Mild androgenic effects may be noted in children. Susceptible females may develop signs of virilization, increased libido, acne, hirsutism and alteration of menstrual cycles. Altered hepatic function may occur in large doses.
Precautions: Use with caution in presence of cardiac disease, nephritis, nephrosis and hepatic damage. Observe for possible masculinization, altered liver function and alteration of epiphyseal development.
Supplied: 2.5 mg., 50; 5 mg., 30.

A.E.A. Pharmavite
Dextromethorphan Compound — **Antitussive**

SYRUP: Each 5 cc. contains: Dextromethorphan HBr 5 mg., Methapyrilene Fumarate 5 mg., Ammonium Chloride 100 mg., Sodium Citrate 45 mg., in a patatable syrup base.
Indications: Cough control.
Side Actions: Nausea, drowsiness and dizziness may occur.
Precautions: Ambulant patients operating heavy machinery or driving automobiles should be cautioned as to the possibility of drowsiness occurring.
Supplied: 4 and 8 fl. oz.

AEROBILINE Lippens
Dehydrocholic Acid Compound
Laxative—Choleretic

CAPSULES: Each capsule contains: Benzoxyline 60 mg., Dehydrocholic Acid 100 mg., Benzyl Succinate 60 mg., Pepsin 65 mg., Sodium Citrate 60 mg. and Powdered Extract of Rhubarb 20 mg.
Indications: Relief of gas, to stimulate the flow of bile and relieve occasional constipation.
Administration: 1 capsule with tepid water, 20 minutes after meals and at bedtime.
Contraindications: Biliary tract obstruction and acute hepatitis.
Precautions: More than 4 capsules daily increases laxative action.
Supplied: 60 and 500.

AERODRIN B. W. & Co. — **Nasal Decongestant**

SOLUTION, SPRAY: Antibiotic nasal decongestant, pH 5.5, containing in each cc.: Polymyxin B Sulfate 5M units, Neomycin Sulfate 5 mg. (equivalent to 3.5 mg. Neomycin base), Methoxamine HCl 5 mg.
Indications: For engorgement and/or infection of nose, nasopharynx or sinuses, e.g. acute rhinitis, chronic rhinitis, sinusitis, allergic rhinitis.
Administration: Adults, 3 or 4 drops or sprays in each nostril 4 or 5 times a day, or as required.
Children 1-3 drops or sprays.
Supplied: Nasal Solution: ½ fl. oz. with dropper.
Nasal Spray: ½ fl. oz. plastic spray bottle.

AEROHALOR Abbott
Powder Inhaler — **Inhalation Therapy**

INHALER: A plastic powder inhaler to hold the Abbott Sifter Cartridges. For use with Norisodrine Sulfate for Oral Inhalation and Penicillin G Potassium for inhalation. Complete directions are included.
Precautions: The device is designed for use by a single patient only; any attempt at sterilization followed by re-use by another patient is not recommended.
Supplied: Individual boxes, complete with mouthpiece and nasal attachment.

AEROLONE COMPOUND Lilly
Cyclopentamine-Isoprenaline Compound
Bronchodilator

INHALANT: Each 100 cc. contains: Cyclopentamine HCl 0.5 Gm., Isoprenaline HCl 0.25 Gm., in a vehicle of Propylene Glycol and Distilled Water.
Indications: Treatment of asthma, status asthmaticus and emphysema.
Administration: A special nebulizer is required, one capable of producing mist of particles of 1 micron or less in diameter. Place a small amount (1-2 cc. in the nebulizer). Aim the mouthpiece through the mouth at the pharynx. Inhale deeply and squeeze hand bulb. Usually, 6-12 inhalations will bring adequate relief. Mild cases may require only 1 inhalation per day; severe cases possibly every 15 minutes.
Precautions: Use with caution in presence of hyperthyroidism, acute coronary disease, cardiac asthma, limited cardiac reserve or hypersensitivity to sympathomimetic amines.
Supplied: 1 fl. oz.

AEROSPORIN B. W. & Co.
Polymyxin B Sulfate — **Antibiotic**

OTIC SOLUTION: Contains 0.1% Polymyxin B Sulfate (10M units in 1 cc.) in acidified Propylene Glycol, sterile.
STERILE POWDER Rx: Vials containing 500M units equivalent to 50 mg. Polymyxin Standard.
TABLETS Rx: Scored, containing 500M units equivalent to 50 mg. Polymyxin Standard.
Indications: Infections due to gram-negative organisms.
Otic Solution: for ear infections, especially when due to *Ps. aeruginosa; Powder:* systemic infections due to *Ps. aeruginosa* and some other gram-negative organisms; *Tablets:* bacillary dysentery, especially chronic due to *Shigella* and other gram-negative bacteria; pre-operative sterilization of intestinal tract (with other antibiotics).
Administration: Otic Solution: By instillation or by

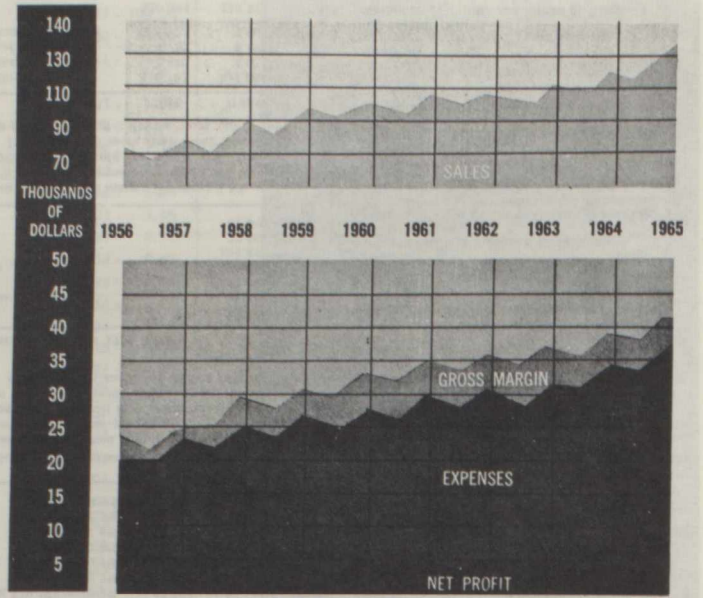
. . . Modern drugs merit modern precautionary usage. Report suspected adverse drug reactions to the Food and Drug Directorate.

Canadian Pharmaceutical Association

24th

CPhA Annual Survey Of RETAIL PHARMACY

PUBLISHED SEPTEMBER 1, 1966 BY THE CANADIAN PHARMACEUTICAL JOURNAL



THE ANNUAL BREAKDOWN OF THE REVENUES AND THE COSTS OF RETAIL PHARMACY OPERATIONS ACROSS CANADA

BY H. J. FULLER, PROFESSOR OF PHARMACY ADMINISTRATION, FACULTY OF PHARMACY, UNIVERSITY OF TORONTO.

Canadian retail pharmacy in 1965

CPhA SURVEY

INDICATING CANADA'S rising prosperity the average sales of the 595 pharmacies reporting in the 1965 Survey increased from $131,039 in 1964 to $138,471, an increase of $7,432 or 5.6%. Prescription receipts increased $3,210 or 8.8% accounting for 43.2% of the total increase in sales.

Simply multiplying these figures by 5,033, the number of pharmacies in Canada, according to provincial registrars, we get the projection of Total Sales in Canada in 1965 of $696,924,543 with $200,017,343 of this coming from the dispensing of 60,246,187 prescriptions.

The 5,261,924 prescriptions in our sample were dispensed at an average price of $3.32, just **one cent** above the 1964 figure. Per capita expenditure on prescriptions was $10.22 ($8.88 in 1964) with a per capita usage rate of 3.07 prescriptions (2.68 in 1964).

Better buying and expense control are shown by the following facts:

Gross margin increased 0.4% from 34.2% in 1964 to 34.6% in 1965; expenses decreased 0.4% from 29.4% in 1964 to 29.0% in 1965 thus increasing net profit 0.8% of sales from 4.8% in 1964 to 5.6%; the average increase in sales of $7,432 was obtained with an increase in average inventory of only $520. Annual rate of inventory turnover increased from 3.4 to 3.5 times.

There was little change in most operating ratios. Those that caused the reduction in total expenses were rent, down from 2.9% to 2.7%, proprietor's salary down from 8.1% to 7.8% and an increase in bad debt losses up from 0.1% to 0.2%. The increase in bad debt losses occurred in all provinces except Ontario, Quebec, and Saskatchewan.

Distribution of Reporting Pharmacies

Approximately **one out of four** pharmacies in Prince Edward Island, Nova Scotia, New Brunswick, and Saskatchewan, and one out of five in British Columbia are represented in the Survey. The 595 reporting pharmacies represent practically 12% of all pharmacies in Canada.

Trend Indicator

Fifty percent of the reporting pharmacies also reported in 1964. Comparing these, Table No. 4, we find an average increase in sales of $12,563 or 9.0% increase over 1964. The operating ratios of these 297 pharmacies was little different from all 595 reporting pharmacies. However, the trend was not equal in all provinces. The following is a summary of selected data from Table No. 4:

	Average Increase in Sales	Change in Net Profit	Change in Total Income
Alberta	$ 1,029 or 0.9%	—$ 556	—$ 773
British Columbia	$19,179 or 10.2%	+$2,706	+$2,141
Manitoba	$ 7,287 or 8.5%	+$ 164	+$ 646
New Brunswick	$14,210 or 10.5%	+$2,320	+$4,490
Nova Scotia	$ 3,548 or 2.4%	+$1,669	+$1,374
Ontario	$10,335 or 7.4%	+$ 786	+$1,266
Saskatchewan	$12,607 or 11.9%	+$1,069	+$2,100
Canada	$12,563 or 9.0%	+$1,071	+$1,621

161 Identical Pharmacies for 10 Years

These 161 pharmacies reported both in 1956 and 1965. Average sales over the ten year period increased 70.9%; net profit increased 107.8% total income increased 72.7% and prescription receipts increased 92.3%. Again, growth has not been even across Canada as shown by the following:

Increase in Sales 1956 - 1965

Alberta	33.7%
British Columbia	88.5%
Manitoba	73.8%
New Brunswick	30.8%
Nova Scotia	105.8%
Ontario	37.6%
Saskatchewan	61.9%

In this ten year period gross margin increased 2.5% of sales from 32.1% to 34.6%; expenses increased 1.4% from 27.6% to 29.0% and net profit increased 1.1% from 4.5% to 5.6%. It requires 75% more assets today to operate one of these pharmacies than it did ten years ago:

	1956	1965
Average Inventory	$16,793	$31,084
Average Accounts Receivable	2,440	4,022
Average Value of Fixtures	4,785	8,195
Less Average Accounts Payable	3,923	7,965
	$20,095	$35,336

However, considering these figures to be approximately the total assets, net profit as a percentage of assets increased from 18.27% in 1956 to 21.60 in 1965 and the return to each dollar invested in inventory increased from 22¢ to 25¢.

Location of Reporting Pharmacies

Community	31.5%
Downtown	47.7%
Shopping Plazas	7.7%
Medical Buildings	3.5%

Three are in hotels and hence classed with downtown. 78 are in towns with no other pharmacy and classed as downtown. Approximately 10% did not indicate their locations.

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Table No. 1

AVERAGE COSTS AND PROFITS OF 595 PHARMACIES IN CANADA

	1964*	1965
Sales	$131,039 - 100.0%	$138,471 - 100.0%
Cost of Goods Sold	86,224 - 65.8%	90,560 - 65.4%
Gross Margin	44,815 - 34.2%	47,911 - 34.6%
EXPENSES		
Proprietor's or Manager's Salary	$ 10,614 - 8.1%	$ 10,801 - 7.8%
Employees' Wages	13,890 - 10.6%	14,678 - 10.6%
Rent	3,800 - 2.9%	3,739 - 2.7%
Advertising	1,573 - 1.2%	1,662 - 1.2%
Delivery	1,048 - 0.8%	1,108 - 0.8%
Depreciation on Fixtures and Equipment	1,573 - 1.2%	1,523 - 1.1%
Heat, Light, Power	917 - 0.7%	969 - 0.7%
Taxes	524 - 0.4%	554 - 0.4%
Insurance	524 - 0.4%	554 - 0.4%
Interest	524 - 0.4%	554 - 0.4%
Repairs	524 - 0.4%	554 - 0.4%
Telephone	393 - 0.3%	415 - 0.3%
Bad Debts	131 - 0.1%	277 - 0.2%
Miscellaneous	2,490 - 1.9%	2,769 - 2.0%
Total Expenses	$ 38,525 - 29.4%	$ 40,157 - 29.0%
NET PROFIT (before taxes)	$ 6,290 - 4.8%	$ 7,754 - 5.6%
Add: Other Income	$ 863	$ 807
Proprietor's Salary	$ 10,614	$ 10,801
TOTAL INCOME	$ 17,767 ($16,288)	$ 19,362 ($17,199)
Value of Merchandise Stock	$ 25,642	$ 26,162
Annual Rate of Turnover	3.4	3.5
Average Value of Fixtures	$ 9,213	$ 7,573
Average Accounts Receivable	$ 3,112	$ 3,568
Average Accounts Payable	$ 7,093	$ 7,705
Average Price per Prescription	$ 3.31	$ 3.32
Average Price of a New Prescription	$ 3.47	$ 3.27
Average Price of a Repeat Prescription	$ 3.29	$ 3.35
Average Number of Prescriptions	10,962	11,904
Average Receipts from Prescriptions	$ 36,375	$ 39,585
Ratio of Prescription Receipts to Total Receipts	27.4%	28.7%
Cost of Dispensing a Prescription	$ 1.26	$ 1.32
Number of Hours per week Pharmacy was open	67	67
Number of Hours per week worked by Proprietor	49	48

* 476 pharmacies

THE RESULTS OF THE 24TH C. PH. A. PHARMACY SURVEY

(with figures of former surveys for comparison)
Total Pharmacy Sales for 1965 – $696,924,543

NUMBER OF PRESCRIPTIONS

1965	60,246,187
1964	51,635,671
1963	48,946,090
1962	44,630,198
1961	42,540,814
1960	42,840,810
1959	43,916,605
1958	40,445,325
1957	40,036,416
1956	35,102,361

VALUE OF PRESCRIPTIONS

1965	$200,017,343
1964	170,914,399
1963	156,627,512
1962	141,031,428
1961	133,578,157
1960	131,092,880
1959	130,187,483
1958	112,438,004
1957	103,230,236
1956	87,404,881

AVERAGE COST OF A PRESCRIPTION

1965	$3.32
1964	3.31
1963	3.20
1962	3.16
1961	3.14
1960	3.06
1959	2.98
1958	2.78
1957	2.61
1956	2.49

Table No. 2

AVERAGE COSTS AND PROFITS OF 595 PHARMACIES IN CANADA BY PROVINCES

	ALBERTA 73 Pharmacies	BRITISH COLUMBIA 109 Pharmacies	MANITOBA 38 Pharmacies	NEW BRUNSWICK 28 Pharmacies	NEWFOUNDLAND 3 Pharmacies	NOVA SCOTIA 45 Pharmacies	ONTARIO 191 Pharmacies
Sales	$101,241 - 100.0%	$198,225 - 100.0%	$101,030 - 100.0%	$144,084 - 100.0%	$150,080 - 100.0%	$146,920 - 100.0%	$134,764 - 100.0%
Cost of Goods Sold	66,414 - 65.6%	132,613 - 66.9%	66,276 - 65.6%	89,476 - 62.1%	97,552 - 65.0%	98,583 - 67.1%	87,597 - 65.0%
Gross Margin	34,827 - 34.4%	65,612 - 33.1%	34,754 - 34.4%	54,608 - 37.9%	52,528 - 35.0%	48,337 - 32.9%	47,167 - 35.0%
EXPENSES							
Proprietor's or Manager's Salary	$ 8,605 - 8.5%	$ 11,695 - 5.9%	$ 8,891 - 8.8%	$ 11,815 - 8.2%	$ 9,755 - 6.5%	$ 9,990 - 6.8%	$ 11,050 - 8.2%
Employees's Wages	8,909 - 8.8%	23,589 - 11.9%	10,204 - 10.1%	16,137 - 11.2%	15,909 - 10.6%	14,545 - 9.9%	15,094 - 11.2%
Rent	3,037 - 3.0%	5,748 - 2.9%	2,324 - 2.3%	3,314 - 2.3%	2,852 - 1.9%	3,673 - 2.5%	3,639 - 2.7%
Advertising	1,215 - 1.2%	3,172 - 1.6%	808 - 0.8%	1,585 - 1.1%	901 - 0.6%	1,028 - 0.7%	1,617 - 1.2%
Delivery	506 - 0.5%	1,586 - 0.8%	909 - 0.9%	1,441 - 1.0%	450 - 0.3%	881 - 0.6%	1,213 - 0.9%
Depreciation on Fixtures and Equipment	1,316 - 1.3%	1,982 - 1.0%	1,415 - 1.4%	1,297 - 0.9%	1,201 - 0.8%	1,469 - 1.0%	1,617 - 1.2%
Heat, Light, Power	810 - 0.8%	1,586 - 0.8%	707 - 0.7%	720 - 0.5%	1,351 - 0.9%	881 - 0.6%	809 - 0.6%
Taxes	405 - 0.4%	595 - 0.3%	505 - 0.5%	1,009 - 0.7%	450 - 0.3%	735 - 0.5%	404 - 0.3%
Insurance	506 - 0.5%	595 - 0.3%	505 - 0.5%	865 - 0.6%	600 - 0.4%	735 - 0.5%	539 - 0.4%
Interest	506 - 0.5%	1,189 - 0.6%	606 - 0.6%	432 - 0.3%	150 - 0.1%	588 - 0.4%	404 - 0.3%
Repair	405 - 0.4%	793 - 0.4%	404 - 0.4%	576 - 0.4%	150 - 0.1%	294 - 0.2%	404 - 0.3%
Telephone	304 - 0.3%	595 - 0.3%	202 - 0.2%	432 - 0.3%	300 - 0.2%	294 - 0.2%	404 - 0.3%
Bad Debts	203 - 0.2%	396 - 0.2%	202 - 0.2%	288 - 0.2%	450 - 0.3%	441 - 0.3%	135 - 0.1%
Miscellaneous	1,924 - 1.9%	4,757 - 2.4%	1,718 - 1.7%	2,738 - 1.9%	2,251 - 1.5%	4,555 - 3.1%	2,561 - 1.9%
Total Expenses	$ 28,651 - 28.3%	$ 58,278 - 29.4%	$ 29,400 - 29.1%	$ 42,649 - 29.6%	$ 36,770 - 24.5%	$ 40,109 - 27.3%	$ 39,890 - 29.6%
NET PROFIT	$ 6,176 - 6.1%	$ 7,334 - 3.7%	$ 5,354 - 5.3%	$ 11,959 - 8.3%	$ 15,758 - 10.5%	$ 8,228 - 5.6%	$ 7,277 - 5.4%
Add: Other Income	$ 428	$ 1,748	$ 928	$ 594	$ 40	$ 943	$ 475
Proprietor's Salary	$ 8,605	$ 11,695	$ 8,891	$ 11,815	$ 9,755	$ 9,990	$ 11,050
TOTAL INCOME	$15,209 ($15,034)	$ 20,777 ($18,048)	$ 15,173 ($14,687)	$ 24,368 ($22,551)	$ 25,553 ($24,447)	$ 19,161 ($18,138)	$ 18,802 ($17,300)
Value of Merchandise Stock	$ 22,969	$ 33,192	$ 18,608	$ 26,060	$ 18,411	$ 25,070	$ 25,849
Annual Rate of Turnover	3.0	3.7	3.7	3.4	5.5	3.9	3.6
Average Value of Fixtures	$ 7,797	$ 7,996	$ 6,752	$ 10,085	$ 7,000	$ 7,451	$ 7,734
Average Accounts Receivable	$ 3,267	$ 4,191	$ 2,347	$ 4,546	$ 3,061	$ 4,381	$ 3,492
Average Accounts Payable	$ 5,344	$ 9,100	$ 4,646	$ 10,011	$ 20,000	$ 11,119	$ 7,653
Average Price per Rx	$ 3.54	$ 3.18	$ 3.42	$ 3.62	$ 3.09	$ 3.00	$ 3.47
Average Number of Rx	9,150	13,782	9,375	19,038	9,471	13,525	10,272
Average Receipts from Rx	$ 32,418	$ 43,853	$ 32,088	$ 68,964	$ 29,318	$ 40,602	$ 35,696
Ratio of Rx Receipts to Total Receipts	30.9%	21.8%	32.8%	45.9%	16.8%	32.7%	27.8%
Cost of Dispensing a Rx	$ 1.30	$ 1.37	$ 1.27	$ 1.40	$ 1.10	$ 1.26	$ 1.36
Number of hours per week Pharmacy was open	61	73	60	73	93	70	66
Number of hours per week Worked by proprietor	51	44	48	51	60	45	50

Table No. 2 (Cont'd.)

AVERAGE COSTS AND PROFITS OF PHARMACIES IN CANADA BY PROVINCES

	PRINCE EDWARD ISLAND 7 Pharmacies	QUEBEC 14 Pharmacies	SASKATCHEWAN 87 Pharmacies
Sales	$131,171 - 100.0%	$129,591 - 100.0%	$114,774 - 100.0%
Cost of Goods Sold	86,573 - 66.0%	82,031 - 63.3%	74,259 - 64.7%
Gross Margin	44,598 - 34.0%	47,560 - 36.7%	40,515 - 35.3%
EXPENSES			
Proprietor's or Manager's Salary	$ 10,756 - 8.2%	$ 10,108 - 7.8%	$ 9,985 - 8.7%
Employees' Wages	10,625 - 8.1%	16,328 - 12.6%	10,559 - 9.2%
Rent	2,230 - 1.7%	3,629 - 2.8%	3,328 - 2.9%
Advertising	1,836 - 1.4%	1,037 - 0.8%	1,377 - 1.2%
Delivery	1,574 - 1.2%	1,944 - 1.5%	689 - 0.6%
Depreciation on Fixtures and Equipment	1,443 - 1.1%	1,425 - 1.1%	1,377 - 1.2%
Heat, Light, Power	787 - 0.6%	778 - 0.6%	803 - 0.7%
Taxes	525 - 0.4%	648 - 0.5%	689 - 0.6%
Insurance	525 - 0.4%	1,166 - 0.9%	574 - 0.5%
Interest	787 - 0.6%	389 - 0.3%	689 - 0.6%
Repair	262 - 0.2%	778 - 0.6%	459 - 0.4%
Telephone	262 - 0.2%	648 - 0.5%	230 - 0.2%
Bad Debts	262 - 0.2%	129 - 0.1%	115 - 0.1%
Miscellaneous	2,493 - 1.9%	1,944 - 1.5%	2,066 - 1.8%
Total Expenses	$ 34,367 - 26.2%	$ 40,951 - 31.6%	$ 32,940 - 28.7%
NET PROFIT	$ 10,231 - 7.8%	$ 6,609 - 5.1%	$ 7,575 - 6.6%
Add: Other Income	$ 604	$ 900	$ 650
Proprietor's Salary	$ 10,756	$ 10,108	$ 9,985
TOTAL INCOME	$ 21,591($20,737)	$ 17,617($16,735)	$ 18,210($16,185)
Value of Merchandise Stock	$ 26,295	$ 22,637	$ 25,315
Annual Rate of Turnover	3.5	3.7	3.2
Average Value of Fixtures	$ 8,079	$ 9,322	$ 6,173
Average Accounts Receivable	$ 4,590	$ 1,680	$ 3,012
Average Accounts Payable	$ 8,133	$ 9,532	$ 5,789
Average Price per Rx	$ 2.95	$ 3.35	$ 3.22
Average Number of Rx	12,395	15,005	12,137
Average Receipts from Rx	$ 36,652	$ 50,334	$ 39,049
Ratio of Rx Receipts to Total Receipts	27.9%	36.3%	32.5%
Cost of Dispensing a Rx	$ 1.10	$ 1.44	$ 1.26
Number of hours per week Pharmacy was open	62	80	59
Number of hours per week Worked by proprietor	58	48	49

Table No. 3

STANDARD PROPRIETOR'S COMPENSATION

BELOW $40,000 — 15% OF SALES

Sales	Minimum Compensation	Sales	Minimum Compensation	Sales	Minimum Compensation
$ 40,000	$ 6,000	$ 94,000	$ 7,468	$148,000	$ 8,936
$ 41,000	$ 6,020	$ 95,000	$ 7,490	$149,000	$ 8,968
$ 42,000	$ 6,040	$ 96,000	$ 7,512	$150,000	$ 9,000
$ 43,000	$ 6,060	$ 97,000	$ 7,534	$151,000	$ 9,028
$ 44,000	$ 6,080	$ 98,000	$ 7,556	$152,000	$ 9,056
$ 45,000	$ 6,100	$ 99,000	$ 7,578	$153,000	$ 9,084
$ 46,000	$ 6,120	$100,000	$ 7,600	$154,000	$ 9,112
$ 47,000	$ 6,140	$101,000	$ 7,632	$155,000	$ 9,140
$ 48,000	$ 6,160	$102,000	$ 7,664	$156,000	$ 9,168
$ 49,000	$ 6,180	$103,000	$ 7,696	$157,000	$ 9,196
$ 50,000	$ 6,200	$104,000	$ 7,728	$158,000	$ 9,224
$ 51,000	$ 6,228	$105,000	$ 7,760	$159,000	$ 9,252
$ 52,000	$ 6,256	$106,000	$ 7,792	$160,000	$ 9,280
$ 53,000	$ 6,284	$107,000	$ 7,824	$161,000	$ 9,304
$ 54,000	$ 6,312	$108,000	$ 7,856	$162,000	$ 9,328
$ 55,000	$ 6,340	$109,000	$ 7,888	$163,000	$ 9,352
$ 56,000	$ 6,368	$110,000	$ 7,920	$164,000	$ 9,376
$ 57,000	$ 6,396	$111,000	$ 7,944	$165,000	$ 9,400
$ 58,000	$ 6,424	$112,000	$ 7,968	$166,000	$ 9,424
$ 59,000	$ 6,452	$113,000	$ 7,992	$167,000	$ 9,448
$ 60,000	$ 6,480	$114,000	$ 8,016	$168,000	$ 9,472
$ 61,000	$ 6,511	$115,000	$ 8,040	$169,000	$ 9,496
$ 62,000	$ 6,542	$116,000	$ 8,064	$170,000	$ 9,520
$ 63,000	$ 6,573	$117,000	$ 8,088	$171,000	$ 9,540
$ 64,000	$ 6,604	$118,000	$ 8,112	$172,000	$ 9,560
$ 65,000	$ 6,635	$119,000	$ 8,136	$173,000	$ 9,580
$ 66,000	$ 6,666	$120,000	$ 8,160	$174,000	$ 9,600
$ 67,000	$ 6,697	$121,000	$ 8,189	$175,000	$ 9,620
$ 68,000	$ 6,728	$122,000	$ 8,218	$176,000	$ 9,640
$ 69,000	$ 6,759	$123,000	$ 8,247	$177,000	$ 9,660
$ 70,000	$ 6,790	$124,000	$ 8,276	$178,000	$ 9,680
$ 71,000	$ 6,815	$125,000	$ 8,305	$179,000	$ 9,700
$ 72,000	$ 6,840	$126,000	$ 8,334	$180,000	$ 9,720
$ 73,000	$ 6,865	$127,000	$ 8,363	$181,000	$ 9,736
$ 74,000	$ 6,890	$128,000	$ 8,392	$182,000	$ 9,752
$ 75,000	$ 6,915	$129,000	$ 8,421	$183,000	$ 9,768
$ 76,000	$ 6,940	$130,000	$ 8,450	$184,000	$ 9,784
$ 77,000	$ 6,965	$131,000	$ 8,473	$185,000	$ 9,800
$ 78,000	$ 6,990	$132,000	$ 8,496	$186,000	$ 9,816
$ 79,000	$ 7,015	$133,000	$ 8,519	$187,000	$ 9,832
$ 80,000	$ 7,040	$134,000	$ 8,542	$188,000	$ 9,848
$ 81,000	$ 7,074	$135,000	$ 8,565	$189,000	$ 9,864
$ 82,000	$ 7,108	$136,000	$ 8,588	$190,000	$ 9,880
$ 83,000	$ 7,142	$137,000	$ 8,611	$191,000	$ 9,932
$ 84,000	$ 7,176	$138,000	$ 8,634	$192,000	$ 9,984
$ 85,000	$ 7,210	$139,000	$ 8,657	$193,000	$10,036
$ 86,000	$ 7,244	$140,000	$ 8,680	$194,000	$10,088
$ 87,000	$ 7,278	$141,000	$ 8,712	$195,000	$10,140
$ 88,000	$ 7,312	$142,000	$ 8,744	$196,000	$10,192
$ 89,000	$ 7,346	$143,000	$ 8,776	$197,000	$10,244
$ 90,000	$ 7,380	$144,000	$ 8,808	$198,000	$10,296
$ 91,000	$ 7,402	$145,000	$ 8,840	$199,000	$10,348
$ 92,000	$ 7,424	$146,000	$ 8,872	$200,000	$10,400
$ 93,000	$ 7,446	$147,000	$ 8,904		

TOTAL INCOME minus STANDARD PROPRIETOR'S COMPENSATION equals NET PROFIT

Table No. 4

297 IDENTICAL CANADIAN PHARMACIES

	CANADA 297 Pharmacies*		ALBERTA 27 Pharmacies		BRITISH COLUMBIA 76 Pharmacies		MANITOBA 19 Pharmacies	
	1965	1964	1965	1964	1965	1964	1965	1964
Sales	$151,903 - 100.0%	$139,340 - 100.0%	$107,349 - 100.0%	$106,320 - 100.0%	$205,886 - 100.0%	$186,707 - 100.0%	$ 93,124 - 100.0%	$ 85,837 - 100.0%
Cost of Goods Sold	99,648 - 65.6%	91,964 - 66.0%	69,777 - 65.0%	69,533 - 65.4%	140,208 - 68.1%	127,521 - 68.3%	61,741 - 66.3%	57,082 - 66.5%
Gross Margin	52,255 - 34.4%	47,376 - 34.0%	37,572 - 35.0%	36,787 - 34.6%	65,678 - 31.9%	59,186 - 31.7%	31,383 - 33.7%	28,755 - 33.5%
EXPENSES								
Proprietor's or Manager's Salary	$ 11,241 - 7.4%	$ 10,729 - 7.7%	$ 9,125 - 8.5%	$ 9,250 - 8.7%	$ 11,118 - 5.4%	$ 11,949 - 6.4%	$ 8,567 - 9.2%	$ 7,897 - 9.2%
Employees' Wages	16,709 - 11.0%	14,910 - 10.7%	9,769 - 9.1%	8,612 - 8.1%	24,295 - 11.8%	21,658 - 11.6%	9,126 - 9.8%	7,639 - 8.9%
Rent	4,253 - 2.8%	3,902 - 2.8%	2,899 - 2.7%	2,764 - 2.6%	6,382 - 3.1%	5,975 - 3.2%	2,235 - 2.4%	1,974 - 2.3%
Advertising	1,974 - 1.3%	1,672 - 1.2%	1,288 - 1.2%	1,170 - 1.1%	3,500 - 1.7%	3,174 - 1.7%	838 - 0.9%	687 - 0.8%
Delivery	1,215 - 0.8%	1,115 - 0.8%	752 - 0.7%	638 - 0.6%	1,647 - 0.8%	1,680 - 0.9%	652 - 0.7%	601 - 0.7%
Depreciation on Fixtures and Equipment	1,519 - 1.0%	1,533 - 1.1%	1,181 - 1.1%	1,382 - 1.3%	1,647 - 0.8%	1,867 - 1.0%	1,397 - 1.5%	1,373 - 1.6%
Heat, Light, Power	1,063 - 0.7%	975 - 0.7%	859 - 0.8%	850 - 0.8%	1,647 - 0.8%	1,680 - 0.9%	745 - 0.8%	687 - 0.8%
Taxes	608 - 0.4%	557 - 0.4%	429 - 0.4%	319 - 0.3%	412 - 0.2%	560 - 0.3%	466 - 0.5%	429 - 0.5%
Insurance	608 - 0.4%	557 - 0.4%	429 - 0.4%	425 - 0.4%	412 - 0.2%	374 - 0.2%	373 - 0.4%	429 - 0.5%
Interest	608 - 0.4%	557 - 0.4%	429 - 0.4%	532 - 0.5%	1,235 - 0.6%	1,120 - 0.6%	466 - 0.5%	515 - 0.6%
Repair	456 - 0.3%	557 - 0.4%	429 - 0.4%	425 - 0.4%	824 - 0.4%	747 - 0.4%	279 - 0.3%	515 - 0.6%
Telephone	456 - 0.3%	418 - 0.3%	215 - 0.2%	213 - 0.2%	618 - 0.3%	560 - 0.3%	186 - 0.2%	258 - 0.3%
Bad Debts	304 - 0.2%	279 - 0.2%	107 - 0.1%	213 - 0.2%	206 - 0.1%	187 - 0.1%	93 - 0.1%	86 - 0.1%
Miscellaneous	3,342 - 2.2%	2,787 - 2.0%	2,147 - 2.0%	1,914 - 1.8%	4,735 - 2.3%	3,361 - 1.8%	1,676 - 1.8%	1,545 - 1.8%
Total Expenses	$ 44,356 - 29.2%	$ 40,548 - 29.1%	$ 30,058 - 28.0%	$ 28,707 - 27.0%	$ 58,678 - 28.5%	$ 54,892 - 29.4%	$ 27,099 - 29.1%	$ 24,635 - 28.7%
NET PROFIT	$ 7,899 - 5.2%	$ 6,828 - 4.9%	$ 7,514 - 7.0%	$ 8,080 - 7.6%	$ 7,000 - 3.4%	$ 4,294 - 2.3%	$ 4,284 - 4.6%	$ 4,120 - 4.8%
Add: Other Income	$ 1,061	$ 1,023	$ 518	$ 600	$ 2,094	$ 1,828	$ 1,203	$ 1,391
Proprietor's Salary	$ 11,241	$ 10,729	$ 9,125	$ 9,250	$ 11,118	$ 11,949	$ 8,567	$ 7,897
TOTAL INCOME	$ 20,201 ($18,100)	$ 18,580 ($16,920)	$ 17,157 ($16,251)	$ 17,930 ($17,070)	$ 20,212 ($19,096)	$ 18,071 ($17,348)	$ 14,054 ($14,220)	$ 13,408 ($13,683)
Value of Merchandise Stock	$ 28,956	$ 28,212	$ 24,484	$ 22,908	$ 35,058	$ 38,496	$ 17,847	$ 16,212
Annual Rate of Turnover	3.6	3.4	3.0	3.1	4.0	3.7	3.6	3.6
Average Value of Fixtures	$ 7,785	$ 9,428	$ 7,666	$ 6,020	$ 7,916	$ 11,733	$ 6,864	$ 7,417
Average Accounts Receivable	$ 3,706	$ 3,403	$ 3,128	$ 2,608	$ 3,523	$ 3,160	$ 1,962	$ 2,492
Average Accounts Payable	$ 7,472	$ 6,880	$ 5,257	$ 4,684	$ 8,013	$ 7,548	$ 4,609	$ 4,705
Average Price per Rx	$ 3.34	$ 3.28	$ 3.59	$ 3.47	$ 3.18	$ 3.18	$ 3.37	$ 3.19
Average Number of Rx	12,307	11,246	10,013	10,143	13,033	11,731	8,355	8,197
Average Receipts from Rx	$ 41,150	$ 36,978	$ 36,037	$ 35,277	$ 41,450	$ $ 37,355	$ 28,154	$ 26,167
Ratio of Rx Receipts to Total Receipts	27.1%	25.9%	32.5%	32.4%	20.0%	19.5%	30.7%	29.7%
Cost of Dispensing a Rx	$ 1.33	$ 1.22	$ 1.33	$ 1.27	$ 1.35	$ 1.23	$ 1.29	$ 1.14
Number of hours per week Pharmacy was open	64	67	56	58	63	76	59	58
Number of hours per week Worked by proprietor	47	48	47	50	43	45	50	50

*Includes 1 in Prince Edward Island and 5 in Quebec

Table No. 4 (Cont'd)

297 IDENTICAL CANADIAN PHARMACIES

	NEW BRUNSWICK 13 Pharmacies		NOVA SCOTIA 28 Pharmacies		ONTARIO 86 Pharmacies		SASKATCHEWAN 42 Pharmacies	
	1965	1964	1965	1964	1965	1964	1965	1964
Sales	$148,721 - 100.0%	$134,511 - 100.0%	$151,997 - 100.0%	$148,449 - 100.0%	$150,151 - 100.0%	$139,816 - 100.0%	$118,478 - 100.0%	$105,871 - 100.0%
Cost of Goods Sold	89,530 - 60.2%	81,514 - 60.6%	101,534 - 66.8%	101,984 - 68.7%	96,547 - 64.3%	90,321 - 64.6%	76,774 - 64.8%	69,346 - 65.5%
Gross Margin	59,191 - 39.8%	52,997 - 39.4%	50,463 - 33.2%	46,465 - 31.3%	53,604 - 35.7%	49,495 - 35.4%	41,704 - 35.2%	36,525 - 34.5%
EXPENSES								
Proprietor's or Manager's Salary	$ 11,898 - 8.0%	$ 9,954 - 7.4%	$ 10,032 - 6.6%	$ 10,391 - 7.0%	$ 11,862 - 7.9%	$ 11,185 - 8.0%	$ 10,189 - 8.6%	$ 9,317 - 8.8%
Employees' Wages	17,995 - 12.1%	16,679 - 12.4%	14,591 - 9.6%	13,064 - 8.8%	18,319 - 12.2%	16,918 - 12.1%	11,255 - 9.5%	9,846 - 9.3%
Rent	3,123 - 2.1%	3,228 - 2.4%	4,408 - 2.9%	4,305 - 2.9%	4,354 - 2.9%	4,055 - 2.9%	3,199 - 2.7%	2,753 - 2.6%
Advertising	1,487 - 1.0%	1,345 - 1.0%	1,064 - 0.7%	891 - 0.6%	1,952 - 1.3%	1,818 - 1.3%	1,422 - 1.2%	1,165 - 1.1%
Delivery	2,082 - 1.4%	1,345 - 1.0%	1,064 - 0.7%	594 - 0.4%	1,352 - 0.9%	1,259 - 0.9%	592 - 0.5%	635 - 0.6%
Depreciation on Fixtures and Equipment	1,190 - 0.8%	1,076 - 0.8%	1,368 - 0.9%	1,484 - 1.0%	1,802 - 1.2%	1,678 - 1.2%	1,422 - 1.2%	1,165 - 1.1%
Heat, Light, Power	892 - 0.6%	942 - 0.7%	912 - 0.6%	891 - 0.6%	901 - 0.6%	839 - 0.6%	829 - 0.7%	741 - 0.7%
Taxes	1,041 - 0.7%	807 - 0.6%	912 - 0.6%	891 - 0.6%	601 - 0.4%	559 - 0.4%	711 - 0.6%	529 - 0.5%
Insurance	892 - 0.6%	942 - 0.7%	760 - 0.5%	594 - 0.4%	601 - 0.4%	559 - 0.4%	592 - 0.5%	423 - 0.4%
Interest	149 - 0.1%	134 - 0.1%	608 - 0.4%	594 - 0.4%	450 - 0.3%	419 - 0.3%	356 - 0.3%	423 - 0.4%
Repair	298 - 0.2%	538 - 0.4%	152 - 0.1%	297 - 0.2%	450 - 0.3%	419 - 0.3%	474 - 0.4%	529 - 0.5%
Telephone	446 - 0.3%	404 - 0.3%	304 - 0.2%	445 - 0.3%	450 - 0.3%	419 - 0.3%	237 - 0.2%	212 - 0.2%
Bad Debts	149 - 0.1%	269 - 0.2%	456 - 0.3%	445 - 0.3%	150 - 0.1%	140 - 0.1%	119 - 0.1%	106 - 0.1%
Miscellaneous	3,123 - 2.1%	3,228 - 2.4%	5,928 - 3.9%	5,344 - 3.6%	3,003 - 2.0%	2,657 - 1.9%	2,251 - 1.9%	1,694 - 1.6%
Total Expenses	$ 44,765 - 30.1%	$ 40,891 - 30.4%	$ 42,559 - 28.0%	$ 40,230 - 27.1%	$ 46,247 - 30.8%	$ 42,924 - 30.7%	$ 33,648 - 28.4%	$ 29,538 - 27.9%
NET PROFIT	$ 14,426 - 9.7%	$ 12,106 - 9.0%	$ 7,904 - 5.2%	$ 6,235 - 4.2%	$ 7,357 - 4.9%	$ 6,571 - 4.7%	$ 8,056 - 6.8%	$ 6,987 - 6.6%
Add: Other Income	$ 857	$ 631	$ 1,210	$ 1,146	$ 449	$ 646	$ 772	$ 613
Proprietor's Salary	$ 11,898	$ 9,954	$ 10,032	$ 10,391	$ 11,862	$ 11,185	$ 10,189	$ 9,317
TOTAL INCOME	$ 27,181($24,813)	$ 22,691($20,401)	$ 19,146($17,732)	$ 17,772($16,040)	$ 19,668($18,244)	$ 18,402($17,610)	$ 19,017($17,164)	$ 16,917($15,614)
Value of Merchandise Stock	$ 23,091	$ 28,221	$ 25,832	$ 24,842	$ 30,791	$ 26,816	$ 27,014	$ 25,936
Annual Rate of Turnover	3.7	3.1	3.9	4.1	3.8	3.4	3.0	2.8
Average Value of Fixtures	$ 8,289	$ 17,884	$ 7,536	$ 6,922	$ 8,821	$ 12,381	$ 6,039	$ 5,490
Average Accounts Receivable	$ 3,794	$ 4,209	$ 4,259	$ 3,040	$ 4,762	$ 4,290	$ 2,850	$ 2,794
Average Accounts Payable	$ 6,549	$ 8,399	$ 10,459	$ 9,132	$ 8,278	$ 7,361	$ 5,498	$ 5,201
Average Price per Rx	$ 3.60	$ 3.49	$ 3.22	$ 3.27	$ 3.53	$ 3.47	$ 3.21	$ 3.07
Average Number of Rx	23,348	18,010	12,745	11,593	10,844	9,855	12,950	12,298
Average Receipts from Rx	$ 84,120	$ 62,966	$ 41,117	$ 37,874	$ 38,318	$ 34,247	$ 41,597	$ 37,789
Ratio of Rx Receipts to Total Receipts	52.3%	47.3%	26.4%	24.6%	28.6%	27.1%	35.0%	30.4%
Cost of Dispensing a Rx	$ 1.16	$ 1.29	$ 1.31	$ 1.17	$ 1.42	$ 1.31	$ 1.25	$ 1.12
Number of hours per week Pharmacy was open	76	73	70	72	66	66	60	57
Number of hours per week Worked by proprietor	48	47	45	49	48	49	52	49

Table No. 5

161 IDENTICAL PHARMACIES REPORTING FOR TEN YEARS

	CANADA 161 Pharmacies*		ALBERTA 12 Pharmacies		BRITISH COLUMBIA 62 Pharmacies		MANITOBA 7 Pharmacies	
	1965	1956	1965	1956	1965	1956	1965	1956
Sales	$169,632 - 100.0%	$ 99,244 - 100.0%	$ 94,079 - 100.0%	$ 70,344 - 100.0%	$219,235 - 100.0%	$116,306 - 100.0%	$ 96,724 - 100.0%	$ 55,634 - 100.0%
Cost of Goods Sold	112,805 - 66.5%	67,387 - 67.9%	59,834 - 63.6%	47,553 - 67.6%	151,272 - 69.0%	77,227 - 66.4%	63,257 - 65.4%	37,386 - 67.2%
Gross Margin	56,827 - 33.5%	31,857 - 32.1%	34,245 - 36.4%	22,791 - 32.4%	67,963 - 31.0%	39,079 - 33.6%	33,467 - 34.6%	18,248 - 32.8%
EXPENSES								
Proprietor's or Manager's Salary	$ 11,365 - 6.7%	$ 7,443 - 7.5%	$ 8,844 - 9.4%	$ 7,386 - 10.5%	$ 10,304 - 4.7%	$ 6,281 - 5.4%	$ 9,092 - 9.4%	$ 5,563 - 10.0%
Employees' Wages	19,677 - 11.6%	11,413 - 11.5%	8,938 - 9.5%	5,839 - 8.3%	26,308 - 12.0%	20,237 - 17.4%	9,479 - 9.8%	3,616 - 6.5%
Rent	4,750 - 2.8%	2,481 - 2.5%	2,164 - 2.3%	1,548 - 2.2%	6,796 - 3.1%	3,605 - 3.1%	1,548 - 1.6%	835 - 1.5%
Advertising	2,205 - 1.3%	1,191 - 1.2%	1,129 - 1.2%	563 - 0.8%	3,946 - 1.8%	1,977 - 1.7%	580 - 0.6%	334 - 0.6%
Delivery	1,357 - 0.8%	695 - 0.7%	565 - 0.6%	211 - 0.3%	1,973 - 0.9%	1,047 - 0.9%	387 - 0.4%	223 - 0.4%
Depreciation on Fixtures and Equipment	1,527 - 0.9%	794 - 0.8%	941 - 1.0%	492 - 0.7%	1,535 - 0.7%	814 - 0.7%	1,257 - 1.3%	668 - 1.2%
Heat, Light, Power	1,187 - 0.7%	794 - 0.8%	753 - 0.8%	633 - 0.9%	1,754 - 0.8%	1,163 - 1.0%	677 - 0.7%	278 - 0.5%
Taxes	679 - 0.4%	298 - 0.3%	470 - 0.5%	211 - 0.3%	439 - 0.2%	233 - 0.2%	484 - 0.5%	278 - 0.5%
Insurance	509 - 0.3%	397 - 0.4%	470 - 0.5%	281 - 0.4%	219 - 0.1%	233 - 0.2%	580 - 0.6%	111 - 0.2%
Interest	679 - 0.4%	298 - 0.3%	282 - 0.3%	141 - 0.2%	1,315 - 0.6%	349 - 0.3%	580 - 0.6%	56 - 0.1%
Repair	679 - 0.4%	496 - 0.5%	470 - 0.5%	422 - 0.6%	1,096 - 0.5%	930 - 0.8%	194 - 0.2%	278 - 0.5%
Telephone	339 - 0.2%	198 - 0.2%	188 - 0.2%	141 - 0.2%	439 - 0.2%	233 - 0.2%	290 - 0.3%	167 - 0.3%
Bad Debts	339 - 0.2%	99 - 0.1%	282 - 0.3%	70 - 0.1%	219 - 0.1%	116 - 0.1%	194 - 0.2%	
Miscellaneous	3,902 - 2.3%	1,588 - 1.6%	1,411 - 1.5%	844 - 1.2%	5,043 - 2.3%	698 - 0.6%	1,257 - 1.3%	1,168 - 2.1%
Total Expenses	$ 49,194 - 29.0%	$ 28,185 - 28.4%	$ 26,907 - 28.6%	$ 18,782 - 26.7%	$ 61,386 - 28.0%	$ 37,916 - 32.6%	$ 26,599 - 27.5%	$ 13,575 24.4%
NET PROFIT	$ 7,633 - 4.5%	$ 3,672 - 3.7%	$ 7,338 - 7.8%	$ 4,009 - 5.7%	$ 6,577 - 3.0%	$ 1,163 - 1.0%	$ 6,868 - 7.1%	$ 4,673 - 8.4%
Add: Other Income	$ 1,265	$ 614	$ 138	$ 69	$ 2,362	$ 1,362	$ 818	$ 161
Proprietor's Salary	$ 11,365	$ 7,443	$ 8,844	$ 7,386	$ 10,304	$ 6,281	$ 9,092	$ 5,563
TOTAL INCOME	$ 20,263($18,349)	$ 11,729($10,860)	$ 16,320($15,545)	$ 11,464($10,235)	$ 19,243($19,429)	$ 8,806($ 8,711)	$ 16,778($17,037)	$ 10,397($ 9,571)
Value of Merchandise Stock	$ 31,084	$ 16,793	$ 24,546	$ 16,281	$ 36,560	$ 17,692	$ 19,775	$ 10,745
Annual Rate of Turnover	3.7	4.1	2.5	2.8	4.1	4.5	3.4	3.0
Average Value of Fixtures	$ 8,195	$ 4,785	$ 6,739	$ 4,567	$ 5,935	$ 4,860	$ 4,225	$ 3,488
Average Accounts Receivable	$ 4,022	$ 2,440	$ 3,788	$ 1,954	$ 3,480	$ 2,188	$ 3,078	$ 1,126
Average Accounts Payable	$ 7,965	$ 3,923	$ 4,156	$ 4,018	$ 7,874	$ 1,989	$ 3,268	$ 2,585
Average Price per Rx	$ 3.27	$ 2.64	$ 3.40	$ 2.36	$ 3.15	$ 2.99	$ 3.23	$ 2.22
Average Number of Rx	11,876	7,655	8,574	6,927	12,765	7,610	9,918	6,854
Average Receipts from Rx	$ 38,853	$ 20,198	$ 29,153	$ 16,348	$ 40,312	$ 22,777	$ 32,092	$ 15,248
Ratio of Rx Receipts to Total Receipts	23.2%	23.0%	29.4%	22.8%	18.3%	19.8%	35.3%	23.8%
Cost of Dispensing a Rx	$ 1.33	$	$ 1.25		$ 1.34		$ 1.12	
Number of hours per week Pharmacy was open	70		52		79		50	
Number of hours per week Worked by proprietor	44		48		40		47	

*includes 2 from Quebec

Table No. 5 (Cont'd)

161 IDENTICAL PHARMACIES REPORTING FOR TEN YEARS

	NEW BRUNSWICK 5 Pharmacies		NOVA SCOTIA 16 Pharmacies		ONTARIO 39 Pharmacies		SASKATCHEWAN 18 Pharmacies	
	1965	1956	1965	1956	1965	1956	1965	1956
Sales	$165,691 - 100.0%	$126,670 - 100.0%	$151,096 - 100.0%	$ 73,393 - 100.0%	$165,159 - 100.0%	$120,022 - 100.0%	$113,235 - 100.0%	$ 69,941 - 100.0%
Cost of Goods Sold	106,374 - 64.2%	77,649 - 61.3%	103,954 - 68.8%	52,770 - 71.9%	106,528 - 64.5%	83,175 - 69.3%	71,791 - 63.4%	46,930 - 67.1%
Gross Margin	59,317 - 35.8%	49,021 - 38.7%	47,142 - 31.2%	20,623 - 28.1%	58,631 - 35.5%	36,847 - 30.7%	41,444 - 36.6%	23,011 - 32.9%
EXPENSES								
Proprietor's or Manager's Salary	$ 11,598 - 7.0%	$ 10,133 - 8.0%	$ 9,972 - 6.6%	$ 6,459 - 8.8%	$ 11,892 - 7.2%	$ 8,042 - 6.7%	$ 10,078 - 8.9%	$ 7,414 - 10.6%
Employees' Wages	19,220 - 11.6%	16,087 - 12.7%	13,901 - 9.2%	5,137 - 7.0%	22,131 - 13.4%	12,242 - 10.2%	11,550 - 10.2%	4,826 - 6.9%
Rent	3,645 - 2.2%	2,913 - 2.3%	4,382 - 2.9%	1,982 - 2.7%	4,459 - 2.7%	2,281 - 1.9%	3,284 - 2.9%	1,608 - 2.3%
Advertising	1,657 - 1.0%	1,267 - 1.0%	1,058 - 0.7%	440 - 0.6%	2,147 - 1.3%	1,440 - 1.2%	1,019 - 0.9%	420 - 0.6%
Delivery	994 - 0.6%	760 - 0.6%	1,662 - 1.1%	440 - 0.6%	1,652 - 1.0%	1,080 - 0.9%	453 - 0.4%	210 - 0.3%
Depreciation on Fixtures and Equipment	1,326 - 0.8%	2,153 - 1.7%	907 - 0.6%	514 - 0.7%	1,652 - 1.0%	1,080 - 0.9%	1,472 - 1.3%	699 - 1.0%
Heat, Light, Power	1,326 - 0.8%	1,647 - 1.3%	907 - 0.6%	587 - 0.8%	991 - 0.6%	720 - 0.6%	906 - 0.8%	629 - 0.9%
Taxes	1,160 - 0.7%	887 - 0.7%	604 - 0.4%	294 - 0.4%	661 - 0.4%	360 - 0.3%	679 - 0.6%	350 - 0.5%
Insurance	1,326 - 0.8%	887 - 0.7%	604 - 0.4%	294 - 0.4%	661 - 0.4%	480 - 0.4%	679 - 0.6%	280 - 0.4%
Interest	663 - 0.4%	127 - 0.1%	756 - 0.5%	440 - 0.6%	495 - 0.3%	120 - 0.1%	340 - 0.3%	210 - 0.3%
Repair	828 - 0.5%	760 - 0.6%	151 - 0.1%	73 - 0.1%	495 - 0.3%	360 - 0.3%	453 - 0.4%	280 - 0.4%
Telephone	331 - 0.2%	380 - 0.3%	302 - 0.2%	294 - 0.4%	330 - 0.2%	240 - 0.2%	340 - 0.3%	140 - 0.2%
Bad Debts	663 - 0.4%	127 - 0.1%	302 - 0.2%	73 - 0.1%	330 - 0.2%	240 - 0.2%	113 - 0.1%	70 - 0.1%
Miscellaneous	3,148 - 1.9%	3,040 - 2.4%	8,008 - 5.3%	3,156 - 4.3%	2,973 - 1.8%	1,921 - 1.6%	2,038 - 1.8%	1,049 - 1.5%
Total Expenses	$ 47,885 - 28.8%	$ 41,168 - 32.5%	$ 43,516 - 28.8%	$ 20,183 - 27.5%	$ 50,869 - 30.8%	$ 30,606 - 25.5%	$ 33,404 - 29.5%	$ 18,185 - 26.0%
NET PROFIT	$ 11,432 - 6.9%	$ 7,853 - 6.2%	$ 3,626 - 2.4%	$ 440 - 0.6%	$ 7,762 - 4.7%	$ 6,241 - 5.2%	$ 8,040 - 7.1%	$ 4,826 - 6.9%
Add: Other Income	$ 602 -	$ 382	$ 1,418	$ 449	$ 270	$ 276	$ 720	$ 116
Proprietor's Salary	$ 11,598	$ 10,133	$ 9,972	$ 6,459	$ 11,892	$ 8,042	$ 10,078	$ 7,414
TOTAL INCOME	$ 23,632($23,795)	$ 18,368($14,018)	$ 15,016($15,421)	$ 7,348($ 7,168)	$ 19,924($18,484)	$ 14,559($14,770)	$ 18,838($18,166)	$ 12,356($12,530)
Value of Merchandise Stock	$ 32,328	$ 20,639	$ 24,648	$ 11,446	$ 32,603	$ 19,948	$ 23,683	$ 13,249
Annual Rate of Turnover	3.3	4.0	4.1	4.7	3.6	4.0	3.2	3.5
Average Value of Fixtures	$ 14,075	$ 10,470	$ 6,708	$ 2,751	$ 9,680	$ 5,468	$ 7,348	$ 4,900
Average Accounts Receivable	$ 4,752	$ 2,992	$ 3,910	$ 1,022	$ 6,124	$ 4,600	$ 2,265	$ 1,161
Average Accounts Payable	$ 12,200	$ 7,951	$ 9,824	$ 3,594	$ 10,117	$ 6,487	$ 4,804	$ 3,614
Average Price per Rx	$ 3.49	$ 2.23	$ 3.27	$ 2.27	$ 3.67	$ 2.62	$ 3.22	$ 2.33
Average Number of Rx	14,385	12,340	11,645	6,331	9,967	9,558	13,516	6,426
Average Receipts from Rx	$ 50,240	$ 27,552	$ 38,158	$ 14,373	$ 36,634	$ 25,046	$ 43,543	$ 15,011
Ratio of Rx Receipts to Total Receipts	30.3%	21.7%	24.2%	21.4%	27.5%	22.4%	39.6%	23.6%
Cost of Dispensing a Rx	$ 1.37		$ 1.33		$ 1.51		$ 1.27	
Number of hours per week Pharmacy was open	69		71		65		61	
Number of hours per week Worked by proprietor	46		42		46		52	

Table No. 6

AVERAGE COSTS AND PROFITS OF ALBERTA PHARMACIES IN 1965

	Sales BELOW $40,000 2 Pharmacies	Sales $40,000 to $60,000 11 Pharmacies	Sales $60,000 to $80,000 18 Pharmacies	Sales $80,000 to $100,000 7 Pharmacies	Sales $100,000 to $125,000 16 Pharmacies	Sales $125,000 to $150,000 7 Pharmacies	Sales $150,000 to $200,000 10 Pharmacies	Sales OVER $200,000 2 Pharmacies
Sales	$ 36,506 - 100.0%	$ 48,858 - 100.0%	$ 70,656 - 100.0%	$ 92,129 - 100.0%	$111,474 - 100.0%	$131,517 - 100.0%	$162,961 - 100.0%	$264,809 - 100.0%
Cost of Goods Sold	22,816 - 62.5%	32,833 - 67.2%	46,280 - 65.5%	56,199 - 61.0%	75,579 - 67.8%	88,642 - 67.4%	102,991 - 63.2%	171,861 - 64.9%
Gross Margin	13,690 - 37.5%	16,025 - 32.8%	24,376 - 34.5%	35,930 - 39.0%	35,895 - 32.2%	42,875 - 32.6%	59,970 - 36.8%	92,948 - 35.1%
EXPENSES								
Proprietor's or Manager's Salary	$ 4,782 - 13.1%	$ 5,326 - 10.9%	$ 7,419 - 10.5%	$ 8,476 - 9.2%	$ 6,577 - 5.9%	$ 9,600 - 7.3%	$ 9,778 - 6.0%	$ 19,331 - 7.3%
Employees' Wages	3,906 - 10.7%	2,199 - 4.5%	6,006 - 8.5%	8,199 - 8.9%	10,256 - 9.2%	15,124 - 11.5%	19,555 - 12.0%	14,564 - 5.5%
Rent	3,541 - 9.7%	1,075 - 2.2%	2,049 - 2.9%	3,132 - 3.4%	3,010 - 2.7%	3,682 - 2.8%	5,052 - 3.1%	6,885 - 2.6%
Advertising	767 - 2.1%	586 - 1.2%	989 - 1.4%	1,106 - 1.2%	1,115 - 1.0%	1,184 - 0.9%	1,792 - 1.1%	3,178 - 1.2%
Delivery	36 - 0.1%	195 - 0.4%	353 - 0.5%	553 - 0.6%	558 - 0.5%	526 - 0.4%	815 - 0.5%	2,383 - 0.9%
Depreciation on Fixtures and Equipment	219 - 0.6%	733 - 1.5%	777 - 1.1%	1,474 - 1.6%	1,672 - 1.5%	1,578 - 1.2%	1,629 - 1.0%	1,324 - 0.5%
Heat, Light, Power	292 - 0.8%	538 - 1.1%	494 - 0.7%	737 - 0.8%	892 - 0.8%	921 - 0.7%	978 - 0.6%	1,589 - 0.6%
Taxes	365 - 1.0%	293 - 0.6%	283 - 0.4%	276 - 0.3%	334 - 0.3%	658 - 0.5%	326 - 0.2%	1,059 - 0.4%
Insurance	511 - 1.4%	342 - 0.7%	353 - 0.5%	369 - 0.4%	446 - 0.4%	526 - 0.4%	489 - 0.3%	265 - 0.1%
Interest	548 - 1.5%	244 - 0.5%	424 - 0.6%	369 - 0.4%	780 - 0.7%	658 - 0.5%	163 - 0.1%	265 - 0.1%
Repair	37 - 0.1%	342 - 0.7%	283 - 0.4%	184 - 0.2%	446 - 0.4%	395 - 0.3%	489 - 0.3%	794 - 0.3%
Telephone	146 - 0.4%	195 - 0.4%	283 - 0.4%	276 - 0.3%	334 - 0.3%	263 - 0.2%	489 - 0.3%	265 - 0.1%
Bad Debts		98 - 0.2%	141 - 0.2%	92 - 0.1%	223 - 0.2%	263 - 0.2%	326 - 0.2%	530 - 0.2%
Miscellaneous	949 - 2.6%	1,075 - 2.2%	1,201 - 1.7%	2,488 - 2.7%	1,672 - 1.5%	1,973 - 1.5%	3,585 - 2.2%	7,680 - 2.9%
Total Expenses	$ 16,099 - 44.1%	$ 13,241 - 27.1%	$ 21,055 - 29.8%	$ 27,731 - 30.1%	$ 28,315 - 25.4%	$ 37,351 - 28.4%	$ 45,466 - 27.9%	$ 60,112 - 22.7%
NET PROFIT	$ 2,409 - 6.6%*	$ 2,784 - 5.7%	$ 3,321 - 4.7%	$ 8,199 - 8.9%	$ 7,580 - 6.8%	$ 5,524 - 4.2%	$ 14,504 - 8.9%	$ 32,836 - 12.4%
Add: Other Income	$ 722 -	$ 226	$ 313	$ 140	$ 278	$ 938	$ 531	$ 2,093
Proprietor's Salary	$ 4,782	$ 5,326	$ 7,419	$ 8,476	$ 6,577	$ 9,600	$ 9,778	$ 19,331
TOTAL INCOME	$ 3,095($ 3,059)	$ 8,336($ 8,271)	$ 11,053($10,977)	$ 16,815($16,789)	$ 14,435($14,527)	$ 16,062($16,297)	$ 24,813($24,929)	$ 54,260($44,925)
Value of Merchandise Stock	$ 9,106	$ 13,116	$ 18,025	$ 22,366	$ 27,142	$ 29,227	$ 31,614	$ 34,169
Annual Rate of Turnover	2.6	2.6	2.7	2.6	2.9	2.3	3.5	5.1
Average Value of Fixtures	$ 7,649	$ 4,227	$ 5,505	$ 13,481	$ 8,306	$ 9,200	$ 10,391	$ 4,922
Average Accounts Receivable	$ 859	$ 3,761	$ 4,161	$ 3,491	$ 2,844	$ 2,019	$ 4,203	$ 9,002
Average Accounts Payable	$ 1,760	$ 2,446	$ 4,913	$ 6,516	$ 6,250	$ 6,800	$ 5,992	$ 9,269
Average Price per Rx	$ 3.25	$ 3.13	$ 3.48	$ 3.70	$ 3.41	$ 3.64	$ 3.66	$ 3.72
Average Number of Rx	7,536	5,424	7,575	9,811	7,950	9,792	14,073	16,748
Average Receipts from Rx	$ 24,491	$ 16,999	$ 26,362	$ 36,333	$ 27,122	$ 35,690	$ 51,557	$ 62,331
Ratio of Rx Receipts to Total Receipts	61.3%	34.7%	37.7%	40.1%	24.3%	27.5%	31.4%	23.5%
Cost of Dispensing a Rx	$ 1.74	$ 1.15	$ 1.24	$ 1.37	$ 1.30	$ 1.38	$ 1.41	$ 1.31
Number of hours per week Pharmacy was open	55	54	57	64	66	64	60	74
Number of hours per week Worked by proprietor	50	50	52	50	53	48	49	54

* LOSS

Table No. 7

AVERAGE COSTS AND PROFITS OF BRITISH COLUMBIA PHARMACIES IN 1965

	Sales $40,000 to $60,000 4 Pharmacies	Sales $60,000 to $80,000 7 Pharmacies	Sales $80,000 to $100,000 4 Pharmacies	Sales $100,000 to $125,000 5 Pharmacies	Sales $125,000 to $150,000 10 Pharmacies	Sales $150,000 to $200,000 29 Pharmacies	Sales OVER $200,000 48 Pharmacies
Sales	$ 56,335 - 100.0%	$ 71,144 - 100.0%	$ 95,739 - 100.0%	$110,926 - 100.0%	$135,565 - 100.0%	$190,524 - 100.0%	$242,322 - 100.0%
Cost of Goods Sold	35,547 - 63.1%	44,252 - 62.2%	61,081 - 63.8%	74,875 - 67.5%	90,557 - 66.8%	129,366 - 67.9%	163,567 - 67.5%
Gross Margin	20,788 - 36.9%	26,892 - 37.8%	34,658 - 36.2%	36,051 - 32.5%	45,008 - 33.2%	61,158 - 32.1%	78,755 - 32.5%
EXPENSES							
Proprietor's or Manager's Salary	$ 6,253 - 11.1%	$ 5,692 - 8.0%	$ 7,851 - 8.2%	$ 8,209 - 7.4%	$ 9,625 - 7.1%	$ 10,479 - 5.5%	$ 10,904 - 4.5%
Employees' Wages	5,971 - 10.6%	7,612 - 10.7%	9,287 - 9.7%	12,535 - 11.3%	13,150 - 9.7%	21,910 - 11.5%	32,713 - 13.5%
Rent	1,577 - 2.8%	1,992 - 2.8%	3,064 - 3.2%	2,440 - 2.2%	4,338 - 3.2%	5,525 - 2.9%	7,270 - 3.0%
Advertising	338 - 0.6%	925 - 1.3%	1,628 - 1.7%	1,220 - 1.1%	1,898 - 1.4%	3,048 - 1.6%	4,362 - 1.8%
Delivery	789 - 1.4%	356 - 0.5%	1,053 - 1.1%	555 - 0.5%	949 - 0.7%	1,524 - 0.8%	1,939 - 0.8%
Depreciation on Fixtures and Equipment	1,127 - 2.0%	996 - 1.4%	1,053 - 1.1%	1,442 - 1.3%	1,762 - 1.3%	1,905 - 1.0%	1,696 - 0.7%
Heat, Light, Power	507 - 0.9%	498 - 0.7%	670 - 0.7%	1,220 - 1.1%	1,085 - 0.8%	1,524 - 0.8%	1,939 - 0.8%
Taxes	282 - 0.5%	285 - 0.4%	383 - 0.4%	222 - 0.2%	407 - 0.3%	381 - 0.2%	485 - 0.2%
Insurance	282 - 0.5%	213 - 0.3%	383 - 0.4%	666 - 0.6%	542 - 0.4%	381 - 0.2%	485 - 0.2%
Interest	113 - 0.2%	640 - 0.9%	287 - 0.3%	1,996 - 1.8%	813 - 0.6%	953 - 0.5%	1,212 - 0.5%
Repair	113 - 0.2%	142 - 0.2%	287 - 0.3%	222 - 0.2%	542 - 0.4%	953 - 0.5%	969 - 0.4%
Telephone	507 - 0.9%	356 - 0.5%	191 - 0.2%	444 - 0.4%	678 - 0.5%	381 - 0.2%	727 - 0.3%
Bad Debts	56 - 0.1%	569 - 0.8%	287 - 0.3%	222 - 0.2%	136 - 0.1%	191 - 0.1%	242 - 0.1%
Miscellaneous	1,183 - 2.1%	2,846 - 4.0%	2,394 - 2.5%	2,329 - 2.1%	3,660 - 2.7%	4,763 - 2.5%	5,573 - 2.3%
Total Expenses	$ 19,098 - 33.9%	$ 23,122 - 32.5%	$ 28,818 - 30.1%	$ 33,722 - 30.4%	$ 39,585 - 29.2%	$ 53,918 - 28.3%	$ 70,516 - 29.1%
NET PROFIT	$ 1,690 - 3.0%	$ 3,770 - 5.3%	$ 5,840 - 6.1%	$ 2,329 - 2.1%	$ 5,423 - 4.0%	$ 7,240 - 3.8%	$ 8,239 - 3.4%
Add: Other Income	$ 763	$ 112	$ 326	$ 720	$ 1,532	$ 2,020	$ 2,247
Proprietor's Salary	$ 6,253	$ 5,692	$ 7,851	$ 8,209	$ 9,625	$ 10,479	$ 10,904
TOTAL INCOME	$ 8,706 ($ 8,666)	$ 9,574 ($ 9,487)	$ 14,017 ($14,140)	$ 11,258 (11,424)	$ 16,580 ($16,270)	$ 19,739 ($19,473)	$ 21,390 ($21,148)
Value of Merchandise Stock	$ 12,334	$ 19,905	$ 14,755	$ 26,012	$ 26,072	$ 34,051	$ 41,205
Annual Rate of Turnover	3.5	2.3	4.2	3.0	3.6	3.8	4.0
Average Value of Fixtures	$ 4,082	$ 4,784	$ 1,995	$ 3,841	$ 10,392	$ 8,381	$ 12,633
Average Accounts Receivable	$ 2,835	$ 5,538	$ 1,966	$ 2,233	$ 3,414	$ 3,176	$ 5,205
Average Accounts Payable	$ 2,131	$ 9,640	$ 2,926	$ 7,409	$ 6,569	$ 7,799	$ 11,374
Average Price per Rx	$ 3.39	$ 3.33	$ 3.06	$ 3.30	$ 3.40	$ 2.99	$ 3.24
Average Number of Rx	7,492	9,408	10,514	8,305	8,017	14,218	15,933
Average Receipts from Rx	$ 25,400	$ 31,335	$ 32,204	$ 27,461	$ 27,422	$ 42,569	$ 51,658
Ratio of Rx Receipts to Total Receipts	45.1%	45.0%	33.9%	24.7%	20.1%	21.9%	20.5%
Cost of Dispensing a Rx	$ 1.36	$ 1.35	$ 1.24	$ 1.37	$ 1.33	$ 1.35	$ 1.39
Number of hours per week Pharmacy was open	56	57	74	72	65	76	76
Number of hours per week Worked by proprietor	46	48	46	60	45	42	41

Two reports with sales below $40,000 withheld to avoid disclosing individual operations

Table No. 8

AVERAGE COSTS AND PROFITS OF MANITOBA PHARMACIES IN 1965

	Sales $40,000 to $60,000 6 Pharmacies	Sales $60,000 to $80,000 8 Pharmacies	Sales $80,000 to $100,00 7 Pharmacies	Sales $100,000 to $125,000 7 Pharmacies	Sales $125,000 to $150,000 3 Pharmacies	Sales OVER $150,000 6 Pharmacies
Sales	$ 49,432 - 100.0%	$ 69,405 - 100.0%	$ 91,150 - 100.0%	$113,566 - 100.0%	$135,432 - 100.0%	$185,120 - 100.0%
Cost of Goods Sold	31,389 - 63.5%	45,599 - 65.7%	60,979 - 66.9%	73,931 - 65.1%	93,990 - 69.4%	120,328 - 65.0%
Gross Margin	18,043 - 36.5%	23,806 - 34.3%	30,171 - 33.1%	39,635 - 34.9%	41,442 - 30.6%	64,792 - 35.0%
EXPENSES						
Proprietor's or Manager's Salary	$ 5,240 - 10.6%	$ 6,455 - 9.3%	$ 7,383 - 8.1%	$ 11,470 - 10.1%	$ 8,939 - 6.6%	$ 10,367 - 5.6%
Employees' Wages	4,101 - 8.3%	6,385 - 9.2%	9,206 - 10.1%	13,060 - 11.5%	9,887 - 7.3%	24,991 - 13.5%
Rent	1,384 - 2.8%	1,874 - 2.7%	2,097 - 2.3%	2,158 - 1.9%	2,302 - 1.7%	3,702 - 2.0%
Advertising	495 - 1.0%	624 - 0.9%	456 - 0.5%	1,022 - 0.9%	677 - 0.5%	1,851 - 1.0%
Delivery	692 - 1.4%	347 - 0.5%	638 - 0.7%	795 - 0.7%	2,438 - 1.8%	2,036 - 1.1%
Depreciation on Fixtures and Equipment	1,088 - 2.2%	1,110 - 1.6%	1,185 - 1.3%	1,476 - 1.3%	813 - 0.6%	2,036 - 1.1%
Heat, Light, Power	395 - 0.8%	763 - 1.1%	729 - 0.8%	568 - 0.5%	677 - 0.5%	926 - 0.5%
Taxes	395 - 0.8%	486 - 0.7%	456 - 0.5%	341 - 0.3%	406 - 0.3%	741 - 0.4%
Insurance	445 - 0.9%	278 - 0.4%	274 - 0.3%	341 - 0.3%	542 - 0.4%	555 - 0.3%
Interest	544 - 1.1%	625 - 0.9%	365 - 0.4%	454 - 0.4%	1,355 - 1.0%	185 - 0.1%
Repair	346 - 0.7%	278 - 0.4%	182 - 0.2%	341 - 0.3%	135 - 0.1%	741 - 0.4%
Telephone	149 - 0.3%	208 - 0.3%	182 - 0.2%	227 - 0.2%	135 - 0.1%	185 - 0.1%
Bad Debts	149 - 0.3%		91 - 0.1%	114 - 0.1%	135 - 0.1%	741 - 0.4%
Miscellaneous	445 - 0.9%	972 - 1.4%	2,005 - 2.2%	1,703 - 1.5%	2,844 - 2.1%	4,258 - 2.3%
Total Expenses	$ 15,868 - 32.1%	$ 20,405 - 29.4%	$ 25,249 - 27.7%	$ 34,070 - 30.0%	$ 31,285 - 23.1%	$ 53,315 - 28.8%
NET PROFIT	$ 2,175 - 4.4%	$ 3,401 - 4.9%	$ 4,922 - 5.4%	$ 5,565 - 4.9%	$ 10,157 - 7.5%	$ 11,477 - 6.2%
Add: Other Income	$ 1,384	$ 231	$ 2,076	$ 868	$ 998	$ 247
Proprietor's Salary	$ 5,240	$ 6,455	$ 7,383	$ 11,470	$ 8,939	$ 10,367
TOTAL INCOME	$ 8,799($ 9,018)	$ 10,087($ 9,937)	$ 14,381($14,160)	$ 17,903($17,908)	$ 20,094($20,166)	$ 22,091($21,949)
Value of Merchandise Stock	$ 12,374	$ 14,727	$ 13,689	$ 18,889	$ 22,857	$ 31,568
Annual Rate of Turnover	2.8	3.3	3.3	4.2	4.2	4.1
Average Value of Fixtures	$ 3,036	$ 7,161	$ 8,827	$ 6,854	$ 7,064	$ 10,000
Average Accounts Receivable	$ 1,303	$ 1,292	$ 1,683	$ 2,316	$ 1,829	$ 6,037
Average Accounts Payable	$ 2,510	$ 3,223	$ 3,298	$ 7,419	$ 2,624	$ 9,424
Average Price per Rx	$ 3.11	$ 3.23	$ 3.31	$ 3.45	$ 3.50	$ 3.33
Average Number of Rx	7,499	6,148	7,643	9,446	8,051	19,607
Average Receipts from Rx	$ 23,381	$ 19,902	$ 25,325	$ 37,679	$ 28,161	$ 65,255
Ratio of Rx Receipts to Total Receipts	48.8%	29.3%	27.8%	33.5%	20.6%	35.3%
Cost of Dispensing a Rx	$ 1.20	$ 1.30	$ 1.25	$ 1.28	$ 1.34	$ 1.36
Number of hours per week Pharmacy was open	50	67	62	58	59	66
Number of hours per week Worked by proprietor	41	58	42	50	49	46

One report with sales below $40,000 withheld to avoid disclosing individual operation

Table No. 9

AVERAGE COSTS AND PROFITS OF NEW BRUNSWICK PHARMACIES IN 1965

	Sales $40,000 to $60,000 2 Pharmacies		Sales $60,000 to $80,000 4 Pharmacies		Sales $80,000 to $100,000 7 Pharmacies		Sales $100,000 to $125,000 5 Pharmacies		Sales OVER $200,000 9 Pharmacies	
Sales	$ 48,449 -	100.0%	$ 73,397 -	100.0%	$ 87,397 -	100.0%	$106,981 -	100.0%	$256,888 -	100.0%
Cost of Goods Sold	27,228 -	56.2%	47,708 -	65.0%	55,847 -	63.9%	68,254 -	63.8%	154,647 -	60.2%
Gross Margin	21,221 -	43.8%	25,689 -	35.0%	31,550 -	36.1%	38,727 -	36.2%	102,241 -	39.8%
EXPENSES										
Proprietor's or Manager's Salary	$ 5,281 -	10.9%	$ 7,413 -	10.1%	$ 9,438 -	10.8%	$ 7,809 -	7.3%	$ 13,872 -	5.4%
Employees' Wages	3,779 -	7.8%	5,652 -	7.7%	10,051 -	11.5%	11,554 -	10.8%	34,680 -	13.5%
Rent	630 -	1.3%	2,129 -	2.9%	2,360 -	2.7%	1,284 -	1.2%	6,165 -	2.4%
Advertising	194 -	0.4%	440 -	0.6%	961 -	1.1%	535 -	0.5%	4,367 -	1.7%
Delivery	1,114 -	2.3%	440 -	0.6%	524 -	0.6%	214 -	0.2%	4,110 -	1.6%
Depreciation on Fixtures and Equipment	339 -	0.7%	1,028 -	1.4%	787 -	0.9%	428 -	0.4%	2,826 -	1.1%
Heat, Light, Power	388 -	0.8%	440 -	0.6%	612 -	0.7%	321 -	0.3%	1,028 -	0.4%
Taxes	775 -	1.6%	440 -	0.6%	612 -	0.7%	642 -	0.6%	1,284 -	0.5%
Insurance	436 -	0.9%	367 -	0.5%	524 -	0.6%	642 -	0.6%	1,284 -	0.5%
Interest			147 -	0.2%	175 -	0.2%			1,798 -	0.7%
Repair	339 -	0.7%	147 -	0.2%	350 -	0.4%	642 -	0.6%	771 -	0.3%
Telephone	194 -	0.4%	220 -	0.3%	350 -	0.4%	214 -	0.2%	1,028 -	0.4%
Bad Debts	97 -	0.2%	147 -	0.2%	262 -	0.3%	107 -	0.1%	514 -	0.2%
Miscellaneous	630 -	1.3%	1,248 -	1.7%	1,136 -	1.3%	2,567 -	2.4%	6,422 -	2.5%
Total Expenses	$ 14,196 -	29.3%	$ 20,258 -	27.6%	$ 28,142 -	32.2%	$ 26,959 -	25.2%	$ 80,149 -	31.2%
NET PROFIT	$ 7,025 -	14.5%	$ 5,431 -	7.4%	$ 3,408 -	3.9%	$ 11,768 -	11.0%	$ 22,092 -	8.6%
Add: Other Income			$ 442		$ 353				$ 1,178	
Proprietor's Salary	$ 5,281		$ 7,413		$ 9,438		$ 7,809		$ 13,872	
TOTAL INCOME	$ 12,306($12,576)		$ 13,286($13,344)		$ 13,199($13,461)		$ 19,577($19,570)		$ 37,142($35,541)	
Value of Merchandise Stock	$ 12,477		$ 14,850		$ 20,375		$ 17,774		$ 42,919	
Annual Rate of Turnover	2.4		3.7		2.9		4.1		3.5	
Average Value of Fixtures	$ 3,000		$ 4,712		$ 5,355				$ 19,037	
Average Accounts Receivable	$ 1,275		$ 1,700		$ 2,412		$ 2,271		$ 8,532	
Average Accounts Payable	$ 2,375		$ 7,903		$ 5,402		$ 1,873		$ 17,895	
Average Price per Rx	$ 3.45		$ 3.76		$ 3.47		$ 3.29		$ 3.70	
Average Number of Rx	6,935		10,922		11,088		13,499		31,597	
Average Receipts from Rx	$ 23,902		$ 41,076		$ 38,555		$ 44,449		$116,895	
Ratio of Rx Receipts to Total Receipts	49.3%		55.9%		44.4%		42.3%		44.8%	
Cost of Dispensing a Rx	$ 1.28		$ 1.35		$ 1.33		$ 1.23		$ 1.55	
Number of hours per week Pharmacy was open	69		69		76		76		72	
Number of hours per week Worked by proprietor	50		46		53		62		48	

One report with sales between $150,000 and $200,000 withheld to avoid disclosing individual operation

How to Use the Survey

In three or four different ways you can analyze your pharmacy by comparing it with others in similar situations. You can compare your operation with the average of those in your province with similar sales volume by turning to your provincial Table. There are separate tables, No's 6 through 12, for each province except Newfoundland, Quebec and Prince Edward Island. If you wish to compare your pharmacy with others in a population centre similar to yours there is a table for seven different sales categories with six different population sizes. These however include all pharmacies reporting regardless of provincial location. The last column of each of these tables permits you to broadly compare your pharmacy with all of a similar sales volume regardless of location. Finally, you can compare your pharmacy with others of similar sales volume and dispensing approximately the same number of prescriptions daily as your own. Again the columns represent pharmacies from all over Canada, not just your own province.

Profits and Losses

Table No. 31 gives the "Geographical Distribution of Profits and Losses" and Table No. 32 gives the distribution by sales categories. In both tables profit is considered to be what remains after all operating expenses. including a standard proprietor's salary as set forth in Table No. 3, have been met. (For sales volume over $200,000, add $50 to proprietor's salary of $10,400 for each additional $1,000 sales above $200,000). Losses are those in which total income did not equal the standard proprietor's compensation for the sales category as set forth in Table No. 3. In all other tables net profit ratios are the averages of the net profit reported by the pharmacists themselves with no reference to standard proprietor's salary.

Remarkably, the ratio of pharmacies operating at a loss to the total number reporting is exactly the same as in 1964, namely 10.1%. However, approximately 5% more pharmacies reported net profit over 10% of sales than in 1964. Since 347 of the reporting pharmacies are limited companies it must not be assumed that total income accrued to one person. Only if one person owns all the assets would this be so.

Table No. 1 is a MODEL giving broad useful working ratios but it should NOT be designated as "the average Canadian Pharmacy" since only 220 or 36.9% of the 595 pharmacies reported sales of $138,471 or over, and only 187 or 31.4% earned total income of $19,362 or over.

Bracketed Figures

In the various tables the statistical total income is given as the sum of the net profit, other income and proprietor's salary. Other income is usually from sub-post offices, and telephone pay stations. The bracketed figure following is the average of the actual reported total income dollars of all the pharmacies in the group. If most of the components of a group are in narrow sales volume the bracketed and unbracketed figures are usually very close but if there is a wide difference in sales volume among the components.

Table No. 10

AVERAGE COSTS AND PROFITS OF NOVA SCOTIA PHARMACIES IN 1965

	Sales $40,000 to $60,000 2 Pharmacies	Sales $60,000 to $80,000 2 Pharmacies	Sales $80,000 to $100,000 4 Pharmacies	Sales $100,000 to $125,000 21 Pharmacies	Sales $125,000 to $150,000 2 Pharmacies	Sales $150,000 to $200,000 7 Pharmacies	Sales OVER $200,000 7 Pharmacies
Sales	$ 54,096 - 100.0%	$ 72,266 - 100.0%	$ 88,508 - 100.0%	$119,450 - 100.0%	$131,024 - 100.0%	$176,096 - 100.0%	$285,926 - 100.0%
Cost of Goods Sold	33,810 - 62.5%	52,104 - 72.1%	59,831 - 67.6%	77,165 - 64.6%	87,000 - 66.4%	118,337 - 67.2%	212,729 - 74.4%
Gross Margin	20,286 - 37.5%	20,162 - 27.9%	28,677 - 32.4%	42,285 - 35.4%	44,024 - 33.6%	57,759 - 32.8%	73,197 - 25.6%
EXPENSES							
Proprietor's or Manager's Salary	$ 5,301 - 9.8%	$ 5,998 - 8.3%	$ 7,877 - 8.9%	$ 8,600 - 7.2%	$ 8,779 - 6.7%	$ 9,509 - 5.4%	$ 13,439 - 4.7%
Employees' Wages	7,141 - 13.2%	7,877 - 10.9%	8,320 - 9.4%	11,945 - 10.0%	17,426 - 13.3%	17,786 - 10.1%	21,444 - 7.5%
Rent	812 - 1.5%	1,084 - 1.5%	2,213 - 2.5%	2,867 - 2.4%	4,324 - 3.3%	4,050 - 2.3%	9,435 - 3.3%
Advertising	433 - 0.8%	361 - 0.5%	619 - 0.7%	836 - 0.7%	786 - 0.6%	2,289 - 1.3%	1,715 - 0.6%
Delivery	162 - 0.3%	578 - 0.8%	443 - 0.5%	1,075 - 0.9%	524 - 0.4%	704 - 0.4%	858 - 0.3%
Depreciation on Fixtures and Equipment	108 - 0.2%	1,662 - 2.3%	1,593 - 1.8%	956 - 0.8%	786 - 0.6%	2,290 - 1.3%	2,573 - 0.9%
Heat, Light, Power	108 - 0.2%	650 - 0.9%	620 - 0.7%	597 - 0.5%	1,048 - 0.8%	1,057 - 0.6%	1,430 - 0.5%
Taxes	325 - 0.6%	72 - 0.1%	531 - 0.6%	597 - 0.5%	786 - 0.6%	1,057 - 0.6%	1,430 - 0.5%
Insurance	325 - 0.6%	578 - 0.8%	531 - 0.6%	597 - 0.5%	131 - 0.1%	704 - 0.4%	858 - 0.3%
Interest	54 - 0.1%	361 - 0.5%	620 - 0.7%	478 - 0.4%	131 - 0.1%	704 - 0.4%	286 - 0.1%
Repair	54 - 0.1%	434 - 0.6%	177 - 0.2%	119 - 0.1%		352 - 0.2%	858 - 0.3%
Telephone	162 - 0.3%	145 - 0.2%	177 - 0.2%	239 - 0.2%	393 - 0.3%	528 - 0.3%	572 - 0.2%
Bad Debts	54 - 0.1%	145 - 0.2%	88 - 0.1%	478 - 0.4%	262 - 0.2%	528 - 0.3%	572 - 0.2%
Miscellaneous	757 - 1.4%	1,228 - 1.7%	1,239 - 1.4%	5,734 - 4.8%	2,621 - 2.0%	3,698 - 2.1%	3,717 - 1.3%
Total Expenses	$ 15,796 - 29.2%	$ 21,173 - 29.3%	$ 25,048 - 28.3%	$ 35,118 - 29.4%	$ 37,997 - 29.0%	$ 45,256 - 25.7%	$ 59,187 - 20.7%
NET PROFIT	$ 4,490 - 8.3%	$ 1,011 - 1.4%*	$ 3,629 - 4.1%	$ 7,167 - 6.0%	$ 6,027 - 4.6%	$ 12,503 - 7.1%	$ 14,010 - 4.9%
Add: Other Income	$ 348	$ 76	$ 313	$ 380	$ 3,095	$ 445	$ 3,294
Proprietor's Salary	$ 5,301	$ 5,998	$ 7,877	$ 8,600	$ 8,779	$ 9,509	$ 13,439
TOTAL INCOME	$ 10,139($10,436)	$ 5,063($ 5,066)	$ 11,819($11,732)	$ 16,147($16,080)	$ 17,901($17,856)	$ 22,457($22,947)	$ 30,743($29, 160)
Value of Merchandise Stock	$ 12,002	$ 14,280	$ 18,288	$ 21,435	$ 22,965	$ 29,984	$ 42,359
Annual Rate of Turnover	3.1	3.6	3.4	3.7	3.8	4.0	5.1
Average Value of Fixtures	$ 1,500	$ 7,500	$ 4,151	$ 4,503	$ 2,210	$ 11,463	$ 10,649
Average Accounts Receivable	$ 2,353	$ 725	$ 3,567	$ 3,805	$ 4,242	$ 5,107	$ 6,469
Average Accounts Payable	$ 2,089	$ 5,216	$ 6,136	$ 6,425	$ 11,230	$ 12,891	$ 25,008
Average Price per Rx	$ 2.49	$ 2.80	$ 3.39	$ 3.13	$ 3.12	$ 2.51	$ 3.27
Average Number of Rx	9,098	5,968	7,745	13,494	14,205	20,048	11,856
Average Receipts from Rx	$ 22,644	$ 16,701	$ 26,295	$ 42,218	$ 44,369	$ 50,443	$ 38,826
Ratio of Rx Receipts to Total Receipts	46.1%	23.6%	29.3%	34.9%	33.8%	28.7%	13.5%
Cost of Dispensing a Rx	$ 1.11	$ 1.19	$ 1.24	$ 1.34	$ 1.33	$ 1.18	$ 1.00
Number of hours per week Pharmacy was open	40	73	59	69	71	75	74
Number of hours per week Worked by proprietor	40	35	58	44	48	47	44

* Loss

Table No. 11

AVERAGE COSTS AND PROFITS OF ONTARIO PHARMACIES IN 1965

	Sales BELOW $40,000 5 Pharmacies	Sales $40,000 to $60,000 14 Pharmacies	Sales $60,000 to $80,000 30 Pharmacies	Sales $80,000 $100,000 35 Pharmacies	Sales $100,000 to $125,000 24 Pharmacies	Sales $125,000 $150,000 26 Pharmacies	Sales $150,000 to $200,000 29 Pharmacies	Sales OVER $200,000 28 Pharmacies
Sales	$ 33,846 - 100.0%	$ 53,713 - 100.0%	$ 71,460 - 100.0%	$ 89,175 - 100.0%	$109,941 - 100.0%	$138,772 - 100.0%	$173,952 - 100.0%	$295,092 - 100.0%
Cost of Goods Sold	21,831 - 64.5%	35,343 - 65.8%	46,163 - 64.6%	58,231 - 65.3%	72,561 - 66.0%	88,259 - 63.6%	114,982 - 66.1%	190,039 - 64.4%
Gross Margin	12,015 - 35.5%	18,370 - 34.2%	25,297 - 35.4%	30,944 - 34.7%	37,380 - 34.0%	50,513 - 36.4%	58,970 - 33.9%	105,053 - 35.6%
EXPENSES								
Proprietor's or Manager's Salary	$ 5,686 - 16.8%	$ 6,016 - 11.2%	$ 7,861 - 11.0%	$ 7,669 - 8.6%	$ 9,565 - 8.7%	$ 10,547 - 7.6%	$ 9,045 - 5.2%	$ 14,460 - 4.9%
Employees' Wages	1,117 - 3.3%	3,330 - 6.2%	6,717 - 9.4%	9,898 - 11.1%	12,643 - 11.5%	16,514 - 11.9%	21,570 - 12.4%	43,083 - 14.6%
Rent	982 - 2.9%	1,343 - 2.5%	1,786 - 2.5%	2,318 - 2.6%	2,748 - 2.5%	4,024 - 2.9%	4,697 - 2.7%	9,443 - 3.2%
Advertising	305 - 0.9%	752 - 1.4%	929 - 1.3%	892 - 1.0%	1,209 - 1.1%	1,249 - 0.9%	2,261 - 1.3%	4,131 - 1.4%
Delivery	135 - 0.4%	215 - 0.4%	786 - 1.1%	981 - 1.1%	879 - 0.8%	1,110 - 0.8%	1,218 - 0.7%	2,656 - 0.9%
Depreciation on Fixtures and Equipment	948 - 2.8%	591 - 1.1%	786 - 1.1%	1,070 - 1.2%	1,429 - 1.3%	1,804 - 1.3%	1,913 - 1.1%	2,656 - 0.9%
Heat, Light, Power	440 - 1.3%	430 - 0.8%	500 - 0.7%	535 - 0.6%	550 - 0.5%	694 - 0.5%	696 - 0.4%	1,181 - 0.4%
Taxes	135 - 0.4%	268 - 0.5%	286 - 0.4%	268 - 0.3%	440 - 0.4%	416 - 0.3%	696 - 0.4%	885 - 0.3%
Insurance	203 - 0.6%	322 - 0.6%	286 - 0.4%	357 - 0.4%	440 - 0.4%	555 - 0.4%	696 - 0.4%	1,181 - 0.4%
Interest	135 - 0.4%	161 - 0.3%	215 - 0.3%	267 - 0.3%	440 - 0.4%	555 - 0.4%	348 - 0.2%	590 - 0.2%
Repair	169 - 0.5%	161 - 0.3%	215 - 0.3%	357 - 0.4%	330 - 0.3%	416 - 0.3%	522 - 0.3%	885 - 0.3%
Telephone	102 - 0.3%	107 - 0.2%	357 - 0.5%	268 - 0.3%	330 - 0.3%	278 - 0.2%	522 - 0.3%	590 - 0.2%
Bad Debts		54 - 0.1%	71 - 0.1%	89 - 0.1%	110 - 0.1%	139 - 0.1%	174 - 0.1%	590 - 0.2%
Miscellaneous	440 - 1.3%	806 - 1.5%	1,358 - 1.9%	1,605 - 1.8%	2,309 - 2.1%	3,053 - 2.2%	3,131 - 1.8%	5,607 - 1.9%
Total Expenses	$ 10,797 - 31.9%	$ 14,556 - 27.1%	$ 22,153 - 31.0%	$ 26,574 - 29.8%	$ 33,422 - 30.4%	$ 41,354 - 29.8%	$ 47,489 - 27.3%	$ 87,938 - 29.8%
NET PROFIT	$ 1,218 - 3.6%	$ 3,814 - 7.1%	$ 3,144 - 4.4%	$ 4,370 - 4.9%	$ 3,958 - 3.6%	$ 9,159 - 6.6%	$ 11,481 - 6.6%	$ 17,115 - 5.8%
Add: Other Income	$ 204	$ 316	$ 390	$ 174	$ 364	$ 437	$ 618	$ 1,055
Proprietor's Salary	$ 5,686	$ 6,016	$ 7,861	$ 7,669	$ 9,565	$ 10,547	$ 9,045	$ 14,460
TOTAL INCOME	$ 7,108($ 7,037)	$ 10,146($10,219)	$ 11,395($11,426)	$ 12,213($12,394)	$ 13,887($13,779)	$ 20,143($20,028)	$ 21,144($20,743)	$ 32,630($32,022)
Value of Merchandise Stock	$ 11,019	$ 13,735	$ 15,991	$ 19,197	$ 21,424	$ 25,013	$ 31,643	$ 51,412
Annual Rate of Turnover	2.8	2.7	3.1	3.2	3.6	3.8	4.1	4.2
Average Value of Fixtures	$ 3,000	$ 2,543	$ 4,149	$ 5,345	$ 6,064	$ 8,819	$ 11,077	$ 15,512
Average Accounts Receivable	$ 290	$ 779	$ 1,342	$ 1,428	$ 1,638	$ 3,139	$ 4,477	$ 10,475
Average Accounts Payable	$ 1,730	$ 2,221	$ 4,338	$ 5,359	$ 6,130	$ 7,714	$ 8,902	$ 17,414
Average Price per Rx	$ 3.78	$ 3.50	$ 3.38	$ 3.39	$ 3.63	$ 3.66	$ 3.30	$ 3.58
Average Number of Rx	616	4,488	7,597	6,792	8,279	11,447	16,687	16,195
Average Receipts from Rx	$ 2,327	$ 15,691	$ 25,696	$ 23,058	$ 30,084	$ 41,934	$ 55,202	$ 58,011
Ratio of Rx Receipts to Total Receipts	6.2%	28.3%	36.1%	26.0%	27.2%	30.4%	31.8%	22.0%
Cost of Dispensing a Rx	$ 1.24	$ 1.23	$ 1.32	$ 1.33	$ 1.39	$ 1.43	$ 1.35	$ 1.43
Number of hours per week Pharmacy was open	60	56	60	67	67	68	67	75
Number of hours per week Worked by proprietor	58	52	51	49	49	50	49	48

Table No. 12

AVERAGE COSTS AND PROFITS OF SASKATCHEWAN PHARMACIES IN 1965

	Sales BELOW $40,000 4 Pharmacies	Sales $40,000 to $60,000 11 Pharmacies	Sales $60,000 to $80,000 14 Pharmacies	Sales $80,000 to $100,000 13 Pharmacies	Sales $100,000 to $125,000 16 Pharmacies	Sales $125,000 to $150,000 8 Pharmacies	Sales $150,000 $200,00 13 Pharmacies	Sales OVER $200,000 8 Pharmacies
Sales	$ 30,083 - 100.0%	$ 52,662 - 100.0%	$ 72,086 - 100.0%	$ 87,921 - 100.0%	$109,792 - 100.0%	$139,146 - 100.0%	$167,477 - 100.0%	$260,815 - 100.0%
Cost of Goods Sold	20,035 - 66.6%	33,809 - 64.2%	47,577 - 66.0%	57,940 - 65.9%	68,840 - 62.7%	87,801 - 63.1%	107,520 - 64.2%	172,399 - 66.1%
Gross Margin	10,048 - 33.4%	18,853 - 35.8%	24,509 - 34.0%	29,981 - 34.1%	40,952 - 37.3%	51,345 - 36.9%	59,957 - 35.8%	88,416 - 33.9%
EXPENSES								
Proprietor's or Manager's Salary	$ 3,941 - 13.1%	$ 5,898 - 11.2%	$ 8,074 - 11.2%	$ 7,649 - 8.7%	$ 9,003 - 8.2%	$ 10,436 - 7.5%	$ 10,216 - 6.1%	$ 14,084 - 5.4%
Employees' Wages	1,384 - 4.6%	2,370 - 4.5%	4,397 - 6.1%	7,649 - 8.7%	10,760 - 9.8%	15,584 - 11.2%	22,107 - 13.2%	37,818 - 14.5%
Rent	1,143 - 3.8%	843 - 1.6%	1,802 - 2.5%	2,198 - 2.5%	3,513 - 3.2%	4,592 - 3.3%	6,029 - 3.6%	8,346 - 3.2%
Advertising	181 - 0.6%	474 - 0.9%	793 - 1.1%	967 - 1.1%	1,537 - 1.4%	1,670 - 1.2%	2,345 - 1.4%	3,390 - 1.3%
Delivery	151 - 0.5%	316 - 0.6%	433 - 0.6%	440 - 0.5%	659 - 0.6%	835 - 0.6%	670 - 0.4%	2,087 - 0.8%
Depreciation on Fixtures and Equipment	331 - 1.1%	1,053 - 2.0%	793 - 1.1%	1,143 - 1.3%	1,537 - 1.4%	1,391 - 1.0%	1,172 - 0.7%	2,087 - 0.8%
Heat, Light, Power	271 - 0.9%	579 - 1.1%	433 - 0.6%	615 - 0.7%	768 - 0.7%	974 - 0.7%	1,172 - 0.7%	1,304 - 0.5%
Taxes	241 - 0.8%	421 - 0.8%	361 - 0.5%	527 - 0.6%	549 - 0.5%	974 - 0.7%	837 - 0.5%	782 - 0.3%
Insurance	120 - 0.4%	316 - 0.6%	288 - 0.4%	440 - 0.5%	659 - 0.6%	557 - 0.4%	670 - 0.4%	782 - 0.3%
Interest	120 - 0.4%	105 - 0.2%	144 - 0.2%	352 - 0.4%	659 - 0.6%	1,391 - 1.0%	1,842 - 1.1%	2,608 - 1.0%
Repair	60 - 0.2%	421 - 0.8%	216 - 0.3%	264 - 0.3%	439 - 0.4%	418 - 0.3%	670 - 0.4%	1,043 - 0.4%
Telephone	120 - 0.4%	158 - 0.3%	144 - 0.2%	176 - 0.2%	329 - 0.3%	278 - 0.2%	335 - 0.2%	522 - 0.2%
Bad Debts	30 - 0.1%	53 - 0.1%	72 - 0.1%	88 - 0.1%	110 - 0.1%	418 - 0.3%	167 - 0.1%	261 - 0.1%
Miscellaneous	481 - 1.6%	1,159 - 2.2%	1,081 - 1.5%	1,143 - 1.3%	2,196 - 2.0%	2,922 - 2.1%	3,351 - 2.0%	5,999 - 2.3%
Total Expenses	$ 8,574 - 28.5%	$ 14,166 - 26.9%	$ 19,031 - 26.4%	$ 23,651 - 26.9%	$ 32,718 - 29.8%	$ 42,440 - 30.5%	$ 51,583 - 30.8%	$ 81,113 - 31.1%
NET PROFIT	$ 1,474 - 4.9%	$ 4,687 - 8.9%	$ 5,478 - 7.6%	$ 6,330 - 7.2%	$ 8,234 - 7.5%	$ 8,905 - 6.4%	$ 8,374 - 5.0%	$ 7,303 - 2.8%
Add: Other Income	$ 376	$	$ 210	$ 322	$ 231	$ 849	$ 1,149	$ 2,814
Proprietor's Salary	$ 3,941	$ 5,898	$ 8,074	$ 7,649	$ 9,003	$ 10,436	$ 10,216	$ 14,084
TOTAL INCOME	$ 5,791($ 5,818)	$ 10,585($10,502)	$ 13,762($13,239)	$ 14,301($14,328)	$ 17,468($17,550)	$ 20,190($20,276)	$ 19,739($20,294)	$ 24,201($23,864)
Value of Merchandise Stock	$ 8,452	$ 12,986	$ 16,597	$ 24,008	$ 29,727	$ 28,272	$ 33,376	$ 39,939
Annual Rate of Turnover	3.1	2.8	3.1	2.6	2.8	3.3	3.5	4.3
Average Value of Fixtures	$ 2,514	$ 2,275	$ 3,364	$ 4,507	$ 7,769	$ 8,195	$ 9,477	$ 15,665
Average Accounts Receivable	$ 831	$ 1,029	$ 1,289	$ 2,419	$ 3,032	$ 4,780	$ 3,976	$ 9,093
Average Accounts Payable	$ 1,825	$ 2,529	$ 4,122	$ 3,111	$ 7,016	$ 7,966	$ 9,711	$ 11,555
Average Price per Rx	$ 3.11	$ 3.28	$ 3.32	$ 3.21	$ 3.28	$ 3.25	$ 3.08	$ 3.17
Average Number of Rx	5,413	5,506	8,998	9,147	13,401	14,246	14,827	23,740
Average Receipts from Rx	$ 16,856	$ 18,081	$ 29,909	$ 29,438	$ 44,029	$ 46,296	$ 45,782	$ 75,279
Ratio of Rx Receipts to Total Receipts	59.9%	34.8%	42.1%	33.7%	40.0%	33.2%	27.5%	28.2%
Cost of Dispensing a Rx	$ 1.15	$ 1.12	$ 1.17	$ 1.19	$ 1.24	$ 1.36	$ 1.44	$ 1.46
Number of hours per week Pharmacy was open	46	50	54	58	59	62	66	76
Number of hours per week Worked by proprietor	45	48	46	52	51	53	46	51

Table No. 13

COSTS IN 1965 IN CANADIAN PHARMACIES WITH SALES VOLUME $40,000 TO $60,000

	SALES BELOW $40,000 14 Pharmacies	UNDER 1,000 Population 14 Pharmacies	1,000 to 5,000 Population 19 Pharmacies	5,000 to 20,000 Population 3 Pharmacies	20,000 to 100,000 Population 3 Pharmacies	OVER 100,000 Population 11 Pharmacies	ALL 50 Pharmacies
Sales	$ 33,061 - 100.0%	$ 49,909 - 100.0%	$ 51,766 - 100.0%	$ 54,460 - 100.0%	$ 57,408 - 100.0%	$ 52,528 - 100.0%	$ 51,915 - 100.0%
Cost of Goods Sold	21,556 - 65.2%	33,090 - 66.3%	34,010 - 65.7%	34,963 - 64.2%	34,674 - 60.4%	32,777 - 62.4%	33,589 - 64.7%
Gross Margin	11,505 - 34.8%	16,819 - 33.7%	17,756 - 34.3%	19,497 - 35.8%	22,734 - 39.6%	19,751 - 37.6%	18,326 - 35.3%
EXPENSES							
Proprietor's or Manager's Salary	$ 4,992 - 15.1%	$ 5,490 - 11.0%	$ 5,435 - 10.5%	$ 6,699 - 12.3%	$ 5,511 - 9.6%	$ 6,146 - 11.7%	$ 5,711 - 11.0%
Employees' Wages	1,554 - 4.7%	2,046 - 4.1%	3,520 - 6.8%	3,159 - 5.8%	5,109 - 8.9%	4,360 - 8.3%	3,323 - 6.4%
Rent	1,422 - 4.3%	1,098 - 2.2%	621 - 1.2%	1,471 - 2.7%	1,895 - 3.3%	1,891 - 3.6%	1,142 - 2.2%
Advertising	364 - 1.1%	399 - 0.8%	518 - 1.0%	1,089 - 2.0%	804 - 1.4%	578 - 1.1%	571 - 1.1%
Delivery	99 - 0.3%	250 - 0.5%	311 - 0.6%	327 - 0.6%	746 - 1.3%	525 - 1.0%	363 - 0.7%
Depreciation on Fixtures and Equipment	529 - 1.6%	799 - 1.6%	932 - 1.8%	1,089 - 2.0%	804 - 1.4%	578 - 1.1%	831 - 1.6%
Heat, Light, Power	364 - 1.1%	499 - 1.0%	466 - 0.9%	654 - 1.2%	517 - 0.9%	367 - 0.7%	467 - 0.9%
Taxes	232 - 0.7%	250 - 0.5%	414 - 0.8%	490 - 0.9%	230 - 0.4%	367 - 0.7%	363 - 0.7%
Insurance	198 - 0.6%	299 - 0.6%	362 - 0.7%	218 - 0.4%	344 - 0.6%	367 - 0.7%	311 - 0.6%
Interest	165 - 0.5%	349 - 0.7%	207 - 0.4%	54 - 0.1%		53 - 0.1%	208 - 0.4%
Repair	165 - 0.5%	449 - 0.9%	259 - 0.5%	109 - 0.2%	402 - 0.7%	158 - 0.3%	260 - 0.5%
Telephone	165 - 0.5%	200 - 0.4%	155 - 0.3%	163 - 0.3%	115 - 0.2%	263 - 0.5%	208 - 0.4%
Bad Debts	33 - 0.1%	50 - 0.1%	104 - 0.2%		57 - 0.1%	53 - 0.1%	52 - 0.1%
Miscellaneous	496 - 1.5%	998 - 2.0%	828 - 1.6%	980 - 1.8%	746 - 1.3%	998 - 1.9%	934 - 1.8%
Total Expenses	$ 10,778 - 32.6%	$ 13,176 - 26.4%	$ 14,132 - 27.3%	$ 16,502 - 30.3%	$ 17,280 - 30.1%	$ 16,704 - 31.8%	$ 14,744 - 28.4%
NET PROFIT	$ 727 - 2.2%	$ 3,643 - 7.3%	$ 3,624 - 7.0%	$ 2,995 - 5.5%	$ 5,454 - 9.5%	$ 3,047 - 5.8%	$ 3,582 - 6.9%
Add: Other Income	$ 271 -	$ 253	$ 514			$ 517	$ 380
Proprietor's Salary	$ 4,992	$ 5,490	$ 5,435	$ 6,699	$ 5,511	$ 6,146	$ 5,711
TOTAL INCOME	$ 5,990 ($ 5,955)	$ 9,386 ($ 9,417)	$ 9,573 ($ 9,594)	$ 9,694 ($ 9,749)	$ 10,965 ($10,983)	$ 9,710 ($ 9,825)	$ 9,673 ($ 9,688)
Value of Merchandise Stock	$ 10,067	$ 13,195	$ 13,910	$ 14,940	$ 13,369	$ 10,812	$ 13,040
Annual Rate of Turnover	2.8	2.7	2.6	2.5	2.6	3.4	2.8
Average Value of Fixtures	$ 3,109	$ 3,482	$ 2,485	$ 2,000	$ 3,050	$ 4,005	$ 3,057
Average Accounts Receivable	$ 933	$ 2,429	$ 1,539	$ 916	$ 1,021	$ 1,327	$ 1,723
Average Accounts Payable	$ 1,766	$ 2,647	$ 2,061	$ 2,232	$ 2,589	$ 2,573	$ 2,371
Average Price per Rx	$ 3.37	$ 3.12	$ 3.09	$ 3.30	$ 3.86	$ 3.49	$ 3.25
Average Number of Rx	4,422	5,020	6,655	6,501	4,169	6,281	5,889
Average Receipts from Rx	$ 14,907	$ 15,682	$ 20,602	$ 21,473	$ 16,124	$ 21,919	$ 19,182
Ratio of Rx Receipts to Total Receipts	44.7%	32.1%	39.2%	38.3%	28.0%	42.4%	37.0%
Cost of Dispensing a Rx	$ 1.30	$ 1.09	$ 1.15	$ 1.26	$ 1.30	$ 1.32	$ 1.20
Number of hours per week Pharmacy was open	52	52	52	51	58	59	54
Number of hours per week Worked by proprietor	50	49	47	49	53	49	48

Table No. 14

COSTS IN 1965 IN CANADIAN PHARMACIES WITH SALES VOLUME $60,000 TO $80,000

	UNDER 1,000 Population 12 Pharmacies	1,000 to 5,000 Population 28 Pharmacies	5,000 to 20,000 Population 13 Pharmacies	20,000 to 100,000 Population 11 Pharmacies	100,000 to 1,000,000 Population 20 Pharmacies	OVER 1,000,000 Population 3 Pharmacies	ALL 87 Pharmacies
Sales	$ 69,313 - 100.0%	$ 70,445 - 100.0%	$ 74,000 - 100.0%	$ 69,984 - 100.0%	$ 72,104 - 100.0%	$ 71,359 - 100.0%	$ 71,175 - 100.0%
Cost of Goods Sold	46,509 - 67.1%	46,494 - 66.0%	46,398 - 62.7%	44,860 - 64.1%	47,661 - 66.1%	40,175 - 56.3%	46,335 - 65.1%
Gross Margin	22,804 - 32.9%	23,951 - 34.0%	27,602 - 37.3%	25,124 - 35.9%	24,443 - 33.9%	31,184 - 43.7%	24,840 - 34.9%
EXPENSES							
Proprietor's or Manager's Salary	$ 8,110 - 11.7%	$ 6,763 - 9.6%	$ 7,770 - 10.5%	$ 7,278 - 10.4%	$ 7,066 - 9.8%	$ 11,846 - 16.6%	$ 7,402 - 10.4%
Employees' Wages	3,258 - 4.7%	5,988 - 8.5%	7,696 - 10.4%	7,278 - 10.4%	7,283 - 10.1%	5,780 - 8.1%	6,334 - 8.9%
Rent	1,525 - 2.2%	1,409 - 2.0%	1,924 - 2.6%	2,589 - 3.7%	2,236 - 3.1%	2,284 - 3.2%	1,851 - 2.6%
Advertising	693 - 1.0%	775 - 1.1%	1,184 - 1.6%	840 - 1.2%	793 - 1.1%	1,070 - 1.5%	854 - 1.2%
Delivery	485 - 0.7%	282 - 0.4%	370 - 0.5%	910 - 1.3%	505 - 0.7%	2,997 - 4.2%	569 - 0.8%
Depreciation on Fixtures and Equipment	1,109 - 1.6%	916 - 1.3%	888 - 1.2%	770 - 1.1%	649 - 0.9%	856 - 1.2%	854 - 1.2%
Heat, Light, Power	416 - 0.6%	634 - 0.9%	592 - 0.8%	280 - 0.4%	577 - 0.8%		498 - 0.7%
Taxes	277 - 0.4%	282 - 0.4%	370 - 0.5%	210 - 0.3%	288 - 0.4%	143 - 0.2%	285 - 0.4%
Insurance	277 - 0.4%	422 - 0.6%	296 - 0.4%	280 - 0.4%	288 - 0.4%	428 - 0.6%	356 - 0.5%
Interest	485 - 0.7%	282 - 0.4%	444 - 0.6%	210 - 0.3%	216 - 0.3%	214 - 0.3%	285 - 0.4%
Repair	139 - 0.2%	352 - 0.5%	222 - 0.3%	210 - 0.3%	288 - 0.4%	286 - 0.4%	214 - 0.3%
Telephone	208 - 0.3%	211 - 0.3%	296 - 0.4%	350 - 0.5%	288 - 0.4%	571 - 0.8%	285 - 0.4%
Bad Debts	69 - 0.1%	141 - 0.2%	296 - 0.4%	140 - 0.2%	72 - 0.1%	143 - 0.2%	142 - 0.2%
Miscellaneous	832 - 1.2%	1,127 - 1.6%	2,072 - 2.8%	1,400 - 2.0%	1,154 - 1.6%	2,283 - 3.2%	1,281 - 1.8%
Total Expenses	$ 17,883 - 25.8%	$ 19,584 - 27.8%	$ 24,420 - 33.0%	$ 22,745 - 32.5%	$ 21,703 - 30.1%	$ 28,901 - 40.5%	$ 21,210 - 29.8%
NET PROFIT	$ 4,921 - 7.1%	$ 4,367 - 6.2%	$ 3,182 - 4.3%	$ 2,379 - 3.4%	$ 2,740 - 3.8%	$ 2,283 - 3.2%	$ 3,630 - 5.1%
Add: Other Income	$ 236	$ 138	$ 183	$ 694	$ 426	$ 97	$ 293
Proprietor's Salary	$ 8,110	$ 6,763	$ 7,770	$ 7,278	$ 7,066	$ 11,846	$ 7,402
TOTAL INCOME	$ 13,267($13,230)	$ 11,268($11,322)	$ 11,135($11,075)	$ 10,351($10,225)	$ 10,232($10,268)	$ 14,226($14,411)	$ 11,325($11,271)
Value of Merchandise Stock	$ 15,328	$ 17,098	$ 20,733	$ 16,743	$ 16,411	$ 9,266	$ 16,891
Annual Rate of Turnover	3.3	3.0	2.3	2.8	2.9	5.2	3.0
Average Value of Fixtures	$ 1,656	$ 5,569	$ 4,296	$ 3,181	$ 4,981	$ 16,535	$ 4,832
Average Accounts Receivable	$ 1,736	$ 1,081	$ 3,799	$ 1,950	$ 1,798	$ 3,287	$ 1,909
Average Accounts Payable	$ 4,090	$ 4,805	$ 9,181	$ 3,481	$ 4,533	$ 6,782	$ 5,274
Average Price per Rx	$ 3.54	$ 3.23	$ 3.38	$ 3.58	$ 3.30	$ 3.64	$ 3.40
Average Number of Rx	6,853	7,843	9,538	8,698	6,993	15,469	8,098
Average Receipts from Rx	$ 24,312	$ 25,342	$ 32,293	$ 31,119	$ 23,134	$ 56,306	$ 27,497
Ratio of Rx Receipts to Total Receipts	34.5%	36.2%	44.2%	44.7%	32.1%	77.1%	38.7%
Cost of Dispensing a Rx	$ 1.19	$ 1.20	$ 1.32	$ 1.26	$ 1.26	$ 1.60	$ 1.25
Number of hours per week Pharmacy was open	52	60	57	65	66	66	67
Number of hours per week Worked by proprietor	48	49	49	54	58	52	52

Table No. 15

COSTS IN 1965 IN CANADIAN PHARMACIES WITH SALES VOLUME $80,000 TO $100,000

	UNDER 5,000 Population 29 Pharmacies	5,000 to 20,000 Population 13 Pharmacies	20,000 to 50,000 Population 6 Pharmacies	50,000 to 100,000 Population 3 Pharmacies	100,000 to 1,000,000 Population 22 Pharmacies	OVER 1,000,000 Population 8 Pharmacies	ALL 81 Pharmacies
Sales	$ 85,435 - 100.0%	$ 91,406 - 100.0%	$ 91,042 - 100.0%	$ 92,833 - 100.0%	$ 91,933 - 100.0%	$ 88,266 - 100.0%	$ 89,127 - 100.0%
Cost of Goods Sold	54,935 - 64.3%	60,511 - 66.2%	55,627 - 61.1%	60,434 - 65.1%	60,492 - 65.8%	59,226 - 67.1%	58,022 - 65.1%
Gross Margin	30,500 - 35.7%	30,895 - 33.8%	35,415 - 38.9%	32,399 - 34.9%	31,441 - 34.2%	29,040 - 32.9%	31,105 - 34.9%
EXPENSES							
Proprietor's or Manager's Salary	$ 8,116 - 9.5%	$ 7,861 - 8.6%	$ 9,286 - 10.2%	$ 7,705 - 8.3%	$ 7,630 - 8.3%	$ 6,355 - 7.2%	$ 7,843 - 8.8%
Employees' Wages	7,775 - 9.1%	7,770 - 8.5%	8,649 - 9.5%	6,962 - 7.5%	10,756 - 11.7%	11,739 - 13.3%	9,002 - 10.1%
Rent	1,623 - 1.9%	2,651 - 2.9%	2,913 - 3.2%	4,549 - 4.9%	2,850 - 3.1%	2,383 - 2.7%	2,317 - 2.6%
Advertising	855 - 1.0%	914 - 1.0%	1,366 - 1.5%	1,300 - 1.4%	1,011 - 1.1%	530 - 0.6%	891 - 1.0%
Delivery	342 - 0.4%	366 - 0.4%	1,366 - 1.5%	1,392 - 1.5%	1,103 - 1.2%	1,324 - 1.5%	802 - 0.9%
Depreciation on Fixtures and Equipment	1,025 - 1.2%	1,371 - 1.5%	820 - 0.9%	1,485 - 1.6%	1,011 - 1.1%	706 - 0.8%	1,069 - 1.2%
Heat, Light, Power	513 - 0.6%	640 - 0.7%	455 - 0.5%	743 - 0.8%	644 - 0.7%	530 - 0.6%	624 - 0.7%
Taxes	427 - 0.5%	457 - 0.5%	273 - 0.3%	186 - 0.2%	368 - 0.4%	353 - 0.4%	357 - 0.4%
Insurance	427 - 0.5%	457 - 0.5%	455 - 0.5%	371 - 0.4%	368 - 0.4%	177 - 0.2%	357 - 0.4%
Interest	256 - 0.3%	274 - 0.3%	273 - 0.3%	650 - 0.7%	460 - 0.5%	177 - 0.2%	357 - 0.4%
Repair	342 - 0.4%	274 - 0.3%	182 - 0.2%	557 - 0.6%	276 - 0.3%	530 - 0.6%	357 - 0.4%
Telephone	256 - 0.3%	183 - 0.2%	273 - 0.3%	464 - 0.5%	276 - 0.3%	353 - 0.4%	267 - 0.3%
Bad Debts	171 - 0.2%	91 - 0.1%	182 - 0.2%		184 - 0.2%	88 - 0.1%	89 - 0.1%
Miscellaneous	1,367 - 1.6%	1,096 - 1.2%	2,458 - 2.7%	1,393 - 1.5%	2,114 - 2.3%	1,500 - 1.7%	1,604 - 1.8%
Total Expenses	$ 23,495 - 27.5%	$ 24,405 - 26.7%	$ 28,951 - 31.8%	$ 27,757 - 29.9%	$ 29,051 - 31.6%	$ 26,745 - 30.3%	$ 25,936 - 29.1%
NET PROFIT	$ 7,005 - 8.2%	$ 6,490 - 7.1%	$ 6,464 - 7.1%	$ 4,642 - 5.0%	$ 2,390 - 2.6%	$ 2,295 - 2.6%	$ 5,169 - 5.8%
Add: Other Income	$ 302	$ 195	$ 31	$ 17	$ 885	$ 24	$ 384
Proprietor's Salary	$ 8,116	$ 7,861	$ 9,286	$ 7,705	$ 7,630	$ 6,355	$ 7,843
TOTAL INCOME	$ 15,423($16,079)	$ 14,546($14,662)	$ 15,781($15,856)	$ 12,364($12,303)	$ 10,905($10,958)	$ 8,674($ 8,940)	$ 13,396($13,594)
Value of Merchandise Stock	$ 21,250	$ 21,993	$ 20,630	$ 18,036	$ 16,738	$ 18,316	$ 19,716
Annual Rate of Turnover	2.8	3.0	2.8	3.4	3.7	3.6	3.2
Average Value of Fixtures	$ 5,918	$ 2,561	$ 4,960	$ 11,077	$ 5,752	$ 6,153	$ 5,946
Average Accounts Receivable	$ 2,884	$ 2,294	$ 2,079	$ 1,423	$ 1,702	$ 3,136	$ 2,136
Average Accounts Payable	$ 5,208	$ 4,956	$ 4,917	$ 4,789	$ 4,532	$ 13,058	$ 5,606
Average Price per Rx	$ $ 3.52	$ 3.20	$ 3.60	$ 3.66	$ 3.40	$ 3.31	$ 3.44
Average Number of Rx	8,490	7,852	9,747	6,848	7,824	6,443	8,051
Average Receipts from Rx	$ 29,878	$ 25,179	$ 35,049	$ 25,043	$ 26,635	$ 21,382	$ 27,717
Ratio of Rx Receipts to Total Receipts	35.3%	27.3%	39.6%	28.0%	29.0%	24.0%	31.3%
Cost of Dispensing a Rx	$ 1.21	$ 1.08	$ 1.34	$ 1.35	$ 1.39	$ 1.33	$ 1.28
Number of hours per week Pharmacy was open	59	59	60	67	73	82	65
Number of hours per week Worked by proprietor	48	49	53	55	48	55	50

Table No. 16

COSTS IN 1965 IN CANADIAN PHARMACIES WITH SALES VOLUME $100,000 TO $125,000

	BELOW 5,000 Population 41 Pharmacies	5,000 to 20,000 Population 13 Pharmacies	20,000 to 50,000 Population 5 Pharmacies	50,000 to 100,000 Population 5 Pharmacies	100,000 to 1,000,000 Population 30 Pharmacies	OVER 1,000,000 Population 6 Pharmacies	ALL 100 Pharmacies
Sales	$111,344 - 100.0%	$109,807 - 100.0%	$109,010 - 100.0%	$110,492 - 100.0%	$116,026 - 100.0%	$108,123 - 100.0%	$112,196 - 100.0%
Cost of Goods Sold	72,819 - 65.4%	68,410 - 62.3%	70,311 - 64.5%	67,511 - 61.1%	77,853 - 67.1%	71,686 - 66.3%	73,264 - 65.3%
Gross Margin	38,525 - 34.6%	41,397 - 37.7%	38,699 - 35.5%	42,981 - 38.9%	38,173 - 32.9%	36,437 - 33.7%	38,932 - 34.7%
EXPENSES							
Proprietor's or Manager's Salary	$ 9,019 - 8.1%	$ 8,565 - 7.8%	$ 10,138 - 9.3%	$ 11,049 - 10.0%	$ 7,890 - 6.8%	$ 8,650 - 8.0%	$ 8,751 - 7.8%
Employees' Wages	10,578 - 9.5%	12,298 - 11.2%	10,792 - 9.9%	15,358 - 13.9%	12,299 - 10.6%	13,299 - 12.3%	11,669 - 10.4%
Rent	2,338 - 2.1%	2,416 - 2.2%	3,706 - 3.4%	2,762 - 2.5%	3,365 - 2.9%	2,379 - 2.2%	2,805 - 2.5%
Advertising	1,002 - 0.9%	1,318 - 1.2%	1,417 - 1.3%	1,215 - 1.1%	1,044 - 0.9%	973 - 0.9%	1,122 - 1.0%
Delivery	445 - 0.4%	659 - 0.6%	872 - 0.8%	1,215 - 1.1%	1,160 - 1.0%	973 - 0.9%	785 - 0.7%
Depreciation on Fixtures and Equipment	1,447 - 1.3%	1,098 - 1.0%	1,090 - 1.0%	994 - 0.9%	1,393 - 1.2%	1,514 - 1.4%	1,346 - 1.2%
Heat, Light, Power	780 - 0.7%	659 - 0.6%	436 - 0.4%	774 - 0.7%	696 - 0.6%	432 - 0.4%	673 - 0.6%
Taxes	445 - 0.4%	439 - 0.4%	327 - 0.3%	774 - 0.7%	464 - 0.4%	432 - 0.4%	449 - 0.4%
Insurance	445 - 0.4%	659 - 0.6%	872 - 0.8%	442 - 0.4%	580 - 0.5%	541 - 0.5%	561 - 0.5%
Interest	557 - 0.5%	549 - 0.5%	1,090 - 1.0%	110 - 0.1%	696 - 0.6%	108 - 0.1%	561 - 0.5%
Repair	334 - 0.3%	439 - 0.4%	218 - 0.2%	332 - 0.3%	348 - 0.3%	432 - 0.4%	337 - 0.3%
Telephone	334 - 0.3%	329 - 0.3%	218 - 0.2%	221 - 0.2%	348 - 0.3%	432 - 0.4%	337 - 0.3%
Bad Debts	223 - 0.2%	329 - 0.3%	109 - 0.1%	332 - 0.3%	116 - 0.1%		224 - 0.2%
Miscellaneous	2,227 - 2.0%	2,087 - 1.9%	1,418 - 1.3%	2,431 - 2.2%	4,409 - 3.8%	1,839 - 1.7%	2,805 - 2.5%
Total Expenses	$ 30,174 - 27.1%	$ 31,844 - 29.0%	$ 32,703 - 30.0%	$ 38,009 - 34.4%	$ 34,808 - 30.0%	$ 32,004 - 29.6%	$ 32,425 - 28.9%
NET PROFIT	$ 8,351 - 7.5%	$ 9,553 - 8.7%	$ 5,996 - 5.5%	$ 4,972 - 4.5%	$ 3,365 - 2.9%	$ 4,433 - 4.1%	$ 6,507 - 5.8%
Add: Other Income	$ 219	$ 163	$ 445	$ 30	$ 696	$ 338	$ 364
Proprietor's Salary	$ 9,019	$ 8,565	$ 10,138	$ 11,049	$ 7,890	$ 8,650	$ 8,751
TOTAL INCOME	$ 17,589($17,524)	$ 18,281($18,497)	$ 16,579($16,751)	$ 16,051($15,757)	$ 11,951($12,037)	$ 13,421($13,395)	$ 15,622($15,640)
Value of Merchandise Stock	$ 24,644	$ 26,702	$ 22,557	$ 19,995	$ 22,105	$ 17,288	$ 23,338
Annual Rate of Turnover	3.3	2.9	3.3	3.7	3.8	4.3	3.4
Average Value of Fixtures	$ 6,855	$ 7,710	$ 5,131	$ 7,121	$ 7,498	$ 5,683	$ 6,884
Average Accounts Receivable	$ 3,061	$ 3,549	$ 1,766	$ 1,450	$ 2,785	$ 7,785	$ 2,828
Average Accounts Payable	$ 5,907	$ 6,499	$ 5,425	$ 5,798	$ 6,434	$ 9,366	$ 6,400
Average Price per Rx	$ 3.36	$ 3.08	$ 3.24	$ 4.23	$ 3.37	$ 3.07	$ 3.31
Average Number of Rx	10,207	14,286	8,638	8,179	10,510	12,128	10,906
Average Receipts from Rx	$ 34,286	$ 44,030	$ 27,972	$ 34,992	$ 35,431	$ 37,293	$ 36,143
Ratio of Rx Receipts to Total Receipts	30.9%	40.0%	25.8%	31.8%	30.2%	33.8%	32.0%
Cost of Dispensing a Rx	$ 1.23	$ 1.32	$ 1.32	$ 1.60	$ 1.41	$ 1.27	$ 1.33
Number of hours per week Pharmacy was open	62	58	66	70	74	86	67
Number of hours per week Worked by proprietor	53	49	52	46	49	48	50

Table No. 17

COSTS IN 1965 IN CANADIAN PHARMACIES WITH SALES VOLUME $125,000 TO $150,000

	UNDER 5,000 Population 8 Pharmacies	5,000 to 20,000 Population 16 Pharmacies	20,000 to 50,000 Population 4 Pharmacies	50,000 to 100,000 Population 4 Pharmacies	100,000 1,000,000 Population 24 Pharmacies	OVER 1,000,000 Population 3 Pharmacies	ALL 59 Pharmacies
Sales	$133,791 - 100.0%	$140,318 - 100.0%	$137,012 - 100.0%	$132,970 - 100.0%	$137,149 - 100.0%	$140,767 - 100.0%	$137,444 - 100.0%
Cost of Goods Sold	88,837 - 66.4%	87,699 - 62.5%	90,291 - 65.9%	85,101 - 64.0%	90,518 - 66.0%	88,120 - 62.6%	89,064 - 64.8%
Gross Margin	44,954 - 33.6%	52,619 - 37.5%	46,721 - 34.1%	47,869 - 36.0%	46,631 - 34.0%	52,647 - 37.4%	48,380 - 35.2%
EXPENSES							
Proprietor's or Manager's Salary	$ 9,231 - 6.9%	$ 10,945 - 7.8%	$ 7,673 - 5.6%	$ 15,956 - 12.0%	$ 9,052 - 6.6%	$ 8,727 - 6.2%	$ 9,896 - 7.2%
Employees' Wages	13,914 - 10.4%	16,838 - 12.0%	12,194 - 8.9%	14,361 - 10.8%	15,498 - 11.3%	16,329 - 11.6%	15,394 - 11.2%
Rent	2,007 - 1.5%	3,227 - 2.3%	4,248 - 3.1%	3,324 - 2.5%	5,212 - 3.8%	3,238 - 2.3%	3,986 - 2.9%
Advertising	937 - 0.7%	1,684 - 1.2%	1,096 - 0.8%	798 - 0.6%	1,372 - 1.0%	845 - 0.6%	1,374 - 1.0%
Delivery	669 - 0.5%	842 - 0.6%	1,096 - 0.8%	1,330 - 1.0%	1,234 - 0.9%	2,674 - 1.9%	1,100 - 0.8%
Depreciation on Fixtures and Equipment	1,338 - 1.0%	1,403 - 1.0%	1,370 - 1.0%	1,861 - 1.4%	1,783 - 1.3%	1,408 - 1.0%	1,649 - 1.2%
Heat, Light, Power	937 - 0.7%	842 - 0.6%	411 - 0.3%	665 - 0.5%	960 - 0.7%	704 - 0.5%	825 - 0.6%
Taxes	535 - 0.4%	701 - 0.5%	548 - 0.4%	399 - 0.3%	549 - 0.4%	422 - 0.3%	550 - 0.4%
Insurance	535 - 0.4%	561 - 0.4%	411 - 0.3%	532 - 0.4%	549 - 0.4%	1,126 - 0.8%	550 - 0.4%
Interest	268 - 0.2%	842 - 0.6%	959 - 0.7%	665 - 0.5%	823 - 0.6%	704 - 0.5%	687 - 0.5%
Repair	669 - 0.5%	281 - 0.2%	137 - 0.1%	133 - 0.1%	411 - 0.3%	845 - 0.6%	412 - 0.3%
Telephone	401 - 0.3%	421 - 0.3%	274 - 0.2%	266 - 0.2%	411 - 0.3%	563 - 0.4%	412 - 0.3%
Bad Debts	134 - 0.1%	281 - 0.2%	137 - 0.1%	133 - 0.1%	137 - 0.1%	141 - 0.1%	137 - 0.1%
Miscellaneous	2,943 - 2.2%	2,806 - 2.0%	2,877 - 2.1%	2,925 - 2.2%	3,154 - 2.3%	4,223 - 3.0%	3,024 - 2.2%
Total Expenses	$ 34,518 - 25.8%	$ 41,674 - 29.7%	$ 33,431 - 24.4%	$ 43,348 - 32.6%	$ 41,145 - 30.0%	$ 41,949 - 29.8%	$ 39,996 - 29.1%
NET PROFIT	$ 10,436 - 7.8%	$ 10,945 - 7.8%	$ 13,290 - 9.7%	$ 4,521 - 3.4%	$ 5,486 - 4.0%	$ 10,698 - 7.6%	$ 8,384 - 6.1%
Add: Other Income	$ 930	$ 743	$ 250	$ 1,000	$ 1,041	$ 329	$ 852
Proprietor's Salary	$ 9,231	$ 10,945	$ 7,673	$ 15,956	$ 9,052	$ 8,727	$ 9,896
TOTAL INCOME	$ 20,597($20,839)	$ 22,633($22,782)	$ 21,213($21,466)	$ 21,477($21,209)	$ 15,579($15,515)	$ 19,754($20,074)	$ 19,132($19,219)
Value of Merchandise Stock	$ 25,351	$ 28,539	$ 28,813	$ 18,743	$ 25,583	$ 21,455	$ 25,898
Annual Rate of Turnover	3.6	3.3	3.7	4.9	3.7	4.2	3.7
Average Value of Fixtures	$ 7,284	$ 10,109	$ 12,000	$ 7,672	$ 8,183	$ 9,000	$ 10,618
Average Accounts Receivable	$ 3,652	$ 4,324	$ 2,150	$ 1,743	$ 3,065		$ 3,473
Average Accounts Payable	$ 4,807	$ 7,912	$ 6,700	$ 5,266	$ 7,432		$ 6,993
Average Price per Rx	$ 3.21	$ 3.37	$ 3.95	$ 3.44	$ 3.80	$ 4.13	$ 3.53
Average Number of Rx	14,590	13,695	8,465	12,454	8,678	9,092	11,134
Average Receipts from Rx	$ 46,858	$ 46,189	$ 33,434	$ 42,848	$ 33,051	$ 37,630	$ 39,363
Ratio of Rx Receipts to Total Receipts	35.3%	32.7%	24.2%	33.4%	24.3%	29.5%	28.8%
Cost of Dispensing a Rx	$ 1.26	$ 1.35	$ 1.41	$ 1.00	$ 1.47	$ 1.60	$ 1.38
Number of hours per week Pharmacy was open	60	65	54	74	73	83	69
Number of hours per week Worked by proprietor	47	49	46	54	50	53	50

Table No. 18

COSTS IN 1965 IN CANADIAN PHARMACIES WITH SALES VOLUME $150,000 TO $200,000

	UNDER 5,000 Population 17 Pharmacies	5,000 to 20,000 Population 19 Pharmacies	20,000 to 50,000 Population 6 Pharmacies	50,000 to 100,000 Population 7 Pharmacies	100,000 to 1,000,000 Population 42 Pharmacies	OVER 1,000,000 Population 7 Pharmacies	ALL 98 Pharmacies
Sales	$171,724 - 100.0%	$172,780 - 100.0%	$172,297 - 100.0%	$171,845 - 100.0%	$181,800 - 100.0%	$181,409 - 100.0%	$176,982 - 100.0%
Cost of Goods Sold	111,277 - 64.8%	110,925 - 64.2%	110,787 - 64.3%	115,824 - 67.4%	121,988 - 67.1%	119,367 - 65.8%	116,631 - 65.9%
Gross Margin	60,447 - 35.2%	61,855 - 35.8%	61,510 - 35.7%	56,021 - 32.6%	59,812 - 32.9%	62,042 - 34.2%	60,351 - 34.1%
EXPENSES							
Proprietor's or Manager's Salary	$ 11,162 - 6.5%	$ 9,330 - 5.4%	$ 9,132 - 5.3%	$ 9,967 - 5.8%	$ 9,817 - 5.4%	$ 8,345 - 4.6%	$ 9,734 - 5.5%
Employees' Wages	19,405 - 11.3%	20,906 - 12.1%	22,226 - 12.9%	24,058 - 14.0%	21,816 - 12.0%	23,402 - 12.9%	21,592 - 12.2%
Rent	4,122 - 2.4%	3,974 - 2.3%	4,824 - 2.8%	5,327 - 3.1%	6,181 - 3.4%	5,987 - 3.3%	5,132 - 2.9%
Advertising	1,889 - 1.1%	2,592 - 1.5%	3,618 - 2.1%	2,062 - 1.2%	2,545 - 1.4%	1,270 - 0.7%	2,301 - 1.3%
Delivery	515 - 0.3%	864 - 0.5%	1,378 - 0.8%	1,547 - 0.9%	1,455 - 0.8%	2,721 - 1.5%	1,239 - 0.7%
Depreciation on Fixtures and Equipment	1,889 - 1.1%	1,382 - 0.8%	2,240 - 1.3%	2,234 - 1.3%	1,636 - 0.9%	1,996 - 1.1%	1,770 - 1.0%
Heat, Light, Power	1,202 - 0.7%	1,037 - 0.6%	862 - 0.5%	687 - 0.4%	1,272 - 0.7%	907 - 0.5%	1,062 - 0.6%
Taxes	687 - 0.4%	691 - 0.4%	517 - 0.3%	687 - 0.4%	545 - 0.3%	1,270 - 0.7%	708 - 0.4%
Insurance	687 - 0.4%	864 - 0.5%	862 - 0.5%	859 - 0.5%	364 - 0.2%	726 - 0.4%	708 - 0.4%
Interest	343 - 0.2%	864 - 0.5%	689 - 0.4%	172 - 0.1%	1,091 - 0.6%	181 - 0.1%	708 - 0.4%
Repair	515 - 0.3%	518 - 0.3%	862 - 0.5%	516 - 0.3%	727 - 0.4%	544 - 0.3%	708 - 0.4%
Telephone	343 - 0.2%	518 - 0.3%	689 - 0.4%	344 - 0.2%	364 - 0.2%	544 - 0.3%	531 - 0.3%
Bad Debts	172 - 0.1%	518 - 0.3%	172 - 0.1%	172 - 0.1%	182 - 0.1%	181 - 0.1%	177 - 0.1%
Miscellaneous	3,778 - 2.2%	3,456 - 2.0%	3,101 - 1.8%	3,093 - 1.8%	4,000 - 2.2%	3,628 - 2.0%	3,716 - 2.1%
Total Expenses	$ 46,709 - 27.2%	$ 47,514 - 27.5%	$ 51,172 - 29.7%	$ 51,725 - 30.1%	$ 51,995 - 28.6%	$ 51,702 - 28.5%	$ 50,086 - 28.3%
NET PROFIT	$ 13,738 - 8.0%	$ 14,341 - 8.3%	$ 10,338 - 6.0%	$ 4,296 - 2.5%	$ 7,817 - 4.3%	$ 10,340 - 5.7%	$ 10,265 - 5.8%
Add: Other Income	$ 1,314	$ 174	$ 473	$ 728	$ 1,638	$ 903	$ 1,109
Proprietor's Salary	$ 11,162	$ 9,330	$ 9,132	$ 9,967	$ 9,817	$ 8,345	$ 9,734
TOTAL INCOME	$ 26,214($26,211)	$ 23,845($23,868)	$ 19,943($19,788)	$ 14,991($14,359)	$ 19,272($19,181)	$ 19,588($19,512)	$ 21,108($21,022)
Value of Merchandise Stock	$ 33,718	$ 40,441	$ 30,817	$ 29,349	$ 30,124	$ 23,453	$ 32,360
Annual Rate of Turnover	3.5	3.1	3.7	4.1	4.1	$ 5.5	3.9
Average Value of Fixtures	$ 10,386	$ 9,186	$ 8,633	$ 11,602	$ 10,281	$ 10,564	$ 10,016
Average Accounts Receivable	$ 3,421	$ 5,307	$ 4,004	$ 4,808	$ 3,393	$ 3,380	$ 3,966
Average Accounts Payable	$ 8,174	$ 10,239	$ 7,589	$ 6,509	$ 8,672	$ 8,380	$ 8,633
Average Price per Rx	$ 3.29	$ 3.43	$ 3.26	$ 3.01	$ 2.84	$ 3.55	$ 3.12
Average Number of Rx	14,285	18,169	16,254	19,655	13,806	16,076	15,463
Average Receipts from Rx	$ 46,993	$ 62,308	$ 53,046	$ 59,316	$ 39,144	$ 57,100	$ 48,360
Ratio of Rx Receipts to Total Receipts	26.7%	36.4%	30.5%	33.4%	21.5%	32.0%	26.5%
Cost of Dispensing a Rx	$ 1.30	$ 1.37	$ 1.42	$ 1.33	$ 1.36	$ 1.61	$ 1.37
Number of hours per week Pharmacy was open	64	61	62	66	75	78	69
Number of hours per week Worked by proprietor	48	46	49	46	44	50	46

Table No. 19

COSTS IN 1965 IN CANADIAN PHARMACIES WITH SALES VOLUME OVER $200,000

	UNDER 5,000 Population 4 Pharmacies	5,000 to 20,000 Population 22 Pharmacies	20,000 to 100,000 Population 9 Pharmacies	OVER 100,000 Population 53 Pharmacies	SALES $200,000 to $300,000 All 88 Pharmacies	SALES $300,000 to $400,000 11 Pharmacies	SALES OVER $400,000 7 Pharmacies
Sales	$229,512 - 100.0%	$231,293 - 100.0%	$235,654 - 100.0%	$241,468 - 100.0%	$237,786 - 100.0%	$337,342 - 100.0%	$450,955 - 100.0%
Cost of Goods Sold	155,380 - 67.7%	149,878 - 64.8%	144,456 - 61.3%	164,440 - 68.1%	158,365 - 66.6%	217,923 - 64.6%	294,474 - 65.3%
Gross Margin	74,132 - 32.3%	81,415 - 35.2%	91,198 - 38.7%	77,028 - 31.9%	79,421 - 33.4%	119,419 - 35.4%	156,481 - 34.7%
EXPENSES							
Proprietor's or Manager's Salary	$ 12,853 - 5.6%	$ 12,721 - 5.5%	$ 12,961 - 5.5%	$ 10,866 - 4.5%	$ 11,652 - 4.9%	$ 16,530 - 4.9%	$ 18,940 - 4.2%
Employees' Wages	18,590 - 8.1%	32,381 - 14.0%	34,641 - 14.7%	30,666 - 12.7%	30,912 - 13.0%	47,565 - 14.1%	73,957 - 16.4%
Rent	2,984 - 1.3%	5,551 - 2.4%	5,420 - 2.3%	8,210 - 3.4%	7,134 - 3.0%	8,096 - 2.4%	17,136 - 3.8%
Advertising	2,984 - 1.3%	3,469 - 1.5%	4,242 - 1.8%	3,622 - 1.5%	3,567 - 1.5%	6,410 - 1.9%	4,960 - 1.1%
Delivery	1,147 - 0.5%	1,388 - 0.6%	1,650 - 0.7%	2,173 - 0.9%	1,902 - 0.8%	3,036 - 0.9%	8,568 - 1.9%
Depreciation on Fixtures and Equipment	2,984 - 1.3%	2,776 - 1.2%	2,592 - 1.1%	1,449 - 0.6%	1,902 - 0.8%	2,361 - 0.7%	4,059 - 0.9%
Heat, Light, Power	1,147 - 0.5%	1,156 - 0.5%	1,178 - 0.5%	1,690 - 0.7%	1,427 - 0.6%	1,349 - 0.4%	1,804 - 0.4%
Taxes	918 - 0.4%	925 - 0.4%	943 - 0.4%	483 - 0.2%	713 - 0.3%	1,012 - 0.3%	1,804 - 0.4%
Insurance	918 - 0.4%	1,156 - 0.5%	1,178 - 0.5%	483 - 0.2%	713 - 0.3%	1,012 - 0.3%	1,353 - 0.3%
Interest	459 - 0.2%	1,156 - 0.5%	707 - 0.3%	1,207 - 0.5%	1,189 - 0.5%	1,012 - 0.3%	451 - 0.1%
Repair	459 - 0.2%	694 - 0.3%	707 - 0.3%	1,207 - 0.5%	951 - 0.4%	675 - 0.2%	902 - 0.2%
Telephone	459 - 0.2%	694 - 0.3%	471 - 0.2%	483 - 0.2%	713 - 0.3%	675 - 0.2%	1,353 - 0.3%
Bad Debts	459 - 0.2%	463 - 0.2%	236 - 0.1%	242 - 0.1%	238 - 0.1%	1,012 - 0.3%	451 - 0.1%
Miscellaneous	5,279 - 2.3%	4,395 - 1.9%	4,713 - 2.0%	5,554 - 2.3%	4,994 - 2.1%	7,422 - 2.2%	6,764 - 1.5%
Total Expenses	$ 51,640 - 22.5%	$ 68,925 - 29.8%	$ 71,639 - 30.4%	$ 68,335 - 28.3%	$ 68,007 - 28.6%	$ 98,167 - 29.1%	$142,502 - 31.6%
NET PROFIT	$ 22,492 - 9.8%	$ 12,490 - 5.4%	$ 19,559 - 8.3%	$ 8,693 - 3.6%	$ 11,414 - 4.8%	$ 21,252 - 6.3%	$ 13,979 - 3.1%
Add: Other Income	$ 250	$ 1,758	$ 830	$ 2,126	$ 1,817	$ 1,921	$ 3,461
Proprietor's Salary	$ 12,853	$ 12,721	$ 12,961	$ 10,866	$ 11,652	$ 16,530	$ 18,940
TOTAL INCOME	$ 35,595($34,927)	$ 26,969($26,320)	$ 33,350($32,914)	$ 21,685($21,615)	$ 24,883($24,551)	$ 39,703($37,492)	$ 36,380($37,382)
Value of Merchandise Stock	$ 38,823	$ 40,358	$ 42,776	$ 39,400	$ 39,954	$ 47,547	$ 82,404
Annual Rate of Turnover	4.1	3.9%	3.6	4.3	4.1	4.6	3.8
Average Value of Fixtures	$ 10,149	$ 14,674	$ 12,809	$ 8,922	$ 6,812	$ 17,613	$ 23,706
Average Accounts Receivable	$ 8,366	$ 7,326	$ 8,043	$ 4,249	$ 10,661	$ 15,340	$ 22,614
Average Accounts Payable	$ 21,533	$ 12,985	$ 11,607	$ 12,800	$ 13,162	$ 22,753	$ 29,543
Average Price per Rx	$ 3.37	$ 3.48	$ 3.54	$ 3.24	$ 3.35	$ 3.29	$ 3.80
Average Number of Rx	21,154	19,226	20,175	15,355	16,974	23,915	33,711
Average Receipts from Rx	$ 71,300	$ 67,036	$ 71,496	$ 49,731	$ 56,827	$ 78,662	$128,220
Ratio of Rx Receipts to Total Receipts	33.4%	29.0%	30.5%	20.6%	23.9%	23.1%	29.2%
Cost of Dispensing a Rx	$ 1.19	$ 1.47	$ 1.39	$ 1.37	$ 1.38	$ 1.38	$ 1.67
Number of hours per week Pharmacy was open	73	68	74	79	76	72	80
Number of hours per week Worked by proprietor	45	46	44	43	44	47	49

Table No. 20 Table No. 21

AVERAGE COSTS, MARGINS, AND PROFITS IN 1965 ACCORDING TO THE NUMBER OF PRESCRIPTIONS FILLED DAILY

	RECEIPTS $40,000 TO $60,000			RECEIPTS $60,000 TO $80,000			
	Less than 10 Prescriptions Daily 6 Pharmacies	10 to 20 Prescriptions Daily 24 Pharmacies	Over 20 Prescriptions Daily 10 Pharmacies	Less than 10 Prescriptions Daily 2 Pharmacies	10 to 20 Prescriptions Daily 28 Pharmacies	20 to 30 Prescriptions Daily 18 Pharmacies	Over 30 Prescriptions Daily 10 Pharmacies
Sales	$ 56,090 - 100.0%	$ 49,159 - 100.0%	$ 52,767 - 100.0%	$ 63,424 - 100.0%	$ 70,174 - 100.0%	$ 70,817 - 100.0%	$ 73,908 - 100.0%
Cost of Goods Sold	36,515 - 65.1%	$ 32,445 - 66.0%	$ 31,238 - 59.2%	$ 42,621 - 67.2%	$ 45,894 - 65.4%	$ 45,748 - 64.6%	$ 42,645 - 57.7%
Gross Margin	19,575 - 34.9%	16,714 - 34.0%	21,529 - 40.8%	20,803 - 32.8%	24,280 - 34.6%	25,069 - 35.4%	31,263 - 42.3%
EXPENSES							
Proprietor's or Manager's Salary	$ 5,216 - 9.3%	$ 5,604 - 11.4%	$ 6,227 - 11.8%	$ 6,913 - 10.9%	$ 7,719 - 11.0%	$ 7,648 - 10.8%	$ 9,165 - 12.4%
Employees' Wages	4,319 - 7.7%	2,556 - 5.2%	4,380 - 8.3%	5,645 - 8.9%	6,175 - 8.8%	6,090 - 8.6%	6,652 - 9.0%
Rent	1,346 - 2.4%	1,180 - 2.4%	2,163 - 4.1%	2,600 - 4.1%	1,754 - 2.5%	1,629 - 2.3%	3,030 - 4.1%
Advertising	673 - 1.2%	442 - 0.9%	686 - 1.3%	1,395 - 2.2%	632 - 0.9%	921 - 1.3%	1,182 - 1.6%
Delivery	337 - 0.6%	344 - 0.7%	686 - 1.3%	190 - 0.3%	351 - 0.5%	496 - 0.7%	1,700 - 2.3%
Depreciation on Fixtures and Equipment	617 - 1.1%	836 - 1.7%	1,266 - 2.4%	571 - 0.9%	982 - 1.4%	850 - 1.2%	739 - 1.0%
Heat, Light, Power	505 - 0.9%	492 - 1.0%	369 - 0.7%	317 - 0.5%	561 - 0.8%	566 - 0.8%	296 - 0.4%
Taxes	224 - 0.4%	393 - 0.8%	369 - 0.7%	381 - 0.6%	281 - 0.4%	283 - 0.4%	222 - 0.3%
Insurance	337 - 0.6%	344 - 0.7%	369 - 0.7%	127 - 0.2%	351 - 0.5%	354 - 0.5%	517 - 0.7%
Interest	280 - 0.5%	246 - 0.5%	264 - 0.5%	64 - 0.1%	351 - 0.5%	354 - 0.5%	222 - 0.3%
Repair	280 - 0.5%	295 - 0.6%	211 - 0.4%	190 - 0.3%	211 - 0.3%	283 - 0.4%	296 - 0.4%
Telephone	168 - 0.3%	197 - 0.4%	211 - 0.4%	317 - 0.5%	281 - 0.4%	212 - 0.3%	369 - 0.5%
Bad Debts	56 - 0.1%	49 - 0.1%	106 - 0.2%	127 - 0.2%	70 - 0.1%	142 - 0.2%	148 - 0.2%
Miscellaneous	898 - 1.6%	934 - 1.9%	950 - 1.8%	888 - 1.4%	1,123 - 1.6%	1,275 - 1.8%	1,995 - 2.7%
Total Expenses	$ 15,256 - 27.2%	$ 13,912 - 28.3%	$ 18,257 - 34.6%	$ 19,725 - 31.1%	$ 20,842 - 29.7%	$ 21,103 - 29.8%	$ 26,533 - 35.9%
NET PROFIT	$ 4,319 - 7.7%	$ 2,802 - 5.7%	$ 3,272 - 6.2%	$ 1,078 - 1.7%	$ 3,438 - 4.9%	$ 3,966 - 5.6%	$ 4,730 - 6.4%
Add: Other Income	$ 84	$ 443	$ 343	$ 20	$ 439	$ 134	$ 49
Proprietor's Salary	$ 5,216	$ 5,604	$ 6,227	$ 6,913	$ 7,719	$ 7,648	$ 9,165
TOTAL INCOME	$ 9,619($ 9,689)	$ 8,849($ 8,910)	$ 9,842($10,021)	$ 8,011($ 8,025)	$ 11,596($11,256)	$ 11,748($11,784)	$ 13,944($13,742)
Value of Merchandise Stock	$ 13,743	$ 12,573	$ 12,806	$ 18,543	$ 16,768	$ 17,559	$ 15,656
Annual Rate of Turnover	2.7	2.8	2.7	2.8	2.9	2.8	3.5
Average Value of Fixtures	$ 2,250	$ 3,418	$ 9,412		$ 5,965	$ 3,776	$ 5,264
Average Accounts Receivable	$ 799	$ 2,066	$ 1,488	$ 182	$ 1,889	$ 1,799	$ 2,226
Average Accounts Payable	$ 1,919	$ 2,515	$ 2,298	$ 2,302	$ 4,501	$ 4,468	$ 4,373
Average Price per Rx	$ 3.59	$ 3.25	$ 3.20	$ 3.79	$ 3.45	$ 3.23	$ 3.54
Average Number of Rx	2,794	4,983	10,135	2,882	5,824	8,440	14,665
Average Receipts from Rx	$ 10,034	$ 16,216	$ 32,419	$ 10,915	$ 20,082	$ 27,295	$ 51,856
Ratio of Rx Receipts to Total Receipts	17.9%	32.2%	33.2%	17.2%	28.6%	38.5%	70.1%
Cost of Dispensing a Rx	$ 1.25	$ 1.16	$ 1.32	$ 1.36	$ 1.23	$ 1.23	$ 1.44
Number of hours per week Pharmacy was open	55	53	53	64	63	58	62
Number of hours per week Worked by proprietor	52	48	44	48	55	49	52

Table No. 22

Table No. 23

AVERAGE COSTS, MARGINS, AND PROFITS IN 1965 ACCORDING TO THE NUMBER OF PRESCRIPTIONS FILLED DAILY

	RECEIPTS $80,000 TO $100,000				RECEIPTS $100,000 TO $125,000			
	10 to 20 Prescriptions Daily 32 Pharmacies	20 to 30 Prescriptions Daily 19 Pharmacies	30 to 40 Prescriptions Daily 9 Pharmacies	Over 40 Prescriptions Daily 4 Pharmacies	10 to 20 Prescriptions Daily 16 Pharmacies	20 to 30 Prescriptions Daily 20 Pharmacies	30 to 40 Prescriptions Daily 23 Pharmacies	Over 40 Prescriptions Daily 11 Pharmacies
Sales	$ 89,040 - 100.0%	$ 88,913 - 100.0%	$ 89,652 - 100.0%	$ 93,350 - 100.0%	$108,622 - 100.0%	$112,045 - 100.0%	$116,413 - 100.0%	$112,917 - 100.0%
Cost of Goods Sold	59,568 - 66.9%	56,638 - 63.7%	54,150 - 60.4%	58,530 - 62.7%	72,125 - 66.4%	74,622 - 66.6%	76,949 - 66.1%	66,395 - 58.8%
Gross Margin	29,472 - 33.1%	32,275 - 36.3%	35,502 - 39.6%	34,820 - 37.3%	36,497 - 33.6%	37,423 - 33.4%	39,464 - 33.9%	46,522 - 41.2%
EXPENSES								
Proprietor's or Manager's Salary	$ 7,301 - 8.2%	$ 8,002 - 9.0%	$ 8,965 - 10.0%	$ 8,495 - 9.1%	$ 8,473 - 7.8%	$ 8,852 - 7.9%	$ 8,964 - 7.7%	$ 10,614 - 9.4%
Employees' Wages	8,904 - 10.0%	8,536 - 9.6%	9,772 - 10.9%	10,082 - 10.8%	11,080 - 10.2%	11,429 - 10.2%	11,059 - 9.5%	14,792 - 13.1%
Rent	2,493 - 2.8%	2,223 - 2.5%	1,524 - 1.7%	2,334 - 2.5%	2,607 - 2.4%	2,689 - 2.4%	2,794 - 2.4%	2,936 - 2.6%
Advertising	891 - 1.0%	889 - 1.0%	896 - 1.0%	1,120 - 1.2%	1,086 - 1.0%	1,121 - 1.0%	1,164 - 1.0%	1,129 - 1.0%
Delivery	712 - 0.8%	711 - 0.8%	717 - 0.8%	1,027 - 1.1%	543 - 0.5%	896 - 0.8%	931 - 0.8%	565 - 0.5%
Depreciation on Fixtures and Equipment	1,069 - 1.2%	978 - 1.1%	986 - 1.1%	1,307 - 1.4%	1,521 - 1.4%	1,569 - 1.4%	1,164 - 1.0%	1,242 - 1.1%
Heat, Light, Power	623 - 0.7%	622 - 0.7%	358 - 0.4%	560 - 0.6%	869 - 0.8%	672 - 0.6%	698 - 0.6%	790 - 0.7%
Taxes	356 - 0.4%	267 - 0.3%	448 - 0.5%	467 - 0.5%	326 - 0.3%	448 - 0.4%	466 - 0.4%	677 - 0.6%
Insurance	356 - 0.4%	355 - 0.4%	448 - 0.5%	747 - 0.8%	543 - 0.5%	560 - 0.5%	582 - 0.5%	677 - 0.6%
Interest	356 - 0.4%	267 - 0.3%	270 - 0.3%	280 - 0.3%	760 - 0.7%	448 - 0.4%	815 - 0.7%	565 - 0.5%
Repair	267 - 0.3%	267 - 0.3%	358 - 0.4%	373 - 0.4%	434 - 0.4%	336 - 0.3%	233 - 0.2%	226 - 0.2%
Telephone	267 - 0.3%	267 - 0.3%	270 - 0.3%	187 - 0.2%	326 - 0.3%	336 - 0.3%	349 - 0.3%	226 - 0.2%
Bad Debts	89 - 0.1%	89 - 0.1%	270 - 0.3%	467 - 0.5%	217 - 0.2%	112 - 0.1%	233 - 0.2%	452 - 0.4%
Miscellaneous	1,514 - 1.7%	2,045 - 2.3%	1,434 - 1.6%	1,213 - 1.3%	1,629 - 1.5%	2,241 - 2.0%	5,355 - 4.6%	1,807 - 1.6%
Total Expenses	$ 25,198 - 28.3%	$ 25,518 - 28.7%	$ 26,716 - 29.8%	$ 28,659 - 30.7%	$ 30,414 - 28.0%	$ 31,709 - 28.3%	$ 34,807 - 29.9%	$ 36,698 - 32.5%
NET PROFIT	$ 4,274 - 4.8%	$ 6,757 - 7.6%	$ 8,786 - 9.8%	$ 6,161 - 6.6%	$ 6,083 - 5.6%	$ 5,714 - 5.1%	$ 4,657 - 4.0%	$ 9,824 - 8.7%
Add: Other Income	$ 430	$ 377	$ 298	$ 66	$ 737	$ 532	$ 412	$ 71
Proprietor's Salary	$ 7,301	$ 8,002	$ 8,965	$ 8,495	$ 8,473	$ 8,852	$ 8,964	$ 10,614
TOTAL INCOME	$ 12,005($12,073)	$ 15,136($15,222)	$ 18,049($18,168)	$ 14,722($14,858)	$ 15,293($15,255)	$ 15,098($14,950)	$ 14,033($13,978)	$ 20,509($20,763)
Value of Merchandise Stock	$ 19,333	$ 19,284	$ 17,285	$ 15,104	$ 26,127	$ 21,700	$ 22,896	$ 19,039
Annual Rate of Turnover	3.2	2.9	3.2	4.0	2.9	3.7	3.6	3.3
Average Value of Fixtures	$ 6,375	$ 7,452	$ 4,794	$ 5,216	$ 5,850	$ 6,736	$ 8,561	$ 7,102
Average Accounts Receivable	$ 2,147	$ 2,092	$ 2,805	$ 3,289	$ 2,518	$ 2,564	$ 3,104	$ 2,723
Average Accounts Payable	$ 4,786	$ 5,492	$ 4,638	$ 4,626	$ 6,397	$ 6,912	$ 7,047	$ 6,289
Average Price per Rx	$ 3.30	$ 3.34	$ 3.42	$ 3.26	$ 3.67	$ 3.53	$ 3.27	$ 3.03
Average Number of Rx	5,826	9,273	11,527	16,629	5,568	9,152	12,280	18,911
Average Receipts from Rx	$ 19,206	$ 30,944	$ 39,474	$ 54,217	$ 20,464	$ 32,272	$ 40,215	$ 57,276
Ratio of Rx Receipts to Total Receipts	21.6%	34.8%	44.0%	58.0%	18.8%	28.8%	34.6%	50.7%
Cost of Dispensing a Rx	$ 1.28	$ 1.27	$ 1.28	$ 1.30	$ 1.34	$ 1.32	$ 1.34	$ 1.30
Number of hours per week Pharmacy was open	68	63	67	65	66	69	68	66
Number of hours per week Worked by proprietor	50	48	47	54	53	51	49	48

Table No. 24 Table No. 25

AVERAGE COSTS, MARGINS, AND PROFITS IN 1965 ACCORDING TO THE NUMBER OF PRESCRIPTIONS FILLED DAILY

	RECEIPTS $125,000 TO $150,000				RECEIPTS $150,000 TO $200,000			
	10 to 20 Prescriptions Daily 7 Pharmacies	20 to 30 Prescriptions Daily 19 Pharmacies	30 to 40 Prescriptions Daily 6 Pharmacies	Over 40 Prescriptions Daily 8 Pharmacies	20 to 30 Prescriptions Daily 12 Pharmacies	30 to 40 Prescriptions Daily 31 Pharmacies	40 to 50 Prescriptions Daily 8 Pharmacies	Over 50 Prescriptions Daily 21 Pharmacies
Sales	$130,221 - 100.0%	$137,225 - 100.0%	$141,204 - 100.0%	$134,000 - 100.0%	$166,418 - 100.0%	$186,732 - 100.0%	$169,123 - 100.0%	$177,955 - 100.0%
Cost of Goods Sold	87,769 - 67.4%	90,431 - 65.9%	$ 90,653 - 64.2%	81,874 - 61.1%	110,668 - 66.5%	126,044 - 67.5%	104,518 - 61.8%	113,713 - 63.9%
Gross Margin	42,452 - 32.6%	46,794 - 34.1%	50,551 - 35.8%	52,126 - 38.9%	55,750 - 33.5%	60,688 - 32.5%	64,605 - 38.2%	64,242 - 36.1%
EXPENSES								
Proprietor's or Manager's Salary	$ 8,595 - 6.6%	$ 9,469 - 6.9%	$ 11,014 - 7.8%	$ 12,998 - 9.7%	$ 8,987 - 5.4%	$ 9,897 - 5.3%	$ 10,486 - 6.2%	$ 10,499 - 5.9%
Employees' Wages	12,110 - 9.3%	15,506 - 11.3%	15,109 - 10.7%	15,812 - 11.8%	21,468 - 12.9%	22,034 - 11.8%	22,155 - 13.1%	23,312 - 13.1%
Rent	4,427 - 3.4%	4,803 - 3.5%	4,518 - 3.2%	2,546 - 1.9%	6,158 - 3.7%	5,229 - 2.8%	4,905 - 2.9%	4,805 - 2.7%
Advertising	1,693 - 1.3%	1,372 - 1.0%	1,977 - 1.4%	1,072 - 0.8%	1,331 - 0.8%	2,801 - 1.5%	1,860 - 1.1%	3,025 - 1.7%
Delivery	781 - 0.6%	961 - 0.7%	1,130 - 0.8%	938 - 0.7%	832 - 0.5%	1,494 - 0.8%	2,199 - 1.3%	1,246 - 0.7%
Depreciation on Fixtures and Equipment	1,563 - 1.2%	1,647 - 1.2%	1,553 - 1.1%	938 - 0.7%	1,498 - 0.9%	1,494 - 0.8%	1,184 - 0.7%	1,957 - 1.1%
Heat, Light, Power	1,042 - 0.8%	960 - 0.7%	847 - 0.6%	670 - 0.5%	832 - 0.5%	1,307 - 0.7%	1,015 - 0.6%	890 - 0.5%
Taxes	521 - 0.4%	549 - 0.4%	1,130 - 0.8%	402 - 0.3%	666 - 0.4%	560 - 0.3%	846 - 0.5%	534 - 0.3%
Insurance	391 - 0.3%	412 - 0.3%	565 - 0.4%	402 - 0.3%	499 - 0.3%	373 - 0.2%	1,184 - 0.7%	890 - 0.5%
Interest	521 - 0.4%	960 - 0.7%	1,130 - 0.8%	670 - 0.5%	1,664 - 1.0%	934 - 0.5%	507 - 0.3%	534 - 0.3%
Repair	391 - 0.3%	412 - 0.3%	423 - 0.3%	670 - 0.5%	666 - 0.4%	747 - 0.4%	507 - 0.3%	534 - 0.3%
Telephone	260 - 0.2%	412 - 0.3%	423 - 0.3%	402 - 0.3%	499 - 0.3%	373 - 0.2%	338 - 0.2%	534 - 0.3%
Bad Debts	130 - 0.1%	274 - 0.2%	141 - 0.1%	402 - 0.3%	166 - 0.1%	187 - 0.1%	338 - 0.2%	356 - 0.2%
Miscellaneous	2,604 - 2.0%	2,882 - 2.1%	4,660 - 3.3%	2,948 - 2.2%	3,162 - 1.9%	4,295 - 2.3%	2,875 - 1.7%	4,271 - 2.4%
Total Expenses	$ 35,029 - 26.9%	$ 40,619 - 29.6%	$ 44,620 - 31.6%	$ 40,870 - 30.5%	$ 48,428 - 29.1%	$ 51,725 - 27.7%	$ 50,399 - 29.8%	$ 53,387 - 30.0%
NET PROFIT	$ 7,423 - 5.7%	$ 6,175 - 4.5%	$ 5,931 - 4.2%	$ 11,256 - 8.4%	$ 7,322 - 4.4%	$ 8,963 - 4.8%	$ 14,206 - 8.4%	$ 10,855 - 6.1%
Add: Other Income	$ 390	$ 1,103	$ 802	$ 1,006	$ 1,074	$ 1,592	$ 786	$ 929
Proprietor's Salary	$ 8,595	$ 9,469	$ 11,014	$ 12,998	$ 8,987	$ 9,897	$ 10,486	$ 10,499
TOTAL INCOME	$ 16,408($15,974)	$ 16,747($16,811)	$ 17,747($17,847)	$ 25,260($25,208)	$ 17,383($17,282)	$ 20,452($20,082)	$ 25,478($25,762)	$ 22,283($22,324)
Value of Merchandise Stock	$ 25,786	$ 24,013	$ 32,628	$ 24,084	$ 30,719	$ 31,491	$ 33,654	$ 33,882
Annual Rate of Turnover	3.7	3.8	3.0	3.4	3.8	4.1	3.2	3.7
Average Value of Fixtures	$ 10,252	$ 6,508	$ 13,682	$ 5,849	$ 11,119	$ 9,057	$ 9,921	$ 9,948
Average Accounts Receivable	$ 2,104	$ 2,662	$ 5,211	$ 4,448	$ 3,362	$ 3,016	$ 4,345	$ 5,648
Average Accounts Payable	$ 5,951	$ 7,899	$ 5,920	$ 6,627	$ 7,027	$ 8,008	$ 11,109	$ 7,865
Average Price per Rx	$ 3.86	$ 3.67	$ 3.32	$ 3.20	$ 3.45	$ 3.09	$ 3.47	$ 3.09
Average Number of Rx	6,291	9,345	12,615	19,096	8,864	12,928	16,845	25,284
Average Receipts from Rx	$ 24,276	$ 34,322	$ $ 41,875	$ 61,258	$ 30,618	$ 39,130	$ 58,502	$ 78,144
Ratio of Rx Receipts to Total Receipts	18.6%	25.0%	29.7%	45.7%	18.4%	20.9%	35.0%	43.9%
Cost of Dispensing a Rx	$ 1.36	$ 1.43	$ 1.39	$ 1.23	$ 1.41	$ 1.33	$ 1.41	$ 1.36
Number of hours per week Pharmacy was open	69	71	69	60	67	76	67	63
Number of hours per week Worked by proprietor	47	48	51	48	45	44	44	46

Table No. 26

AVERAGE COSTS, MARGINS, AND PROFITS IN 1965 ACCORDING TO THE NUMBER OF PRESCRIPTIONS FILLED DAILY

RECEIPTS OVER $200,000

	Less than 40 Prescriptions Daily 50 Pharmacies	40 to 50 Prescriptions Daily 14 Pharmacies	50 to 60 Prescriptions Daily 9 Pharmacies	OVER 60 Prescriptions Daily 16 Pharmacies
Sales	$248,302 - 100.0%	$268,818 - 100.0%	$215,819 - 100.0%	$264,227 - 100.0%
Cost of Goods Sold	171,328 - 69.0%	178,226 - 66.3%	138,987 - 64.4%	160,122 - 60.6%
Gross Margin	76,974 - 31.0%	90,592 - 33.7%	76,832 - 35.6%	104,105 - 39.4%
EXPENSES				
Proprietor's or Manager's Salary	$ 10,925 - 4.4%	$ 13,979 - 5.2%	$ 13,597 - 6.3%	$ 12,947 - 4.9%
Employees' Wages	30,045 - 12.1%	36,828 - 13.7%	27,193 - 12.6%	41,219 - 15.6%
Rent	8,690 - 3.5%	8,602 - 3.2%	4,964 - 2.3%	6,342 - 2.4%
Advertising	3,725 - 1.5%	4,032 - 1.5%	3,021 - 1.4%	4,228 - 1.6%
Delivery	1,986 - 0.8%	1,882 - 0.7%	1,295 - 0.6%	3,699 - 1.4%
Depreciation on Fixtures and Equipment	1,738 - 0.7%	2,419 - 0.9%	2,590 - 1.2%	2,907 - 1.1%
Heat, Light, Power	1,738 - 0.7%	1,076 - 0.4%	1,295 - 0.6%	1,321 - 0.5%
Taxes	497 - 0.2%	806 - 0.3%	863 - 0.4%	793 - 0.3%
Insurance	497 - 0.2%	1,076 - 0.4%	647 - 0.3%	1,321 - 0.5%
Interest	1,490 - 0.6%	806 - 0.3%	432 - 0.2%	1,321 - 0.5%
Repair	1,241 - 0.5%	806 - 0.3%	432 - 0.2%	528 - 0.2%
Telephone	497 - 0.2%	806 - 0.3%	432 - 0.2%	793 - 0.3%
Bad Debts	248 - 0.1%	269 - 0.1%	647 - 0.3%	528 - 0.2%
Miscellaneous	4,966 - 2.0%	4,570 - 1.7%	4,101 - 1.9%	7,134 - 2.7%
Total Expenses	$ 68,283 - 27.5%	$ 77,957 - 29.0%	$ 61,509 - 28.5%	$ 85,081 - 32.2%
NET PROFIT	$ 8,691 - 3.5%	$ 12,635 - 4.7%	$ 15,323 - 7.1%	$ 19,024 - 7.2%
Add: Other Income	$ 2,407	$ 2,974	$ 303	$ 1,819
Proprietor's Salary	$ 10,925	$ 13,979	$ 13,597	$ 12,947
TOTAL INCOME	$ 22,023($21,799)	$ 29,588($28,693)	$ 29,223($28,322)	$ 33,790($31,420)
Value of Merchandise Stock	$ 40,640	$ 46,016	$ 39,499	$ 41,521
Annual Rate of Turnover	4.4	5.4	3.6	3.9
Average Value of Fixtures	$ 11,107	$ 13,533	$ 13,066	$ 13,208
Average Accounts Receivable	$ 3,985	$ 6,853	$ 9,525	$ 9,992
Average Accounts Payable	$ 11,265	$ 14,337	$ 13,879	$ 24,488
Average Price per Rx	$ 3.21	$ 3.60	$ 3.30	$ 3.48
Average Number of Rx	13,126	16,271	20,204	33,662
Average Receipts from Rx	$ 42,202	$ 58,583	$ 66,652	$117,092
Ratio of Rx Receipts to Total Receipts	17.0%	21.8%	30.9%	44.3%
Cost of Dispensing a Rx	$ 1.34	$ 1.43	$ 1.39	$ 1.55
Number of hours per week Pharmacy was open	78	72	65	76
Number of hours per week Worked by proprietor	42	47	53	43

*Net Profit per Dollar invested in merchandise inventory

Dramatic Change in Prescription Pricing

Of the 442 pharmacies reporting Prescription Data 179 or 40.49% reported that their method of prescription pricing was **cost plus professional fee.** Manitoba leads all provinces with Ontario as a close second in acceptance of the professional fee method. The statistics are as follows:

Province	Number Reporting Prescription Data	Number Using Professional Fee	Percentage
Manitoba	32	27	84.37%
Ontario	125	98	78.40%
British Columbia	92	25	27.17%
Alberta	51	18	24.65%
New Brunswick	22	4	18.18%
Quebec	9	1	11.11%
Saskatchewan	70	5	7.14%
Nova Scotia	32	1	3.12%
Others	9	0	
Canada	442	179	40.49%

24.8% of all prescriptions were priced by the cost plus professional fee method. See Table No. 37.

Where Prescriptions Were Filled

Of the 5,261,924 prescriptions filled in the 442 reporting pharmacies:

68.4% were filled in independent pharmacies

18.5% were filled in chain pharmacies

7.2% were filled in pharmacies in shopping plazas

5.9% were filled in pharmacies in medical buildings

8.9% were filled at an average price of $3.24 in towns having only one pharmacy.

Dispensary Size and Location

Reported dispensary size in square feet and also the average value of the dispensary inventory is set forth by provinces in Table No. 34. The average size of a dispensary in Canada is 190 square feet and the average inventory in the dispensary is $7,187.

Salaries of Employed Pharmacists

Salaries of employed pharmacists range from below $5,000 to over $10,000. One hundred and fifty-four pharmacists received salaries between $6,001 and $7,000 and 144 received between $7,001 and $8,000, that is 298 of the 599 pharmacists 49.7% received salaries between $6,000 and $8,000. Twenty-three point nine percent received less than $6,000 while 26.4% received over $8,000.

Table No. 27

COMPARISON OF PHARMACIES ACCORDING TO LOCATION, OWNERSHIP, AND PRESCRIPTION VOLUME

	490 Independent Pharmacies	105 Chain Pharmacies	46 Pharmacies in Shopping Plazas	21 Pharmacies in Medical Buildings	89 Pharmacies with Prescription Receipts Over 40% Total Receipts
Sales	$124,593 - 100.0%	$203,233 - 100.0%	$194,301 - 100.0%	$113,886 - 100.0%	$112,364 - 100.0%
Cost of Goods Sold	80,985 - 65.0%	137,589 - 67.7%	130,959 - 67.4%	64,801 - 56.9%	67,980 - 60.5%
Gross Margin	43,608 - 35.0%	65,644 - 32.3%	63,342 - 32.6%	49,085 - 43.1%	44,384 - 39.5%
EXPENSES					
Proprietor's or Manager's Salary	$ 10,466 - 8.4%	$ 10,162 - 5.0%	$ 10,881 - 5.6%	$ 12,300 - 10.8%	$ 10,899 - 9.7%
Employees' Wages	12,584 - 10.1%	25,608 - 12.6%	23,510 - 12.1%	13,780 - 12.1%	12,135 - 10.8%
Rent	3,240 - 2.6%	7,113 - 3.5%	7,772 - 4.0%	5,011 - 4.4%	3,146 - 2.8%
Advertising	1,371 - 1.1%	2,845 - 1.4%	1,749 - 0.9%	1,481 - 1.3%	1,461 - 1.3%
Delivery	872 - 0.7%	2,032 - 1.0%	1,166 - 0.6%	2,278 - 2.0%	1,124 - 1.0%
Depreciation on Fixtures and Equipment	1,620 - 1.3%	1,423 - 0.7%	2,137 - 1.1%	1,367 - 1.2%	1,461 - 1.3%
Heat, Light, Power	872 - 0.7%	1,423 - 0.7%	1,166 - 0.6%	342 - 0.3%	562 - 0.5%
Taxes	498 - 0.4%	610 - 0.3%	777 - 0.4%	455 - 0.4%	562 - 0.5%
Insurance	623 - 0.5%	406 - 0.2%	777 - 0.4%	455 - 0.4%	674 - 0.6%
Interest	498 - 0.4%	1,423 - 0.7%	1,360 - 0.7%	569 - 0.5%	449 - 0.4%
Repair	498 - 0.4%	813 - 0.4%	583 - 0.3%	228 - 0.2%	337 - 0.3%
Telephone	374 - 0.3%	406 - 0.2%	583 - 0.3%	455 - 0.4%	449 - 0.4%
Bad Debts	125 - 0.1%	406 - 0.2%	194 - 0.1%	228 - 0.2%	225 - 0.2%
Miscellaneous	2,367 - 1.9%	5,487 - 2.7%	3,886 - 2.0%	2,847 - 2.5%	2,248 - 2.0%
Total Expenses	$ 36,008 - 28.9%	$ 60,157 - 29.6%	$ 56,541 - 29.1%	$ 41,796 - 36.7%	$ 35,732 - 31.8%
NET PROFIT	$ 7,600 - 6.1%	$ 5,487 - 2.7%	$ 6,801 - 3.5%	$ 7,289 - 6.4%	$ 8,652 - 7.7%
Add: Other Income	$ 577	$ 1,883	$ 1,694	$ 183	$ 345
Proprietor's Salary	$ 10,466	$ 10,162	$ 10,881	$ 12,300	$ 10,899
TOTAL INCOME	$ 18,643($17,055)	$ 17,532($17,879)	$ 19,376($19,168)	$ 19,772($19,470)	$ 19,896($18,772)
Value of Merchandise Stock	$ 24,564	$ 33,467	$ 34,431	$ 18,611	$ 21,720
Annual Rate of Turnover	3.4	4.2	4.0	3.8	3.3
Average Value of Fixtures	$ 7,306	$ 11,102	$ 11,812	$ 7,081	$ 6,546
Average Accounts Receivable	$ 3,827	$ 2,567	$ 3,685	$ 3,829	$ 3,757
Average Accounts Payable	$ 7,302	$ 9,348	$ 12,617	$ 7,005	$ 6,252
Average Price per Rx	$ 3.35	$ 3.22	$ 3.40	$ 3.42	$ 3.36
Average Number of Rx	11,736	12,546	12,048	19,479	17,619
Average Receipts from Rx	$ 39,351	$ 40,478	$ 41,052	$ 66,589	$ 59,262
Ratio of Rx Receipts to Total Receipts	32.5%	20.0%	20.1%	61.7%	52.7%
Cost of Dispensing a Rx	$ 1.31	$ 1.39	$ 1.41	$ 1.46	$ 1.35
Number of hours per week Pharmacy was open	65	74	71	64	61
Number of hours per week Worked by proprietor	50	41	49	46	49

*Net Profit per Dollar invested in merchandise inventory

Comparison of Different Locations and Ownership

Many differences in important ratios exist among pharmacies depending on (1) location (2) type of ownership, and (3) ratio of prescription receipts to total receipts.

Gross margin is highest in pharmacies in medical buildings. Gross margin is higher in pharmacies under independent ownership than chains or pharmacies in shopping plazas. Pharmacies with prescription receipts above 40% of total receipts earn gross margins lower than pharmacies in medical buildings but higher than all others regardless of location or type of ownership.

Rent is highest in medical building locations, shopping plazas come second, chains third, and independents the lowest. Since the 33.8% of pharmacists who own their buildings are among the independents part of the lower rent situation is attributable to the fact that many do not impute sufficient rent to their pharmacy operation and in fact some fail to impute any.

Net Profit, both percentagewise and dollarwise, is higher in the independents than in chains and shopping plaza locations. Pharmacies with prescription receipts above 40% of total receipts have the highest net profit both percentagewise and dollarwise reflecting the apparent fact that professional activities are more rewarding than merchandising activities.

Independents, chains, and pharmacies in shopping plazas dispensed approximately the same number of prescriptions for approximately the same number of dollars. However, the ratio of prescription receipts to total receipts in chains and shopping plazas is only 20.0% as against 32.1% for the independents. Pharmacies in medical buildings have the highest ratio, 61.7%, and pharmacies with prescription receipts over 40% averaged 52.7%.

Pharmacies in medical buildings and with prescription receipts over 40% of total receipts not only earn higher net profits both percentagewise and dollarwise than chains and shopping plaza pharmacies but they are able to do this on inventories approximately $12,000 lower.

Population Size

186 or 31.2% are in population centres of less than 5,000

100 or 16.8% are in population centres from 5,000 to 20,000

70 or 11.8% are in population centres from 20,000 to 100,000

210 or 35.3% are in population centres from 100,000 to 1,000,000

29 or 4.9% are in population centres over 1,000,000 (Toronto and Montreal)

Table No. 28

DISTRIBUTION OF REPORTING PHARMACIES BY SALES VOLUME

	Sales BELOW $40,000	Sales $40,000 to $60,000	Sales $60,000 to $80,000	Sales $80,000 to $100,000	Sales $100,00 to $125,000	Sales $125,000 to $150,000	Sales $150,000 to $200,000	Sales OVER $200,000
Newfoundland					1 or 1.0%	1 or 1.7%		1 or 0.9%
Prince Edward Island			1 or 1.1%	2 or 2.5%	2 or 2.0%		1 or 1.0%	1 or 0.9%
Nova Scotia		2 or 4.0%	2 or 2.3%	4 or 5.0%	21 or 21.0%	2 or 3.4%	7 of 7.2%	7 or 6.6%
New Brunswick		2 or 4.0%	4 or 4.6%	7 or 8.6%	5 or 5.0%		1 or 1.0%	9 or 8.5%
Quebec			3 or 3.5%	2 or 2.5%	3 or 3.0%	2 or 3.4%	3 or 3.1%	1 or 0.9%
Ontario	5 or 35.7%	14 or 28.0%	30 or 34.5%	35 or 43.2%	24 or 24.0%	26 or 44.0%	29 or 28.9%	28 or 26.5%
Manitoba	1 or 7.1%	6 or 12.0%	8 or 9.2%	7 or 8.6%	7 or 7.0%	3 or 5.1%	5 or 5.2%	1 or 0.9%
Saskatchewan	4 or 28.6%	11 or 22.0%	14 or 16.1%	13 or 16.1%	16 or 16.0%	8 or 13.6%	13 or 13.4%	8 or 7.6%
Alberta	2 or 14.3%	11 or 22.0%	18 or 20.7%	7 or 8.6%	16 or 16.0%	7 or 11.9%	10 or 10.3%	2 or 1.9%
British Columbia	2 or 14.3%	4 or 8.0%	7 or 8.0%	4 or 4.9%	5 or 5.0%	10 or 16.9%	29 or 29.9%	48 or 45.3%
Canada (total)	14 or 100.0%	50 or 100.0%	87 or 100.0%	81 or 100.0%	100 or 100.0%	59 or 100.0%	98 or 100.0%	106 or 100.0%
Percentage Relationship to Number of Replies:								
1965	2.4%	8.4%	14.6%	13.6%	16.8%	9.9%	16.5%	17.8%
1964	2.7%	8.2%	17.8%	15.6%	14.3%	11.1%	18.3%	12.0%

Table No. 29

GEOGRAPHICAL DISTRIBUTION OF REPORTING PHARMACIES

	Number of Pharmacies in Canada in 1965	Percentage of all Pharmacies in Canada	Number of Pharmacies Reporting in Province	Percentage of Pharmacies Reporting to Pharmacies in Province	Percentage of Replies to all Reporting
Newfoundland	74	1.5%	3	4.0%	0.5%
Prince Edward Island	24	0.5%	7	29.1%	1.2%
Nova Scotia	185	3.7%	45	24.3%	7.6%
New Brunswick	106	2.1%	28	26.4%	4.7%
Quebec	1,277	25.3%	14	1.1%	2.3%
Ontario	1,787	35.5%	191	10.6%	32.1%
Manitoba	301	6.0%	38	12.6%	6.4%
Saskatchewan	317	6.3%	87	27.4%	14.6%
Alberta	484	9.6%	73	15.1%	12.3%
British Columbia	478	9.5%	109	22.8%	18.3%
Canada (Total)	5,033	100.0%	595	11.8%	100.0%

Table No. 30

1965 PHARMACEUTICAL SURVEY OF 595 CANADIAN PHARMACIES AND COMPARISON WITH 476 IN 1964

	1964	1965
Number of prescriptions Dispensed per Pharmacy	10,962	11,904
Average Price per Prescription	$ 3.31	$ 3.32
Average Price per REPEAT Prescriptions	$ 3.29	$ 3.35
Ratio of Prescription Receipts to Total Receipts	27.4%	28.7%
Average Receipts from Prescriptions	$36,375	$39,585
Own Building	37.8%	33.8%
Individual Proprietorships	38.9%	36.5%
Partnerships	4.8%	4.9%
Corporations	55.9%	58.3%
CO-OPS	0.4%	0.3%

Table No. 31

NET PROFITS EARNED BY 595 CANADIAN PHARMACIES IN 1965
GEOGRAPHICAL DISTRIBUTION OF PROFITS AND LOSSES

	LOSS	Profit less than 2% of Sales	Profit 2% to 5% of Sales	Profit 5% to 10% of Sales	Profit Over 10% of Sales	Total No. in Province
Newfoundland				1 or 33.7%*	2 or 66.7%	3
Prince Edward Island			1 or 14.3%*	2 or 28.6%	4 or 57.1%	7
Nova Scotia	6 or 13.3%*	1 or 2.2%	16 or 35.5%	11 or 24.5%	11 or 24.5%	45
New Brunswick	1 or 3.5%		4 or 14.3%	8 or 28.6%	15 or 53.6%	28
Quebec		1 or 7.4%	5 or 35.7%	6 or 42.9%	2 or 14.9%	14
Ontario	24 or 12.6%	14 or 7.3%	41 or 21.5%	67 or 35.0%	45 or 23.6%	191
Manitoba	3 or 7.9%	5 or 13.2%	10 or 26.3%	11 or 28.9%	9 or 23.7%	38
Saskatchewan	11 or 12.6%	5 or 5.8%	9 or 10.3%	32 or 36.8%	30 or 34.5%	87
Alberta	7 or 9.6%	8 or 11.0%	8 or 11.0%	29 or 39.7%	21 or 28.7%	73
British Columbia	8 or 7.3%	2 or 1.8%	71 or 65.1%	14 or 12.9%	14 or 12.9%	109
Canada – total	60 or 10.1%**	36 or 6.1%**	165 or 27.7%**	181 or 30.4%**	153 or 25.7%**	595
Canada – total 1964	48 or 10.1%**	47 or 9.9%**	134 or 28.1%**	150 or 31.5%**	97 or 20.4%**	476

* % of Total Reporting from Province
** % of Total Number of Pharmacies Reporting

Table No. 32

DISTRIBUTION OF PROFITS AND LOSSES BY SALES VOLUME

	LOSS	Profit less than 2% of Sales	Profit 2% to 5% of Sales	Profit 5% to 10% Sales	Profit Over 10% of Sales	Total No. in Sales Category
Below $40,000	6 or 42.8%*		4 or 28.6%*	2 or 14.3%*	2 or 14.3%*	14
$40,000 to $60,000	7 or 14.0%	9 or 18.0%	5 or 10.0%	14 or 28.0%	15 or 30.0%	50
$60,000 to $80,000	10 or 11.5%	9 or 10.3%	13 or 15.0%	35 or 40.0%	20 or 23.0%	87
$80,000 to $100,000	9 or 11.1%	7 or 8.7%	14 or 17.3%	26 or 32.1%	25 or 30.9%	81
$100,000 to $125,000	7 or 7.0%	4 or 4.0%	26 or 26.0%	34 or 34.0%	29 or 29.0%	100
$125,000 to $150,000	3 or 5.1%	3 or 5.1%	14 or 23.7%	21 or 35.6%	18 or 30.5%	59
$150,000 to $200,000	10 or 10.2%	1 or 1.0%	37 or 37.8%	26 or 26.5%	24 or 24.5%	98
Over $200,000	8 or 7.5%	3 or 2.8%	52 or 49.1%	23 or 21.7%	20 or 18.9%	106
Total 1965	60 or 10.1%**	36 or 6.1%**	165 or 27.7%**	181 or 30.4%**	153 or 25.7%**	595
Total 1964	48 or 10.1%**	47 or 9.9%**	134 or 28.1%**	150 or 31.5%**	97 or 20.4%**	476

* % of Total in Sales Category
** % of Total Number of Pharmacies Reporting

Table No. 33

AVERAGE COSTS, MARGINS AND PROFITS OF ALL PHARMACIES A FIFTEEN YEAR SUMMARY

Year	Number of Replies	Sales	Cost of Goods Sold
1951	149	$ 60,862	$42,664
1952	250	63,601	44,756
1953	225	77,285	53,273
1954	418	76,448	52,726
1955	361	78,809	53,961
1956	463	83,650	56,799
1957	448	92,803	62,643
1958	510	98,270	66,234
1959	511	103,079	68,857
1960	664	106,688	71,054
1961	619	106,312	70,379
1962	511	111,684	74,046
1963	600	116,290	76,751
1964	476	131,039	86,224
1965	595	138,471	90,560

Year	Gross Margin	Proprietor's or Manager's Salary	Employees' Wages
1951	$18,198 - 29.9%	$ 3,652 - 6.0%	$ 5,173 - 8.5%
1952	18,845 - 29.6%	4,261 - 6.7%	4,859 - 7.6%
1953	24,012 - 31.1%	5,758 - 7.5%	7,249 - 9.4%
1954	23,722 - 31.1%	5,978 - 7.8%	6,980 - 9.1%
1955	24,848 - 31.5%	6,415 - 8.1%	7,605 - 9.6%
1956	26,851 - 32.1%	7,027 - 8.4%	8,030 - 9.6%
1957	30,160 - 32.5%	7,517 - 8.1%	9,095 - 9.8%
1958	32,036 - 32.6%	8,058 - 8.2%	9,630 - 9.8%
1959	34,222 - 33.2%	8,659 - 8.4%	9,896 - 9.6%
1960	35,634 - 33.4%	8,855 - 8.3%	10,562 - 9.9%
1961	35,933 - 33.8%	8,930 - 8.4%	10,950 - 10.3%
1962	37,638 - 33.7%	9,381 - 8.4%	11,392 - 10.2%
1963	39,429 - 34.0%	9,652 - 8.3%	11,978 - 10.3%
1964	44,815 - 34.2%	10,614 - 8.1%	13,890 - 10.6%
1965	47,911 - 34.6%	10,801 - 7.8%	14,678 - 10.6%

Year	Rent	Total Expenses	Net Profit
1951	$ 1,339 - 2.2%	$14,424 - 23.7%	$ 3,744 - 6.2%
1952	1,406 - 2.2%	14,514 - 22.8%	4,331 - 6.8%
1953	1,808 - 2.3%	20,179 - 26.1%	3,833 - 4.9%
1954	1,804 - 2.4%	20,259 - 26.5%	3,463 - 4.5%
1955	1,946 - 2.5%	21,672 - 27.5%	3,176 - 4.0%
1956	2,008 - 2.4%	23,087 - 27.6%	3,764 - 4.5%
1957	2,227 - 2.4%	25,428 - 27.4%	4,732 - 5.1%
1958	2,359 - 2.4%	27,417 - 27.9%	4,619 - 4.7%
1959	2,577 - 2.5%	28,862 - 28.0%	5,360 - 5.2%
1960	2,774 - 2.6%	30,300 - 28.4%	5,334 - 5.0%
1961	2,764 - 2.6%	30,937 - 29.1%	4,996 - 4.7%
1962	2,792 - 2.5%	32,612 - 29.2%	5,026 - 4.5%
1963	3,140 - 2.7%	34,073 - 29.3%	5,466 - 4.7%
1964	3,800 - 2.9%	38,525 - 29.4%	6,290 - 4.8%
1965	3,739 - 2.7%	40,157 - 29.0%	7,754 - 5.6%

Table No. 34

AVERAGE SIZE OF DISPENSARY IN SQUARE FEET AND AVERAGE SIZE OF DISPENSARY INVENTORY 511 PHARMACIES REPORTING

	Sales BELOW $40,000	Sales $40,000 to $60,000	Sales $60,000 to $80,000	Sales $80,000 to $100,000	Sales $100,000 to $125,000	Sales $125,000 to $150,000	Sales $150,000 to $200,000	Sales OVER $200,000	Average for Province
		sq. ft. $	sq. ft. $	sq. ft. $	sq. ft. $	sq. ft. $	sq. ft. $	sq. ft. $	sq. ft. $
Newfoundland						140 - $ 5,200		250 - $10,000	195 - $ 7,600
Prince Edward Island			150 - $ 8,000	145 - $ 4,325	160 - $ 4,817		400 - $19,000	100 - $14,000	180 - $ 8,469
Nova Scotia		196 - $16,436		330 - $14,850	241 - $ 9,235	197 - $ 6,600	122 - $ 7,480	180 - $ 6,508	197 - $ 9,179
New Brunswick		196 - $ 7,522	202 - $ 4,407	128 - $ 9,718	171 - $ 7,269		200 - $15,600	353 - $ 8,625	243 - $ 8,254
Quebec				303 - $ 8,000	270 - $ 7,404		270 - $ 6,282	250 - $11,600	278 - $ 7,819
Ontario	117 - $ 3,200	106 - $ 3,559	167 - $ 4,923	172 - $ 6,625	168 - $ 6,986	192 - $ 7,504	194 - $12,142	293 - $16,713	182 - $ 8,176
Manitoba		236 - $ 4,070	207 - $ 3,906	153 - $ 3,200	294 - $ 9,125	162 - $ 3,651	117 - $ 4,000		216 - $ 4,935
Saskatchewan	97 - $ 3,782	152 - $ 3,975	151 - $ 7,174	177 - $ 6,007	226 - $ 7,938	192 - $ 6,776	178 - $ 6,337	169 - $ 9,375	178 - $ 6,658
Alberta	234 - $ 4,954	88 - $ 3,643	222 - $ 5,975	346 - $ 5,949	149 - $ 4,448	135 - $ 7,735	239 - $ 8,220	68 - $ 5,000	192 - $ 5,978
British Columbia		173 - $ 3,900	270 - $ 3,600	150 - $ 4,320	178 - $ 5,262	175 - $ 6,226	177 - $ 6,799	175 - $ 7,237	180 - $ 6,906
Canada – Total	132 - $ 7,783	143 - $ 4,346	187 - $ 5,325	195 - $ 6,444	200 - $ 6,964	179 - $ 6,860	187 - $ 8,803	210 - $ 9,307	190 - $ 7,187

Table No. 35

RELATIONSHIPS OF PHARMACIES TO POPULATION BY PROVINCES AND OTHER SELECTED DATA

Province	Population*	Number of Pharmacists**	Number of Pharmacies**	Average Number of Persons per Phamacy	Type of Ownership of Reporting Pharmacies				Average Prescription Price in Selected Cities		
					Single Proprietorships	Partnerships	Limited Companies	Own Building	City	Number of Pharmacies Reporting Rx Data	Average Prescription Price
Newfoundland	498,000	140	74	6,730	3			1	Vancouver	67	$3.09
Prince Edward Island	108,000	28	24	4,500	3	1	3	4	Edmonton	9	$3.50
Nova Scotia	761,000	245	185	4,113	11		34	15	Calgary	10	$3.60
New Brunswick	623,000	165	106	5,877	9	3	16	9	Regina	6	$3.36
Quebec	5,657,000	3,079***	1,277	4,430	13	1		8	Saskatoon	15	$3.13
Ontario	6,731,000	4,309	1,787	3,766	89	11	91	60	Winnipeg	16	$3.26
Manitoba	962,000	623	301	3,196	22	2	14	24	Kitchener-Waterloo	4	$3.75
Saskatchewan	951,000	639	317	3,000	34	5	46	42	London	10	$3.60
Alberta	1,451,000	814	484	2,997	26	5	42	26	Toronto	21	$3.37
British Columbia	1,789,000	1,268	478	3,742	7	1	101	12	Montreal	3	$3.98
Yukon & N.W.T.	40,000								Halifax	19	$3.28
Canada	19,571,000	11,310	5,033	3,888	217	29	347	201			

* Dominion Bureau of Statistics, June 1965 ** Reported by Provincial Registrars *** Estimated

Table No. 36

SALARIES OF EMPLOYED PHARMACISTS IN CANADIAN PHARMACIES IN 1965

SALARY RANGE	Under $5,000	$5,000 – $6,000	$6,001 – $7,000	$7,001 – $8,000	$8,001 – $9,000	$9,001 – $10,000	Over $10,000	Total
Newfoundland				1 - 100.0%				1 - 100.0%
Prince Edward Island		3 - 60.0%		2 - 40.0%				5 - 100.0%
Nova Scotia	15 - 22.4%	19 - 28.3%	14 - 20.9%	9 - 13.4%	7 - 10.5%	1 - 1.5%	2 - 3.0%	67 - 100.0%
New Brunswick	7 - 18.9%	10 - 27.0%	8 - 21.7%	6 - 16.2%	2 - 5.4%		4 - 10.8%	37 - 100.0%
Quebec	1 - 11.2%	3 - 33.3%	2 - 22.2%	3 - 33.3%				9 - 100.0%
Ontario	18 - 11.3%	10 - 6.3%	21 - 13.1%	40 - 25.0%	16 - 10.0%	22 - 13.7%	33 - 20.6%	160 - 100.0%
Manitoba	2 - 7.2%	2 - 7.2%	7 - 25.0%	3 - 10.7%	2 - 7.2%	7 - 25.0%	5 - 17.7%	28 - 100.0%
Saskatchewan	7 - 9.7%	13 - 18.0%	12 - 16.7%	19 - 26.4%	9 - 12.5%	4 - 5.6%	8 - 11.1%	72 - 100.0%
Alberta	7 - 14.3%	12 - 24.5%	18 - 36.7%	10 - 20.4%		2 - 4.1%		49 - 100.0%
British Columbia	9 - 5.3%	5 - 3.0%	72 - 42.1%	51 - 29.8%	26 - 15.2%	4 - 2.3%	4 - 2.3%	171 - 100.0%
Total	66 - 11.0%	77 - 12.9%	154 - 25.7%	144 - 24.0%	62 - 10.4%	40 - 6.7%	56 - 9.3%	599 - 100.0%

Table No. 37

COMPARISON OF SELECTED DATA OF PHARMACIES ON PROFESSIONAL FEE AND ALL OTHER PHARMACIES

PROFESSIONAL FEE METHOD	ALBERTA	BRITISH COLUMBIA	MANITOBA	NEW BRUNSWICK	ONTARIO	SASKATCHEWAN	ALL CANADA
Total Sales	$ 1,484,685	$ 2,208,390	$ 2,426,234	$ 779,990	$ 8,600,813	$ 140,776	$15,640,888
Number of Prescriptions	108,197	190,900	228,557	100,277	649,624	27.092	1,304,647
Prescription Receipts	$ 391,635	$ 648,139	$ 762,041	$ 372,941	$ 2,269,330	$ 85,412	$ 4,529,498
Prescription Price	$ 3.62	$ 3.39	$ 3.33	$ 3.72	$ 3.49	$ 3.15	$ 3.47
Cost of Dispensing	$ 1.30	$ 1.37	$ 1.27	$ 1.40	$ 1.36	$ 1.26	$ 1.32
Ratio of Prescription Receipts to Total Receipts	26.4%	29.3%	31.4%	47.8%	26.3%	60.6%	28.9%
ALL OTHER METHODS							
Total Sales	$ 3,859,927	$16,293,917	$ 698,040	$ 2,526,503	$ 7,413,261	$ 9,844,600	$45,350,842
Number of Prescriptions	359,122	1,077,102	71,471	318,622	634,454	822,883	3,957,27`,
Prescription Receipts	$ 1,262,356	$ 3,386,422	$ 264,803	$ 1,144,419	$ 2,192,712	$ 2,649,152	$12,967,510
Prescription Price	$ 3.51	$ 3.14	$ 3.70	$ 3.59	$ 3.46	$ 3.21	$ 3.27
Cost of Dispensing	$ 1.30	$ 1.37	$ 1.27	$ 1.40	$ 1.36	$ 1.26	$ 1.32
Ratio of Prescription Receipts to Total Receipts	32.7%	20.7%	37.9%	45.3%	29.5%	26.9%	28.6%

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966-67

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 30

THURSDAY, JANUARY 26, 1967

TUESDAY, JANUARY 31, 1967

WITNESSES:

From the 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; and Mr. K. M. Render, Chief, Field Programmes Division.

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

25520—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

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

and

Mr. Brand,
Mr. Clancy,
Mr. Côté (*Dorchester*),
Mr. Enns,
Mr. Forrestall,
Mr. Goyer,
Mr. Howe (*Hamilton South*),
Mr. Howe (*Wellington-Huron*),
Mr. Hymmen,
Mr. Isabelle,
Mr. Johnston,
Mr. MacDonald (*Prince*),
Mr. Mackasey,
Mr. MacLean (*Queens*),
Mr. O'Keefe,
Mr. Orlikow,
Mrs. Rideout,
Mr. Roxburgh,
Mr. Rynard,
Mr. Tardif,
Mr. Whelan,
Mr. Yanakis—24.

(Quorum 10)

Gabrielle Savard,
Clerk of the Committee.

MINUTES OF PROCEEDINGS

THURSDAY, January 26, 1967.
(41)

The Special Committee on Drug Costs and Prices met this day at 11.10 o'clock a.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout, Messrs. Brand, Forrestall, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), Hymmen, Isabelle, Mackasey, MacLean (*Queens*), Rynard, Yanakis—(12).

In attendance: *From the 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.

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

The Chairman presented the Third Report of the Subcommittee on Agenda and Procedure as follows:

"The Subcommittee recommends:

1. That the submission received a few days ago from The Canadian Drug Manufacturers on the subject matter of Sales Tax on Pharmaceuticals be received and made part of the Committee's record, but that the Chairman, Mr. Leslie L. Dan be not required to appear again before the Committee.

2. That Mr. Orlikow's Motion be tabled until the Committee has seen the comprehensive report Mr. Blakely, Accountant for the Committee, is preparing at the present time."

On motion of Mrs. Rideout, seconded by Mr. Isabelle, the Third Report of the Subcommittee was adopted. (*See Appendix A*)

Agreed, That copies of the submission mentioned in paragraph (1) be distributed to the members.

On motion of Mr. Howe (*Hamilton South*) seconded by Mr. Forrestall,

Resolved,—That reasonable living and travelling expenses be paid to Mr. J. K. Lawton, Ph. C., of Halifax, who was called to appear on Monday, January 23, 1967, and to Dr. Irwin M. Hilliard, M. D., F.R.C.P. (c), of Toronto, who has been called to appear on Friday, February 3, 1967.

Mr. Brand, being unavoidably absent at last Monday's meeting when the Canadian Pharmaceutical Association, Inc. presented a supplementary brief, registered strong objections to certain statements contained in the brief which, in his opinion, were grossly inaccurate. He referred particularly to some of the comments about the prescribing of physicians.

25520—1½

Dr. Chapman was called. He introduced the other members of the Directorate and made introductory remarks. Dr. Chapman tabled the following documents, a copy of which was distributed to the members:

1. Summary of Data on Drugs including

(a) A Comparative Survey of Quality of Brand Name and Generic Drugs, Domestic and Imported, 1965;

(b) Table of Drugs Analyzed for the Department of Veterans Affairs, 1965 and 1966;

(c) Drug Recalls Involving Food and Drug Directorate, June 1965 to January 1967;

(d) Convictions Registered Against Drug Manufacturers, 1963 to 1966;

(e) Instances of a Significant Hazard to Health Involving Pharmaceutical Products, 1959 to 1966.

2. Some observations on Drug Control in Europe.

3. An Examination of Trifluoperazine Tablets marketed in Canada.

4. Copy of correspondence relating to the question of the "new drug" status of Trifluoperazine, and to the recommendations of the Hilliard Committee in this regard.

Agreed—That the above information be printed as part of the proceedings. (*See Appendices B, C, D, and E*)

Dr. Chapman read a prepared statement which was also distributed to the members, and was questioned thereon. He was assisted by Dr. Levi and Dr. Hardman.

At 1.30 p.m., the Committee adjourned until 7.00 o'clock this evening.

EVENING SITTING
(42)

The Special Committee on Drug Costs and Prices reconvened at 7.15 p.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Messrs. Brand, Forrestall, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), Hymmen, Isabelle, Mackasey, MacLean (*Queens*), O'Keefe, Yanakis—(11).

In attendance: Same as at the morning sitting.

Mr. Hollett supplied answers to questions asked at the morning sitting.

Agreed—That the following correspondence be printed as appendices to this day's proceedings:

1. Letter dated January 9, 1967, to Mr. Laidlaw, Legal Counsel for the Committee, from Mr. Guy Beauchemin, Executive Vice-President of the Pharmaceutical Manufacturers Association of Canada, supplying information requested previously; (*See Appendix F*)

2. Letter dated January 12, 1967, from Mr. R. G. McClenahan, Barrister, to the Chairman of the Committee, re: Submission to Micro Chemicals Limited,

Gryphon Laboratories Limited and Paul Maney Laboratories Canada Limited; (*See Appendix G*)

3. Letter dated January 10, 1967, to the Chairman of the Committee from Mr. C. A. Nowotny, Assistant Secretary of Hoffman-LaRoche Limited. (*See Appendix H*).

Dr. Chapman was questioned at length. He was assisted by Mr. Allmark, Dr. Levi, and Mr. Hollett.

On behalf of the Committee the Chairman thanked the officials of the Food and Drug Directorate.

At 10.00 o'clock p.m. the Committee adjourned to the call of the Chair.

TUESDAY, January 31, 1967.
(43)

The Special Committee on Drug Costs and Prices met this day at 1.15 o'clock p.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Messrs. Forrestall, Harley, Hymmen, Isabelle, Mackasey, MacLean (*Queens*), Orlikow.

In attendance: From the 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. Jeffrey Bishop, Chief, Medicine and Pharmacology Division; Dr. L. Levi, Chief, Pharmaceutical Chemistry Division; Mr. K. M. Render, Chief, Field Programme Division.

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

The Committee resumed the examination of the officials of the Food and Drug Directorate.

Dr. Chapman was called. He read an opening statement about the Recalls, Convictions and Health Hazards.

He answered questions about Appendix IV, Convictions Registered against Drug Manufacturers, and commented on Appendix V, Instances of a Significant Hazard to Health involving Pharmaceutical Products.

Dr. Levi answered questions on disintegration and dissolution tests.

Dr. Chapman was further questioned.

The Chairman thanked the officials of the Food and Drug Directorate on behalf of the Committee and at 2.20 o'clock p.m. the Committee adjourned until 9.30 a.m. Friday, February 3.

Gabrielle Savard,
Clerk of the Committee.

EVIDENCE

(Recorded by Electronic Apparatus)

THURSDAY, January 26, 1967.

The CHAIRMAN: Ladies and gentlemen, we have a quorum.

There are some matters of an administrative nature which we would like to dispose of first.

Dr. R. A. Chapman, the Director-General of the Food and Drug Directorate, is here to present to this meeting a great deal of evidence and documentation that the Committee has asked for in one form or another.

First of all, the Steering Committee on Agenda and Procedure has the honour to present its Third Report. We held a meeting on Thursday, January 19.

Your subcommittee recommends:

> That the submission received a few days ago from the Canadian Drug Manufacturers on the subject matter of sales tax and pharmaceuticals be received and made part of the Committee's record, but that the chairman, Mr. Leslie L. Dan, be not required to appear again before the Committee.

This is a submission by Mr. Dan's group, suggesting an alternative method of dealing with the federal sales tax. What it is actually is for the government to retain the federal sales tax but to keep the money separate and to use it for setting up a drug institute.

I will see that each member gets a copy. It will become part of today's record.

Secondly, we have Mr. Orlikow's motion that asks for detailed financial statements from drug companies to be tabled until the Committee has seen the comprehensive report of Mr. Blakely, the accountant for the Committee, which was being prepared at that time and which is now completed. I would suggest that we continue to table Mr. Orlikow's motion.

When members of the Committee have a chance to read Mr. Blakely's report, which I now have in my possession I think they will find that Mr. Orlikow's motion is not necessary to the work of the Committee. He sought a detailed financial statement from many drug companies. I think Mr. Blakely, in a general way, has been able to give us the same information that Mr. Orlikow's motion would have done.

May we have a motion for the adoption of the Steering Committee's report?

Mrs. RIDEOUT: I so move.

Mr. ISABELLE: I second the motion.

The CHAIRMAN: All in agreement? Opposed?

Some hon. MEMBERS: Agreed.

The CHAIRMAN: The next item is the recommendation by Mr. Forrestall that the Committee ask Mr. Lawton from Halifax to appear with the Canadian Pharmaceutical Association; and it was also recommended by Mrs. Rideout and Dr. Raynard that Dr. Hilliard be called. As the Committee has asked both of these people to appear as individuals I think that the Committee should pay their reasonable travelling and living expenses. Is that a reasonable suggestion?

Dr. HOWE (*Hamilton South*): I so move.

Mr. MACKASEY: Was he here the other evening?

The CHAIRMAN: It was Mr. Lawton who was here the other evening, Dr. Hilliard will be appearing before the committee on Friday, February 3. Are there any opposed?

Some hon. MEMBERS: Agreed.

The CHAIRMAN: Ladies and gentlemen, we will now move on to the business part of today's meeting.

We have with us today Dr. Chapman, the Director-General of the Food and Drug Directorate, Department of National Health and Welfare.

Mr. BRAND: Mr. Chairman, before we continue I would like to make a very brief statement in view of the fact that I was unable to be here on Monday night because of matters beyond my control. Because of the airlines and the weather and what have you I was stuck in "Toronto the Good."

An hon. MEMBER: Hear, hear.

Mr. BRAND: I put that comment in parentheses. Since I did not have an opportunity to comment at that time on the supplementary brief of the Canadian Pharmaceutical Association I would like to place on the record the strongest possible objection to some of the statements made therein. I regret very much that I did not have an opportunity to challenge the obvious inaccuracies and deliberate falsehoods which are present in this brief. I would like to place this on the record now, particularly in view of some of the comments about the prescribing of physicians and because no attempt made by this group to show that they were other than with the angels in their comments. Some of the explanatory comments on the type of prescribing done by physicians are absolutely inaccurate and I trust that they knew they were so.

The CHAIRMAN: Are you referring to Appendix 3?

Mr. BRAND: Yes; 3, Appendix I believe. This is grossly inaccurate, and I do not think I can let this pass without making these comments.

I have no intention of commenting at all on some of the other inaccuracies in the brief, including the net profits of the pharmacists, which vary in their brief from 4.8 to 5 per cent to 7 per cent to .06 per cent, and each of them declared as being the profit of a pharmacy; but I did want to register that objection most strongly. I would, indeed, welcome the opportunity at some future time to bring these gentlemen back and to question them on where they got these figures and why they included them in this report. Thank you.

The CHAIRMAN: All right.

Dr. Chapman, I know, and as I mentioned, has brought a great deal of data and information that has been discussed on one way or another before the Committee.

If there is some question about the best way to proceed with this material, Dr. Chapman also has a statement, and perhaps the best thing to do would be for him to tell the Committee what material he has brought with him and we can distribute it as we go along and allow questioning on it.

Dr. Chapman, would you care to make a few remarks before we stand?

Dr. R. A. CHAPMAN (*Director-General, Food and Drug Directorate, Department of National Health and Welfare*): Yes; thank you very much, Mr. Chairman. I may say that my colleagues and I are very pleased indeed to be with you this morning.

If I can introduce the other members of the directorate, I have with me Mr. M. G. Allmark, Assistant Director-General, Drugs; Dr. L. Levi, Chief of our Pharmaceutical Chemistry Division; Mr. A. Hollett, Director of our Bureau of Operations; and Dr. A. C. Hardman who is Director of our Bureau of Scientific Advisory Services. I am sure that these gentlemen, will be in a position to fill in the details that I may not be able to supply. After having read through the various briefs and the proceedings of your meetings I have prepared a relatively short statement. I felt that this might be helpful to you because I believe I have covered the most important areas that have been discussed, as they relate to the activities of the Food and Drug Directorate.

In addition to the statements I have a summary of data on drugs which we had available in the Food and Drug Directorate and which I felt might be of interest to the Committee. For example, we carried out a comparative survey of the quality of brand name and generic drugs, both domestic and imported, for 1965. We have a table of the drugs analyzed for the Department of Veterans Affairs for 1965, and a portion of 1966: drug recalls involving the Food and Drug Directorate, June 1965 to 1967; convictions registered against manufacturers, 1963 to 1966; and instances of significant hazards to health involving pharmaceutical products. In this latter case we have gone back to 1959 up to the present. I should be pleased to table that material if the Committee wishes.

An hon. MEMBER: I move that it be tabled, Mr. Chairman.

Mr. MACKASEY: Mr. Chairman, is that all the material Dr. Chapman has?

The CHAIRMAN: No.

Mr. CHAPMAN: No; I have additional material.

At one stage in our deliberations a request was made, I believe, by Mr. Mackasey, for the tabling of a report on some observations on drug control in Europe. I pointed out at that time that this was a document which had been presented in confidence to the Canadian Drug Advisory Committee. The words "in confidence" did not indicate that it was a highly confidential document but that it was not intended for publication. At this point I would certainly wish to apologize if I in any way cast any reflection on the integrity of any member of this Committee. That was certainly not my intention.

I have asked the authors of that report to go through the document and to remove any statements which might prove of embarrassment to individuals, or

to the Directorate, or, as a matter of fact, to the agencies in the countries they visited. The authors did this and then presented it to me. I have read through this second draft and I believe it contains all the substance of the original report. I should be pleased to table that document if the Committee so wishes.

Mr. MACKASEY: As a point of information, what you are saying then, Dr. Chapman, is that the only difference in the two drafts is the deletion of the names of particular individuals who helped you in your study, which names would add nothing to our knowledge. You have left them out to avoid embarrassment or betraying their confidence?

Mr. CHAPMAN: That is correct. There have been some editorial changes made, too.

Mr. MACKASEY: But they do not change the content?

Mr. CHAPMAN: No.

Mr. MACKASEY: I would hope, Mr. Chairman, that we could have that particular document in our hands as soon as possible because it could be very relevant, if not to this meeting, to the next.

The CHAIRMAN: All of these documents will be given to you this morning.

Mr. MACKASEY: Mr. Chairman, again, because this could be a very fruitful discussion with Dr. Chapman, is it our intention to limit Dr. Chapman's appearance to just this morning?

The CHAIRMAN: No; I am sure that if the Committee so wishes Dr. Chapman would be pleased to come back again. I am sure there will be many questions.

Mr. MACKASEY: Could we have Dr. Chapman back again today?

The CHAIRMAN: If that is possible and if we can find the facility.

You mean you would like to have a little time to peruse some of the documents and then come back this afternoon?

Mr. MACKASEY: Yes; particularly on this one document, so far as I am concerned.

The CHAIRMAN: We will wait and see how the meeting progresses this morning. Dr. Chapman?

Mr. CHAPMAN: There has been a good deal of discussion with regard to the analysis of trifluoperazine tablets marketed in Canada. Our Pharmaceutical Chemistry Division has carried out an exhaustive study of these various products, and we have a complete report which I would like to table.

Mr. HOWE (*Hamilton South*): Mr. Chairman, does this particular document contain comparatives of S.K.F. and Paul Maney's specifically, because I have a series of questions I wish to ask you on this. These could conceivably be avoided, or cut down, if this document contains these comparisons.

The CHAIRMAN: Yes, I think it has. What I suggest is that perhaps we should let Dr. Chapman go through his own information and we can come back and deal with the documents one at a time.

Mr. HOWE (*Hamilton South*): Mr. Chairman, I asked only because it was current at this particular moment, and to get clear what is in the documents. I am in favour of our—

The CHAIRMAN: Would you care to tell Dr. Howe?

Mr. HOWE (*Hamilton South*): I am not asking for specific figures, Dr. Chapman. I just want that information.

Mr. CHAPMAN: The scope of the investigation includes the products of four companies. Smith Kline and French, Stelazine; Mowatt & Moore, Clinazine; Paul Maney Laboratories, Triflurin; and Jules R. Gilbert, Triperazine.

Mr. HOWE (*Hamilton South*): Thank you, Dr. Chapman.

Mr. CHAPMAN: We also have photocopies of correspondence which Mr. Robert F. Dailey of Smith Kline and French, in a letter to the Chairman, suggested he would be pleased to have tabled, relating to the question of the new drug status of trifluoperazine and particularly Stelazine. We will of course, be pleased to table this correspondence if the Committee so desires.

I feel, however, that in order to give a complete picture we should also table additional correspondence including a letter from Dr. W. W. Wigle, President of PMAC to the Minister in June 1966; a second letter by Dr. Wigle also to the Minister; a letter from Frederick R. Hume, Q.C. to Robert E. Curran, Q.C., July 12, 1966; a letter of D. S. Thorson, Assistant Deputy Minister, Department of Justice, to Mr. R. E. Curran, Q.C. in September 1966; a letter of Mr. R. E. Curran, Q.C. to Frederick R. Hume, Q.C. on October 20, 1966; and then, finally, the letter from Mr. Hume to Mr. Curran in October 1966. It would seem to me that this would then give the complete picture with regard to the situation relating to the new drug status of trifluoperazine and the recommendations of the Hilliard committee in this regard.

Mr. HOWE (*Hamilton South*): Can you identify Mr. Curran for me?

Mr. CHAPMAN: Mr. Curran is legal counsel for the Department of National Health and Welfare.

The CHAIRMAN: Thank you, Dr. Chapman.

Ladies and gentlemen, this is the documentation that Dr. Chapman has brought with him. I think it is very obvious that this should become part of today's record of proceedings. Is it agreed?

Some hon. MEMBERS: Agreed.

The CHAIRMAN: Does the Committee wish to receive this documentation one item at a time and go through them, or just to have general questioning.

Mr. HOWE (*Hamilton South*): May I make a suggestion? With this unexpected amount of documentation it is going to be very difficult for the members of the Committee to question intelligently, at a glance, within committee. I am sure that a large number of the questions I have are going to be answered by these documents. Are we not, therefore, going to be repeating ourselves by asking questions the answers to which may be contained in this documentation? Perhaps we should have time to peruse and consider these documents before we continue with questioning at this time?

Mr. MACKASEY: Mr. Chairman, in support of Dr. Howe's remarks, I would very much like to have an opportunity to scrutinize the documents closely. However, in order that we can carry on this meeting and make use of the time between this meeting and another later in the day, perhaps Dr. Chapman, who is no doubt very familiar with the documents, could tell us what questions are fairly well answered in the documents. That might prevent our asking questions that normally we might not ask. I think we could trust Dr. Chapman's judgment on whether the information is best obtained from the documents or from his explanation. But I do agree with Dr. Howe.

The CHAIRMAN: I think perhaps the best course at the moment would be for Dr. Chapman to read the statement he has, to have general questioning and then perhaps recess and come back after lunch, if that is possible. By that time Committee members—

Mr. HOWE (*Hamilton South*): I think that is too soon, Mr. Chairman. Could we not meet later than that? We have the House sitting at 2.30 this afternoon. Even leaving it till after that still does not give us the opportunity to do justice to this amount of documentation. I think it should be later on this afternoon or evening so that we have time to do justice to this.

I hardly think that Dr. Chapman can be expected to know everything that is in this documentation, because I am sure he did not prepare it all, and that some of it was prepared for him.

The CHAIRMAN: In all fairness to Dr. Chapman, I also think that Mr. Mackasey's suggestion, that he would be able to say whether the answers are in the documents, is expecting too much of Dr. Chapman.

Mr. CHAPMAN: I think, Mr. Chairman, that if I read the statement, or go through it and indicate the highlights, as you wish, this would indicate the areas that I try to cover, and I could, at the appropriate stage, indicate the information that is in the additional documents.

Mr. MACKASEY: That is fine.

Dr. HOWE: I think this should constitute our morning meeting and that we should have time before we ask,—

The CHAIRMAN: When we have finished that aspect of it we can decide when we will meet later.

Mr. CHAPMAN: Dr. Harley would you like to distribute these documents that are now available?

The CHAIRMAN: All right.

Mr. HOWE: Do these contain the other documents that you were speaking of.

Mr. CHAPMAN: With the exception of the correspondence. I did not know, of course, whether or not the Committee would wish to have this correspondence tabled. I have just one set of the correspondence that I would propose to table, and I would be pleased to speak to that.

Mr. HOWE: Does this contain all these specific figures that you were speaking of, or are they in a separate appendix?

The CHAIRMAN: I suggest that we distribute all the documents that we have at this point.

Mr. CHAPMAN: The documents will consist of my statement: the report on some observations on drug control in Europe, by Mr. Allmark, Dr. Levi and Mr. Ferrier; a summary of the data on drugs available in the Food and Drug Directorate; and, finally, the report on the examination of trifluoperazine tablets marketed in Canada.

Mr. MACKASEY: Mr. Chairman, in view of the fact that, very properly, these documents are being distributed to the press—and I emphasize that they should be—would I be out of order if I suggested that the same courtesy be extended to Judge Thorson and other people who will follow these deliberations, such as PMAC who, I think, are represented here by Dr. Wigle?

There is nothing secret about it. The press are getting it, as they should and the members have it. Am I wrong in making this suggestion?

The CHAIRMAN: I am not sure what is the feeling of the members of the Committee. It is a question of the copies that are available.

Mr. CHAPMAN: I think we have about 35 copies of each of these documents.

Mr. MACKASEY: Mr. Chairman, there are present representatives of the group that perhaps are unfairly labelled as generic firms—and I say "unfairly" because they are part of an industry—and there is also present the president of the PMAC. Perhaps we could limit the distribution to these two.

The CHAIRMAN: Has anyone any objection to Mr. Mackasey's suggestion, as far as the distribution will allow?

If everyone has all the documents Dr. Chapman can go through his statement and give us the highlights without actually quoting the figures, and perhaps it would be possible for the Committee members to follow it.

Mr. CHAPMAN: Thank you, Mr. Chairman.

I propose to confine my remarks to a few essential points which I believe would be of interest to you and which I hope may clarify some of the concepts relating to the Food and Drugs Act which may have become slightly distorted during your hearings.

As my Minister, the Honorable Allan J. MacEachen, pointed out in his opening remarks on June 7, the basic federal legislation governing the production and distribution of drugs in Canada is the Food and Drugs Act. The purpose of this legislation is to protect the Canadian consumer from hazards to health and fraud in the sale of foods, drugs, cosmetics and medical devices. It is based on the authority of the federal government to legislate on criminal matters. It is essentially a prohibitive Act. It does not instruct or request pharmaceutical manufacturers or distributors to perform certain duties or functions. It does require that such manufacturers and distributors ensure that the provisions of the Act and Regulations are not violated in the sale of their products. Furthermore, the Act does not provide authority to regulate, in any way, the price of drugs.

Now, having said that, there is no doubt the requirements of the Food and Drugs Act and Regulations contribute to the cost of drugs. At the same time, I

consider these requirements essential in order to reduce the hazards involved in the use of drugs to the lowest practicable level. I am sure that reputable manufacturers of pharmaceutical products consider it necessary to meet these requirements as a minimum to ensure the quality, efficacy and safety of their products. However, I also consider that our regulations should be reviewed at regular intervals to ensure that no unnecessary obstacles are being placed in the way of the pharmaceutical industry and at the same time to strengthen any areas where additional hazards have become apparent. I shall refer to a number of such areas later in this statement.

Some of the most important and basic requirements of the Food and Drugs Act are to be found in Section 9 (1), with which I am sure you are all familiar. It reads:

> 9. (1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

You will note that there is no requirement that a drug must be "safe". There is a requirement that no person shall sell a drug in a manner that is likely to create an erroneous impression in regard to its safety and other specified characteristics. The provision of positive assurance to the physician, pharmacist and consumer that all drugs on the market are always of high quality, safe and effective for the purpose recommended, would indeed be an ideal situation. But the number of pharmaceutical products on sale in Canada makes the attainment of this ideal situation completely impracticable. It is estimated that there are between 25,000 and 30,000 different drug preparations in a wide variety of dosage forms on the Canadian market, produced by approximately 500 pharmaceutical manufacturers. No information is available on the number of lots or batches of each drug produced each year by each of these firms. It is clearly evident, however, that it would require many times the present resources of the Directorate to conduct limited tests on each lot of drugs to confirm compliance with label claims alone. Therefore, under our present legislation which does not limit the number of pharmaceutical products which may be placed on the market, the responsibility for the quality, efficacy and safety of a drug must rest with the manufacturer.

With this introduction, I would like to outline the action we have taken or propose to take to ensure that manufacturers are fully meeting these responsibilities:

1. *Establishment, Food and Drug Directorate*

During the past two years we have significantly improved our capacity to maintian an adequate surveillance of drugs on the market as well as to evaluate new drugs. We have also developed a plan to increase our resources over the next ten years. The establishment of the Directorate for 1964, 1966, and projected figures for 1970 and 1975, are shown in Table I.

I will not read the table. The table follows:

TABLE I

Establishment, Food and Drug Directorate, 1964-1975

	Year			
	1964	1966	1970[1]	1975[1]
Senior Management	10	10	10	10
Research Laboratories	148	182	302	430
Bureau of Scientific Advisory Services	13[2]	76	131	189
Bureau of Operations	315	401	736	835
Narcotic Division	57	63	76	85
Consumer Division	10	12	20	25
Administrative Services	51	76	117	159
Totals	604	820	1,392	1,733

[1] Projected figures.
[2] Division of Medicine only.

A five and ten year plan for the operation and expansion of the Food and Drug Directorate to cover current responsibilities, for the period 1965 to 1975 as outlined in Table I, was approved in principle by the Treasury Board in August, 1965. However, the Board requested that this expansion be extended over a period of twelve years. Thus, the projected expansion will be extended to 1977.

This is the reason, of course for the error in the years that I made in my first draft.

The Bureau of Scientific Advisory Services, which has as a major responsibility the review of preclinical and new drug submissions, was established in July, 1965. Therefore, the figure opposite this unit for 1964 includes only the Division of Medicine, and you will note that that are 13 positions. A building programme to provide the necessary facilities in Ottawa for this expansion is in the initial planning stage.

2. *Regulatory Actions*

During 1965, the Directorate carried out the following actions in relation to pharmaceutical products. I wish to emphasize that these data relate only to drugs and do not include our work on foods, cosmetics or medical devices. Furthermore the list is incomplete.

(a) 16 prosecutions were conducted in which convictions were registered with fines totalling $1,865;

(b) 77 seizures of drugs with a value of $14,822 were initiated;

(c) 76 seizures of drugs with a value of $21,542 were disposed of;

(d) voluntary disposal of 86 lots of drugs with a value of $238,673 was supervised;

(e) 2,733 samples were examined in our laboratory for quality control aspects, e.g. identity, potency, weight variation and disintegration time;

(f) 3,677 labels, cartons, inserts and circulars were reviewed;

(g) 6,873 radio and television commercials were scrutinized;

(h) 18,820 advertisements were reviewed;

(i) 2,853 proprietary medicines were licensed;

(j) 72 new drug submissions, 45 major supplemental submissions and 87 preclinical submissions were cleared;

(k) since February, 1965 approximately 5,000 reports of suspected adverse reactions to drugs have been evaluated.

The necessary regulatory action was taken in those instances where there was a violation of the requirements of the Act or Regulations.

I should emphasize, however, that this was not necessarily prosecution action; but some action was taken. In many instances it required only that the matter be drawn to the attention of the particular manufacturer or distributor.

I might add here that our budget for 1965-66 was approximately $5.5 million. We consider that approximately 40 per cent of our resources are devoted to the control of drugs; and this works out to a per capita cost of approximately 11 cents. In 1966-67, the budget was $6.7 million and the cost has gone up to 13 cents per person. The Canadian public, in my opinion, are receiving a very good return on this investment.

3. *Drug Notification*

In line with the recommendation of this Committee in its Fifth Report, the Food and Drug Regulations were amended in May, 1966 to require the manufacturers of drugs to provide the Directorate with information on all their products. These data include

(a) the name and address of the manufacturer;

(b) the name under which the drug is sold;

(c) the use or purpose for which the drug is recommended;

(d) a quantitative list of the medicinal ingredients contained in the drug by their proper names or, if they have no proper names, by their common names; and

(e) the recommended dosage of the drug.

Such information must also be provided under these same regulations within thirty days of the initial sale of a drug by a manufacturer. Information must also be provided when a manufacturer withdraws a drug from the market or changes its formulation or recommended dosage or use. These regulations which went into effect on October 1, 1966 also apply to any person who imports a drug into Canada. These data when fully collated should provide us with a complete picture of the drugs on the Canadian market at any time.

4. *Imported Drugs*

We believe that our regulations relating to imported drugs could be improved. At the present time under Section C.01.055, the Director-General "may require" information regarding the conditions of manufacture and certain testing to be carried out in Canada. We believe that it should be mandatory

(a) to have available in Canada information and evidence that the conditions of manufacture prescribed in C.01.052 have been met and that,

(b) each lot or batch of drug in dosage form has been tested in Canada by an acceptable method to ensure identity, potency and purity for its recommended use, or evidence is available in Canada that the drug has been adequately tested in the country of origin.

These proposals are also in accord with Recommendation 10 of the Report of the Hilliard Committee which reads as follows:

> Distributors receiving bulk, semi-finished or finished drug products from outside Canada must provide satisfactory evidence of testing of the imported drug with regard to identity, purity, and potency before marketing such drugs in Canada.

5. *Adequate Directions for Use*

At the present time, the Food and Drug Regulations require that the label of a drug carry "adequate directions for use." However, this phrase has not been defined in the regulations. It is proposed to recommend that "adequate directions for use" be defined as follows:

> All information, including such cautions and warnings as may be necessary for the proper and recommended use of the drug and shall include:—
>
> (i) subject to Section 3 of the Act (this relates to schedule A diseases) indications for use;
>
> (ii) an indication of the route of administration;
>
> (iii) the recommended single and daily dose.

This definition should provide more effective control over the information given on the labels of drugs or the package inserts.

6. *Definition of a New Drug*

This matter was considered by the Hilliard Committee which recommended (Recommendation 5):

> That the definition of a new drug be amended to include a drug not currently in new drug status if it is to be manufactured or produced by a method or process that is substantially different from the method or process currently being used in Canada; or if with prolonged use, new or more serious or more frequent side effects, develop.

We consider that the first portion of this recommendation may already be covered under our present definition, i.e. a drug that has not been sold in Canada for a sufficient time and in sufficient quantity to establish its safety and effectiveness. However, it is proposed to clarify this point when the New Drug Regulations are amended in line with the recommendation of the Boyd Committee.

There was a question as to whether authority was provided in the Act to define as a new drug, a pharmaceutical product "if with prolonged use, new or more serious or more frequent side effects, develop." This was referred to the Department of Justice who 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." Nevertheless officers of the Directorate believe that the intent of the Hilliard Committee in this regard can be achieved by requiring that regula-

tions along the following lines be adopted—and we have this authority under section 24 of the Act, which states that the Governor in Council may make regulations relating to the condition of sale of a drug.

(a) that no manufacturer shall sell a drug unless he has established and maintained records including adequately organized and indexed files containing full information respecting any
  (i) substitution of another substance for that drug or any mixing of another substance with that drug,
  (ii) error in the labelling of that drug or in the use of labels designed for that drug,
  (iii) bacteriological or any significant chemical or physical or other change or deterioration in any lot of that drug,
  (iv) failure of one or more distributed lots of that drug to meet the specifications established for that drug,
  (v) adverse reaction associated with the use of that drug, and
  (vi) unusual failure of that drug to produce its pharmacological activity.

It is intended that the information contemplated under subparagraphs (i) to (iii) should be furnished immediately upon receipt by the manufacturer and within fifteen days for the information referred to in subparagraphs (iv) to (vi). These proposals are now under consideration by the Department of Justice.

I should emphasize that point, because we are not absolutely certain that we have the authority to make these regulations. However, if it is found that we have, then we would recommend that regulations be adopted along these lines.

7. *Drug Sold by a Manufacturer for the First Time*

The Directorate also has under consideration a regulation requiring that a drug manufacturer who intends to market a drug for the first time in Canada which has previously been marketed by others and is in old drug status, must supply certain basic information including the manufacturing process, specifications, methods of analysis and a quantitative list of all ingredients. At the present time a drug manufacturer may place a drug on the market without taking any such action except for the limited information required within thirty days under the Drug Notification Regulations. This proposal is also included in the draft amendments currently under review by the Department of Justice.

In the Briefs submitted to the Committee, or during the questioning of witnesses, there have been numerous statements made which may have given a misleading impression of the authority and activities of the Directorate. It would not be possible for me to refer to all these points. In fact, it is probably unnecessary since the members of this Committee already have a very good background in this field and can, no doubt, assess the accuracy of these comments.

However, a number of statements have been made which are definitely incorrect. I believe it would be wise to draw these to your attention:

1. *Minutes of Proceedings and Evidence, No. 5—Submission by Pharmaceutical Manufacturers Association of Canada, page 312, paragraph 11.9*

Crucial in this regard is the decision by the Food and Drug Directorate whether a particular product still has the status of a 'New Drug.' If

the product is still a 'New Drug,' then the licensee must meet the extensive scientific requirements of a new Drug Submission; if it is not, then the controls which the FDD can exercise are very limited. Because of this technical difference, a very potent drug, one which the originating manufacturer is still subjecting to clinical tests because of significant side effects, would be treated as a comparatively innocuous substance.

It is not correct to say that if a product is not considered to be a new drug "then the controls which the FDD can exercise are very limited" and that it "would be treated as a comparatively innocuous substance." In fact, the full force of the Food and Drugs Act and Regulations, other than those regulations pertaining specifically to new drugs, would apply including authority to place the drug on Schedule H which would completely prohibit its sale.

If less drastic action were required, and in most instances this would be the case, such action as placing the drug on Schedule G (controlled drugs) or Schedule F (prescription drugs) could be taken. Furthermore, all requirements of the Act and Regulations including those pertaining to manufacturing facilities and controls, labelling including any required warning statements, packaging and advertising, would be applicable.

2. *Minutes of Proceedings and Evidence, No. 12—Statement by Dr. H. L. Smith, Vice-President, Ayerst, McKenna and Harrison Limited, pages 855 and 856*

The point, I think, which, perhaps, a lot of people do not realize is that you can have a drug on the market today, say, in England, which is being freely marketed and used by the medical profession, which is not still on the market in Canada because we have to repeat just about all the pharmacology, all the toxicology, all the clinical investigations and generally a lot more before we can market that here. Therefore, even though it is on the market in England today, it may be three to four years before we get it on the market in Canada; and we bear all of these costs.

This statement is not correct. Reports of clincial and toxicological studies conducted outside Canada have always been accepted in new drug submissions. The extent and the quality of the work, rather than its country of origin, form the basis for judging its acceptance.

It is true that a statement indicating that a drug is on the market in another country is not accepted as evidence of compliance with the regulations governing new drugs in Canada nor should it be—and I would like to emphasize that. It is also true that we encourage manufacturers to carry out some of their investigational work in Canada, but they are not required to do so by any regulation under the Food and Drugs Act.

3. *Minutes of Proceedings and Evidence, No. 17—Brief Submitted by the Consumers Association of Canada, page 1173*

Twenty-three brands of phenylbutazone tablets were tested for potency, content uniformity, disintegration and dissolution characteristics. Five, or 21.7 per cent, failed to meet existing specification. Three others were classified by the researcher as unsatisfactory. One was faulty enough (the product delivered little phenylbutazone to the blood) to constitute an absolute hazard to health.

This statement was based on the results of a survey carried out under the supervision of Dr. M. Pernarowski, Associate Professor, Faculty of Pharmacy, University of British Columbia. Dr. Pernarowski was formerly head of the Pharmaceutical Chemistry Division of the Directorate. He is a well-qualified and highly competent pharmaceutical chemist. Since the report of this study has not as yet been published, I discussed this matter with Dr. Pernarowski to determine the background for his statement.

He provided me with the following information:

(i) two products assayed less than 95 per cent potency,
(ii) one product did not meet the disintegration time of 60 minutes,
(iii) two products did not meet the content uniformity requirements of the National Formulary,
(iv) five products did not, in Dr. Pernarowski's opinion, meet a dissolution test, and
(v) three products did not, in his opinion, meet requirements for adequate availability.

Dr. Pernarowski stated that he was looking at these products from the point of view of a control chemist in a reputable pharmaceutical firm and it was from this point of view that he considered them unsatisfactory. Since he is thoroughly familiar with the Food and Drug Regulations he agreed that we would probably only be in a position to take regulatory action against three of the products, i.e. the two that were low in potency and the one which did not meet the requirements for disintegration.

I, therefore, asked our Bureau of Operations to obtain samples from these three companies and Dr. Pernarowski gave me their names, to be examined in our Pharmaceutical Chemistry Division, Research Laboratories. The report which I received stated that the two products which were low in potency had not been on the market for more than a year. A sample from current production of the product which failed the disintegration test in Dr. Pernarowski's study, —incidentally, the lot, from current production was not from the same lot which Dr. Pernarowski examined,—was found to meet specifications for potency (102.3 per cent) and disintegration time averaged 38 minutes. Our requirement is 60 minutes.

In summary, I can only say that we were unable to confirm Dr. Pernarowski's results and, therefore, cannot agree with his conclusions.

4. *Minutes of Proceedings and Evidence, No. 18—Brief Submitted by Dr. Alan S. Davidson, pages 1263 and 1264, paragraphs 4.9 and 5.0*

I do not think I need to read these two statements.

(The above mentioned statements follow)

4. *Minutes of Proceedings and Evidence, No. 18—Brief Submitted by Dr. Alan S. Davidson, pages 1263 and 1264, paragraphs 4.9 and 5.0*

(a) *Monase*, para. 4.9, page 1263

Dr. Davidson states that "Monase was marketed by Upjohn of Canada as a new treatment for psychosomatic disorders—with no substantiating evidence other than four uncontrolled clinical reports ... and a host of unpublished testimonials." Furthermore, he indicated that the drug's chemical class was

misrepresented, the advertising contained a misleading and spurious bibliography and it was marketed before adequate efficacy and safety testing had been carried out.

Dr. Davidson, of course, did not have access to the New Drug Submission on Monase submitted by the Upjohn Company of Canada and, therefore, is in no position to make statements regarding the basis on which a Notice of Compliance was issued. The facts are as follows:

The New Drug Submission on Monase indicated that a total of 1,037 patients were treated with this drug of whom 704 were suffering from psychiatric disorders. Of these, 428 were given the dose clinically recommended and 276 were given higher doses. The submission indicated that 604 psychiatric cases benefitted from Monase. A total of 65 qualified clinical investigators were involved in the studies on this drug.

A Notice of Compliance for Monase was issued on December 16, 1960. The first advertisement that we were able to locate in the Canadian Medical Association Journal appeared in the issue of September 2, 1961. We were unable to find any evidence that the drug's chemical class was misrepresented. We were not able to substantiate Dr. Davidson's statement that the advertising contained a misleading and spurious bibliography.

Monase was withdrawn from the market by the Upjohn Company on March 15, 1962. In a letter to the professions, Dr. E. L. Masson, Medical Director, stated that:

> In spite of extensive pre-marketing animal and clinical studies which indicated a wide margin of safety, an occasional patient has developed agranulocytosis in association with the administration of Monase. Because of this unforeseen and non-predictable occurrence, The Upjohn Company is withdrawing Monase from the market.
>
> It has not been possible to establish definitely that Monase was the causative agent, as other drugs were administered concurrently. These latter drugs included those which are known to cause blood dyscrasias. Nevertheless, in view of the doubt cast on the safety of Monase, we have chosen to take this action.

The Food and Drug Directorate was kept fully informed of these developments by the Upjohn Company and was in agreement with the withdrawal.

(b) *Parnate and Parstelin*, para. 5, page 1263

Dr. Davidson states that "Parnate (SKF) was not only marketed (in 1961) as a unique antidepressant, but also as a combination drug (Parstelin) before efficacy and safety were clearly established. . . ." Again, Dr. Davidson is in no position to make such a statement since he did not have access to the New Drug Submission on these drugs. The pharmacological and toxicological data contained in the Parnate New Drug Submission and in the Parstelin Submission were reviewed in the Food and Drug Directorate and were considered to be adequate. The clinical report submitted in the Parnate Submission provided data on over 1,200 patients treated by 70 investigators. The Parstelin New Drug Submission included reports on 2,246 patients treated by 90 clinicians. In addition, 24 psychiatrists submitted their preliminary results on 360 patients. A Notice of

Compliance was issued by the Food and Drug Directorate for Parstelin tablets on May 5, 1960 and for Parnate tablets on May 6, 1960.

Parnate contains the mono-amine oxidase inhibitor, tranylcypromine, while Parstelin consisted of a combination of tranylcypromine and trifluoperazine.

Early in 1964, adverse reactions from drugs containing mono-amine oxidase inhibitors, were considered sufficiently serious that a Special Committee was appointed by the Minister of National Health and Welfare to advise the Directorate on the distribution of mono-amine oxidase inhibitor drugs in Canada. Dr. K. J. R. Wightman, acted as Chairman of this Committee. The Committee's report included the following recommendation:

> A mono-amine oxidase inhibitor should not be marketed in formulations containing other drugs. This is recommended to obviate their use in trivial disorders, to avoid obscuring their value in various situations, and to prevent the introduction of complicating factors or unexpected reactions. Physicians wishing to combine them with other drugs will still be free to do so by prescribing them separately in dosage combinations which may be more appropriate to the individual patient and which can be given in various time relationships with them.

> On July 24, 1964, a letter was forwarded by the Directorate to all physicians in Canada attaching a copy of the report of the Special Committee and indicating that the Committee had recommended that the Notice of Compliance for Parstelin be withdrawn. The letter stated that Smith Kline & French had already notified the Directorate that they would discontinue the distribution of Parstelin as of that date. I consider that both the company, Smith Kline & French, and the Department, acted in a responsible manner in this situation and proceeded immediately to implement the recommendations of the Special Committee.

The important point is that Dr. Davidson did not have access to the new drug submissions. He did not have access to additional information that the companies have made available to us and, therefore, he was in no position to make the statements which he did.

I think, Mr. Chairman, that that is all I wish to say at this time in regard to this statement.

The CHAIRMAN: What I think we might do if it is satisfactory to you is to open the meeting for general questioning. If there is something in the general questioning that relates to these documents, perhaps you could just say "well, that is in the document" and we will discuss that later.

Mr. CHAPMAN: Very good.

Mrs. RIDEOUT: Dr. Chapman, I would like to compliment you and your staff on this excellent brief. I am sorry I did not have an opportunity to look at it before, but my questioning really is limited to the proceedings of this Committee and copies of minutes I read before I became a member of this Committee. I would be very interested to know if you could tell the Committee how far you have progressed with your plans for the registration of Canadian drug manufacturers and their distributors, if this information is available.

Mr. CHAPMAN: The drug notification regulations by drug manufacturers were promulgated on May 25, 1966. They became effective on October 1, 1966.

Mr. MACKASEY: On a point of order, Dr. Chapman, maybe I am presuming your answer which is unfair. I think Mrs. Rideout's question pertained to registration rather than drug notification. There is a difference, is there not?

Mr. CHAPMAN: Yes, there is a difference. The recommendation of the Fifth Report of this Committee recommended registration.

Mr. MACKASEY: That is right.

Mr. CHAPMAN: I am not a lawyer but this question has been raised on a number of occasions and, therefore, I can at least give my opinion to the members of this Committee.

The authority of the Food and Drugs Act rests, of course, on section 91 of the B.N.A Act which relates to criminal law legislation and which is a federal responsibility. The criminal law basis for the Food and Drugs Act is its purpose in protecting the public from injury to health or from fraud in the manufacture and sale of foods, drugs, cosmetics and devices, and regulations under the act must, therefore, be related directly or indirectly to either of these objectives.

There is a second possible basis on which the Food and Drugs Act could rest as a federal statute and this would be the heading in section 91 of the British North America Act "regulation of trade and commerce". It is under this heading that a number of the agricultural statutes rest and these statutes apply only in respect of goods which are subject to the act when moving in interprovincial or international trade.

Prior registration as a condition of sale or licensing of a pharmaceutical manufacturer it is considered by our legal counsel, might relate to regulation of trade and commerce, and therefore, if we carried out a registration or licensing we might then lose authority over the control of the product sold within a province.

Mrs. RIDEOUT: Would you say that drug notification could be covered?

Mr. CHAPMAN: Yes. This was discussed, of course, at considerable length with the Department of Justice and the recommendation was that we should require drug notification—

Mrs. RIDEOUT: And have you?

Mr. CHAPMAN: Yes. This is the legislation to which I refer. Drug notification, not as a condition of sale, but to provide certain information which would relate to our authority to protect the public from injury to health or from fraud in the manufacture and sale of drugs.

Mrs. RIDEOUT: Have you had any difficulty in getting this information?

Mr. CHAPMAN: No. I think it is fair to say that the response has been very good. I might just explain a little further. I have already indicated that as of October 1, 1966, every drug manufacturer should have notified us of all drugs which he has on the market and within 30 days any old drug which he proposes to put on the market for the first time. He must also notify us when he withdraws the drug from the market or changes the formulation of the drug or its recommended dosage or use. As of January 18, this year, we had 17,249 forms submitted from 427 firms.

Mrs. RIDEOUT: This represents a substantial number of firms, then?

Mr. CHAPMAN: Yes. We consider that there are approximately 500 firms. The latest tabulation that we have is 516 drug manufacturers, distributors or agencies. The information that we do not have is with regard to the number of pharmacists, for example, who might be putting up a product and selling it under their own name, but the volume of this type of product would be very small indeed. We consider that the 427 firms that have submitted certainly cover the vast majority of the drugs on the Canadian market.

Mr. MACKASEY: A supplementary question, Dr. Chapman; this, of course, includes firms, in other words, who manufacture drugs outside of what we call the prescription field, but do come under you?

Mr. CHAPMAN: It does not cover manufactures of drugs that are registered under the Proprietary or Patent Medicine Act but many of those firms also sell drugs that are not so registered, and, therefore, they would have to notify us of the sale of these products that were not registered under the P. or P.M. Act.

Mrs. RIDEOUT: Dr. Chapman, just one brief question. If you are not able to get drug notification of all the firms, and I realize it is practically impossible, will this system work effectively?

Mr. CHAPMAN: I would not wish to agree with that statement. We are going to get notification of all drug manufacturers and of all products.

Mrs. RIDEOUT: You are going to get them all but you still have some who have not complied. Why would they not have complied if this is not unreasonable? Is it because they procrastinate?

Mr. CHAPMAN: I think that only the firms themselves can answer that; but we propose at this stage, in fact, we have proceeded to issue to each regional office a list of the firms located within its regional boundaries which have submitted drug notification forms, and a delinquent firm will be contacted and the necessary action will be taken to insist that these firms provide us with the necessary information. I think we will get them all.

Mrs. RIDEOUT: Good, I hope you do. Thank you, Dr. Chapman.

Mr. HOWE (*Hamilton South*): Mr. Chairman, I am trying to get some information here from some of the questions because some of them, from what I have read here so far, have been answered in your documents. However, my questions of interest are actually contained in a comparison of S.K.F.'s Stelazine and Maney's Triflurin. I see by your documents that you have checked these extensively, which is part of what I was interested in. One of my questions is: Did you find as wide a variation in S.K.F.'s products or wider than you did in Maney's? I see by one of the documents here that actually the variation was wider on S.K.F.'s than it was on Paul Maney's drugs. This is Table 5. It shows the standard deviation of the individual tablets of Paul Maney's range from 1.14—I presume that is per cent—to 1.62; whereas Smith, Kline and French's ranged as high as 3.91. That answers that question fairly well. I want to ask you some questions in regard to this, if I may. One is—considering that the standard increase in dosage of trifluoperazine is about 100 per cent, would you say that the individual tablet deviations are hazardous or dangerous as found in Maney's product triflurin? In other words, 100 per cent is borne out in the fact that Smith, Kline and French state that the usual starting dosage is 1 or 2 milligrams, a 1 or a 2 milligram tablet, b.i.d., that means, twice a day. Allowing 100 per cent

variation in the starting dose, would you say that Maney's product is in any way dangerous in its variation from what they claim the potency to be?

Mr. CHAPMAN: Certainly not.

Mr. HOWE (*Hamilton South*): If a manufacturer produces trifluoperazine tablets and has individual tablet variations to the extent that you have found in stelazine and triflurin, would you say that there is a dangerous or hazardous drug on the market, keeping those figures in mind? Neither of them is dangerous. In other words, Paul Maney's product, as labelled, is not dangerous or you would not have passed it. Is that not correct?

Mr. CHAPMAN: That is correct. We consider that the variation in the Paul Maney, Mowatt and Moore, and Smith, Kline and French products would be entirely satisfactory. There was one lot of Jules R. Gilbert where we felt that the variation was too wide.

Mr. HOWE (*Hamilton South*): That was 11.22?

Mr. CHAPMAN: Yes. This is not actually a violation of any specification. However, it does indicate poor manufacturing procedures, and we have already drawn this matter to the attention of Mr. Gilbert.

Mr. HOWE (*Hamilton South*): Then, by using your own words, you would say that the manufacturing procedure of Paul Maney was actually superior to that of Smith, Kline and French. You say that the high figure indicated a poor method of manufacture. Therefore, in reverse, the low figure could indicate a better method of manufacture.

Mr. CHAPMAN: I would not state it in quite that way. I would say that these figures indicate that the manufacturing procedures of Paul Maney, Mowatt and Moore and Smith, Kline and French were all adequate.

Mr. HOWE (*Hamilton South*): But you will admit that Paul Maney's figures are a little bit lower in the table that you submitted, and therefore are a little bit better?

Mr. CHAPMAN: There is less variation in their product; that is correct.

Mr. MACKASEY: May I ask a supplementary question, Dr. Howe? I think you are making a very good point, if there is variation. Would your point not have more effect if, instead of using Paul Maney and Smith and Kline and French, since we have mentioned names, you used the extremes? The extremes run from Paul Maney to Jules Gilbert, and not Paul Maney to Smith, Kline and French.

Mr. HOWE (*Hamilton South*): I realize that, Mr. Mackasey, but I am trying to bring out a point here as far as SKF and Maney are concerned because of certain statements that were made by SKF with regard to Paul Maney's product.

Mr. MACKASEY: In other words, you are clarifying this personal feud between them on this particular product.

Mr. HOWE (*Hamilton South*): Well, I am asking questions about it in the hope that it will lead to clarification. On this claim that Maney's tablets have 16 per cent less potency on the average, is there a 16 per cent difference in potency in the label claims of Maney's triflurin against the label claims of Smith, Kline and French?

Mr. CHAPMAN: There has been a great deal of confusion engendered with regard to the labelling of these products. It stems largely from the fact that Smith, Kline and French were putting up this product and labelling the strength in terms of the base. Then the British pharmacopœia issued a monograph which was based on the dihydrochloride. I would like to ask Dr. Levi, if he would, to expand on this question. Would you care to repeat your question, Dr. Howe?

Mr. HOWE (*Hamilton South*): On this claim that Maney's tablets have 16 per cent less potency on the average, is there a 16 per cent difference in potency in the label claims of Maney's triflurin as against the label claims of Smith, Kline and French?

Dr. LEVI: I might just say at the outset that at the present time this would refer to current production lots. There is no difference between products put up by the four different manufacturers, that is to say, Triflurin, Clinazine, Stelazine and Triperazine. All of these products that are at present on the Canadian market are formulated in terms of the base. Label claims, if this is the question, are perhaps not as concisely conveyed as one would desire. All the products are labelled as trifluoperazine B.P. Now, the B.P. requires that trifluoperazine tablets contain trifluoperazine hydrochloride. Therefore, if you read the label "trifluoperazine B.P." you would expect that this product should contain trifluoperazine hydrochloride, and the figure that you notice on the label would indicate that this is the amount of the hydrochloride that is present in the tablet. The label that is placed on these products for Stelazine and Clinazine are, perhaps, not clear on this point.

Mr. HOWE (*Hamilton South*): My next question actually is right on that line. Was it evident to your department how much trifluoperazine was in Maney's product, both in terms of the base and in terms of the hydrochloride, looking at the label?

Mr. LEVI: Yes. You have the data for each of these companies listed in Table 1 for Stelazine, Table 2 for Clinazine, Table 3 for Triflurin and in Table 4 for Triperazine.

Mr. HOWE (*Hamilton South*): Did you realize that I asked you whether this was evident, looking at the label, in Maney's product?

Mr. LEVI: In Maney's product there is a clear statement of the presence of the base, and the equivalent amount of hydrochloride.

Mr. HOWE (*Hamilton South*): So you could easily compare the labels of both SKF and Maney to find the relative potency for the product?

Mr. LEVI: Our analysis would indicate the potency of the product without looking at the label claims.

Mr. HOWE (*Hamilton South*): Yes; but I am asking you about the labels specifically.

Mr. LEVI: Just merely looking at the labels?

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

Mr. LEVI: As I said before, SKF and Mowatt and Moore's labels could lead to misinterpretation, in that they state "trifluoperazine B.P. tablets", but express the figure that is noted on the label in terms of the base.

Mr. HOWE (*Hamilton South*): So that Maney's label was actually more clearly stated?

Mr. LEVI: I would agree with that.

Mr. HOWE (*Hamilton South*): Would you say that anyone specializing in trifluoperazine could as easily interpret one label, as the other?

Mr. LEVI: As I said, I would think that both the label claims for Triperazine by Gilbert and for Triflurin by Paul Maney are clearer than the ones for Clinazine and Stelazine.

Mr. HOWE (*Hamilton South*): You are accepting this question blindly without having had an opportunity to look this up.

Mr. LEVI: I can read these labels for you if you like. I have them here.

Mr. HOWE (*Hamilton South*): I was going to get labels; that would be a good idea. If you do not mind, I have some so I would have them for a later meeting this afternoon.

The CHAIRMAN: These two labels are part of the record of the Committee.

Mr. HOWE (*Hamilton South*): I was absent during Smith, Kline and French's presentation. This is not necessary, Mr. Chairman.

The CHAIRMAN: It was not during the SKF presentation. It was the Maney presentation that produced the labelling, and it is part of the record.

Mr. HOWE (*Hamilton South*): My point here is that I was trying to bring forth that Paul Maney's label actually is clearer and more precise as to what the tablets contain than is the label for the product of Smith, Kline and French as far as your department is concerned?

Mr. LEVI: I agree with that statement.

Mr. HOWE (*Hamilton South*): While anyone specializing in trifluoperazine could easily interpret both these labels, it appears that the experts at SKF could not do so, but your department was able to do so, as you have just stated. If not, this Committee has been supplied with false information deliberately by SKF, knowing full well the truth and that the press releases of the information which, incidentally, include the trade papers and magazine as well, was privileged. In other words, they released information to this committee that was not just quite true as far as the labelling of their products is concerned?

Mr. CHAPMAN: Mr. Chairman, if I might just comment here, as a matter of fact, Smith, Kline and French have indicated to us that they propose to change their labels in a manner that would possibly make them clearer. I understand that they propose to remove the B.P. designation from the label, but the Directorate has been in discussion with the firm in regard to this matter.

Mr. HOWE (*Hamilton South*): Mr. Chairman, I am going to leave that. There is just one more question that I would like to ask and this is with regard to chlopromazine at the Essendale Mental Hospital. Did you receive a complaint from this hospital concerning clinical ineffectiveness of chlopromazine?

The CHAIRMAN: I think this has already been referred to in the record of our proceedings, some time ago.

Mr. MACKASEY: I forget which one came up with that particular problem.

Mr. HOWE (*Hamilton South*): May I ask this department, did you receive this complaint?

Mr. CHAPMAN: I do not believe that we have received any official complaint, certainly not directly to Ottawa. There may have been contact with our regional office in Vancouver. We were aware that there has been a complaint from the Essendale Hospital.

Mr. HOWE (*Hamilton South*): Would it be possible to find out about this and what the department did, and what the hospital received as a report from your department, and so forth? Apparently there was a letter, too, that was sent from the department to Essendale, and it is the essence of this in which I am interested.

Mr. CHAPMAN: I should be pleased to do that, Mr. Chairman.

Mr. HOWE (*Hamilton South*): Thank you. That concludes my questioning.

Mr. MACKASEY: Dr. Chapman, you are a medical doctor, I presume?

Mr. CHAPMAN: No, I am not, sir. I am a chemist.

Mr. MACKASEY: I see; that is even better. I am only a layman and I am at a disadvantage in discussing trifluoperazine—in fact, I have a hard time even to pronounce it, certainly with the efficiency that Dr. Howe can, and I must apologize. But I ask this sincerely for information, based on Table 5 and the points that Dr. Howe made. I do not want Dr. Chapman, to appear as an apologist for any firm at this particular Committee, which is the reason I take a dim view of comparing two firms—Paul Maney and Smith, Kline and French—when Smith, Kline and French is certainly not the extreme on this table.

What I am more interested in is the more important problem; in other words, the best product. What are the standard deviations permitted by the British pharmacopeia?

Mr. CHAPMAN: I understand that there is no variation actually laid down for variations in trifluoperazine tablets, B.P., but I would like to ask Dr. Levi to speak to this point. He can give you the variations that have been established for certain other products.

Mr. LEVI: As we stated before, the active ingredient of trifluoperazine tablets should be trifluoperazine hydrochloride, and the B.P. merely requires that in accordance with the assay that is part of their monograph on trifluoperazine tablets the content of trifluoperazine hydrochloride should lie between 92.5 to 107.5 per cent.

Mr. MACKASEY: May I speak directly to Dr. Levi? In other words, between 92 and 107.5 per cent which is 8 per cent one way and 7 per cent the other, there is a wide range of 15 per cent. Do you feel that any product falling within this range meets the requirements of safety, potency and efficacy and, in other words, is not being misrepresented to the public or to the doctor prescribing it?

Mr. LEVI: All this test really tells you is that the potency in terms of the presence of the active ingredient lies between this limit. This is itself would not reflect on the safety or efficacy or potency of the product.

Mr. MACKASEY: These limits, Dr. Levi, must have been set up for a purpose; what was the purpose then in establishing these limits, the plus and minus variants? What was the basic purpose?

Mr. LEVI: The basic purpose is to ensure that the patient gets the proper dose of the material.

Mr. MACKASEY: Now, looking at table 5, and again as a layman analysing the results of Maney, Mowatt and Moore, Smith Kline and French and Jules Gilbert, which cover sixteen samplings—

Mr. LEVI: Yes.

Mr. MACKASEY: —am I right in presuming that with the exception of one particular batch, that of Jules Gilbert, all the other batches fit within the definition you just gave, namely, that they present no hazard to the public; that they do contain the degree of potency which you think desirable?

Mr. LEVI: I agree with you, this is a very important point. I do not think it is fair to really draw any valid conclusions from the figures shown for Paul Maney, Smith Kline and French and Mowatt and Moore. They are all satisfactory with regard to pharmaceutical workmanship.

Mr. MACKASEY: And even for Mr. Gilbert, with one exception.

Mr. LEVI: Even for Mr. Gilbert with one exception. In other words, these tests, on which the content uniformity is based, imply that you utilize 20 tablets selected at random from a given lot and there may, certainly, be variations in the individual tablets making up this lot. So these are composite assays and you may have variations even wider than the 7 per cent permitted for individual tablets, but the same may average out at the end you see.

Mr. MACKASEY: Over the dosage that the patient usually gets?

Mr. LEVI: That is correct but individual variations are very important in that you can get an idea of the homogeneity of the batch, the thoroughness with which it has been prepared and mixed and the uniformity with which the tablets are being punched from the tablet machine.

Mr. MACKASEY: I see. Excuse me, but even in the case of Mr. Gilbert in the three batches he would not be too badly off from the standard you require. If you take his 11.22 deviation, all the others fit pretty well within the range.

Mr. LEVI: It could very well be within the range and if you compare these data, the standard deviations are all coming from the individual experimental data that are shown in this brief. Even here in this sample that had 11.22 per cent standard deviation, the B.P. assay is met.

Mr. MACKASEY: Just in conclusion on this point, Dr. Levi, of the 16 tests there is only one that falls outside the deviation. In other words, if we happened to be lucky or unlucky enough to have required any one of these products from these batches, we were fully protected by the Food and Drug Directorate? These products meet the standards you expect from firms?

Mr. LEVI: They do meet the standards but some do meet the standards better than others.

Mr. MACKASEY: Perfection would be no deviation?

Mr. LEVI: Right.

Mr. MACKASEY: Yes, but of course we are all striving for perfection, are we not? Thank you, Dr. Levi.

Mr. HOWE (*Wellington-Huron*): I have a supplementary in connection with the consumers' submission; you take objection to Dr. Pernarowski's statement. I was just wondering, in this same connection, talking about batches, if the tests which your department made were on the same batch that Dr. Pernarowski's were made on?

Mr. CHAPMAN: No, they were not.

Mr. HOWE (*Wellington-Huron*): Well then, there would be some variation in batches?

Mr. CHAPMAN: Oh, very definitely. I think, really, this is the reason for the discrepancy between the results which we obtained and those which Dr. Pernarowski obtained. I discussed this matter with him and he said that, of course, he now had to get the tablets wherever he could. He was no longer a member of the Food and Drug Directorate and, therefore, could not go to a firm and request an official sample. Therefore, he collected the tablets that were analysed, over a period of time and from whatever source he could obtain them. I am sure that this is the reason for the variation in the results between those which we obtained and those which Dr. Pernarowski obtained.

Mr. HOWE (*Wellington-Huron*): His conclusions were not so bad after all, were they? You object to his conclusions, apparently. You said you cannot agree with them, but on the same basis of different batches and different examinations and different components that may be found in different batches he was probably right in his conclusion in the first instance?

Mr. CHAPMAN: There are two points here. I do not know whether it is fair to take a tablet off a drug-store shelf when you do not know how long it has been sitting there and then analyse that tablet, find that it does not disintegrate properly and then blame the manufacturer for this situation. Now, certainly, the better firms keep checking up on their products and make sure they are not on the shelves for too long.

Mr. HOWE (*Wellington-Huron*): Of course, this occurs in the food business, too. A lot of firms like Canada Packers, for instance, put a date on their products; something to indicate the date they were produced. Is this not true of all drugs?

Mr. CHAPMAN: No; this is not true. There is not an expiry date required on all drugs.

Mr. HOWE (*Wellington-Huron*): You made the statement that this drug might have been on the shelf and its ingredients or components or qualifications changed owing to age. Now, should there not be some regulation to indicate the date on which every drug of this type was produced.

Mr. CHAPMAN: Would any of my colleagues care to comment on that? This is a matter that we have considered from time to time. We do require an expiry date on certain products where this would appear to be necessary and essential, but not on all drugs.

Mr. HOWE (*Wellington-Huron*): But, Dr. Chapman, you just indicated that this drug that Dr. Pernarowski might have taken from the shelf might have deteriorated because of age?

Mr. CHAPMAN: Yes.

Mr. HOWE (*Wellington-Huron*): Would this not be a hazard to the health of people using drugs? Could it not become so and should there not be some regulation indicating that there should be a date put on all these products?

Mr. CHAPMAN: Dr. Levi would you care to comment?

Mr. LEVI: I would agree that this would be a desirable situation. However, I would also emphasize that we do ask for stability data from manufacturers for all new drugs. We would not approve or clear any new drug submission without having adequate data presented to us testifying to the stability of the material in storage. Still I think the danger of decomposition does exist because we have no control over the manner in which a drugstore stores its products. They may be stored in the sunshine out in the window display or maybe handled in any other way. Tablets may be removed. They may not be closing their bottles completely and oxidation may take place. There are many factors involved in this question of stability.

Mr. HOWE (*Hamilton South*): Excuse my interruption, but there would not be many prescription item drugs put out in a window display, would there?

Mr. LEVI: Not prescription drugs, but all types of manufactured specialties and products.

Mr. HOWE (*Wellington-Huron*): Excuse me, Mr. Mackasey, this is on your time.

Mr. MACKASEY: I do not mind; it is on your time, so go right ahead.

Mr. HOWE (*Wellington-Huron*): I do not care about time as you do; it does not bother me. Mr. Chairman, in connection with this point, why cannot regulations be made to control this? You have inspectors going into stores; they take spot checks of all this type of drug and see how long it has been there. If it is not marketed, how do they know?

Mr. CHAPMAN: The problem is that, first of all, before we could require that an expiry date be placed on all drugs we would have to indicate there was a hazard to health if such a procedure were not followed. I do not think we have at the present time sufficient evidence for this. We do require expiry dates in those cases where we do consider there is a hazard to health. But to require this across the board, I think, would be very difficult to justify.

Now, in addition, this would require a tremendous amount of work, not only on our part but also on the part of the company, of course, to determine what should be the appropriate expiry date and it would require checking on our part to determine whether or not this was an appropriate expiry date. I would feel that there are other areas where we might better devote our time to protecting the consumer from the hazards to health from drugs.

Mr. HOWE (*Wellington-Huron*): Let us go back to this quotation in the Consumers Association of Canada brief; Dr. Pernarowski found that the others were classified, with research, as unsatisfactory; one was faulty enough to

constitute an absolute hazard to health. Did he have no right to make these statements? You say that he may have got his sample from an area different from where you got your samples. He says they constitute an absolute hazard to health.

Mr. CHAPMAN: I can only say that the Committee should ask Dr. Pernarowski what he meant by that statement. I asked him and I did not get a satisfactory answer. As you know, phenylbutazone is used for arthritis and gout.

Mr. HOWE (*Wellington-Huron*): Thank you, Mr. Chairman.

The CHAIRMAN: Have you finished, Mr. Mackasey?

Mr. MACKASEY: No, I have only started.

Mr. ISABELLE: Mr. Chairman, I have just one question on this Pernarowski affair. This puzzles me a little bit. Who sponsored Dr. Pernarowski's investigation into 23 brands of phenylbutazone?

Mr. CHAPMAN: I beg your pardon, sir?

Mr. ISABELLE: Who sponsored him? Who asked him to make an investigation into these 23 brands? If the investigation dealt only with two or three brands, well, I would think it would be companies who asked him to these investigations. Is it part of his job, or what?

Mr. CHAPMAN: Yes; I would say this would certainly be a part of the job of a member of a pharmaceutical faculty, to carry out such an investigation. It would be perfectly justified.

Mr. BRAND: As a point of explanation, was it not done as a doctorate study by Mr. Searl? Was Dr. Pernarowski head of the department? It was both Searl and Pernarowski, was it not, as part of the fulfilment of the requirement for a doctorate degree?

Mr. CHAPMAN: It was not a doctorate degree.

Mr. BRAND: Well, some degree anyway.

Mr. CHAPMAN: It was abstracted from a thesis submitted by R. O. Searl to the Faculty of Pharmacy, University of British Columbia, Vancouver, B.C. in partial fulfilment of the Master of Science in Pharmacy Degree requirements.

Mr. MACKASEY: This is my last point on labelling. Dr. Levi, obviously at the present moment in Canada, Smith Kline & French, Mowatt & Moore label their particular product based on the salt. Am I wrong?

Mr. LEVI: It is based on the base.

Mr. MACKASEY: On the base rather, and there is a slightly different label in the case of Paul Maney. The Food and Drug Directorate so far have permitted both labels to appear.

Mr. LEVI: Yes.

Mr. MACKASEY: Why do you not make the label uniform. It seems to me it would be simple enough to ask the various firms to conform to one uniform label which would avoid this confusion. Which label went on the market first?

Mr. LEVI: In sequence it would be Stelazine, Clinazine, Triflurine and Triperazine.

Mr. MACKASEY: Did they all come on the market at the same time?

Mr. LEVI: This is the chronological sequence.

Mr. MACKASEY: How long was Stelazine on the market, labelled as it is, exclusively?

Mr. CHAPMAN: Seven or eight years.

Mr. MACKASEY: Now, Paul Maney have come on under compulsory licence and their label varies slightly from Smith Kline & French. How long have we had two different labels in existence at the same time? I think this is the point Dr. Howe was getting at.

Mr. CHAPMAN: Probably not longer than a year.

Mr. MACKASEY: I see. Have you made any recommendations to the four firms to standardize or uniform their labels?

Mr. CHAPMAN: Could I answer that Mr. Mackasey. This problem is a difficult one. Even the British pharmacopœia, but the British Pharmacopœia Commission—that they should consider in the future requireing that the potency be indicated in terms of the base.

Mr. MACKASEY: Of the base.

Mr. CHAPMAN: Yes. Now, they are referring to all drugs. Therefore, you see there is actually a trend away from the declaration, as has been required in the past by the British Pharmacopœia, to a uniform declaration in terms of the active ingredient, in this case the base.

Mr. MACKASEY: Dr. Levi, are you a medical doctor?

Mr. LEVI: No, I am not sir.

Mr. MACKASEY: Neither is Dr. Chapman. Dr. Harley, you are; am I right in presuming that?

The CHAIRMAN: Yes, and Dr. Hardman is also a medical doctor.

Mr. MACKASEY: Dr. Hardman, in all fairness to both Paul Maney and Smith Kline & French, in order that this be the last we hear of this awfully insignificant problem, would a medical doctor be expected to have enough knowledge to distinguish between the potency as outlined on one label and the potency on another. Should he have enough knowledge to form his own conclusion?

Mr. HARDMAN: I would say that a competent medical doctor, who is dealing with this drug, gains experience generally with one product. If he is planning to prescribe a replacement product or to prescribe the generic name product, then I feel he has the ability and the background knowledge to distinguish between the products on the information which is provided on the label. Whether he does so or not would be an indication of his professional application.

The CHAIRMAN: Could I add to this, and I think Dr. Brand would agree with me, that the average general practitioner would never see either label.

Mr. MACKASEY: Would he consider it important?

The CHAIRMAN: No.

Mr. MACKASEY: Thank you, Mr. Chairman, you have made the point better than I could have.

Mr. Chapman, I understand that you people do a certain amount of work for the Department of Industry in inspecting potential sources of supply to the department?

The CHAIRMAN: Mr. Mackasey means the government specifications people, Dr. Showalter's committee.

Mr. CHAPMAN: Yes.

Mr. MACKASEY: Fine. Now, Dr. Chapman, I think it the right of the Department of Industry to set up their own standards like anyone buying drugs. You are also part of an interdepartmental committee, I would imagine, because I think the Food and Drug Directorate would be represented on an interdepartmental committee?

Mr. CHAPMAN: Could I just clarify two points. The standard for manufactured control and distribution of drugs, 74-GP-1b, is established by the Canadian Government Specifications Board, which is under the Department of Defence Production in Ottawa; so the Department of Industry is not involved.

Mr. MACKASEY: I should have said the Department of Defence Production.

Mr. CHAPMAN: The interdepartmental board is the Interdepartmental Advisory Board on Standards for Pharmaceutical Manufacturers, Distributors and Agents and we are represented on that board.

Mr. MACKASEY: Who are potential sources of supply to the Department of Defence Production? I am talking about the interdepartmental board again.

Mr. CHAPMAN: The list of companies found to conform to the standard 74-GP-1b are potential suppliers.

Mr. MACKASEY: Right. Are the standards under 74-GP-1b which is the amended one, in your opinion higher than the ones which Food and Drug Directorate enforces or expects from those people who have not shown any desire to meet the test of 74-GP-1b standard?

Mr. CHAPMAN: I would say that the standard is more detailed and of course, it covers a number of additional areas over which the Food and Drug Directorate has no authority.

Mr. MACKASEY: Well in the area where you do have the authority?

Mr. CHAPMAN: I would only say that the standard is more detailed.

Mr. MACKASEY: All right, but what does this more detailed end up with, a better standard?

Mr. CHAPMAN: It might result in better facilities, but I feel that if a pharmaceutical firm meets the requirements of the manufacturing facilities and control as laid down under the Food and Drug regulations, this would be entirely adequate.

Mr. MACKASEY: Not adequate for sale to the Department of Defence Production?

Mr. CHAPMAN: Oh, yes; if they meet all our requirements, I would say that they would be almost certain to meet the requirements in the same area of the standard.

Mr. MACKASEY: Well, what confuses me is why we have two standards, one for the general public and one for the Department of Defence Production.

Mr. CHAPMAN: Mr. Chairman, could I just refer you to the cover page that is found on the list of companies found to conform with standard 74-GP-1b and I think this may help to clarify the situation?

Mr. MACKASEY: Do we have that with us here?

Mr. CHAPMAN: No, you do not.

Mr. MACKASEY: Dr. Chapman, that list of firms is formed only from those who have volunteered or conformed to it; in other words, who have requested to be considered to be potential suppliers. Am I right?

Mr. CHAPMAN: Could I read the information that is here:

> The following is a list of Canadian manufacturers, distributors and agents deemed by the interdepartmental advisory board on standards for pharmaceutical manufacturers, distributors and agents to conform with the Canadian Government Specifications Board Standard 74GP-1b. This list is maintained by the board and is subject to amendment at any time. It has been established to assist in the purchasing of pharmaceuticals by the Government of Canada, but is available to others who wish to purchase such products by competitive tender and who understand its purpose and method of use.

I discussed this matter with Dr. Showalter within the last few days, and he has indicated that the list would also be made available to any interested group.

Mr. MACKASEY: But, Dr. Chapman, does the word "deemed" not imply that these are the only firms. For instance, could a highly respectable long established firm not be included on that list although they may at one time or another have chosen not to be potential sources of supply?

Mr. CHAPMAN: Certainly. If I might be permitted to continue, I think this should be made clear.

> In the use of this list, these very important considerations should be kept in mind:
>
> 1. Companies not listed are not necessarily adjudged to have failed to conform with the standard. The companies listed are those which have requested inspection and have been found to conform with the standard.
>
> 2. Conformity with the standard is not a statement that a company's products meets any particular specifications or standard of quality.
>
> 3. The standard provides that the rating assigned to a company upon inspection may be reduced in the event that the company has been found to supply to a purchaser pharmaceuticals which do not meet the terms of the purchase order or contract.

Mr. MACKASEY: In other words, then, Dr. Chapman, a person could fail that particular standard and pass the Food and Drug Directorate standard, because he could have failed in that area which is administrative?

Mr. CHAPMAN: That is correct.

Mr. MACKASEY: And, therefore, the unfortunate inference could be drawn that because they failed to meet 74-GP-1b standard, they automatically did not live up to the levels that the Food and Drug Directorate expected of them, if they were being inspected on routine visits?

Mr. CHAPMAN: I agree that this impression could be reached, and we were certainly most happy to see that the Interdepartmental Advisory Board on Standards for Pharmaceutical Manufacturers, Distributors and Agents put this cover page on their list to indicate exactly what this standard represented and what the list represented.

Mr. MACKASEY: You mentioned the word "agent", which brings me to another point. Some time ago when we had representatives of the various departments here—and the Chairman may be able to be more specific on this—including Mr. Showalter, there was a list supplied, I believe, of potential suppliers to D.D.P. Am I right?

Mr. CHAPMAN: Yes.

Mr. MACKASEY: There was one which stuck in my mind, because it represented, so far as I can gather by the address, a potential supplier located on Sherbrooke Street, suite such and such. How can your department carry out the full spirit of 74-GP-1b in so far as this particular source of supply is concerned?

Mr. CHAPMAN: I feel, sir, that this question really should be directed to Dr. Showalter.

Mr. MACKASEY: He suggested I direct it to you, Dr. Chapman.

The CHAIRMAN: I think Mr. Mackasey's point is that some of the names on the list were distributors and when we checked into it, the drugs were actually bought overseas and in this case, you would not have not been able to carry out an inspection if they had asked you to.

Mr. MACKASEY: Which is what I wanted Dr. Chapman to tell me.

Mr. HARDMAN: They may have been licensed drugs, in which case we do it.

Mr. MACKASEY: Would you repeat that for me; it does not matter who said it.

Mr. CHAPMAN: These very well may have been licensed drugs. Licensed drugs are required to have a very rigid inspection of the facilities under which they are produced before the licence is issued.

Mr. MACKASEY: Which licence are we talking about now?

Mr. CHAPMAN: We are talking about a licence to sell a schedule C or D drug. I do have this information in a complete list here. However, this requires that the inspection of the plant, wherever it is in the world, is actually carried out by one of our inspectors, before they are permitted to sell. Now, it could have been one or two drugs; I do not know.

Mr. MACKASEY: Dr. Chapman, let me take a case, you will excuse me if I am not specific, because some of these names I cannot get around my tongue, but I want to be fair to the Gilberts, the Maneys and the Smith Kline & Frenchs, because they represent different areas of the Canadian pharmaceutical industry.

Is it not possible, therefore, that this particular distributor or agent on Sherbrooke Street could compete tenderwise and pricewise for a substantial purchase through DDP and that Gilbert or Maney could be temporarily rejected for not meeting some administrative section of 74-GP-1b or because dust could be found on their light standards? The same thing being true of Smith Kline & French, but the firm represented by the Sherbrooke agent may be located in Poland or some other country where you have been unable to inspect or do not inspect, and could conceivably get that order?

Mr. CHAPMAN: Mr. Chairman, I feel that we are getting into the area of the problem of how we enforce the requirements of the Food and Drugs Act and regulations to imported drugs.

Mr. MACKASEY: Not quite; there is a greater implication. How does this man get on the list without as far as I am concerned, it being physically possible for the Department of Food and Drug Directorate to make that person on Sherbrooke Street conform to the same inspection as Gilbert or Maney or Smith Kline and French.

Mr. CHAPMAN: Well, Mr. Mackasey, I can only speak to the requirements of the Food and Drugs Act and regulations. This particular person that you are referring to has been placed on that list by an interdepartmental committee.

Mr. MACKASEY: Which you are a part of.

Mr. CHAPMAN: Yes; we have one member.

Mr. MACKASEY: That is right.

Mr. CHAPMAN: One member; is that correct?

Mr. MACKASEY: Perhaps that one member could give us some clarification?

Mr. CHAPMAN: The member is not present.

Mr. MACKASEY: Well, this afternoon will be fine. The point I am getting at, Dr. Chapman, calling a spade a spade, is how come people from outside the country are not subject to the same rules and regulations that manufacturing facilities are subject to inside the country?

Mr. CHAPMAN: Well, I think this is the point. The point is the problem associated with our difficulty of ensuring that imported drugs meet all requirements of the Food and Drugs Act and regulations.

Mr. MACKASEY: Just a moment, Dr. Chapman, I am aware of them and I sympathise with the Food and Drug Directorate; I know the physical problem and the staff problem. The point I am getting at is, in the interval, until such time as your staff is big enough, until such time as you have reciprocal inspection with legitimate countries around the world, how can the situation be tolerated, allowed to exist, or exist, until something is done to protect Canadians? You cannot check every possible batch that comes in from Europe.

Mr. CHAPMAN: No, we cannot.

Mr. MACKASEY: So a tender could be lost or denied the Maney's and the Gilberts and the Smith Kline and French's by some unknown source in Italy, or Poland or any other country, the Department of Defence Production purchases drugs from a firm on Sherbrooke street that has the right to quote? Am I right or wrong here?

Mr. CHAPMAN: You are right. We have the responsibility for giving a report to the interdepartmental committee. We have done so. The interdepartmental committee then decided that that firm met whatever the requirements were, and placed them on the list. We do not have that responsibility.

Mr. MACKASEY: I realise, Mr. Chapman, that it would be perhaps better if we got this interdepartmental committee before us, and I will fight this out with the chairman afterwards. But help me out. Presume at the time the interdepartmental committee said to the Federal Food and Drug Directorate; This firm "X" on Sherbrooke Street,—I have no knowledge of them, I do not even remember their name—would like to tender, and would you mind checking out their source of supply? You do and you find it satisfactory. Is it not possible that the sources of supply will vary from tender to tender, from product to product?

Mr. CHAPMAN: I would think this is possible.

Mr. MACKASEY: Well, you do not think it is probable?

Mr. CHAPMAN: Yes, I would say I think it is probable, too.

Mr. MACKASEY: Therefore your original inspection does not really mean too much, unless you were to say to the interdepartmental committee: "We inspected a factory in Denmark which we find competent, clean," and so forth, "provided firm X, on Sherbrooke Street is importing a specific drug from that specific factory, and it should be permitted to tender only on that specific drug".

Mr. CHAPMAN: Well, as you have suggested, really it is the interdepartmental committee that makes this decision.

Mr. MACKASEY: Well, would it be possible to have your representative on this committee here today, because I am sure, since he has got a foot in both camps, he would be probably the most knowledgeable member of the interdepartmental committee, and perhaps he would answer this satisfactorily.

Mr. CHAPMAN: I would be pleased to have him if he is available; it is Mr. Ferrier, is it not?

Mr. LEVI: It is Dr. Pugsley.

Mr. CHAPMAN: Dr. Pugsley is our representative?

Mr. LEVI: Yes.

Mr. CHAPMAN: Well, I am sorry; it is Dr. L. I. Pugsley, Deputy Director-General, and Dr. Pugsley is just recovering from a serious operation and is not on duty.

Mr. MACKASEY: Mr. Chairman, would it be possible to get somebody else? I think this is a very important area.

Mr. BRAND: Mr. Chapman has already answered questions along this line.

The CHAIRMAN: Yes, I am sure he has, and you will find that Dr. Showalter answered the question that you asked. He, I believe, said "we go on the knowledge that we have of the companies in the various countries"—

Mr. MACKASEY: Supplied by the Food and Drug Directorate.

The CHAIRMAN: No.

Some hon. MEMBERS: Oh, no.

Mr. MACKASEY: Where else would he get it from?

The CHAIRMAN: Well, he was not able to give us his source of information, but I am sure if you review the testimony you will find that this—

Mr. MACKASEY: I think they were in answer to my questions, if I am not mistaken. All right, let me put it another way.

The CHAIRMAN: Yes, they were.

Mr. MACKASEY: If you cannot tell us he cannot give it. Dr. Chapman, with your wide experience, do you mind telling me who can? Who could give me the information I am seeking?

Mr. CHAPMAN: I think Dr. Showalter.

Mr. MACKASEY: No; he said he could not.

Mr. BRAND: Dr. Showalter did make the statement that they did not examine these companies overseas, because it was not practical, and therefore there were drugs coming encapsulated and in tablets into this country which had never been examined and were going directly to the hospitals.

Mr. MACKASEY: Thank you, Dr. Brand. What I really want to know then, how can this firm be put on the list of tenders by the interdepartmental committee, in view of the statement of Dr. Showalter?

Mr. BRAND: This is something he would not answer, as you know.

The CHAIRMAN: Well, he said that he had sources of information, as I remember, that were not the Food and Drug Directorate.

Mr. MACKASEY: Well, then, perhaps we should get him back to tell us who they were. I did not pursue the point because I fully expected to get this information from the Food and Drug Directorate when they appeared.

The CHAIRMAN: I think you will find, when you review the testimony, he admitted it was not the Food and Drug Directorate, and the question was not followed up at that time. I suggest you have a chat with Dr. Showalter.

Mr. MACKASEY: No, I do not want a chat with Dr. Showalter. I want you, perhaps as Chairman, to tell me where I can get this information, because it is awfully important to the safety of the Canadian people.

The CHAIRMAN: From Dr. Showalter.

Mr. MACKASEY: The fact is, as Dr. Brand has pointed out more eloquently than I can, because of a loophole, the people who eventually are serviced by these drugs through hospitals, etc., through the DDP, could conceivably be receiving goods of an inferior brand, and their only hope is that these things are constantly checked at the request of the purchaser.

The CHAIRMAN: Dr. Showalter said that when they got in a tender from a company—he gave us an example of tetracycline that had been purchased in Holland,—or any new manufacturer of this kind, if they are not known to their department, the samples are carefully checked when they are imported into Canada, by the Food and Drug Directorate; that has been done.

Mr. MACKASEY: Dr. Chapman, when is the last time that somebody from the Food and Drug Directorate has inspected a factory or a manufacturer in Holland, not the batch, but the—

The CHAIRMAN: Now, if you are inferring from my statement that it was in Holland it was manufactured, and it was inspected there, it is not.

Mr. MACKASEY: No; I certainly would not want to do that, Mr. Chairman. It could have been another country, I know your main point and I think you understand mine. There are two standards here, as I understand it: those who are within a reasonable travelling distance, or who are in Canada, are subject to a much more stringent surveillance than obviously the sources of supply outside of Canada. But these drugs still come into the country. What I want to know from Dr. Chapman is, when was the last time any factory was inspected in Holland?

Mr. CHAPMAN: Well, I cannot give you the exact time that a factory in Holland was inspected. What I can tell you is that Dr. Greenberg—

Mr. MACKASEY: Who is Dr. Greenberg?

Mr. CHAPMAN: Dr. Greenberg is with the laboratory of hygiene of the Department of National Health and Welfare, and Dr. Greenberg is the expert on the production of biologics, and does the inspection for the Food and Drug Directorate—

Mr. MACKASEY: Of the end product that gets here.

Mr. CHAPMAN: No, sir.

Mr. MACKASEY: Then what—in Europe?

Mr. CHAPMAN: Yes. Dr. Greenberg at the present time is in the United States doing just this. He will be leaving shortly for the Far East, Japan. When he is there he will be visiting a number of plants other than biologics, looking at these plants, not making a full inspection, but looking at these plants in order to bring back information to us. He makes frequent trips to Europe to do the same thing.

Mr. MACKASEY: Is he the only man doing this in Health and Welfare?

Mr. CHAPMAN: Yes.

Mr. MACKASEY: Is he attached to the Food and Drug Directorate?

Mr. CHAPMAN: No, sir, he is not.

Mr. MACKASEY: Well, do you have anybody doing this work full time?

Mr. CHAPMAN: Do you mean inspecting drug plants in Europe full time?

Mr. MACKASEY: Yes.

Mr. CHAPMAN: No, we do not.

Mr. MACKASEY: You do not. Well, this is my point, of course. And until such time as you do, do you think it is advisable that we take a second look at what I think is the advantage that these firms have over Canadian factories, Canadian manufacturers?

Mr. CHAPMAN: Well, again, our responsibility is to protect the public from hazards to health, and fraud in the sale of drugs. Now, in relation to that, we do analyses for the Department of Veterans Affairs, and other government departments, that are purchasing drugs under the standard 74-GP-1a. From February, 1965 until September, 1966—this table is in one of the files that you have—the

Department of Veterans Affairs sumbitted to us 72 samples. I note that practically all of these are Canadian manufacturers; I see that there are two from the United Kingdom.

Now, I would assume that these are all the lots about which the Department of Veterans Affairs had any particular concern. Of these 72 lots, only one was found to be unsatisfactory, and that was a sample of chlorpromazine hydrochloride tablets—25 mgs.—produced by Bell-Craig Pharmaceuticals, Toronto, and it exceeded the potency level; I think it averaged about 110 per cent. That was the only unsatisfactory one.

Mr. MACKASEY: Dr. Chapman, you used the expression "particular concern". In other words, there could have been other imports from Europe that were not brought to your attention?

Mr. CHAPMAN: This is true.

Mr. MACKASEY: And they may not have been brought to your attention because past experiences proved them to be worth while.

Mr. CHAPMAN: Yes.

Mr. MACKASEY: Now, I was wondering,—perhaps you can answer, but perhaps it would be best answered by someone else—if this Sherbrooke firm—and I keep mentioning it, because it is a symbol to me—or if acceptance of their product whenever they have the opportunity of supplying drugs is based on the fact that that particular agent in the past had always introduced a product satisfactory? I come back to my point, is it possible that they change their source of supply all the time, or could, depending on the product? In other words, they are buying on the world market as cheaply as they can.

Mr. CHAPMAN: You use the word "complacency" Mr. Mackasey—

Mr. MACKASEY: I used the word "complacency"?

Mr. CHAPMAN: Yes, I believe so.

Mr. MACKASEY: Well, if I did, I did not mean it as far as the Food and Drug Directorate are concerned.

Mr. CHAPMAN: This is just the point I was going to make.

Mr. MACKASEY: I know about the complacency of those who submit samples to you for testing.

Mr. CHAPMAN: We are very much concerned about problems associated with imported drugs. Could I give you a brief statement, sir—

Mr. MACKASEY: Certainly.

Mr. CHAPMAN: —in relation to this matter. It certainly is more difficult to ensure that important drugs meet all the requirements of the Food and Drugs Act and regulations, than those produced in Canada. And this is particularly true in regard to regulations pertaining to manufacturing facilities and controls. We can check out the end product, the dosage form, when it arrives in Canada, but it is much more difficult to check on the manufacturing facilities and controls. Now, there are a number of approaches that could be taken to this problem. We could require inspection at regular intervals of the plants of all pharmaceutical manufacturers located outside Canada who export drugs to Canada. We could obtain,

or try to obtain, international agreement on inspection requirements and accept the inspection reports of the appropriate regulatory agency in the exporting country or possibly we could combine these two approaches with more effective control over imported drugs on entry into Canada. Now, I would like to explore these possibilities. First, the inspection of foreign plants. A the present time the manufacturing facilities and controls of all foreign manufacturers exporting biologics, namely, sera, toxoids, vaccines, parenteral antibiotics, insulin and anterior pituitary hormones, to Canada must meet rigid requirements before the manufacturer receives a licence to sell his products in Canada. These inspections are carried out by officers of the department. I referred to Dr. Greenberg and he has an assistant that also does some of these inspections.

At the present time such licences are held by 75 firms with the following geographical distribution. Only 19 are in Canada; U.S.A., 34; United Kingdom, 7; Netherlands, 3; Denmark, 2; Portugal, 2; France, 2; West Germany, 2; Austria, 1; Japan, 1; Italy, 1 and Sweden, 1.

Mr. MACKASEY: Could I ask you a question at this point?

Mr. CHAPMAN: Yes, sir.

Mr. MACKASEY: Are only these 75 firms permitted to meet a source of supply for purchases for the DDP?

Mr. CHAPMAN: Yes.

Mr. MACKASEY: Only these 75?

Mr. CHAPMAN: For biologics.

Mr. MACKASEY: You are qualifying it. I am talking about any purchases they make.

Mr. CHAPMAN: Oh, no.

Mr. MACKASEY: So, it is not really that relevant? Could you not at least insist in the tender that if the source of supply is outside of the country that it be confined to these 75 firms?

Mr. CHAPMAN: Again, this is beyond my field of jurisdiction.

Mr. MACKASEY: Well, whose field of jurisdiction would it be, the interdepartmental committee; is that right?

Mr. CHAPMAN: Yes.

Mr. MACKASEY: It is partly under your jurisdiction. When I say yours I mean the Food and Drug Directorate since you are represented on that committee. In other words, you have done, or Dr. Greenberg has done a marvellous job in inspecting 75 firms and bringing in favourable reports of 75 companies in half a dozen or more countries. Yet, we still have the odd situation that outside these 75 sources of supply drugs can still come into Canada.

The CHAIRMAN: I would like to comment that the 75 have only been inspected for biological products. This would be done, perhaps, in a separate part. Other parts of the facilities might be completely unsatisfactory.

Mr. MACKASEY: Exactly. I do not want to exaggerate the point but the point I am getting at is that at least we could say that the 75 firms that exist are not in basements; they are not in attics; they are not in back lanes and they are

not refilling old capsules. These 75 have been inspected by Dr. Greenberg. Yet we do not have a regulation recommenation by the interdepartmental committee that at least those sources of supply coming from outside of the country into Canada for DDP purchases be confined to those 75 sources of supply.

Mr. CHAPMAN: I think we should consider this in terms of the whole of the drug supply, not only to the government but also to the general public.

Mr. MACKASEY: Exactly.

Mr. CHAPMAN: Could I continue, please, with my statement?

Mr. MACKASEY: Sure.

Mr. CHAPMAN: To extend such inspection to the plants of all firms exporting drugs to Canada would require a major increase in the staff of the directorate. Furthermore, there would be difficulties in some countries in obtaining permission for such inspection. In fact, in one instance, at least, there is legislation preventing this practice. In addition, if each country insisted on inspection of all drug plants within their borders, this could mean a horde of inspectors descending on every country exporting drugs, including Canada.

Mr. MACKASEY: May I ask a question at this point? Has this one country whose law specifies that you cannot go into the factory—Switzerland, I presume —any law that says they cannot export to Canada? Are they quite happy to have our business?

Mr. CHAPMAN: Yes.

Mr. MACKASEY: Fine, go ahead.

Mr. CHAPMAN: At least I assume that they are.

The CHAIRMAN: I would suggest we let Dr. Chapman finish and then during the next meeting today at a time to be decided in a few moments—

Mr. CHAPMAN: I will just take a couple of minutes. It is obvious then, that this would not appear to be a long term solution to our problem except for the biologics, in which case I consider that it is absolutely essential that our present requirements be maintained.

My second point deals with agreement on international standards for drug plant inspection. International agreement on minimum requirements for manufacturing facilities and controls, combined with uniform inspection procedures in exporting countries, would certainly appear to be the ultimate solution to this problem. It would then be possible to accept the protocols from the appropriate government agency and these countries in turn could accept our inspection reports. Now, unfortunately there is little likelihood that these procedures will be developed in the near future. It would require the active participation of an agency such as the World Health Organization to develop such a program, and this has not been started although there have been informal discussions along this line between officers of our department and officers of the World Health Organization.

I think then for the present the best we can do is a combination of these two with improved control over drugs entering Canada. As this Committee is aware, and I have tried to emphasize this, the Directorate has considerable information about the manufacturing facilities and controls of drug manufacturers supplying

drugs to Canada. Visits to other drug plants are frequently made during the inspection of foreign companies who have applied for a licence to sell biologics in Canada. In 1965, in addition, three professional members of the directorate staff visited pharmaceutical manufacturers, manufacturing associations and control agencies in Italy, Switzerland, Germany, France, the Netherlands, Belgium, England, Denmark and Sweden.

Mr. MACKASEY: Did you mention Poland?

Mr. CHAPMAN: No sir, I did not. At the present time the Director-General and I quote "may require" information regarding the condition of manufacture of a drug sought to be imported into Canada. We believe it should be mandatory that information and evidence regarding the conditions of manufacture prescribed in C.01.052 should be available in Canada and that adequate testing be carried out on the finished product. As I indicated in my initial statement, such an amendment to the regulations is presently under consideration. I might also add that our examination of imported drugs is reassuring. A survey of the quality of domestic and imported drugs, based on laboratory examination, revealed that 10.1 per cent of domestic production was unsatisfactory as compared to 12.5 per cent of imports. The number of imports was relatively small and therefore this difference is not considered significant.

Furthermore, a study of the quality of bulk drugs entering the country has been carried out in our Pharmaceutical Chemistry Division. A total of 124 samples of 16 different chemicals from 10 Canadian manufacturers who were using these drugs in their finished formulations were analysed. Trace impurities were found in 15 samples. We have no evidence that these impurities represent a hazard to health. However, it is proposed to identify the unknown impurities and if warranted to determine their toxicity.

In summary then, we do not have evidence that imported drugs represent a significant hazard to health. However, we feel that to ensure that this situation prevails in the future it will be necessary to periodically assess the manufacturing facilities and controls of foreign firms exporting drugs to Canada.

Mr. MACKASEY: You are right, Mr. Chairman, I will ask my question later.

The CHAIRMAN: Gentlemen, I think we should adjourn the meeting. There are a lot of documents here and it is now almost 1.30 p.m. If we try to get through them and have some lunch and then reconvene another meeting this afternoon is, I think, impractical. I would like to suggest, unless someone feels to the contrary, that next week we have only one meeting. Perhaps Dr. Chapman and I could line up a meeting not to conflict with other committees. I was going to suggest that we have a meeting from one o'clock in the afternoon and go from one to two-thirty.

Mr. MACKASEY: We are probably going to need another one next week anyway. There are an awful lot of documents and I apologize for the time I took up but I purposely stayed out of areas that Dr. Brand and Mr. Forrestall had shown interest in and I am sure we are not going to get by with one more meeting.

The CHAIRMAN: What is the feeling of the Committee?

Mr. BRAND: Frankly, I would agree with Mr. Mackasey. This could go on a lot longer if we could stay.

The CHAIRMAN: Do you wish to meet tonight at 8 o'clock? Is this agreeable?

Mr. CHAPMAN: Yes, Mr. Chairman.

The CHAIRMAN: This is unknown to Dr. Chapman and it might be that his officials have other commitments.

Mr. CHAPMAN: No; we would be pleased to meet with you.

The CHAIRMAN: As far as I am concerned, it may be even more convenient to start a little earlier, perhaps.

Mr. MACKASEY: Yes, I would say seven o'clock.

The CHAIRMAN: Is everyone in agreement? Perhaps we should pass the questioning and start off with Dr. Brand.

Mr. MACKASEY: Yes, fine.

The CHAIRMAN: The meeting is adjourned until seven o'clock.

EVENING SITTING

The CHAIRMAN: Ladies and gentlemen, we will reconvene the meeting that we adjourned this afternoon. First of all, I think Dr. Chapman can now answer the question that you asked, Dr. Howe, about the Essendale Mental Hospital and their troubles with chlopromazine.

Mr. CHAPMAN: I would like to ask Mr. Hollett to reply to this question if I could, Mr. Chairman.

Mr. A. HOLLETT (*Director, Bureau of Operations, Department of National Health and Welfare*): Mr. Chairman, a complaint was received by our Vancouver office concerning chlopromazine tablets and, as a result, 13 lots of chlopromazine tablets in assorted strengths of 25, 50, 100 and 200 milligrams, and two lots of chlopromazine injections, were obtained and submitted to the Vancouver laboratory for identification and assay. All of the products, with the exception of three, were quite satisfactory with respect to potency, and of the three lots that did not meet the full requirements with respect to potency one had a potency content of 92.9 per cent and the others of 94.0 per cent. I should explain that the B.P. requirements ranged from 92.5 to 107.5, and the U.S.P. from 95 to 105, so the discrepancy is a maximum of 1 per cent in one instance—that is so far as the U.S.P. is concerned—and in the other case the difference between 92.9 and 95., which is 2.1.

We consider that these products analytically are satisfactory, since the 1 per cent, or 2.1 per cent would not be considered that significant. The letter about which there was an inquiry from our Vancouver office to the hospital purchasing agency related to an inquiry—this was directed to the purchasing commission and is related to certain aspects of the availability, the strength of the tablets, the dosages and so on, and how many patients were involved. Interesting and desirable information would result if we were to carry on further tests on these products.

Mr. HOWE (*Hamilton South*): Mr. Chairman, could you read this letter into the minutes for us?

Mr. HOLLETT: This letter was dictated over the telephone this afternoon, and I assume that it is reasonably accurate. I do not have the date of it. It is addressed to the British Columbia Purchasing Commission, 501 West 12th Avenue, Vancouver, Attention Mr. F. Leonard. It is from our Inspector Gonzales at Vancouver, and it reads:

> Further to our telephone conversation, I have been contacted by Dr. G. R. Van Petten of the Pharmacology Division of the Food and Drug Directorate in Ottawa. Prior to further consideration being given to the availability dimensions—

Probably that word is incorrect, but that is what I have here.

> —on the above products, Dr. Van Petten would like more background regarding the situation at Riverview Hospital. He requests information along the following lines:
>
> Thirteen lots of drugs were involved in the situation. Question: Were all lots used and thus felt to be suspect? Were any specific lots believed defective regarding their pharmacological action? Was any particular strength of tablet involved to a greater degree? Was any particular dosage used? What dosages were used? How many patients were involved in this situation? What was the frequency of lack of response? How many responded favourably when switched to another brand of product? How many doctors felt this situation was a problem? How long was treatment with the Maney product tried? Were any dramatic side effects or dramatic changes in therapeutic effects noticed upon change from one brand to another? Was there a greater or lesser frequency of side effects with the Maney brand as opposed to those of the other brands used?
>
> We realize some of these questions probably cannot be answered concisely. However, as much information on these questions and any other data the medical people can supply would assist us greatly in our assessment of the situation.

The letter is signed by B. Gonzales, Food and Drug Directorate, Vancouver.

Mr. CHAPMAN: Mr. Chairman, just for the information of the members of the Committee I might make it clear that this is a request from our Division of Pharmacology in the research laboratories in Ottawa for further information in order that we can check out the complaints that had been made with regard to this product, and when we do get this information, of course, we will be continuing our study.

Mr. HOWE (*Hamilton South*): Mr. Chairman, I would like to ask Dr. Chapman if there is an answer to this letter yet? Is this a letter which has been sent but which has not yet been responded to?

Mr. HOLLETT: As far as I know it has not been responded to. If it had been responded to we would know by today.

Mr. HOWE (*Hamilton South*): I see. That letter, although you have not the date, was recent enough to not have had a chance to be answered yet?

Mr. HOLLETT: I think that is correct.

The CHAIRMAN: There was one other question that Mr. Mackasey brought up. Even though he is not here at the moment, I think, to keep things in context,

we should have Dr. Chapman answer it now. It dealt with Mr. Mackasey's questions about a company that obviously maintained just a suite of offices in Montreal, actually importing drugs, and whether these drugs were adequately tested or knowledge known of testing by the Food and Drug Directorate.

Mr. CHAPMAN: Mr. Chairman, we have been able to check this out through our inspection services, and we find that we do have considerable additional information with regard to these three companies. Mr. Hollett has that information, and I would like him to present it.

Mr. HOLLETT: Mr. Chairman, there are two companies located on Sherbrooke Street—I think that is the street that was mentioned this morning—one is Immuno Limited, and it acts solely as the sales agent for an Austrian firm, and it holds a Canadian licence; that is, a licence to manufacture Schedule C and D drugs, and that firm has been inspected by Dr. Greenberg. It sells only Schedule C and D drugs.

The other company, Syntex Chemicals, located at 1420 Sherbrooke Street, West, Montreal, is also included in the list of firms found to conform to standard 74-GP-1b. This company acts as a distributor. They do not manufacture, and at the time of the last inspection the drugs this company distributes were purchased from Charles E. Frosst Limited, Montreal, and Charles E. Frosst is listed as conforming with the requirements of standard 74-GP-1b, and it is on that list. Of course, these manufacturing premises have been inspected by the Food and Drug inspectors.

Mr. HOWE (*Hamilton South*): Does that mean, Mr. Chairman, that Syntex Chemicals Company is purely a distributing agent for Charles E. Frosst and Company?

Mr. HOLLETT: They would put their name on the product, I would presume, and carry out certain checks on their premises, and there would be a check made on this by our inspectors when they carry out inspection of the plant. But manufacturing is not carried out at Syntex Chemicals.

Mr. HOWE (*Hamilton South*): Just so I can get this straight, does this mean that Frosst manufactures for Syntex Chemicals, or does it mean that Syntex is a distributor for Charles E. Frosst?

Mr. HOLLETT: I would say that Frosst manufactures for them.

Mr. HOWE (*Hamilton South*): And Syntex carries on as a pharmaceutical distributor under their own name?

Mr. HOLLETT: Yes, under their own name.

Mr. HOWE (*Hamilton South*): And as far as you know there has not been any financial connection between Frosst and Syntex?

Mr. HOLLETT: As far as I know there is none.

Mr. BRAND: If I may interject, Mr. Chairman, is it not true that the Syntex Corporation is an American firm which, if you look into it, probably has already bought Frosst?

Mr. CHAPMAN: The name of this firm, Mr. Chairman, is Syntex, Limited, 1420 Sherbrooke Street West, Montreal, 25, Quebec. I do not think we in the Food and Drug Directorate have any more information.

The CHAIRMAN: There is a third firm, I think, as well.

Mr. HOLLETT: Colonial Agencies Limited, Halifax. This company does not manufacture drugs. At the time of the inspection of the premises, the drugs distributed by this company were imported from the United Kingdom. Our Halifax Laboratory has analysed and has been analysing importations of drugs consigned to this company and they have found them to be satisfactory.

Mr. BRAND: May I ask a supplementary? Does that include drugs which are encapsulated or entabletted at the time of import?

Mr. HOLLETT: Yes, drugs in finished form.

Mr. BRAND: This is in direct contradiction to the testimony which was given previously, so I am naturally rather curious.

Mr. CHAPMAN: May I ask Dr. Brand what statements were made previously?

Mr. BRAND: I can look them up if you want to give me a little time. I have the statements here.

Mr. CHAIRMAN: Mr. Hollett, can you throw any further light on this subject?

Mr. HOLLETT: There is nothing to indicate, Mr. Chairman, that they get the raw material and manufacture it. They are listed as a distributor.

The CHAIRMAN: They merely buy the drug and distribute it.

Mr. HOLLETT: This is the interpretation which I must place on the inspection which has been carried out of their premises.

Mr. BRAND: We got the distinct impression previously in testimony before this Committee from various sources that the Food and Drug Directorate tested raw materials which were brought into this country, but did not test tablets or capsules which were brought in. It is in here somewhere and I can find it for you.

The CHAIRMAN: That is not the impression that the Chairman has. I gather Food and Drug Directorate test drugs in any form that are brought into the country.

Mr. BRAND: I do not think that is correct, Mr. Chairman.

Mr. MACKASEY: I have a supplementary question, and I apologize for being late. This particular firm in other words, to the best of your knowledge, imports finished products rather than just raw materials?

Mr. HOLLETT: That is correct.

Mr. MACKASEY: In other words, they do no manufacturing in Canada.

Mr. HOLLETT: That is correct.

Mr. MACKASEY: This is in direct contrast to, we will say, other people tendering?

Mr. HOLLETT: I presume that many of the companies which tender manufacture the drug from the raw material, but I am not in a position to know the relative numbers.

Mr. MACKASEY: You do know that this one normally does not?

Mr. HOLLETT: That is correct.

Mr. MACKASEY: You cannot, therefore, examine any manufacturing premises that do not exist in Canada, so far as they are concerned?

Mr. HOLLETT: That is quite correct.

The CHAIRMAN: Do they also act similarly with biologicals?

Mr. HOLLETT: No, I do not think so.

The CHAIRMAN: We were answering the question that you asked this afternoon, Mr. Mackasey, just as you came in. Would you like to proceed with the questioning, Dr. Brand?

Mr. BRAND: I would love to, just on the basis of the question you just asked—

The CHAIRMAN: Could I interrupt you for one moment? I am sorry, but there are three other things that I should have put on the record this morning, and I think we should do it now. I have three letters which should probably become part of the record. One is a communication from PMAC to Mr. Laidlaw, which has already been referred to in testimony; there is a letter from Mr. McClenahan concerning Microchemicals and Paul Maney Laboratories; and there is also a letter from Hoffman-LaRoche from Mr. Nowatny. Is it agreed that these become part of today's record?

Mr. BRAND: What are they about?

The CHAIRMAN: Perhaps the best thing to do is to send them down and let you look at them. They are long, detailed answers to some questions or statements that have been made by other people before the Committee. The letter to Mr. Laidlaw was in answer to some questions that Mr. Laidlaw had actually put to the PMAC, dealing with the history of prescription prices in Canada, the different drugs that are used by DBS for their estimates of drug prices, and the proportions of the amount of money on yearly research budgets of member companies. The other letters, as I say, deal with various submissions before the Committee. Do you wish to see them Dr. Brand?

Mr. BRAND: No; that is fine. We will see them as they come along.

The CHAIRMAN: Is it agreed?

Some hon. MEMBERS: Agreed.

The CHAIRMAN: Dr. Brand, would you carry on.

Mr. BRAND: In answer to one question that was asked as to what pages this information I was referring to appears on, if you look at the December 1st issue of the minutes of the special committee on drugs costs and prices, page 1538 and following—and I do not want to take the Committee's time to read this into the record—I think you will find some substance for the statements that I have made that the impression we had received, certainly from Dr. Showalter and other members of the Department of Defence Production, the Department of Industry, the Department of National Health and Welfare, the Department of Veterans Affairs, and so on, is that there was testing carried out on drugs in Canada, but if they came in an entabletted or encapsulated form they were not tested by the Food and Drug Directorate. Mr. Mackasey's questions were along those lines as well at that time. I do not want to take the time of the Committee to go into it.

Mr. CHAPMAN: I can only say that we test both the bulk drugs and the finished products as they come into Canada.

Mr. MACKASEY: All finished products.

Mr. CHAPMAN: No, sir; we cannot test all.

Mr. MACKASEY: This is my point; just a spot check.

Mr. CHAPMAN: That is correct.

Mr. BRAND: The point I raised was, did all these companies on the 74-GP-1b list have to comply with the very excellent regulations laid out in the Canadian Government Specifications Board standard. The statement was that they did not. On page 1539, Dr. Showalter said this:

> The reason they are included is partly based on history—the fact that government purchases have for a long time allowed non-Canadian products.

You can perhaps appreciate our understandable confusion over a reply like this. Frankly, I could not see how history had anything to do with the quality or efficacy of any particular drug imported into Canada, so perhaps you will understand why we are little concerned about what was going on.

Mr. CHAPMAN: I hope I have satisfactorily clarified that point, Dr. Brand.

Mr. BRAND: Up to a point you have, I do not think completely though because you have just pointed out that you do only spot checks.

Mr. CHAPMAN: This is quite correct.

Mr. BRAND: Quite frankly, I probably have enough questions to keep us going for the next week or so but perhaps we could go to the part which you yourself referred to Doctor, the summary of data on the Food and Drug Directorate. We have here a very long list of drugs which have been recalled, and people who have been fined as a result of infractions of the Food and Drug regulations, and so on.

On page 4, I find a very strong statement that there does not appear to be any significant difference between drugs sold under a generic name and those sold under a brand name. That is a pretty bald statement, and similarly imported drugs appear to be of the same general quality as domestic production. What I would like to know, of course, is, in view of this statement, would you feel that as a result of the facilities you now have in the Food and Drug Directorate you are able to examine sufficiently the drugs which are available, not just to the Department of Veterans Affairs, but to the public; that is, you can with the supervisory measures you use now declare that every drug we now have available is safe for the general public, regardless of whether they are a so-called brand name or a generic name.

Mr. CHAPMAN: Well, of course, Dr. Brand, I did not say that we could guarantee that all the drugs on the Canadian market were safe, or that they all met our requirements. As a matter of fact, I stated quite clearly in my statement this morning that we could not do this.

Mr. BRAND: I am aware that you did. That is why I was curious about this other statement. You make the statement here that there is no significant difference between those sold under a generic name and those sold under a brand

name, and I think this is a key point. In all the hearings that we have had there has been a lot of arguing back and forth whether a generic drug was equivalent to those sold under a brand name.

We have evidence before this Committee from some members of the Department of Defence Production that they would prefer to buy under a brand name although in fact they buy under a generic name. We have evidence from your own group along this line as well and if I may specify, if it comes from a reputable manufacturer you do not examine it necessarily, but if it is not from a reputable manufacturer you do. These statements are all at variance and I think we should have clarification; otherwise we have a statement here which without any doubt is going to have a very significant effect on the sale of drugs in Canada because, since it carries the authority of the Food and Drug, it is like a statement from on high, you might say, as far as many of the users of drugs in Canada are concerned, such as physicians and others.

Mr. CHAPMAN: I would hope, Dr. Brand, that the medical profession would not be that easily influenced. However, let me—

Mr. BRAND: They are no different from anyone else.

Mr. CHAPMAN: Let me proceed to explain the reason that I reached that conclusion. You will note that in Appendix 1 we have a comparative survey of the quality of brand name and generic drugs, domestic and imported, for 1965. Here we find that under domestic drugs, we have brand name 8.1 per cent unsatisfactory generic 12.4 per cent. If we move over to imported, we find 18.4 per cent brand name unsatisfactory, 5.1 per cent of generic unsatisfactory. I would hasten to point out that the numbers here are very small and I do not think that this really represents any significant difference.

Mr. BRAND: Do you think that would depend upon whether you were the one who had received those drugs as a patient or not, doctor; whether it is unimportant or not.

Mr. CHAPMAN: I did not say that it was unimportant. I said that I did not think there was any significant difference, that you should not draw the inference from this that the generic drugs imported were significantly superior to the brand name drugs.

Mr. BRAND: I wonder if you could explain what you mean, first of all, by brand name, and second, what you mean by generic. We know what we are looking at, more or less.

Mr. CHAPMAN: Yes; I would be very pleased to do so. The brand name drugs that are listed here are simply those that were sold under a brand name and so indicated on the analytical reports submitted from our laboratory.

Mr. BRAND: I presume you are talking about prescription drugs, are you, in this series?

Mr. CHAPMAN: No.

Mr. BRAND: Oh, you are not.

Mr. CHAPMAN: Not necessarily.

Mr. BRAND: Well, we are dealing here with the cost of prescription drugs, Dr. Chapman. I wonder if there is any difference; this whether...

Mr. MACKASEY: Dr. Chapman, could we be poisoned by drugs that are not on prescription as well as drugs that are on prescription.

Mr. CHAPMAN: Certainly.

Mr. MACKASEY: That is fine. It is just an observation.

Mr. BRAND: You can be poisoned by an aspirin. There are some times when—well, we will not go into that.

Mr. CHAPMAN: Would you like to know the groups of drugs that were considered among this 973, Dr. Brand.

Mr. BRAND: I would be very interested, indeed, and I am sure the Committee would.

Mr. CHAPMAN: Mr. Allmark, would you give us an indication of the categories of the drugs that were included; can you recall?

Mr. ALLMARK: All classes of drugs are represented in this survey. Just about any class you can mention actually is included in this list of drugs. This would be my answer.

Mr. BRAND: You mean anything that is sold across the counter in a drugstore whether on prescription or not. Is this what you mean?

Mr. ALLMARK: Both, both prescription drugs and O.T.C. products, O.T.C. meaning over the counter.

Mr. CHAPMAN: These were selected to permit a comparison between an approximately equal number of products of each category containing the same active ingredients. We felt that by so doing we might be able to get a comparison between these two categories.

Mr. BRAND: Perhaps you could explain to me what ampicillin Biodiscs are in relationship to an over the counter or a prescription item for that matter.

Mr. CHAPMAN: Where are you referring to?

Mr. BRAND: This in on page 2 of the list of the drugs you have there. It goes on to say that it is put out by British drug houses of Toronto and the date presumably, when you looked into the matter, it was July of 1966, and the offence alleged the potency in excess of labelled claim. I will agree that these are discs that are used in determining the sensitivity of drugs in laboratories.

Mr. CHAPMAN: We are moving on to Appendix III, I was talking about Appendix I, I think if we took these one at a time—

Mr. BRAND: I am sorry, but I thought we had taken out all the appendices, but I guess not. I am sorry.

Mr. CHAPMAN: I was referring to the one entitled: "Comparative Survey of Quality of Brand Name and Generic Drugs, Domestic and Imported, 1965."

Mr. BRAND: I see.

Mr. MACKASEY: Mr. Chairman, on a point of clarification, if I may: Dr. Chapman has brought up the point of this page. I would just like to point out, Dr. Chapman, when my turn comes back—I realise it is a long time away—I would like to investigate this area in its relationship to the Hall Commission

Report on trade marks, not on patents. I do not know whether the Chairman would prefer me to bring it in now as a supplementary question, although it is short, or wait and give me the chance to come back.

Mr. BRAND: Bring it in, Mr. Mackasey if it is appropriate.

Mr. MACKASEY: The point I am trying to get at, Dr. Brand, is that one of the recommendations of the Hall Commission was not only the theoretical abolishment of patents, but also the question of the effect the trademark has on preventing the importation of brand name drugs from other countries. I presume from the Hall Commission Report, Dr. Chapman, that this meant the same brand names. Let us take a company and call it "Ajax" because it is a cleanser and not a drug I think it is the fairest way to deal with it. Let us assume that rather than pay $2.00 for a product manufactured by Ajax in Canada, we somehow facilitate the importation of a product manufactured, say, by Ajax, the parent company, in some other country. We bring it in from a cheaper labour market and are thus able to sell it in Canada for $1.50. The implication in the Hall Commission Report is that this is not possible because of our trade marks. This leads me to the question of imports. It surprises me that the brand name drug coming in from Europe suffers very much in comparison with the brand name drug in Canada, which destroys the implication in the Hall Commission that they are identical, and only the trade mark is preventing our taking advantage of brand names manufactured in a country where the labour costs less.

I come back to the fact that only 8.1 per cent of the brand names in Canada were unsatisfactory, but 18.4 per cent of the brand names imported were unsatisfactory. And then of course, I tied this in with the other report that you gave us here, that showed that the parent company could reside in a country where the standard of inspection is much less restrictive than in Canada. That is the point I wanted to explore.

Mr. CHAPMAN: Well, I am afraid that I am not in a position to comment. As I have indicated, we simply took those laboratory reports, where the products which were examined had a brand name, and compared those with laboratory reports where the product examined was sold under a generic name. But other than that I do not know, and I should hasten to point out that this differentiation between generic and brand name drugs really does not mean very much.

Mr. MACKASEY: Dr. Chapman, I am not trying to make any distinction between generic and brand names. I will conclude with one question and let the thing go back to Dr. Brand. Let us take Frank Horner, or Hoffmann-La Roche or Smith Kline and French. The implication in the Hall Commission report is that if you are buying Librium in Canada, you are paying higher than if there were some way for Librium to come in from Europe; but we are prevented from importing Librium because of restrictions under the trade mark. At first glance, this has a certain degree of attractiveness in bringing down the cost of drugs, but on looking at this table I am left with the uneasy suspicion that the Librium, even though it is called Librium, coming in from Europe, may not necessarily be of the same quality as the Librium manufactured in Montreal, because of the difference in the inspection methods in the two countries.

Mr. CHAPMAN: Well, I would caution the members of the Committee from drawing any firm conclusions about the quality of the imported drugs, because of the small numbers involved.

Mr. MACKASEY: Then, the table does not really mean too much.

Mr. CHAPMAN: Well, in the case of imported drugs, I think that you should be very careful about drawing firm conclusions. The numbers of the domestic, however, I think are sufficient to make the figures meaningful. If we compare the two we find that we have unsatisfactory—this is total, both domestic and imported—8.6 per cent brand name, 11.8 per cent generic. Now, again, there is a difference here of about 3 per cent; it did not appear to me that this was such a significant difference that you could draw any firm conclusion.

Mr. MACKASEY: But it is 50 per cent, Dr. Chapman.

Mr. CHAPMAN: It is 8.6 per cent as compared to 11.8 per cent.

Mr. MACKASEY: I have got 8.1 per cent on mine, as compared to 12.4 per cent.

Mr. CHAPMAN: If you will look at page 2 of the summary of data, you will see I have combined—

Mr. BRAND: Could I interrupt just a moment, and point out that there are some committee members who have not received this particular document, and perhaps it would be only fair if they had them as well. All those who have not raise your hands.

The CHAIRMAN: They were distributed this morning.

Mr. BRAND: No they were not; I received mine afterwards. I am sorry, but this was not distributed this morning. I realize it was, but somebody goofed; let us put it that way.

Mr. MACKASEY: Mr. Howe, have you got this one?

Mr. HOWE (*Hamilton South*): I believe I have got that one, but I have not got—

An hon. MEMBER: This one was distributed when I was here this morning I believe, sir.

Mr. BRAND: I know it was, I got one when I heard Dr. Chapman referring to it.

Mr. MACKASEY: What is the heading of the one you did not get?

Mr. HOWE (*Hamilton South*): "Summary of data on drugs, Food and Drug Directorate". I have just received it. What page are we on so that I can join in this discussion.

Mr. CHAPMAN: If you look at the heading "Comparative Survey of quality of Brand name and generic drugs, Domestic and Imported, 1965", and also look at page 2 of the "Summary and data on drugs, Food and Drug Directorate", you will see that these two statements are related. Now, as Mr. Mackasey has pointed out, per cent unsatisfactory brand name was 8.1 per cent of the domestic, and 12.4 per cent generic, both domestic. If you take both domestic and imported, the percentages unsatisfactory are brand names 8.6 per cent, and generic 11.8 per cent.

Mr. MACKASEY: Dr. Chapman, this is very misleading because you have not made any correlation between the brand imported and brand domestic. Are they identical brands?

Mr. CHAPMAN: No, sir; I would not expect that they would be.

Mr. MACKASEY: Then, these figures on page 2 do not really mean anything.

Mr. BRAND: I can answer that by pointing out that you have on your list such things as Ideal Syringes and I am curious to know how a patient would take them.

Mr. CHAPMAN: Well, we are moving on again to another table. I wonder if there are any further questions.

Mr. BRAND: It is still relating to the same figures though, doctor.

Mr. CHAPMAN: No, sir.

Mr. BRAND: Well if they are not I am very surprised they are included in the same group.

Mr. CHAPMAN: There is not necessarily any relation between the table "Comparative Survey of Quality of Brand Name and Generic Drugs, Domestic and Imported, 1965" and the one labelled "Drugs analysed for Department of Veterans Affairs". May I go on to the next table?

> "Drugs Analyzed for Department of Veterans Affairs, 1965 and 1966". These data were obtained on 72 samples of drugs analyzed in 1965 and to September, 1966 in the laboratories of the Directorate at the request of the Department of Veterans Affairs. One sample only was found to be unsatisfactory, a lot of chlorpromazine hydrochloride tablets manufactured by Bell-Craig Pharmaceuticals, Toronto. The tablets were found to contain from 109.1 to 113.5 per cent of the declared amount of chlorpromazine hydrochloride. This lot was returned to the firm and placed under seizure by the Directorate.

Now, I think, if you will look down this list, most of these were produced by what has previously, at least, been referred to as the generic drug firms.

Mr. BRAND: How do you justify your statement on page 4:

> There does not appear to be any significant difference between drugs sold under a generic name and those sold under a brand name—

—in view of your statement on the bottom of page 2.

Mr. CHAPMAN: My statement on page 4 refers to all the information that appears in all these tables, and all the information that we have available to us.

Mr. BRAND: Have you correlated this, by the way, doctor, recognizing the fact that about 85 per cent of the drugs sold in Canada are produced by the so-called brand name houses, such as the Pharmaceutical Manufacturers Association, and only 15 per cent produced by the generic houses. Have you correlated this to obtain the percentage which was unsatisfactory, from the PMAC group or from the generic house group? And if not why have you not?

Mr. CHAPMAN: I am not at all sure that the 85 per cent refers to the number of drugs on the market.

Mr. BRAND: That has certainly been the evidence that we have had before this Committee.

Mr. CHAPMAN: The number of drugs or the volume of drugs?

Mr. BRAND: Volume, I do not think there is really much difference between volume and number, unless you are referring to variety.

Mr. CHAPMAN: Well, nevertheless, there is not the slightest doubt that out of 72 samples—I do not believe that there are any members of the PMAC on this list. Is this correct? On the list "Drugs Analyzed for Department of Veterans Affairs"? In any event—

Mr. BRAND: I am pretty sure that is true since they have already given us evidence that they buy mostly from generic houses.

Mr. CHAPMAN: I beg your pardon, Dr. Brand?

Mr. BRAND: Officials from the Department of Veterans Affairs have already given evidence that they buy mostly from generic house, or buy generic names.

Mr. CHAPMAN: The point I am making is that out of 72 samples only one was found to be unsatisfactory. This was slightly high, and these were all generic drugs. So this particular piece of evidence would indicate the generic drugs were of a reasonably good quality.

Mr. BRAND: Well, then, as a scientist, which I presume you are, Doctor, since you have not examined at the DVA any of those sold under a brand name, how can you presume they are exactly the same? How can you make a presumption like this when all you have examined are those, by your own evidence, from firms which sell under a generic name. I am curious to know how, scientifically speaking, you make an assumption like this.

Mr. CHAPMAN: I have made this assumption, Dr. Brand, as I have already indicated, on the basis of all the information available to us.

Mr. BRAND: You have already denied me the privilege of bringing in appendix II under this, Dr. Chapman, I do not see any reason why I cannot confine myself to what you confine me to, and that is Appendix II, which has no brand name manufacturers in it. You make the statements on page 4, that:

> There does not appear to be any significant difference between drugs sold under a generic name and those sold under a brand name.

And yet you have made no comparison of those sold under brand names. How, in the name of goodness, can you come up with this regulation when, on your own admission, you have not even examined them?

The CHAIRMAN: There seems to be some misinterpretation here.

Mr. BRAND: Not on my part, sir.

The CHAIRMAN: Well, then on my part.

Mr. BRAND: I am sorry for you, sir, but—

The CHAIRMAN: Dr. Chapman is referring to some examinations that were done of generic brands. He admits that they did not, under that sample—

Mr. BRAND: Oh, I agree.

The CHAIRMAN: —test others; but they have tested the others.

Mr. BRAND: Ah! Just a moment; we will go into those later.

Mr. HOLLETT: All right.

Mr. BRAND: If you want me to bring in things like the syringes that you examined, and things of this nature, as part of your estimate of what drugs are or are not valuable, or do not meet specifications, I will be happy to do so. But as I recall it, it was pointed out to me a few minutes ago that I should not do this.

Mr. CHAPMAN: I am sorry, Dr. Brand; this was not my intention. All that I wished to do was discuss these one at a time. You will note at the bottom of page 3 of my summary:

> The following conclusions can be drawn from the data shown in appendices I to V.

Now, if I might be permitted to discuss these appendices one at a time, and then—

Mr. BRAND: You cannot, can you? With all due respect, Dr. Chapman, how can you discuss them one at a time if you are going to draw conclusions from all five? Surely, I should be able to ask questions relating to tables I to V.

Mr. MACKASEY: Might it help, Dr. Chapman, if I suggest that possibly page 4 should have appeared at the back of appendix V?

Mr. BRAND: This is right.

Mr. MACKASEY: This would eliminate the confusion. I think you are right; we are both right, at least Dr. Brand is right. The conclusion on page 4, as you have mentioned, is:

> The following conclusions can be drawn from the data shown in appendices I to V.

But you have it shoved in here, at the end of your collating, at the end of, I think, appendix I; this, I think, was Dr. Brand's meaning. If sheet number 4 appeared right at the back, you could argue the point on an equal basis; this is all it is, I think.

Mr. CHAPMAN: I am sorry, Mr. Chairman, the problem was that we were simply asked—the Food and Drug Directorate were asked—to appear before this Committee to answer questions. We did not know what those questions were going to be. We had to get together as much information as we could in order that we could present it to you if you wished to discuss the information that we had in our files.

Now, Dr. Brand, I thought that you were referring to my statement in the document entitled "Summary of Data on Drugs, Food and Drug Directorate".

Mr. BRAND: I am.

Mr. CHAPMAN: Which reads at the bottom of page 3:

> The following conclusions can be drawn from the data shown in appendices I to V.

Then the first under (I):

> There does not appear to be any significant difference between drugs sold under generic name and those sold under a brand name. Similarly imported drugs appeared to be of the same general quality as domestic production.

Now, that was based on all the information that was included in appendices I to V.

Mr. BRAND: All right; I will accept that.

The CHAIRMAN: Can we go down and just review the appendices one at a time and then come back to the conclusions? Appendix I,—

Mr. BRAND: I hate to point out that it is very difficult for me to follow what you mean by appendices I to V when they are not numbered as such. This has been part of the confusion that has been resulting.

Mr. CHAPMAN: Would you like me to designate these with numbers? Again, you see, I did not know whether these were going to be submitted as evidence, and therefore I could not number them. Would that help, then?

Mr. BRAND: Yes.

Mr. CHAPMAN: "Comparative Survey of Quality of Brand Name and Generic Drugs, Domestic and Imported, 1965"; Appendix I. "Drugs analyzed for Department of Veterans Affairs"; Appendix II. "Drug Recalls involving Food and Drug Directorate, June 1965 to January 1967;" Appendix III. "Convictions registered against drug manufacturers, 1963 to 1966"; Appendix IV.

The CHAIRMAN: And Appendix V is labelled.

Mr. CHAPMAN: Yes.

The CHAIRMAN: Shall we go back, and then go on to the summary?

Mr. BRAND: This covers all five appendices?

Mr. CHAPMAN: That is correct. Then there is a summary of data on drugs in which I have referred to each one of these appendices. Now, could I ask, Mr. Chairman, if there are any further questions about Appendix I?

Mr. BRAND: Yes, as a matter of fact there is, Mr. Chairman.

The CHAIRMAN: Fine.

Mr. BRAND: It includes your summary, where you draw conclusions from appendices I to V. At the top of page 4, you say:

> There does not appear to be any significant difference between drugs sold under a generic name and those sold under a brand name.

What are you talking about, a chemical difference, or a physical and chemical difference, or a therapeutic difference, or what kind of difference? In other words, let us be specific.

The CHAIRMAN: Excuse me, are we not getting back into the same problem again? You are back into the summary. Can we not go through and take the appendices individually and then come to the summary where he sums them all up. I think we are getting back into the same problem we got into before.

Mr. BRAND: Well, maybe we are.

Mr. CHAPMAN: I can say, Dr. Brand, that the information in appendix I, is strictly physico-chemical.

Mr. MACKASEY: Could I ask a supplementary question, Mr. Chairman?

The CHAIRMAN: Yes.

Mr. MACKASEY: It is fair to presume that, on the analysis of appendix I exclusively, it would be premature to come to the conclusion that appeared at the top of page 4, on that appendix alone.

Mr. CHAPMAN: I would say so.

Mr. MACKASEY: That is fine, I think that is what Dr. Brand really wanted to know.

Mr. BRAND: Yes, that is what I was getting at, but also I am getting at this point. Let us take an example which is not used here. Let us take calcium gluconate tablets which are a notorious one. They are sold across the counter in every drugstore in Canada. I think it is well known to Dr. Chapman and the members of the Food and Drug Directorate that some of these tablets do not dissolve in the bowel at all, and, in fact, can be seen on X-ray as little lumps of cement which pass right through into the excreta with no difficulty; whereas there are others which dissolve. Yet they both have the same chemical composition; is that not correct?

Mr. CHAPMAN: The data included here, included not only potency, but also disintegration, in most instances.

Mr. BRAND: In most instances, but not all?

Mr. CHAPMAN: I could not say that disintegration was carried out on all these samples; but I think in most instances.

Mr. BRAND: Do you not think it would be fair to say there is no significant chemical difference, but in most instances there is a rate of disintegration difference among drugs sold. I want to be accurate there.

Mr. CHAPMAN: I think regardless of therapeutic effect—

Mr. BRAND: Put that in parenthesis if you like.

Mr. CHAPMAN: Yes, we are talking about potency, variability, and disintegration time.

Mr. HOWE (*Hamilton South*): Mr. Chairman, could this not all be summed up in the words "therapeutic effect"?

Mr. CHAPMAN: Not really.

Mr. HOWE (*Hamilton South*): Not really? Well, I do not see why not. The physico-chemical, disintegration availability of the drug, and its potency, produce the therapeutic effect that you want from a drug; would that not sum it all up?

Mr. BRAND: I can produce a considerable amount of evidence to show this is not necessarily true. I think Dr. Chapman well recalls the matter of erythromycin when it was first brought out. There were two separate products, both by reputable companies. One was not usable because of the gastric irritation ensuing in the patients in the use of this drug; and it was due, not at all to the chemical composition or the rate of disintegration; but was due, in fact, to the manner in which it was compounded and the coating produced on the pills. Is this not correct? If you like I will give you the paper which deals with this.

Mr. HOWE (*Hamilton South*): Thereby decreasing the therapeutic effect; is that still not a portion of the therapeutic effect?

Mr. BRAND: Yes, but you can see what I mean. The chemical and disintegration would be the same, and yet the therapeutic effect was entirely different; that is what I am getting at.

Mr. CHAPMAN: That is why I said: Not necessarily.

Mr. BRAND: So this gives a false impression. Would you not agree Dr. Chapman? The impression I get from this—and I am sure every other doctor in Canada will—is that brand names and generic names are equal and therefore you should buy the cheapest possible, regardless, because they have received the blessing of the Food and Drug Directorate—the director himself.

Mr. CHAPMAN: All I can say is that I would anticipate that the physician is going to use his own judgment in regard to this matter.

Mr. BRAND: The physicians, as you know, are busy people, and they are not supermen—they never pretend to be. They look to authoritative—and I hate to admit that this is true—governmental sources as a means of something to grasp onto that they can use as a guideline. Do you think this could, perhaps, be slightly misleading in this regard? I have another half hour of questioning along this line, if you like.

Mr. CHAPMAN: No, thank you.

Mr. BRAND: Do you see what I am getting at, doctor?

Mr. CHAPMAN: Yes; I have no reason to change my mind.

Mr. BRAND: I do not think you know your own strength. The Food and Drug Directorate in Canada is considered—and rightly so, I believe—a very excellent group who do an excellent job, and whose results, and whose comments, are to be looked at with not only interest but with awe, to a certain degree, and certainly with respect. Do you not think it is incumbent upon the Food and Drug Directorate, therefore, to be most careful in the manner in which they make statements?

Mr. CHAPMAN: I certainly agree with that.

Mr. HOWE (*Hamilton South*): Mr. Chairman, may I interject, with Dr. Brand's permission?

Mr. BRAND: Be my guest.

Mr. HOWE (*Hamilton South*): I hate to take away from your time, if we are being timed on this. With proper control by the Food and Drug Directorate, would you say that generic drugs could be just as satisfactory as far as therapeutic use in the doctors' hands is concerned, and much less expensive to the patients?

Mr. CHAPMAN: I would not wish to make that statement.

Mr. HOWE (*Hamilton South*): I made the statement; I am just asking if you agree.

Mr. CHAPMAN: Well, I simply would not put it in those terms. I think we should stick to the evidence that we have in appendix I, which is based on a laboratory examination of potency, variability, and disintegration time. Now, we do know that in most instances, the product which is satisfactory in all these respects will also have the desired therapeutic effect; but there are exceptions.

Mr. BRAND: I do not wish to make too blanket a statement about this. For example, I did make the statement, I believe, on volume of sales anyway, regardless of what other criteria you would use; the brand name manufacturers

sell 85 per cent of the drugs in Canada; I think the Chairman will bear me out on this.

The CHAIRMAN: Yes, definitely.

Mr. BRAND: Fifteen per cent of them come from the so-called generic houses. I did a little figuring over the recess, and I note from all your appendices here—and I find, Mr. Chairman, it is very difficult to deal with them separately—that two thirds of the recalls were from that 15 per cent. Fifty per cent of the health hazards you notice, were in the 15 per cent, and 92 per cent of the convictions were in that 15 per cent. On the basis of this, to read your conclusion based on I to V, naturally I find myself wondering a little if in reality you mean exactly what you say in those words.

Mr. CHAPMAN: I have no reason to change my statement, Mr. Chairman.

The CHAIRMAN: Fine. I am going to ask—

Mr. FORRESTALL: I would like to ask a question, Mr. Chairman, if a layman is permitted to.

The CHAIRMAN: Most certainly.

Mr. MACKASEY: I wanted to ask a question—

Mr. FORRESTALL: I wanted to ask a supplementary first.

Mr. MACKASEY: I am sorry, I thought you had switched; go ahead Mr. Forrestall.

Mr. FORRESTALL: Thank you very much, Mr. Mackasey. May I, Mr. Chairman?

The CHAIRMAN: Perhaps Dr. Brand and Dr. Howe would like to get together and have a separate meeting afterwards and argue this out.

Mr. BRAND: Well, I am not arguing with anybody, Mr. Chairman.

Mr. HOWE (*Hamilton South*): No, not at all.

Mr. BRAND: Dr. Howe can speak for himself.

Mr. FORRESTALL: I just wanted to look, Dr. Chapman, if I could for a moment, at your imported figures. This is on your appendix I, where you have asked us not to draw any firm conclusions because the total number of samples used is relatively low.

Mr. CHAPMAN: Yes.

Mr. FORRESTALL: Why did you include it? Was it what was immediately at hand for you?

Mr. CHAPMAN: No, these were all the figures we had on these groups of imported drugs from 1965. We have been criticized, and I quote:

> We have been accused of remaining silent on drug quality or at the best, tending to generalize and thus confuse further an already confused situation.

If I had not come forward with the evidence we have this accusation could certainly have been levelled at us again. I simply brought forward all the evidence we have.

Mr. FORRESTALL: That is fine, and this is what I am getting at. I would like to follow this along a little further and then I turn you back to Dr. Brand for a further supplementary. What you are suggesting by your caution to us is that if, for example, the total amount imported under brand names had reached 400 or 500, that would have been a satisfactory number of samples upon which we might, as a Committee, have based a firm conclusion?

Mr. CHAPMAN: I think the comparison then certainly would have been much more significant.

Mr. FORRESTALL: That would then hold true with all of your statistics?

Mr. CHAPMAN: It would certainly be much more significant.

Mr. FORRESTALL: That is fine.

Mr. MACKASEY: I would like to clarify Dr. Brand's last point and I apologize to him if I did not quite seize the significance of his calculations—I think he mentioned, for instance—and in this instance I am the devil's advocate for the generic firms, and I have to admit it but based only on that last statement, which I think is a little misleading. I think you asked Dr. Chapman whether 90 per cent of the convictions came from 15 per cent of the drug suppliers in Canada. Am I right in that?

Mr. BRAND: Yes.

Mr. MACKASEY: But is this not the wrong base? Would it not be fair to say that although they may be 15 per cent of the drugs manufactured in Canada, they may be a majority per cent of the drugs supplied to the Department of Defence Production, which Dr. Chapman is talking about?

Mr. BRAND: That is probably a good statement, Mr. Mackasey, but I—

Mr. MACKASEY: It is not a statement; it is a question, Dr. Chapman.

Mr. CHAPMAN: No, sir; I am talking about all drugs that we have examined.

Mr. MACKASEY: Is the relationship of the drugs that you have examined 85 to 15? The PMAC, in their brief, quite accurately say that they manufacture 85 per cent of the drugs in Canada. Dr. Brand has then jumped to the conclusion that 90 per cent of your convictions came from the 15 per cent. I may be wrong in saying 90 per cent.

Mr. BRAND: It is close enough.

Mr. MACKASEY: This is the point I am trying to clarify: Is this a true base, statistically? In other words, is the number of samples which you have tested in the 85 to 15 proportion, or, in fairness to the generics, were there more generic firms tested than brand name firms?

Mr. CHAPMAN: No. You will notice in the first column of the table on Appendix I there were 459 samples which were sold under a brand name and 426 sold under a generic name.

Mr. MACKASEY: I had better get my table.

Mr. CHAPMAN: It is Appendix I, page 2.

The CHAIRMAN: I hate to make things more confused, but I think we should also remember that there are firms which sell under brand names, which are not members of the PMAC.

Mr. MACKASEY: Yes, this is true, and it is unfair to the PMAC, but the brand names within the PMAC do represent 85 per cent. Was the relationship in Canada generally between manufacturers brand or PMAC members, considered to be 85 to 15? The sampling here is fairly close to 50-50.

Mr. CHAPMAN: Yes.

Mr. MACKASEY: This is the point, therefore. It is not true, in a sense, to say that it is 90 per cent of 15. That is the point I am trying to make.

Mr. BRAND: Mr. Chairman, I am merely taking the figures, which were presented by Dr. Chapman in his submission and, if you add them up, I think you will find that—and then we have the figures which I worked out—92 per cent of the convictions were in that 15 per cent and two-thirds of the recalls, or 66⅔ of the recalls, were from, and 50 per cent of the health hazards were in that group which are, by Dr. Chapman's definition, generic houses.

Mr. CHAPMAN: I should like to point out, Dr. Brand, that the analytical survey was from 1965 and the convictions are from 1963 to 1966. You cannot compare these two figures.

Mr. BRAND: But you are comparing them, sir.

Mr. CHAPMAN: No, sir; I was not.

Mr. BRAND: Tell me something, Dr. Chapman. Did you have a statistician work on this, or was this done by members of your department, who are not statisticians?

Mr. CHAPMAN: The material was collected by members of my staff.

Mr. BRAND: Who are not statisticians?

Mr. CHAPMAN: They are not statisticians, and it does not take statisticians to collate data.

Mr. BRAND: It most certainly does, sir, when you do it properly. I will take you back just a bit, if I may, since you brought the subject up. On page 13 of your brief you said:

> Minutes of Proceedings and Evidence No. 17—Brief submitted by the Consumers Association of Canada,... twenty-three brands of phenylbutazone tablets were tested for potency...

You quoted this from the Consumers Association of Canada. And you come to the conclusion that you were unable to confirm Dr. Pernarowski's results and therefore cannot agree with this conclusion. Can you name me one competent statistician who would agree that when you test one brand out of 23 that you can come to any reasonable conclusion about a series which was done on 23 brands. Can you, as a scientist?

Mr. CHAPMAN: I do not follow your question.

Mr. BRAND: You should be able to. Dr. Pernarowski examined 23 brands of phenylbutazone. That is correct, is it not?

Mr. CHAPMAN: Correct.

Mr. BRAND: Your department examined one of those brands and found it to be satisfactory on a different lot of that drug, which you admitted, and yet you

come to conclusions on Dr. Pernarowski's paper when all you have examined is one out of 23. How in the name of goodness can you do this.

Mr. CHAPMAN: There is a misunderstanding.

Mr. BRAND: There certainly must be, doctor.

Mr. CHAPMAN: There was no indication, of course, in the brief presented by the Consumers Association of Canada as to the manufacturers of these brands. However,—

Mr. BRAND: You said there was.

The CHAIRMAN: Let Dr. Chapman finish.

Mr. BRAND: I am sorry.

Mr. CHAPMAN: —I talked to Dr. Pernarowski on three occasions and he was kind enough to give me the names of the three brands which he felt would be in violation of our requirements. We got samples of these brands. Two of them were products which Dr. Pernarowski stated assayed less than 95 per cent potency. The third one Dr. Pernarowski stated did not meet the disintegration time of 60 minutes. The two products which Dr. Pernarowski named, which he said had assayed less than 95 per cent, were no longer on the market; therefore, we could not obtain samples of those two products.

Now, the third product, which Dr. Pernarowski indicated might be in violation of our regulations, was the one product which did not meet the disintegration time of 60 minutes. We went to the same firm and we obtained a sample of current production. We analyzed this in our laboratory and we found that it had a potency of 102.3 per cent and disintegrated in 38 minutes. Therefore, our results did not confirm those of Dr. Pernarowski on the same company's product, but the analyses were not carried out on the same lot.

In summary, I can only say that we were unable to confirm Dr. Pernarowski's results and, therefore, cannot agree with his conclusions. I will stick to that conclusion.

Mr. BRAND: Could I qualify it for you, doctor, since obviously you are off in left field. As far as that one particular drug you examined is concerned, you cannot confirm his findings. Would that satisfy you? I mean, after all, if his findings are wrong with regard to this one drug, what is there to say he is not wrong with regard to the other 20 that you did not even attempt to examine. I admit that you attempted to examine the two that are no longer on the market.

Mr. CHAPMAN: We did not.

Mr. BRAND: Do you follow what I am getting at?

Mr. CHAPMAN: The conclusion that he drew was one was that faulty enough to constitute an absolute hazard to health.

Mr. BRAND: If he is wrong in that, could he not be wrong in saying that the others are all right?

Mr. CHAPMAN: He could be.

Mr. BRAND: Of course, he could. Therefore, as a scientist, how can you make a statement like that? You could not publish one like that in a scientific journal and get away with it, and you know it.

The CHAIRMAN: I am losing the drift of your questioning.

Mr. BRAND: I am sorry you are, doctor, and I wish you would pay more attention.

The CHAIRMAN: I am listening very carefully.

Mr. BRAND: Well, when you have 23 drugs—and I will explain it very slowly—which are examined by a group—

The CHAIRMAN: My point is: What has this got to do with Dr. Chapman and the other 20?

Mr. BRAND: It has a great deal to do with the conclusions Dr. Chapman and his group have made in his brief to this Committee. I do not see, how in all honesty, we can accept one if we cannot accept all of them. Really, Mr. Chairman, let us be honest about this. If he is going to make statements in his brief, he should be able to back them up, or he should not make them in the first place and this is all I am getting at.

Mr. CHAPMAN: And I am contending, Dr. Brand, that we have backed up the statements that I have made.

Mr. BRAND: Yet you admit that you did not examine the other ones in his brief and you make comments on his whole paper. It might interest you to know, Dr. Chapman—

Mr. CHAPMAN: I beg your pardon, Dr. Brand.

Mr. BRAND: —that on December 1, 1966, in the minutes of this Committee, Mr. Allmark who is the Assistant Director General of Drugs made this statement:

The CHAIRMAN: He is in attendance.

Mr. BRAND: I asked this question of Mr. Allmark: "Have you been testing any phenylbutazone? Now, according to Dr. Chapman, I want to point out that you have tested the one". Mr. Allmark said this:

> Yes; over the years we have tested many lots of phenylbutazone. I cannot give you the exact numbers because I have not got them here.
>
> There have been some brands that have been unsatisfactory, but there have been many, many of them that have been satisfactory.

Although I realize that probably the brand that is unsatisfactory this evening has more to do with people than with drugs, but from this I would assume that you have examined more than one brand of phenylbutazone. Where are your results on these, Dr. Chapman?

Mr. CHAPMAN: We would be pleased to table the results of all samples of phenylbutazone that we have examined over whatever period of years the Committee would like us to do so.

Mr. BRAND: I would be very pleased to see them, because if you find there are brands which are unsatisfactory, perhaps it will be more in keeping with some of the findings of Dr. Pernarowski's paper. I am not here to protect Dr. Pernarowski, but I am here to protect a little scientific purity in some of your statements.

Mr. CHAPMAN: Let me read to the Committee again the statement which was made by Dr. Pernarowski at page 13:

> Twenty-three brands of phenylbutazone tablets were tested for potency, content uniformity, disintegration and dissolution characteristics.

That is a plain statement of fact and there is no opinion or conclusion involved. He then goes on to say:

> Five, or 21.7 per cent, failed to meet existing specification. Three others were classified by the researcher as unsatisfactory. One was faulty enough (the product delivered little phenylbutazone to the blood) to constitute an absolute hazard to health.

Now, since I was personally acquainted with Dr. Pernarowski; he was a former member of our staff, I discussed this with him on three separate occasions. He was kind enough to tell me that there were only three actually, out of those that he considered to be unsatisfactory, that might be in violation of our requirements. He gave me the names of these three brands. It would seem obvious then that in order to determine whether or not we could confirm Dr. Pernarowski's results that we should attempt to get those three brands. As a matter of fact, Dr. Pernarowski suggested that if we were going to check these out, these would be the three he would suggest that we examine. We attempted to get those three brands, but we found that two of them were no longer on the market, therefore, we could not get them. However, we were able to get the one which was manufactured by the firm which was described by Dr. Pernarowski as: "One was faulty enough to constitute an absolute hazard to health."

We did not have the same lot number as Dr. Pernarowski, but we did get a sample of current production. When we examined that, we found that it was satisfactory. On this basis, I think I am perfectly justified, as a scientist, in saying that we were unable to confirm Dr. Pernarowski's results and, therefore, cannot agree with his conclusions.

Mr. MACKASEY: Dr. Chapman—

Mr. MACLEAN (*Queens*): Pardon me, Mr. Chairman. I agree with the first part of the doctor's statement but I do not agree with the second part. How can you possibly say that. What you have proven is that the drugs, regarding which Dr. Pernarowski had doubts, are no longer on the market or else the company manufacturing that particular type of drug has improved its standards so that what they are now manufacturing meets your requirements. But you have done nothing, as I understand your statement, to either confirm or deny the accuracy of Dr. Pernarowski's work.

Mr. CHAPMAN: I would not for a moment question the results Dr. Pernarowski obtained.

Mr. MACLEAN (*Queens*): But you say that you have been unable—what was that term you used—

Mr. CHAPMAN: To confirm his results.

Mr. MACLEAN (*Queens*): Confirm his results.

Mr. CHAPMAN: To reproduce them would probably be a better term; reproduce his results or confirm them.

Mr. MACLEAN (*Queens*): All right. You did not actually—I mean there was no opportunity to try to run a test.

Mr. CHAPMAN: We were certainly unable to confirm them; we could not even get the samples.

Mr. MACLEAN (*Queens*): But you could not disagree with them either. You had no evidence whatsoever to disagree with anything he said.

Mr. MACKASEY: Dr. Chapman, would not your conclusions be more logical, along the lines which Mr. MacLean has brought out, if you simply had said in summary: "We are pleased to note that in your analysis of the products of these particular firms indicate that they have now brought themselves up—if at any time they were not—to the standards that the officials in the Food and Drug Directorate feel is necessary."

Mr. CHAPMAN: In the case of the two that we could not examine I could hardly say that. But certainly with respect to the current production of the third one I would agree entirely with your statements.

Mr. MACKASEY: In other words, as Mr. MacLean has so aptly pointed out, you have done Canadians a service by investigating the conclusions of Dr. Pernarowski. You have done your duty as the guardian of our safety to make certain that the conditions which he pointed out did not continue or no longer exist. I think this is really more fundamental to the question of safety, whether the conclusions were accurate or inaccurate. I feel a lot better that you have determined for my benefit that a situation which might have been unsafe has been rectified.

The CHAIRMAN: Dr. Chapman, may I ask one question along the same line. You say you went back to the company and got samples. I have always understood that certain portions of each lot were put aside. Would it not have been possible for you to actually go back to the company and say: "We want a sample of lot No. 2,026?" I thought they kept a sample of each lot number on the shelf.

Mr. CHAPMAN: Yes; I think certainly this is good pharmaceutical manufacturing procedure. Dr. Pernarowski could not tell me where he obtained this sample that he analysed.

The CHAIRMAN: Did it contain a lot number?

Mr. CHAPMAN: I do not know; I did not have the lot number.

Mr. BRAND: The analyses were actually done by Mr. Searl.

Mr. CHAPMAN: Yes, that is correct.

Mr. BRAND: You did not ask Mr. Searl where he got it?

Mr. CHAPMAN: Dr. Pernarowski, of course, was directing this research. He was responsible for the studies—

Mr. BRAND: You know as well as I do, doctor, that when you have a head of a department and you have several research projects going that always the head of the department sticks his name on it. In other words, actually the work may be done by the student in that particular group. Is not that correct?

Mr. CHAPMAN: That is quite correct. As I have acted as a director of research in university I am quite aware of this fact. Dr. Pernarowski indicated to me that he collected the samples.

Mr. BRAND: Did he collect them from drugstores?

Mr. CHAPMAN: Apparently some were obtained from drugstores. He simply said that he got them from whatever source he could. Some of them certainly were from drugstores. He did point out to me that he no longer had the capability, as he had when he was with the Food and Drug Directorate, to ask an inspector to go into a plant and pick up a sample of the drug.

Mr. BRAND: So, in other words, he more likely got the drugs that the public would get and you got the drugs that the inspectors are likely to get. Is that correct.

Mr. CHAPMAN: That is a potent point by the way: a very important one.

The CHAIRMAN: I think this was mentioned this afternoon. The point was made that it might have been on the shelf for quite a long time.

Mr. CHAPMAN: This is quite possible.

Mr. BRAND: I just want to ask you one more question at the moment. I might want to ask more but I would just like to ask one and it is this: Are you familiar with the study done by Williams, Meister and Florsheim in the *Journal of Pharmaceutical Sciences* in 1963 in which they examined 62 samples of thyroid tablets and found only 44 were found to be biologically or clinically effective?

Mr. CHAPMAN: No, I was not aware of that.

Mr. BRAND: Have you done any samples of thyroid tablets in this country?

Mr. ALLMARK: Dr. Brand, is this the United States report?

Mr. BRAND: Yes. I have heard some laudatory comments about the Food and Drug Administration today so naturally I brought them into it.

Mr. ALLMARK: I know a little about this situation. Actually these were contaminated samples. I believe the inactivity was due to the presence of iodinated protein.

Mr. BRAND: I beg your pardon?

Mr. ALLMARK: The inactivity of the sample was due to the presence of iodinated protein.

Mr. BRAND: Whatever that is. But they were still inactive and they were on the market?

Mr. ALLMARK: Yes, they were.

Mr. BRAND: What I want to know, of course, is: Does this situation occur in Canada?

Mr. ALLMARK: Not that I am aware of.

Mr. BRAND: Have you done any studies to prove or disprove this?

Mr. ALLMARK: This happened about 1963. Yes; we were aware of this at the time and actually we did examine thyroid on the Canadian market and there was none of this material on the Canadian market at that time.

Mr. BRAND: You examined all those that were available to the consumer or just an occasional one?

Mr. ALLMARK: We examined, let us say, representative samples that our research laboratory had already picked up at that time.

Mr. BRAND: From every company that was selling thyroid on the Canadian market.

Mr. ALLMARK: Now, I am speaking from memory. I would not say every sample.

Mr. BRAND: The point I am getting at, of course, seems quite clear. If some of these are on the market right now, it is not a very good situation is it? I am not blaming the Food and Drug Directorate. I realize your limitations of personnel and the excellent job you are doing with the personnel you have. I think it is emphasized—if I may say so—in your brief when you point out the projections necessary for increase in staff in order for you to do an adequate job. I can only say that I am distressed that the Treasury Board did not feel that the health of Canadians was more important than the money which is going to be expended in this regard. I think at the moment, Mr. Chairman, I had better shut up and let somebody else have some time.

The CHAIRMAN: Are there any other questions on Appendix No. 1?

Mr. MACKASEY: Mr. Chairman, I have to rediscover it because I do not want to get into an argument again.

The CHAIRMAN: You have to what?

Mr. MACKASEY: I just want to rediscover it.

The CHAIRMAN: As Chairman may I ask this. In your total down at the bottom you have "All Samples"—973. "Unsatisfactory"—101. Unsatisfactory 10 per cent. That sounds like a very high percentage of samples you tested if 10 per cent are unsatisfactory.

Mr. CHAPMAN: No. This is not an exceptionally high percentage. For example, in the United States, the Food and Drug Administration carried out a study of some 2,600 generics and 2,000 brand name products using potency only as the quality standard and they found 7.8 per cent of the generic drugs were not of acceptable potency and 8.8 per cent of the brand name products tested below the acceptable limits.

Mr. MACKASEY: Dr. Chapman, this morning you mentioned—I think Dr. Howe mentioned the comparison among five firms—Smith Kline and French and several others and the question of potency came in.

When you refer to these drugs—and again I apologize for my inability to remember either the generic name or the brand name—I think it seems to me that four of the five firms were using a different name and that only Gilbert was using the generic name. Am I right or wrong?

Mr. CHAPMAN: No; all four were using a brand name.

Mr. MACKASEY: What is the basic significance of brand and generic? Do the generic houses who are using brand names not qualify for the definition of a brand company?

Mr. CHAPMAN: This is the whole difficulty with attempting to differentiate between brand name and generic name drugs or brand name and generic name companies?

Mr. MACKASEY: Dr. Chapman, why are we trying?

Mr. CHAPMAN: I am not trying. I would like very much to get away from it.

Mr. MACKASEY: But in all fairness to us you do use this terminology throughout your brief—

Mr. CHAPMAN: Yes.

Mr. MACKASEY: It subconsciously has crept into, I suppose, the English language. Perhaps innovators and copiers will be the next cycle. To me they are all part of the pharmaceutical industry and I am constantly concerned at our attempts to define and our interpretation of what is brand and what is generic. This puzzled me this morning and I would like to bring it up because Dr. Howe properly questioned the difference in efficiency or potency between a particular product. I cannot name the product but perhaps Dr. Howe could name it to help me out. When you were discussing the potency or the deviation from the base of 100 per cent you mentioned five different names. Perhaps you did not; but perhaps the other doctor was kind enough to do it. He mentioned four out of the five. I think the fifth was the generic. You mentioned Stelazine, I think it was one.

Mr. HOWE (*Hamilton South*): It is trifluoperazine. I was having a little trouble with it myself.

Mr. MACKASEY: All right; trifluoperazine was mentioned just once in the five.

Mr. CHAPMAN: Trifluoperazine is the generic name.

Mr. MACKASEY: I know this. What I am really trying to get at is that even though we have fallen into the trap of saying that Paul Maney is a generic firm and Smith Kline and French is a brand company, when you go to buy the product, you are buying them under a brand name. You do not go in and ask for trifluoperazine nearly as often as you go in and ask for Stelazine or somebody else's product—I do not remember who made it. How can we turn around—in all fairness to everybody concerned—and say that 90 per cent of the generics are bad or a study in the United States said that 50, 51 or 55 per cent of the tests proved that the brands were bad and only 37 per cent proved the generics were bad when nobody has been able to define to me the difference. This confuses me.

Mr. CHAPMAN: Mr. Mackasey, I must agree heartily with you. This is absolutely the problem. Could I quote again from Deputy Commissioner Winton Rankin of the Food and Drug Administration. This is a quote from the food, drug and cosmetics report of October 17, 1966. He said, addressing the American College of Apothecaries Convention in Boston:

> Poor quality found in both generic and brand-name drugs clearly shows that "the furore over generic versus brand names does not come to grips with one of the main issues. If a drug manufacturer cannot put out good drugs then he will have to get out of the drug business."

This is exactly the way I feel and my officers in the Food and Drug Directorate feel. We are not concerned with brand name drugs or generic drugs or imported drugs or domestic drugs. We are concerned about the quality of the drugs which are on the Canadian market and available to the Canadian public.

Mr. MACKASEY: Dr. Chapman, I am back on Appendix 1. I do not want to say that I got away from it. If I were a doctor and I had 20 years of practice and found that the product of a particular manufacturer—we will say Smith Kline and French because their name has come up today—had proven time in and time out to be efficient, safe and so on, and has, in that particular doctor's mind, created an impression, a logical impression, of safety, then, the doctor is fully right in continuing to prescribe that drug. It is equally true if a doctor, from years and years of experience, has found that the product of Paul Maney, in his opinion, represents integrity. But to start classifying firms as brand and generic, it seems to me, indicates that this committee unconsciously is putting a stigma on certain companies and a halo around others. I do not think this is the purpose of the Committee.

I have the greatest respect for the big firms because I think from your statistics, their standard of quality in this country is second to none in the world. They have been the leaders and, if I was a so-called generic firm, and I am falling into the trap, I would want to follow their example. I do think that we will make more progress when we stop trying to analyse your statistics which fall into the very same trap. For instance, you were starting to quote United States figures about brand and generics, in all fairness, some of the brands—by my narrow definition and by the definition we have created—may actually be the trade name of generic houses.

Mr. HOWE (*Hamilton South*): Mr. Chairman, may I generalize here and just say that as a general rule the so-called brand names are drugs manufactured by that private club known as the PMAC group; whereas the generic names, roughly speaking, include all the others?

Mr. CHAPMAN: Again, this is not the case because we know that many firms that are not members of the PMAC are putting out drug products under brand names.

Mr. HOWE (*Hamilton South*): Do you class them as such in your tables because there are not many firms left that manufacture drugs under strictly a generic name? The so-called generic firms are now naming or marking or identifying their drugs in some way, so you have a very, very small percentage. You must have an arbitrary division yourselves of generic firms that are manufacturing brand names?

Mr. CHAPMAN: No, sir. I explained to the Committee how we divided these into brand name and generic name. This was the manner in which the particular product was sold, and was reported as such on the laboratory report. If the laboratory report read trifluoperazine it was listed here as a generic drug. If it was listed as Stelazine (trifluoperazine) it was listed as a brand name drug. Now, I could not agree more heartily with the statements that have been made about the difficulties of attempting to classify either drugs or firms on the basis of brand name and generic name. I think we should get away from this entirely. But our problem was the fact that there had been over a thousand pages of

testimony and every other page referred to generic drugs or brand name drugs. We were attempting somehow to make a comparison, as best we could from the data that we had available to us, of these two drugs.

Mr. MACKASEY: As Dr. Brand so aptly pointed out, you can get by in those thousand pages by using this terminology to distinguish between different groups of manufacturers; one perhaps is large and the other tiny. When you start trying to apply it to statistics it does not really have any validity. I do not think it had any validity, when you were discussing with Dr. Brand the rejects as well as the acceptances. It does not have any more validity when the PMAC said things about the generic. It does not have too much validity in the figures you are about to read out. Before the Chairman calls me out of order, which I think he is going to do, I take objection to Dr. Howe referring to the PMAC as a private club because this is the type of bias that this Committee does not need. I do not regard the PMAC as something unlawful or unworthy. I know—

Mr. HOWE (*Hamilton South*): I did not say they were unlawful or unworthy, Mr. Chairman.

Mr. MACKASEY: —the description private club in this instance has a connotation that I do not think reflects the feeling of everybody on the Committee any more than remarks—

Mr. HOWE (*Hamilton South*): I am not trying to reflect the feeling of everybody on the Committee.

Mr. MACKASEY: Then it would have been just as easy to refer to the PMAC not as a private club. You may be reflecting your own feelings in this case.

Mr. HOWE (*Hamilton South*): That is all I intended to do.

Mr. MACKASEY: I am reflecting mine when I say as far as I am concerned there will be much more progress if we get objective.

Mr. O'KEEFE: May I ask a supplementary, just a short question. As a layman I am sort of lost here but it seems to me, Dr. Chapman, that we as a Committee are concerned with drug costs.

Mr. CHAPMAN: Yes.

Mr. O'KEEFE: We are not necessarily concerned with the purity, not that it is not important to drug costs. That is the purpose of this whole Committee. Now to me with respect to generic drug and the brand drug, one is a much more expensive issue of the same drug? Would that be a fair assumption? That so far as a generic name and a brand name are concerned one is normally much more expensive than the other?

Mr. CHAPMAN: We in the Food and Drug Directorate are not concerned with this aspect of it. I know that there has been evidence presented to this Committee to that effect.

The CHAIRMAN: I should say not necessarily. Under your division of brand name and generic name, if this was a government tender you might find, for instance, that even though the contract was generic and was filled by a generic name the drug could actually be put out by a brand name company and sold as a brand name, right out of the same bottle almost.

Mr. O'KEEFE: The essential point, Mr. Chairman, is that it is cheaper, otherwise it would not be bought. So if Dr. Chapman reaches the conclusions that there does not appear to be any significant difference between drugs sold under a generic name and drugs sold under a brand name and if the generic brand is cheaper, then I suggest Dr. Chapman has made a very worth-while contribution to this Committee.

The CHAIRMAN: I do not think that is a question. I think you have drawn a conclusion.

Mr. HOWE (*Hamilton South*): I see you are talking about brand names—Mr. Chairman—

The CHAIRMAN: I would hope we are still talking about Appendix 1, so that we can dispose of it.

Mr. HOWE (*Hamilton South*): All right, this applies to it because we are talking about brand and generic names. It is true, too, that brand name PMAC houses also manufacture drugs under generic names and, likewise, sell them more cheaply also. Is that true?

Mr. CHAPMAN: I believe that is the case but I certainly—

Mr. HOWE (*Hamilton South*): It was an unfair question in that I have in front of me—

The CHAIRMAN: May I ask a question. Under the Food and Drugs Act each drug that goes out under a trade name has to contain the generic name as well?

Mr. HOWE (*Hamilton South*): No; this is not my point.

The CHAIRMAN: That was the point I wanted to get clear. You are saying they sell them under generic only with no trade name on them at all?

Mr. HOWE (*Hamilton South*): That is right, yes, because Frosst make a Prednisone and Frosst is a member of the PMAC group, as I understand it, and they make a Prednisone which retails to a patient for $3.15 a hundred which is 80 per cent less than the regular list price of the name brand Prednisone.

The CHAIRMAN: But put out by another company?

Mr. HOWE (*Hamilton South*): Put out by another company, yes.

The CHAIRMAN: Put out by Schering.

Mr. HOWE (*Hamilton South*): My point was that the PMAC group brand name houses are also in the generic drug business, so it does not necessarily mean that generic houses are of the small new or cheaper variety ordinarily.

The CHAIRMAN: Yes; I am sorry, but your question implied that it was the same company that was putting out the same drug but under two different labels.

Mr. HOWE (*Hamilton South*): No; I am sorry, Mr. Chairman, that is not what I intended.

Mr. FORRESTALL: I just wanted to go back and finish up the little trend that started to develop. I am curious about these figures. It is my understanding, Dr. Chapman, from previous testimony that we manufacture a relatively small amount of the drugs we use here in Canada and I am wondering, as you have

seen fit—I know you pointed out these were all the drugs you happened to sample in 1965,—

Mr. CHAPMAN: No sir.

Mr. FORRESTALL:—all of the imported drugs you happened to sample. Why would you choose, or was it accidental, a comparatively small number of imported drugs when they constitute the vast majority of the drugs that are used and sold in Canada.

Mr. CHAPMAN: I think there are two areas of confusion here. First of all, these were not all the drugs we examined in 1965. We selected—

Mr. FORRESTALL: I understood you to say that about the imported drugs.

Mr. CHAPMAN: No, sir. We selected a number of different categories of drugs where these were both brand name and generic name drugs. Then we asked for all the laboratory reports in those categories and these are the results we got.

Mr. FORRESTALL: Those are the results that came out.

Mr. CHAPMAN: Yes.

Mr. FORRESTALL: Well, these samples then have been heavily used drugs?

Mr. CHAPMAN: The second point is this. It is my understanding that we do import a significant amount of drugs but these are bulk drugs rather than finished dosage forms and they are put into finished dosage form in Canada.

Mr. FORRESTALL: Here in Canada.

Mr. CHAPMAN: Yes.

Mr. FORRESTALL: So some of them might have again fallen under the domestic terminology, or the tests of those particular samples, on the domestic side of your column here.

Mr. CHAPMAN: If these were sold by a Canadian firm with a Canadian firm's name on the package then, of course, this would come under domestic.

Mr. FORRESTALL: How many sample tests, for example, just roughly—I am not interested in details—might have been conducted on imported dosage form of foreign drugs during 1965? Would it be many hundreds or a couple of hundred or a thousand?

Mr. CHAPMAN: No. Certainly it would not be that. The total number of drugs examined, including vitamins, in 1965 was 2,733 samples. Of these, 916 were vitamin preparations, or vitamin-mineral preparations, and 1,817 were other drugs.

Mr. FORRESTALL: What percentage of those—I am sorry you might have said it at the outset of your remarks—would have been imported in dosage form, that total of 2,733?

Mr. CHAPMAN: No, sir; that is the total number of samples exmined. I do not have the figures for the imported drugs here, other than the proportion that were in these particular categories given in Appendix 1.

Mr. FORRESTALL: Then, my understanding of this table, so I can put it in its proper perspective, is that you took 20 samples and you turned to your files for the experience of tests that you had had during the current year or 1965.

Mr. CHAPMAN: We took 20 categories of drugs.

Mr. FORRESTALL: For the testing area.

Mr. CHAPMAN: And asked for all the reports on those 20 categories; 973 cards came out which represented about 50 per cent of the total number of drugs examined. It was a little over 50 per cent of the total number of drugs examined in 1965.

Mr. FORRESTALL: I have on final question on this. Dr. Chapman, could you tell us how high the percentage of unsatisfactory test figures would have had to go before you became alarmed that, perhaps, something was amiss. Would it be 20 per cent, 25 per cent or 15 per cent? You say that 10.4 is probably a fair run of the mill; what would be alarming?

Mr. CHAPMAN: We like to keep this figure as low as we possibly can. We hope we could reduce this figure of 10.4.

Mr. FORRESTALL: You are not happy with the 10.4?

Mr. CHAPMAN: No.

Mr. FORRESTALL: It is acceptable having regard to all the facts but you would like to see it lower?

Mr. CHAPMAN: Yes indeed.

Mr. FORRESTALL: If it were 12 per cent or 15 per cent, would that scare you?

Mr. CHAPMAN: This percentage of unsatisfactory samples tends to be a bit misleading. You have to look at the reasons why they are unsatisfatory. If there were a number of samples included in that and there was a significant increase in the number of samples that constituted a significant hazard to health we would certainly be very much concerned.

Mr. FORRESTALL: I would hope that if it was more than one per cent you would be concerned.

Mr. CHAPMAN: Yes, indeed.

Mr. FORRESTALL: I am not disputing that; I am accepting the fact you have an awareness of all the things, but I was curious at what point you might feel there was that a balance or an imbalance was beginning to take place in the national picture. I do not necessarily say this is true; I just say that it could happen that 10.4 per cent of the drugs I bought last year were useless. I happened to be one of those people in Canda who spend $2,000 or $3,000 a year on drugs.

Mr. CHAPMAN: Our results would indicate that this is not the case by any means. It simply means that 10.4 per cent of the drugs did not meet one or another of our categories, but this does not mean that the drug might not be effective.

The CHAIRMAN: Are there any other questions on Appendix 1?

Mr. MACLEAN (*Queens*): There are a couple of questions I would like to ask for clarification. In light of the statements you have just made, and for other reasons, it would seem to me that this table may to the layman convey too sweeping a conclusion, when you list as a result of the tests certain groups of

drugs as unsatisfactory and other groups as satisfactory. What this table really means, I take it, is that these drugs have met certain chemical criteria for which they were tested?

Mr. CHAPMAN: That is correct.

Mr. MACLEAN (*Queens*): And that is as far as this table should go. There might be cases—I am a layman—where drugs would satisfactorily pass these tests and still not be an entirely satisfactory pharmaceutical.

Mr. CHAPMAN: This is possible, but it would be unusual.

Mr. MACLEAN (*Queens*): And conversely, even the term unsatisfactory might be a little strong in this case, as you just said these drugs may be 90 per cent effective or even more, and still be unsatisfactory as far as the criteria of these particular chemical tests were concerned.

Mr. CHAPMAN: Our problem is that we have to put these drugs into one category or the other. We have to call them either satisfactory or unsatisfactory.

Mr. MACLEAN (*Queens*): I agree.

Mr. CHAPMAN: If they did not meet any of our requirements—in this particular group it was only a laboratory examination—no matter by whatever small an amount, it went into the unsatisfactory category. If they were very close, for example, if the lower potency limit was 95 per cent and the drug was 94.5 per cent, it would still be listed as unsatisfactory, but we would not likely take any action at all in that case. We might check another sample. If we confirmed that it was again low, we would likely take this up with the company.

Mr. MACLEAN (*Queens*): I have no criticism of the statements used in the context in which they were developed in the laboratory as far as the tests were concerned. My only observation is that perhaps these statements are a bit sweeping for the layman to digest and interpret properly, especially when you say that certain drugs, satisfactory. This indicates to the layman that these particular drugs have been given a stamp of approval, with no reservations whatsoever, by the Food and Drug Directorate, when actually all that this table proves is that these drugs satisfactorily met certain laboratory tests, which are required, it is true, but which may not be quite the entire picture. I am groping for information.

Mr. CHAPMAN: Your statement is correct.

Mr. MACLEAN (*Queens*): Although this is not so important, Mr. Forrestall, for example, just made that statement, am I to conclude that 10 per cent of the drugs I bought in the last year are useless. I think that would be a typical conclusion for the average person to arrive at if he found that he bought drugs, which you had categorized as unsatisfactory, when all you really prove is that it had fallen a little short of the criterion which is an arbitrary figure of potency, for example.

Mr. CHAPMAN: I do not know how else, we can present our data.

Mr. MACLEAN (*Queens*): I do not think you could, except that maybe there should be an explanatory note if this is to appear. For example, to say that these drugs are satisfactory in meeting these criteria, instead of just a blanket statement that they are satisfactory. I admit it is a fine point—

Mr. CHAPMAN: I would quite agree with that. I did state that the data included results of laboratory analyses only.

Mr. MACLEAN (*Queens*): Yes, but that is not on the table.

Mr. CHAPMAN: No; but it is in my comments on the table.

The CHAIRMAN: I should say that these tables are prepared by Dr. Chapman and his department for the use of this Committee and they were not necessarily for publication.

Mr. MACLEAN (*Queens*): They will be published after we have talked about them and I am just trying to make sure that the interpretation of what we are doing is properly made when the evidence is read by the general public.

Mr. CHAPMAN: I sincerely hope that that is the case.

The CHAIRMAN: I am sure we can count on the press media at the back to quote all these correctly.

Mr. MACLEAN (*Queens*): I have other questions, but not with regard to this.

The CHAIRMAN: Are there any other questions on Appendix I?

Mr. BRAND: I presume this is Appendix I, the summary of data on drugs.

The CHAIRMAN: No; it is the summary; Appendix I is the one on Comparative Survey of Quality of Brand Name and Generic Drugs. There are two headings, domestic and imported.

Mr. HOWE (*Hamilton South*): Would somebody number Dr Brand's appendices so that he would have them straight.

Mr. BRAND: Yes; that would be all right. I do not see very much here.

The CHAIRMAN: You have no actual figure to give, instead of unsatisfactory position, hazardous percentage, or health—

Mr. BRAND: Yes, I have in Appendix V.

The CHAIRMAN: We will come to that shortly.

Mr. BRAND: My questions on appendix I would probably come under appendix V, because I can find more than five in the evidence you have given us.

The CHAIRMAN: Perhaps, if everyone is content with appendix I, we can move to appendix II. This is Drugs Analyzed for Department of Veterans Affairs. I think that Dr. Chapman has already said that 72 samples were tested by his department for the Department of Veterans Affairs—drugs boutht on tender, that we can assume—out of that there was one unsatisfactory sample by Bell-Craig Pharmaceuticals, chlorpromazine 25 mg because it was overstrength, rather than—

Mr. MACKASEY: Would it be not only unfair but misleading therefore, to say that since every one of these 75 were generic, and 74 out of the 75 passed, 99.9 of the 15 per cent meet a very high level of efficiency.

Mr. CHAPMAN: It certainly would. That would be a misstatement.

Mr. MACKASEY: Exactly.

Mr. BRAND: Let us clarify that. You said a high level of efficiency. What test did you use, Dr. Chapman?

Mr. CHAPMAN: The words "high level of efficiency" were Mr. Mackasey's.

Mr. BRAND: You agreed, Dr. Chapman, unless I am wrong, by a nod of the head. Perhaps it did not mean that, but I assumed it did.

Mr. CHAPMAN: I was agreeing with his conclusion that you should not conclude therefore that all generic drugs would be of this same quality; that only a little over one per cent might fall down in one or another of the categories of the tests that we applied.

Mr. BRAND: On the small number that you tested that would be true.

Mr. CHAPMAN: Yes.

Mr. MACLEAN (*Queens*): I have a question that I want to ask here; it is something that I am curious about. I know it is somewhat widening the scope of this particular appendix, but some of these are imported drugs, I take it, manufactured by Matthews & Wilson; that is in England.

Mr. CHAPMAN: Yes.

Mr. MACLEAN (*Queens*): In the case of drugs manufactured in Canada, certain standards have to be met by manufacturers in every stage of the manufacture, supervised by your inspectors. Theoretically, I suppose, and perhaps actually, a company might not meet your specifications in its methods of production and yet the final product would pass the test.

Mr. CHAPMAN: Yes.

Mr. MACLEAN (*Queens*): What knowledge do you have or what information do you receive about pharmaceuticals that are imported into Canada at some stage of their manufacture, even in the final dosage form. What do you know about the history prior to that, if anything?

Mr. CHAPMAN: I read a statement into the record this morning, Mr. MacLean—

Mr. MACLEAN (*Queens*): I am sorry, I had to be out of the Committee.

Mr. CHAPMAN: —indicating what we did do and what we are proposing to do with regard to imported drugs.

The CHAIRMAN: I might just say that as these are both injectable drugs, actually the plants are inspected in England, because these are injectables—

Mr. CHAPMAN: This is quite correct.

The CHAIRMAN: —bought by Canadian health people.

Mr. CHAPMAN: Yes.

Mr. BRAND: Calcium gluconate 10 grains is here on page 2 of appendix II. I am quite sure that your test would indicate 10 grains of calcium gluconate. What test did you use to find out whether or not this dissolved in the veterans stomach, or in the bowel, or elsewhere in the gastro-intestinal circuit.

Mr. CHAPMAN: Did you wish to know the methods that we used.

Mr. BRAND: That is correct, yes.

Mr. CHAPMAN: Dr. Levi, could you please outline very briefly the disintegration test that we employed.

Mr. LEVI: We have done a great amount of work in developing a disintegration test. This has been done in close collaboration with the pharmaceutical industry in Canada and we have come up with a test.

Mr. BRAND: With what pharmaceutical industry in Canada?

Mr. LEVI: This involved at one time the Technical Contact Committee of the Canadian Pharmaceutical Manufacturers Association and we had close collaboration with their technical people in examining products of different types for different periods of time. This work has been going on for many, many, months; many, different products, coated, enteric coated, compressed tablets, have been checked and as a result of this work we have now, what we call the official method for disintegration time; as a matter of fact this method takes precedence over those that are described in other official compendia.

This method examines these various tablet formulations in both simulated gastric juice and simulated intestinal juice. Moreover, we carried out, at that time in the vitamin section of the Food and Drug Directorate, tests of physiological availability in order to correlate and make the disintegration test more meaningful than those described in other pharmacopoeia. Our disintegration requirements are actually realistic and have been correlated through physiological availabily studies with clinical effectiveness; and the calcium gluconate product you are referring to has in all likelihood—although I can not assure you at this time, I do not have the records here—been subjected to this disintegration test and as this compilation of data indicates, they must have met our requirement.

Mr. BRAND: I congratulate you on the extent of your examination; it is a little further than was indicated previously. I think it is all to the good. I was interested in your comment that you had been working with the PMAC group to work out these standards. Have they been offering their services to help the Food and Drug Directorate carry out proper methods of study.

Mr. LEVI: Samples have been distributed among various laboratories and these results have been compared, scrutinized and the method has been perfected as a result of a collaborative effort.

Mr. BRAND: Did they offer this collaboration or did you ask them?

Mr. LEVI: I personally was not involved, but I am familiar with the history of this test.

Mr. CHAPMAN: This is not unusual; we have been doing this over many years. We certainly use all the assistance and advice that we can get and a great deal of technical knowledge of course resides in the laboratories of the pharmaceutical industry in Canada.

Mr. MACKASEY: May I ask a supplementary question? I think is setting up the standards the inter departmental committee uses, the GP standard and this is done with the full cooperation of the PMAC. The relationship has been a healthy one. For instance, have they not helped you with the training of inspectors, and so forth.

Mr. CHAPMAN: Yes, indeed; they certainly have.

Mr. MACKASEY: And there is nothing insidious about it; on the contrary, it is something worth while, is it not.

Mr. CHAPMAN: I would very definitely say, it was worth while.

Mr. MACKASEY: To both the PMAC and to the industry in general. We have only one industry, after all.

Mr. CHAPMAN: Yes.

Mr. BRAND: Since we are talking about the methods you used, and you mentioned the Food and Drug Administration and I think the Deputy Commissioner—

Mr. CHAPMAN: Yes.

Mr. BRAND: —are you familiar with the Food and Drugs desires, since they find little difference between brand names and generic names in the normal chemical tests, and their preparation to set up a $4 million study to decide on clinical efficacy and equivalents of drugs?

Mr. CHAPMAN: Yes, I am familiar with that. That, of course, is a requirement of their legislation.

Mr. BRAND: Do we have any similar plans?

Mr. CHAPMAN: No; we do not at the present time.

Mr. BRAND: Then, how are we going to decide on clinical efficacy in equivalents of various drugs?

Mr. CHAPMAN: Let me explain that what they are doing in the United States, as I understand it they are going back over products that have been on the market for many years, and checking these out for efficacy.

Mr. BRAND: Do you think that is a good idea?

Mr. CHAPMAN: Yes; I think it is a very good idea. As far as new drugs coming onto the Canadian market are concerned this, of course, must be checked at the time that the new drug submission is made, and adequate evidence must be provided at that time.

Mr. BRAND: Would you do the same if you had sufficient staff and equipment to carry it out?

Mr. CHAPMAN: We would certainly like to do it. Yes, we would do it if we had sufficient time and staff.

Mr. BRAND: Are you aware that Commissioner Goddard made the statement that 7.6 per cent of prescription drugs in the United States deviated to a material extent from declared potency? It seems like a very large deviation. That refers to those drugs on the market.

Mr. CHAPMAN: Commissioner Goddard has made many statements, but I know that figures in this order have been reported.

Mr. BRAND: He goes on to say that one out of every 14 units manufactured is violative just on potency alone, and this is one of the reasons for setting up this body. Do you think that is a laudable objective? Would you like to see it in Canada; this is what I am getting at.

Mr. CHAPMAN: I would like to see it in Canada, yes.

Mr. BRAND: Do you think it would solve a lot of the difficulties between the so-called—and I will use it for the last time—generic firms and brand name firms—I will say beep-beep in future if that is any better—so that you would be able to state authoritatively that with respect to a certain drug that was on the market it would be—and I say "authoritatively", I know you have stated it today—safe to use an equivalent regardless of which one you bought, and regardless of the price of that particular drug?

Mr. CHAPMAN: Our objective would be to ensure that all drugs on the Canadian market meet all requirements of the Food and Drugs Act and regulations.

Mr. BRAND: But you are unable, owing the limitation of facilities and staff, to do so at the present time. Is that right?

Mr. CHAPMAN: Yes; this is correct, and I would think that we would be unable to do so in the foreseeable future. I do not see any possibility of the Food and Drug Directorate being in a position to check every lot of every drug coming on to the Canadian market.

Mr. BRAND: Can you see it by 1975?

Mr. CHAPMAN: No, sir.

Mr. BRAND: Can you project further than that? When do you think this would be possible? From the viewpoint of the consumer this would be ideal, and then there would be no argument as to who manufactured the drug. It would be all right because the FDD said so.

Mr. CHAPMAN: Are you suggesting, Dr. Brand, that every lot of every drug should be tested in a Canadian or government laboratory before being released?

Mr. BRAND: No; I do not think that is practical, but I do suggest that it would be possible, with sufficient staff and regulations, without smothering the industry with regulations, to satisfy yourself as to every manufacturing house and every particular drug that was put on the market; knowing that the original products that came off the assembly line, if you like, were manufactured in such a way that you had a reasonable expectation of assuming that they would be safe—I am ruling out all such things as side effects which can occur in the future—for use by the Canadian public. If one happened to sell more cheaply than the next company, then good for him, as long as they met those stringent, if you like, regulations and overseeing that were of the Food and Drug Directorate.

Mr. CHAPMAN: This would be our long-term objective, but in view of the number of drugs on the Canadian market at the present time and our projected increase in staff, I would not anticipate that we would be in a position to do that even by 1977.

Mr. MACKASEY: May I ask a supplementary question? Is it not a fact, Dr. Chapman, that the integrity of the industry as a whole is highly important to you?

Mr. CHAPMAN: Yes.

Mr. MACKASEY: You must depend, regardless of how fast your staff is increased, on the integrity of the industry in Canada. You must depend on the

reputation and the record of the known manufacturers in this country. Am I right?

Mr. CHAPMAN: That is quite correct.

Mr. MACKASEY: It is much more difficult to have that same assurance from firms that are located thousands of miles away with which you cannot deal with until some degree of reciprocal arrangements is made.

Mr. CHAPMAN: It is certainly much more difficult to do this with firms in other countries.

Mr. HOWE (*Hamilton South*): I have a supplementary to that, Mr. Chairman. Is that not included on page 4 of your brief of today when you talk about the five and ten year plan of the Food and Drug Directorate. Is that not something you have in mind?

Mr. CHAPMAN: Yes; but I was making a rough calculation. You see, our staff would increase by a little over twice what it is now by 1977.

Mr. MACLEAN (*Queens*): Just to be perfectly clear on this statement on page 4 you say:

—Treasury Board requested that this expansion be extended—

Well, knowing Treasury Board I presume the request was that it be stretched out to 1977. This rate of increase is not going to go on beyond 1975; it means that you will not reach this figure until 1977.

Mr. CHAPMAN: That is correct.

Mr. MACLEAN (*Queens*): The expansion is slowed down rather than extended.

Mr. HOWE (*Hamilton South*): I have a supplementary, too, Mr. Chairman. Do you not tend to concentrate on the examination of the drugs put out, shall we say, by the less known firms?

Mr. CHAPMAN: There are a number of criteria that we use in determining our priorities.

Mr. HOWE (*Hamilton South*): Then, you do have to work on the basis of priorities?

Mr. CHAPMAN: Yes, indeed; we certainly do. Would you care to have Mr. Hollett enlarge on it.

Mr. HOWE (*Hamilton South*): I think it would be emphasizing an interesting point, if no one disagrees.

Mr. CHAPMAN: It is particularly in the area of plant inspections where we have to establish these priorities. Mr. Hollett, do you care to indicate the manner in which we do this?

Mr. HOLLETT: Mr. Chairman, I have this written down somewhere, but perhaps it is not necessary for me to locate just what has been written. Certainly, we consider the performance of a firm. If we analyse drugs from one manufacturer and find over a period that these products are analytically satisfactory, we are not going to concentrate on the manufacture of products of that company. If, on the other hand, we find their products are unsatisfactory

analytically we are going to concentrate to a greater degree on that company. Another factor will be the volume of the product put out. These are two important criteria.

Again, we would concentrate on drugs manufactured for human use rather than on drugs manufactured for veterinary use. There is no distinction in the Food and Drugs Act between drugs for human use and drugs for veterinary use but, obviously, greater attention should be given to the former type of product. So we have the performance, we have the volume, and we have the type of drug.

Mr. MACKASEY: May I ask a supplementary question? The last time Dr. Morrell appeared before us he agreed with my calculations that it would be theoretically possible for a company to open its doors for operation in Canada and exist for almost three years before you people did your first inspection or even knew they existed. Is that situation still possible?

Mr. HOLLETT: With the drug notification that is not possible any more. The drug notification regulation that Dr. Chapman mentioned this morning requires the manufacturer to notify us within 30 days of when he begins to put a drug on the market.

Mr. MACKASEY: If he chooses not to notify you, then your only method of knowing of his existence is a spot check of his products in the drug-store.

Mr. HOLLETT: I believe Dr. Chapman also mentioned that we are giving consideration to having a regulation that would require that we know beforehand when a manufacturer plans to market a drug for the first time.

Mr. MACKASEY: Do you know that we recommended two years ago that these companies be registered? This is a new area, and I apologize, Mr. Chairman, I do not want to go into it extensively, so I will stop.

The CHAIRMAN: Dr. Howe, six supplementaries back you were interrupted on a supplementary.

Mr. HOWE (*Hamilton South*): I asked my question. I came in on page 4 where you had indicated you were extending your operations.

The CHAIRMAN: Are there any other questions then on Appendix II? If not, we will pass to Appendix III, which is on drug recalls involving the Food and Drug Directorate. Before Dr. Brand asks, I should say it is really not only drug recalls; it is anything under the Food and Drugs Act, is it not, such as this carmine red?

Mr. CHAPMAN: This is quite correct. The carmine red is a drug, but Ideal syringes would not be a drug.

Mr. BRAND: Nor the needles.

Mr. CHAPMAN: No, that is quite correct, Dr. Brand.

Mr. BRAND: They are a little hard on the stomach.

Mr. CHAPMAN: Yes, that is quite true.

The CHAIRMAN: Although some people have been known to eat them.

Mr. BRAND: Yes, I believe this is true. Mr. Chapman, are drugs that are recalled the ones where you fine the companies, and are they still available to the general public for purchase in Canada?

Mr. CHAPMAN: No, sir, they are not.

Mr. BRAND: Does that include the vitamins that you mention? Have they all been taken right off the market?

Mr. CHAPMAN: Do you mean, was this a recall?

Mr. BRAND: To go on to the next appendix, where they were fined for producing...

Mr. CHAPMAN: These certainly would be taken off the market. If there is a reason for a recall, then this means that they are taken off the market. Either the firm does it voluntarily, or we place the product under seizure.

Mr. BRAND: I am curious to know how you found out about those syringes. I think contaminated syringes would be a very dangerous thing to have on the market, and I am curious to know how you hear about this.

Mr. CHAPMAN: I beg your pardon?

Mr. BRAND: How do you hear about these syringes? I believe they are mentioned there; produced by the J. F. Hartz Company.

Mr. CHAPMAN: The J. F. Hartz Company?

Mr. BRAND: I am sorry. There is another one here; Jintan needles produced by the Standard Surgical Supply, Calgary, where the containers did not maintain needle sterility. This is a very important point. How do you hear about this?

Mr. CHAPMAN: As I recall, a report came to us from the United States Food and Drug Administration that they had encountered lack of sterility in some of the Jintan needles. We immediately started an investigation and discovered that these were also on the market in Canada. We placed them under detention, checked them out to determine whether or not they were sterile, and found that they were not, and took them off the market.

Mr. MACKASEY: How close was this exchange of information, and how frequent?

Mr. CHAPMAN: Very close.

Mr. MACKASEY: Very immediate.

Mr. CHAPMAN: Yes.

Mr. MACKASEY: While we are talking about needles, I was reading just the other day, and this concerned me, about a very large shipment of needles on the market in the United States that were improperly graduated and were being used in the treatment of diabetics. Has this come to your attention?

Mr. CHAPMAN: Yes; it was brought to my attention some time ago. We have already acted on that particular problem.

Mr. MACKASEY: Out of curiosity, what did you find?

Mr. CHAPMAN: We found that they were improperly graduated.

Mr. MACKASEY: And were they being sold in Canada?

Mr. BRAND: As a matter of interest, was it the J. F. Hartz Company?

Mr. CHAPMAN: Yes; I believe this is the case.

Mr. BRAND: Is that correct, Mr. Hollett?

Mr. HOLLETT: Yes.

Mr. BRAND: I presume they came from the Orient, both Jintan and Ideal.

Mr. CHAPMAN: The Jintan did, but I am not sure about the Ideal.

Mr. BRAND: They are made in Japan, as I recall. What about the mineral oil by Pharmco Products of Toronto containing a poisonous substance, isopropyl alcohol. How did you hear about that? Did someone start vomiting after taking it?

Mr. CHAPMAN: No. There apparently were no cases of illness. It produced a burning sensation, of course, in the mouth and it was returned very quickly to the drugstore where it was purchased and we were notified. An investigation revealed that there were a small number of bottles that had apparently come back to the plant. The isopropyl alcohol labels had been damaged. The bottles were relabelled with the wrong labels.

Mr. BRAND: I take it you had none of these vitamins, which I believe they had in the United States, that were contaminated with estrogyne. Some female children developed some secondary sex characteristics as a result of ingestion of these vitamins pills. Did we have any of those in Canada.

Mr. CHAPMAN: No, we had none. We are certainly aware of this possibility and we are keeping a very close watch on the possibility of cross-contamination of drugs.

Mr. BRAND: On page 3, I note under the heading Chorionic Gonadotrophin Injectable by Norwich Pharmacal Company, Paris, Ontario, "possible pyrogen contamination." What do you mean by possible? Do you mean they were contaminated?

Mr. HOLLETT: I am afraid I cannot answer this question, Mr. Chairman.

Mr. CHAPMAN: Certainly some of them contained pyrogens. This may be the reason.

Mr. BRAND: Were they recalled?

Mr. CHAPMAN: Yes, they were recalled.

Mr. BRAND: In other words—incidentally I am not intending to cast any reflection on your department by this statement—it is the policy here to close the stable door after the horse is stolen. Is that right?

Mr. CHAPMAN: Not if we can possibly help it.

Mr. BRAND: This does happen though, in effect.

Mr. CHAPMAN: Do you mean that products get on the market which are then found to be unsatisfactory?

Mr. BRAND: Yes. I am not talking about adverse reactions due to a product that may be produced; I am talking about adverse reactions due to actual pyrogen contamination of that particular drug, or something of that nature.

Mr. CHAPMAN: Yes.

Mr. BRAND: Do you think this is a desirable situation?

Mr. CHAPMAN: Certainly not.

Mr. BRAND: Do you think, and I ask once again, that by an improvement of the staff of the Food and Drug Directorate and by giving you the proper facilities and by the government granting sufficient money soon enough, you could help to obviate this type of thing happening in Canada?

Mr. CHAPMAN: Yes, under the conditions you suggest we could certainly improve our capacity to do this.

Mr. BRAND: And close the stable door while the horse is still in the stall.

Mr. CHAPMAN: This would be our objective.

Mr. MACKASEY: Do you not mean expand rather than improve?

Mr. BRAND: I mean expand.

Mr. MACKASEY: I know you do, but it might appear on the record that the staff needs improving. I really think Dr. Brand means expanding.

Mr. BRAND: Yes.

The CHAIRMAN: One can also get the opposite reaction, as Dr. Brand did from this possible pyrogen contamination. On page 1 you refer to toxic, diphtheria possible toxicity. If there is any question about it do you take it off the market and then examine it later?

Mr. CHAPMAN: Quite frequently these recalls are initiated by the company in co-operation with the Food and Drug Directorate. There is a suggestion that there may be a toxic effect. The company and ourselves decide that, rather than take a chance the best thing to do is to recall the drug from the market.

Mr. BRAND: I think this is certainly true in the case of those that undoubtedly contain cobalt, after the death of the beer drinkers in Montreal. I presume that is why those containing cobalt were taken off the market. Is that right?

Mr. CHAPMAN: No, sir, that is not correct. They were taken off the market on the basis of tests carried out in our laboratory on cobalt.

An hon. MEMBER: On cobalt alone.

Mr. CHAPMAN: Yes. On rats fed diets nutritionally deficient; protein deficient and also deficient in vitamins.

Mr. MACKASEY: I might also point out, Dr. Chapman, that the Montreal members are under a lot of pressure these days. The beer drinkers were in Quebec City. We are a hardier lot in Montreal and survived the cobalt.

Mr. BRAND: I was just curious. That was only an assumption on my part; in view of the fact that cobalt was taken out of the preparation of beer, I thought perhaps you were in the same category, but apparently you are not. You say roncovite tablets by Hoescht of Montreal, for example, might not be safe and you explained what you did, but you have not said why they might be unsafe.

Mr. CHAPMAN: We found evidence in our experiments that, under certain conditions, when rats were fed protein deficient and vitamin deficient diets and then challenged with massive doses of cobalt, we did get certain effects.

Mr. BRAND: Effects such as what?

Mr. CHAPMAN: It interfered with the metabolism of the heart muscle and certain lesions developed in the heart.

Mr. BRAND: In other words, it is compatible then with some of the possible —and I use the word "possible"—difficulties that were encountered with the use of cobalt and the resultant degeneration of the cardiac fibres that occurred in heavy beer drinkers.

Mr. CHAIRMAN: There is a possible relationship but it has not been established. We have not been able to establish it.

Mr. BRAND: You did this all on your own without knowledge of what went on in Montreal.

Mr. CHAPMAN: In Quebec City?

Mr. BRAND: Yes, Quebec City.

Mr. CHAPMAN: We certainly did not.

Mr. BRAND: That was the impression I got.

Mr. CHAPMAN: I am sorry. Again I have given you the wrong impression.

Mr. BRAND: I was going to congratulate you for being so perspicacious, but I withdraw it.

Mr. CHAPMAN: The reason we were carrying out these experiments, of course, was the fact that these had been the possibility that cobalt might have been a factor in the deaths of individuals in Quebec city who had consumed large amounts of beer containing approximately one part per million of cobalt. We were unable to find any such effects in rats when we fed them the beer or actual extracts of the beer from which the water and the alcohol had been removed. However, we continued our experiments and we were able to produce these adverse effects that I have described in rats, but we had to feed them protein deficient and thiamine deficient diets. No alcohol or beer was involved. The experiments were initiated on the basis of the situation that occurred in Quebec city.

Mr. BRAND: As far as the liver extract injectable by British Drug Houses is concerned, the pyrogen contaminated, did any patients receive any untoward effects from the use of such liver extracts?

Mr. CHAPMAN: In December, 1966.

Mr. BRAND: Yes, December, 1966. That is pretty recently.

Mr. CHAPMAN: Do you recall, Mr. Hollett?

Mr. HOLLETT: No, I do not.

Mr. BRAND: I am just wondering how you caught on to that one. That is rather a serious thing, too.

Mr. CHAPMAN: Yes.

Mr. BRAND: The liver extract would be given parenterally, that is, by needle.

Mr. CHAPMAN: Quite frequently there is a complaint that gets back to the firm concerned and they proceed with the recall and inform us what they are doing.

Mr. BRAND: Have you found all drug firms co-operative when you bring these matters to their attention?

Mr. CHAPMAN: Certainly, in general this has been the case.

Mr. BRAND: But not totally so? There has been the odd man out, you might say? By the way, I am not interested in knowing who it is. I am just curious about whether or not they co-operated.

Mr. CHAPMAN: I cannot think of any case where we did not receive the full co-operation of the pharmaceutical firm concerned when we found that there was something improper about their drugs.

Mr. MACKASEY: If they do not co-operate do you have the authority to step in?

Mr. CHAPMAN: Absolutely.

Mr. MACLEAN (*Queens*): I would assume that reputable firms are just as anxious that their products meet the acceptable standards as you are. If they have any complaints they quickly withdraw the batch or the article to see what is the matter with it. I am more concerned with imported drugs where you do not have this leverage and where there may be fly-by-night outfits who are not concerned with having a reputation to maintain. With regard to the importing of drugs, how large a staff do you have, or is it only through certain ports of entry that drugs can be imported into the country? How do you ensure that foreign drugs are not being imported clandestinely as something else and shoved on the market in some indirect way, so that you have no way of catching them until they are actually being bought. Is this a possibility?

Mr. CHAPMAN: Certainly it is a possibility. If these drugs were not satisfactory I am sure that they would show up. There would be adverse reactions.

Mr. MACLEAN (*Queens*): Yes.

Mr. CHAPMAN: We have not found that this has occurred more frequently with the import drugs than with the domestic production. Again, this is a general statement.

Mr. MACLEAN (*Queens*): Can drugs be imported by any firm directly through any port of entry or how do you check on the importation of drugs? Have you any other means other than the recognized importer reporting the fact to you?

Mr. CHAPMAN: No; we work very closely with the custom officials in this regard.

Mr. HOLLETT: Mr. Chairman, there are no exclusive ports through which drugs have to be imported. We have an arrangement with customs whereby they inform us when shipments of drugs are being imported into Canada and they are held, pending the sampling of the drugs, the examination in the laboratory and their release. In some cases, of course, the products are released without sampling and examination. Again, we do not have the laboratory capability of sampling and examining all shipments of drugs coming into Canada, and also we have to consider the performance of a manufacturer.

If the same type of product has been imported over a considerable period and several examinations have revealed that the product has been analytically satisfactory, naturally that product is less likely to be sampled than the product from a manufacturer being imported for the first time. There are many factors to

be considered here. By this co-operative arrangement with the customs we are aware of the shipments of drugs being imported into Canada. You will appreciate, of course, that we cannot have an inspector at every port in this country.

Mr. MacLEAN (*Queens*): These inspectors have to deal with food as well as drugs? They are not specifically drug inspectors?

Mr. HOLLETT: That is correct and foods, of course, constitute a far greater volume than drugs.

Mr. MacLEAN (*Queens*): Yes.

Mr. ISABELLE: Am I next, Mr. Chairman?

The CHAIRMAN: No, I think it is Mr. Howe.

Mr. HOWE (*Wellington-Huron*): Supplementary to this question of our importing drugs, I imagine if there are drugs exported from Canada there would have to be permits issued by the Department of Trade and Commerce customs in this country. They would have to comply with certain regulations. What co-operation is there with countries that are exporting to give you the information that should be required by the Food and Drug Directorate of Canada?

Mr. HOLLETT: If drugs are being imported into Canada we may require, and often do require, protocols concerning the potency tests that have been carried out on the drug. Indeed, we have specific information that we request be presented before we release the drug. When these protocols are examined and we are satisfied that the drug has been tested and that the tests are satisfactory, quite often they are released without being tested in Canada.

Mr. HOWE (*Wellington-Huron*): That is through co-operation with some foreign country and their regulation?

Mr. HOLLETT: Not so much co-operation with the foreign government or agency, say, but this is information which we require in order to comply with our manufacturing facilities and controls. In order to get some information on the drug we ask that a certain limited amount of information or a certain specific amount of information be provided to us before the shipment is released to the importer.

Mr. HOWE (*Wellington-Huron*): And if he supplies you with information from a foreign country is that satisfactory?

Mr. HOLLETT: Quite often we will accept this. On the other hand, quite often we analyse the drugs, or sometimes anyway, to determine if the analytical findings in our laboratory compare with that supplied by the manufacturer abroad. I know that leads to the next question about what would be the comparative findings. I do not have a comparative findings here. It would entail a great deal of work to make that check.

Mr. HOWE (*Wellington-Huron*): Well, of the 30 countries you mentioned, one statement reads;

> Our 1964 survey showed that during this year bulk drugs and formulated dosage forms from over 30 different countries...

Are there some specific countries you would accept information from? Are their governmental agencies different than others?

Mr. HOLLETT: No; actually we will go on the performance of the manufacturer.

Mr. HOWE (*Wellington-Huron*): In that country?

Mr. HOLLETT: Yes.

Mr. MACLEAN (*Queens*): Can a manufacturer in a foreign country ship drugs, and get them past customs to any addressee in Canada or does the addressee have to be someone who is registered as a distributor or manufacturer of drugs?

Mr. HOLLETT: This will depend on the type of drug. A drug manufacturer, if he is selling drugs to others, in so far as we are concerned, may import a drug if the drug meets our requirements. The conditions of sale may be specified in other respects; they may be laid down, of course. But in so far as the importation is concerned, there is no limitation if the product is satisfactory. If we have sufficient evidence to satisfy us that it is satisfactory, then a firm may import any drug. I do not mean a new drug, of course, but a drug other than a new drug. This will not apply to narcotics which are licensed but I am speaking of drugs in general.

Mr. MACLEAN (*Queens*): Is there any record of any attempts made to get drugs through customs, perhaps improperly declared?

Mr. HOLLETT: No; I am not aware of this. I can see that the possibility does exist for a small quantity of a drug which could be secreted on one's person.

Mr. MACLEAN (*Queens*): Or shipped as something else; an innocuous thing which is not a drug at all?

Mr. HOLLETT: Unquestionably this is possible.

Mr. MACLEAN (*Queens*): You depend on customs entirely for preventing this sort of thing?

Mr. HOLLETT: Yes, the manifest which we can examine and do examine.

Mr. HOWE (*Wellington-Huron*): I have just one further question, Mr. Chairman, in connection with this and the question I asked this morning about the dating of drugs. I notice in the recalls there was only one drug on all these lists that was recalled owing to some dating and that was Protamine Sulfate injection and it was recalled because the expiry date was excessive. That brings me back to the question I asked this morning. What percentage of drugs have an expiry date on them or are there many of them or this is not a regulation that you demand?

Mr. CHAPMAN: On vitamin preparations we do. On certain other classes of drugs we do. Could you give an estimate of the proportion that have to carry an expiry date, Mr. Hollett?

Mr. HOLLETT: It would not be 50 per cent.

Mr. CHAPMAN: It would be something less than 50 per cent in any event.

The CHAIRMAN: Antibiotics and vitamins, what classes of drugs can you put it in?

Mr. HOLLETT: Most of the licensed drugs and all vitamin products.

Mr. HOWE (*Wellington-Huron*): Yes. Should all drugs have it?

Mr. CHAPMAN: This is a very difficult question to answer unless there is a really serious problem involved it could actually be misleading because the usefulness of the drug expiry date is going to depend so much on the manner in which it has been stored. If there is not a problem involved it is probably better not to put an expiry date on it.

Mr. HOWE (*Wellington-Huron*): We felt that might have happened in the case mentioned this morning. The doctor examined the one batch of phenylbutazone and he found that it was not fit for human consumption and you found otherwise, that his conclusions were not correct. Do you think there is a field in here where there should be a little thought and care given to regulations as to time?

Mr. CHAPMAN: Then it becomes a matter of priority, whether this sort of thing is more important than analysing more samples and inspecting more plants.

Mr. MACKASEY: Mr. Chairman, if I may speak on a point of order; have we made arrangements for Dr. Chapman to come back? Before you answer that I would like to tell you some of the areas I am interested in and intend to ask questions about; the Hilliard Report; your overseas report, as I call it; the policy on advertising on television and so forth, which comes under you; the clinical research information that you get, I would like to know the percentages of clinical research reports that you analyse in conjunction with new drugs that actually originate in Canada as opposed to outside the country; and the definitions of a new drug which comes back to the Hilliard Report.

Now, Mr. Chairman, these are some of the categories that have occurred to me to be of particular significance in writing a report. I think every one of these areas is probably very vital and I am sure Mr. Laidlaw has others and, of course, so have other members.

The CHAIRMAN: Yes, well this will come—

Mr. HOWE (*Wellington-Huron*): I have questions on the correlation between the food and drug organization and the patent people.

The CHAIRMAN: I am sure Dr. Chapman and the department and I can arrange to have some mutual time. Perhaps it would be useful for the department if Committee members expressed—similar to what Mr. Mackasey has done—to Dr. Chapman the areas they are interested in so Dr. Chapman, if he has to acquire any evidence or material, can do so.

Mr. MACKASEY: Dr. Chapman has covered the Hilliard Report fairly extensively in his brief. There are references in the brief to clinical research and to new drugs. I would like to get Dr. Chapman's opinion on this Committee, and not at the consumer committee meetings, as to Mrs. Plumptre's suggestion that you divorce yourself from health and welfare and establish elsewhere. I think it is important that you stay with health and welfare but this is my opinion and I would like to get your opinion. Mr. Chairman, I think we have enough material if we stick to the subject—I am more guilty of not doing this than most people—for at least two more meetings.

The CHAIRMAN: We will have to play it by ear as we go along. Dr. Brand, is there anything you have to say?

Mr. BRAND: I will have more questions as well but they are all related to what we have before us. I have one last question.

The CHAIRMAN: Mr. MacLean, is there any particular field you are interested in hearing from the department about?

Mr. MACLEAN (*Queens*): I would have a few more questions if there is another meeting.

The CHAIRMAN: Oh, there will be another meeting, I am sure.

Mr. ISABELLE: I have a supplementary to questions that were answered by Mr. Hollett. Could I direct a question to Mr. Hollett?

The CHAIRMAN: We are hoping to conclude in about two minutes; how is that?

Mr. ISABELLE: It is not an investigation because it has been made. It is only a practical question. Did you ever make a statement a few years ago that you had decided to get rid of fly-by-night drug companies and to try also to weed out the shady operators in the pharmaceutical industry by taking proper steps? Those proper steps, as you mentioned, were two moves to be made: first the formulation of an information form and additional staff for the directorate. You said this could be done within a year. Have these steps been taken?

Mr. HOLLETT: I certainly have not made such a statement.

Mr. ISABELLE: Your name is Andrew Hollett?

Mr. HOLLETT: That is correct.

Mr. BRAND: My last question is to Dr. Chapman. I am relating it to what occurred a little earlier and I just want to get a yes or no answer, if it is possible. With respect to your statement number one on page 4 of this thing we have been spending all our time on, would you say that it was designed to ensure physicians in Canada that, say, starting tomorrow morning at eight o'clock in the hospital that it is safe to prescribe by generic name regardless of the source of the drug?

Mr. CHAPMAN: I do not believe you could infer quite that much from my statement on page four.

The CHAIRMAN: This will be coming up for discussion again because we obviously have not finished with it. Is everyone happy with Appendix III? Could we start the next meeting, perhaps, with Appendix IV? We would not dare leave anything out.

The next meeting actually is listed for next Friday, February 3. Dr. Hilliard of the Hilliard Report will be before the Committee, but I am sure we will be able to work out perhaps at 1 o'clock in the afternoon some meetings with the health and welfare department to try to get these through.

Mr. MACKASEY: I know we are in a rush but I want to get this straight. Do we meet Dr. Hilliard on Friday?

The CHAIRMAN: Yes.

Mr. MACKASEY: At what time?

The CHAIRMAN: At 9.30 in the morning. Tuesday and Thursday are very difficult days for Dr. Hilliard and this was done to suit his convenience.

Mr. MACKASEY: This will only give us an hour and a half. This is really hardly adequate.

The CHAIRMAN: It is a very straightforward report.

Mr. MACKASEY: Could you not start at 8.30?

The CHAIRMAN: We could sit in the afternoon if you wish.

Mr. MACKASEY: Well, you know it is a get-away-day. When will we be seeing Dr. Chapman again?

The CHAIRMAN: At a time mutually convenient to Dr. Chapman, the department and ourselves. It will probably be one o'clock in an afternoon.

Mr. MACKASEY: But in an afternoon before or after the Hilliard Report?

The CHAIRMAN: Probably before.

Mr. MACKASEY: I ask because many of us—I know in my particular case—

The CHAIRMAN: The way the meeting went tonight I think I could say before and after. In other words, we are going to have more than one more meeting.

Mr. MACKASEY: It is a question of scheduling personal problems that I have and I am sure other members have but who still want to be here.

The CHAIRMAN: We will not be seeing Dr. Hilliard for a full week tomorrow.

Mr. MACKASEY: I am not interested in Dr. Hilliard. It is Dr. Chapman I want to question.

The CHAIRMAN: Possibly next Tuesday at one o'clock in the afternoon, if we can work it out. I will have to talk with Dr. Chapman. Thank you gentlemen.

TUESDAY, 31st January, 1967.

The CHAIRMAN: Gentlemen, we shall commence our meeting. We have the Food and Drug Directorate, represented by Dr. Chapman and some of his colleagues, with us today. Before we go on to the consideration of schedule IV, where we left off last time, I think, Dr. Chapman would like to make a brief statement.

Dr. R. A. CHAPMAN (*Director-General of Food and Drug Directorate, Department of National Health and Welfare*): Mr. Chairman, I should like to make a few comments in regard to a statement made at the last meeting concerning recalls, convictions and health hazards, which may have left an erroneous impression in the minds of some members of the Committee.

This relates to the assumption that two-thirds of the drug recalls by the Food and Drug Directorate were among the 15 per cent of the companies in Canada which were "purely generic"; that 50 per cent of the health hazards found by the Food and Drug Directorate were in this same 15 per cent and that 92 per cent of the convictions for breaking the drug regulations were in this group. I presume that the figure of 15 per cent was derived from the statement made on page 97, Minutes of Proceedings and Evidence, No. 4, June 16, 1966, to the effect that "the Pharmaceutical Manufacturers Association of Canada, a non-profit organization whose 57 member companies

account for more than 85 per cent of the pharmaceuticals made and sold in Canada." I can only assume that this refers to the monetary value of the drugs produced by member companies of the PMAC rather than the actual number of pharmaceuticals. This assumption is supported by the data which we have now received through our Drug Notification Program.

To date, 52 companies who are members of the PMAC have notified the Directorate that they market 5,408 drug products (that is dosage forms) in Canada. A total of 375 "other drug manufacturers" have notified us of 11,841 drug products which they have on the market. Therefore, the 12 per cent of the pharmaceutical firms who are members of the PMAC market 31 per cent of the drug products offered for sale in Canada, while the remaining 88 per cent of the pharmaceutical companies market 69 per cent of the drug products offered for sale. If one uses these figures in the same manner as in the statement made at the last meeting of the Committee, one should refer to 88 per cent of the companies. However, I believe it would be more accurate to use the figure of 69 representing the per cent of drug products manufactured by non-PMAC members. In this case, the following statement would apply:

> Two-thirds of the drug recalls by the Food and Drug Directorate were among te the non-PMAC companies producing 69 per cent of the drug products in Canada; 60 per cent of the health hazards found by the Food and Drug Directorate were in this same 69 per cent and 92 per cent of the convictions for breaking drug regulations were in this same group.

Now I wish to emphasize that these figures are on the basis of the information that we have now received under our drug notification program and that the figure of 69 per cent relates to the number of pharmaceutical products on the Canadian market and not to their monetary value.

This figure of 69 per cent for drug products produced by "other drug manufacturers" will increase since it appears that there are a number of firms in this category still to report under our Drug Notification Regulations. As far as we can judge, there is only one member of the PMAC that has not yet reported who is marketing drugs on the Canadian market.

Mr. MACKASEY: Have they been in contact with you as to the reason why they have not reported?

Mr. CHAPMAN: Not as far as I am aware.

Mr. MACKASEY: Did they ask for a delay over a particular problem or something else?

Mr. CHAPMAN: Not as far as I am aware.

The CHAIRMAN: Fine, thank you Dr. Chapman. Are there any comments on Dr. Chapman's remarks?

Mr. FORRESTALL: I wonder if we could have that photostated. The figures were a little difficult to follow, I followed the transcript.

The CHAIRMAN: So you can have it this afternoon?

Mr. MACKASEY: So we can have it right away; we can have it back—

The CHAIRMAN: Yes, we could do that. Do you have other copies of that, Dr. Chapman?

Mr. CHAPMAN: I have other copies, but I have added material, I have not stuck exactly to my text. However, I think that this will give you the context.

The CHAIRMAN: We will send it up to photostat division now and get it done while we are proceeding, so we can come back to that and discuss it later in front if you wish. We shall continue from where we left off when Dr. Chapman and the department officials left. I think we had finished Appendix III and we were going to discuss appendix IV which is the one headed: "Convictions Registered against Drug Manufacturers, 1963 to 1966." Are there any questions on Appendix IV?

Mr. MACKASEY: Dr. Chapman, there seems to be a lot of violations in the field of vitamin tablets. I heard that on television Dr. Goddard had expressed some very strong opinions about vitamins in general. Have you any comment on that?

Mr. CHAPMAN: Yes I have. This is one of the moe difficult of the pharmaceutical products to formulate. There are many ingredients; the ingredients may react with each other, and therefore there is a definite possibility that one or more of the vitamins that are present may have decreased in potency after being on the market for a relatively short time. Now we have recognized this. You will note that in 1964, and in 1965, there were quite a number of prosecutions. We found, however, that our activities were not sufficient to correct this situation, and we therefore have now adopted a procedure whereby an expiry date must appear on all such products. We feel that this has improved the situation considerably as far as the consumer is concerned.

Mr. MACKASEY: Dr. Chapman, Dr. Goddard also made another point that most food products that come under the Food and Drug Directorate today do have vitamins added? Am I right or wrong in this?

Mr. CHAPMAN: No; I would say that that is certainly not correct as far as Canada is concerned. As a matter of fact, we felt that there was a trend in this direction, and we therefore passed regulations stipulating those foods to which vitamins could be added.

Mr. MACKASEY: Those to which it could be added?

Mr. CHAPMAN: Yes. They do not have similar legislation in the United States at the present time.

Mr. MACKASEY: These vitamin tablets that appear here in many areas on this thing, are obtained without prescription, I presume?

Mr. CHAPMAN: Yes, that is correct.

Mr. MACKASEY: Dr. Goddard's experience, of course, was that you get the same effect from a balanced diet, and that the need for these products which may have once been legitimate, no longer exists in view of the fact that you get the same vitamins from a good chocolate bar, and perhaps at a lot less expense.

Mr. CHAPMAN: First of all, I said yes in answer to your question whether these were sold over the counter. I presume that they were although there may have been some of these that were actually for therapeutic use, and under those circumstances, of course, these would be sold on prescription only.

Mr. MACKASEY: One last question, Dr. Chapman: I notice the same firm has been on here once or twice, which is quite logically possible, but on the question of fines, these would seem to be quite a variation here. Is it normal to have a variation in fines for what, on the surface, appears to be the same violation of the law? There seems to be quite a range in the penalty. One person here has been fined $25, which does not seem to me to be much of a deterrent. Is there a progressive scale? Do you have a demerit system or merit system in the standards of the—I forget the number, 74 is it?

Mr. CHAPMAN: 74-GP-1.

Mr. MACKASEY: Do you have the same system in the Food and Drug Directorate, outside of this department?

Mr. CHAPMAN: Well, sir, we have no control over the courts.

Mr. MACKASEY: Do you yourselves have any type or set-up of a merit or demerit system working in conjunction with this?

Mr. CHAPMAN: No, sir; nothing that would relate to the penalties that are to be assessed.

Mr. MACKASEY: In other words, there is nothing in our schedule outlining a fine or restricting a court to a certain fine? As in other fields it is within the wisdom or discretion of the judge.

Mr. CHAPMAN: That is correct.

Mr. MACLEAN (*Queens*): Do you consider the fines that are levied generally a sufficient deterrent. Is the law adequate in this regard?

Mr. CHAPMAN: I would say that the law is adequate. The penalties provided, I think, if they were assessed to the full extent possible, would certainly act as a deterrent. There are times, of course, when we are disappointed in the penalties that are assessed.

The CHAIRMAN: Are there any other questions? Perhaps I can ask you a question, Dr. Chapman. I notice, when you go down the violations, there is no violation there for any drug having impurities in it. Do you get complaints that perhaps there is something in the product that should not be in there; do you have convictions and violations for this offence?

Mr. CHAPMAN: We have had complaints along these lines, but I do not know of any instance where there has been a prosecution for an impurity. You will notice, for example, on page 2, that Lukas International (Canada) Ltd., Toronto were selling chloramphenicol capsules which were labelled as tetracycline. But this is not actually an impurity.

The CHAIRMAN: No, just a wrong drug.

Mr. CHAPMAN: That is correct.

The CHAIRMAN: Are there any other questions on Appendix IV? If not, could we move to Appendix V which is along the same lines; it is entitled: "Instances of a Significant Hazard to Health Involving Pharmaceutical Products, 1959 to 1966." I take it that these are the same ones that are actually on the previous appendices we have discussed but it goes into more detail, and these are the serious ones that could have given rise to health problems.

Mr. CHAPMAN: No, sir, they are not. I do not think you will find them all—

The CHAIRMAN: The dates are a little different; one goes from 1959 to 1966 and the other one from 1963 to 1966.

Mr. CHAPMAN: Yes. The point I wish to make here is that we have a list on Appendix IV of convictions registered against drug manufacturers. But I wish to point out that in most instances these did not represent a significant hazard to health. You will notice that in many instances they are vitamin tablets with low potency. this would not represent a significant hazard to health, although the person who is making the purchase is certainly not getting the full amount he is paying for. In a number of instances there was improper advertising; for example, there was an advertisement for the treatment of a schedule A disease. There are several new drugs. Again, the sale of these products did not represent any significant hazard to health, but the company involved did not meet the requirements for a new drug submission, and therefore it was a violation.

Mr. MACKASEY: I can understand vitamins being prescribed by a doctor or physician, who had analysed his patient and realised that the person needed to overcome a deficiency for a particular period of time. I am also led to believe that an excess of vitamins can be equally harmful, but those people who are induced to a drugstore, to buy vitamins, are usually induced by advertising on television, on radio, and so forth. Do you control the advertising vitamins that are obtainable without a prescription at the present moment?

Mr. CHAPMAN: We have control over advertising for vitamin preparations. It must be truthful and not misleading.

Mr. MACKASEY: Well, if an advertisement were to include vitamins—, vitamins are another field and I have my reservations—but would you say that an advertisement that includes vitamins is truthful when it contains all these claims about the necessity of vitamins in a concentrated form and yet these vitamins can be obtained without a prescription? Are these all truthful?

Mr. CHAPMAN: Well, these are certainly checked very frequently. In 1965, we checked 18,697 advertisements for drugs; we found 123 of these were not satisfactory, not acceptable.

Mr. MACKASEY: Well, I am interested in the fact that Canadian people are induced to buy vitamins available at present without prescription. There seems to be a lot of controversy in the United States. I heard that your counterpart more or less stated to the people, "Well if you want to waste your money by buying vitamins, go ahead, but you can obtain your vitamins in a balanced diet or through food that do have vitamins added" etc. This is further compounded by the fact that not only may you go in and by something that you do not need, but in many instances the vitamins are still under potency. We are susceptible to this because the companies have been asked to put an expiry date on the vitamin label. This is the only point I am wondering about.

The CHAIRMAN: Would you like to comment at all on Appendix V, Dr. Chapman?

Mr. CHAPMAN: Yes, thank you, Mr. Chairman. We have simply listed here five cases where we felt that there was a significant hazard to health. (a) The first involved dicumarol tablets (bishydroxycoumarin, an anticoagulant) pro-

duced by Charles E. Frosst and Co., Montreal. The problem arose here from the re-formulation of the tablet that decreased the availability of the therapeutic agent. The offending lots were recalled by the company and physicians were informed of the change, and no legal action was initiated by the directorate.

(b) In July, 1963, a physician brought to our attention that a product labelled as Dicumarol (bishydroxycoumarin) manufactured by Empire Laboratories, Toronto, Ontario, was not giving the expected results on several of his patients. Laboratory examination revealed that the active ingredient was not as shown on the label but was 4-hydroxycoumarin. The firm was immediately contacted and it was learned that they had already initiated a recall of the lot since a routine analysis to determine stability had indicated low potency, and they were unaware of the mislabelling. The product was recalled from the market and the 70,000 tablets in this lot were destroyed.

(c) The third case involved dimethylsulfoxide (DMSO), when it was found that Stylecraft Products Ltd., Vancouver, British Columbia, were selling a technical grade solvent for therapeutic purposes.

This chemical was a new drug according to the definition in the Food and Drug regulations, and the firm had not made a submission to the directorate on this product. Therefore, the product was removed from the market by seizure action and the firm prosecuted. A fine of $500 was assessed by the court.

(d) In March, 1966, an investigation by the Food and Drug Directorate revealed that capsules labelled as Tetracycline and sold by Lukas International (Canada) Ltd., Toronto, contained chloramphenicol. Immediate recall action was initiated by the company at the instigation of the directorate. Physicians and pharmacists who had received these mislabelled capsules were informed of the situation. It was found that the firm had not carried out the proper analytical controls on the product. Legal action was, therefore, initiated and the firm was fined $2,000.

(e) In June 1966, it was found that J. F. Hartz Co. Ltd., Toronto, had mislabelled a strong germicide as a mild antiseptic. The product was immediately recalled from the market and the firm was sent a formal warning.

These, Mr. Chairman, are the cases over the past seven years where we have felt that there was a significant hazard to health involved in the sale of a drug on the Canadian market.

The CHAIRMAN: One point of small clarification: under (d) you say the tetracycline sold by Lukas, contained chloramphenicol. It not only contained chloramphenicol but it was the only ingredient was it not? It was not that it had tetracycline and chloramphenicol, but that it contained only chloramphenicol.

Mr. CHAPMAN: It was chloramphenicol, they were chloramphenicol capsules.

The CHAIRMAN: Perhaps instead of saying "contained chloramphenicol" it should just read "was chloramphenicol". You could read this to mean that it might have been contaminated with chloramphenicol, but in fact it was pure chloramphenicol.

Mr. CHAPMAN: That would be more correct, Mr. Chairman, and I would like to make that correction.

The CHAIRMAN: I should say that for the non-doctors on the Committee that this is a very significant thing, because chloramphenicol is an antibiotic that has

been known to produce blood dyscrasias leading to death. It is a drug that one uses with great caution. Are there any questions on Appendix V?

Mr. MacLEAN (*Queens*): I have a question on these cases such as (b) (d) and (e), which you classify as mislabelling. How does this mislabelling come about?

For example, take (b), is it that the labels were put in error on the wrong product? Is it something as simple as that? Or is it a case where this company bought this drug in bulk and in good faith, then discovered after they processed it that it was not what they had thought it was, and had not been properly analysed?

Mr. CHAPMAN: In the case of (b) this was a situation where apparently the firm received 4-hydroxycoumarin, and they did not realise that the products they were putting into their capsules was hydroxycoumarin. This chemical is actually an intermediate in the preparation of bishydroxycoumarin.

Mr. MacLEAN (*Queens*): Well, was it an error in the processing, or did they buy the drug in bulk, and were they the victims?

Mr. CHAPMAN: No, sir; I think that it was the responsibility of this company. They had not carried out the proper control procedures or they would have detected this error.

Mr. MacLEAN (*Queens*): Yes, with this I agree, but I am just wondering for our own information how these errors come about; they are very serious things.

Mr. CHAPMAN: Well, in this case they did not carry out the proper control procedures. If they had done so, they would have detected this error. They had to wait until the product was on the market and found that something was wrong when they were checking out the stability.

Mr. FORRESTALL: Does the Food and Drug Directorate have recourse back any further? For example, the hypothetical situation brought up by Mr. MacLean would suggest that indeed company (a) bought something from company (b); it was not what it was represented to be, and it proceeded on faith to produce this drug for the market. Does our directorate have recourse back beyond company (a) to company (b)?

Mr. CHAPMAN: Yes, indeed, provided that the product was sold as a drug. And, as a matter of fact, this is a defence that is frequently employed by a company under such circumstances as you describe.

Mr. FORRESTALL: And under our regulations it is not an adequate defence.

Mr. CHAPMAN: Yes, sir, it is.

Mr. FORRESTALL: It is a good defence.

Mr. CHAPMAN: In this particular case it was not, because they failed to do certain things that they should have done.

Mr. FORRESTALL: Yes.

Mr. CHAPMAN: But if the first company had bought it in good faith, and done everything that they are required to do, then they can use as a defence, the fact that they bought it in good faith. And if the initial company had sold it as a food or drug, why then we could certainly take action against the initial company.

Mr. HYMMEN: Dr. Chapman, would 5 cases in 7 years not be a pretty fair record on behalf of pharmaceutical manufacturers? Could there be cases of error that would be recalled by the manufacturer without the Food and Drug Directorate knowing about it?

Mr. CHAPMAN: Yes, this could certainly occur, but I think it would be most unlikely that it would occur if there were a significant hazard to health involved.

Mr. HYMMEN: This is a hypothetical question. There is nothing in the regulations that insists that the directorate be notified in case of an error which they noted, and attempts made to correct it by the manufacturer.

Mr. CHAPMAN: Only in the case of drugs which are in new drug status at the time. In my statement before the Committee last Thursday, I did refer to proposed regulations which would correct this situation, and make such requirements applicable to all drugs.

Mr. HYMMEN: I have another question but I do not know if it has any relation here. The two tests referred to were potency and disintegration, and I do not want to really go back to the reference made to Dr. Pernarowski's academic analysis. He refers to other factors such as dissollution. Now, I do not want to get into technicalities here, but what is the difference between disintegration tests, which would be the complete disintegration of a tablet, and the dissolution tests he refers to. Is that only of interest, as he states, to a control chemist?

Mr. CHAPMAN: Well there is a distinct difference between the disintegration time and dissolution, and I would like Dr. Levi, chief of our pharmaceutical chemistry division, to comment on that point.

Dr. L. LEVI (*Chief of the Pharmaceutical Chemistry Division, Department of National Health and Welfare*): There certainly are differences between those two tests. The first difference, one may say, is that the disintegration test is an official test, it is officially recognized. The dissolution test is a test that is undergoing very extensive development at the present time in many laboratories in Canada, in the United States and elsewhere. The characteristic difference between the two, one may briefly state, is this: The disintegration tests merely measure the time it takes for a tablet to break up into particles smaller than a given size, under specific conditions. If you meet the requirement of this test, this does not necessarily allow you to conclude that this drug, having met the disintegration test, is a clinically effective formulation. It merely states that the material breaks up. But what is perhaps more important than the breaking up, is the rate at which the active ingredients diffuse out of the individual small particles, and becomes available to do the job that the drug is supposed to do. This is briefly what the dissolution test is. There are great differences between disintegration tests and dissolution rates. Sometimes one can find much greater variation and characterise drugs much more effectively on the basis of the dissolution tests than one can on the basis of the disintegration tests. But, as I say, I believe I have explained the principle behind this, but the dissolution test has not yet achieved a status that it can be made a regulation.

Mr. HYMMEN: Then I was right in my initial question that my assumption that drugs have been and are being, and can be taken off the market under two criteria, namely lack of potency or over potency and improper disintegration.

Mr. LEVI: Yes, this is correct.

Mr. ISABELLE: Dr. Chapman, do you believe that this multi vitamin stuff should be removed from the market?

Mr. CHAPMAN: Dr. Isabelle, I am neither a nutritionist or a medical doctor, and I do not think that I am in any position to comment.

Mr. ISABELLE: But if the Food and Drug Directorate gives its O.K. to certain advertisements over the radio and television on these multivitamins which from my point of view are not worth a nickel, because there are little bits of everything and nothing of something. I think it should be banned as a matter of fact because we cannot lack all vitamins at the same time. We may lack vitamins C we may lack vitamin D, it would be one of these six, but as a whole I think this is something that should be banned. This is why I think that the Food and Drug Directorate, with all the violations that are on this sheet here should ban the vitamins forever as a whole, though not individually.

Mr. CHAPMAN: Mr. Chairman, I would simply comment that of course we can only act within the authority of the Food and Drugs Act and this simply states that no person shall advertise any drug in a manner that is false, misleading, or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety. The Food and Drugs Act is criminal law and therefore we must have a very strong case before we can obtain a conviction. I think that we have taken action in those instances wherever there was any violation of this regulation.

Mr. ISABELLE: I think it is misleading the people on the value of those pseudo vitamins, I do not believe in those things, anyhow. May I ask you another general question. To your knowledge, who do you think is fixing the prices of drugs.

Mr. CHAPMAN: I have not the slightest idea.

The CHAIRMAN: Any other questions.

Mr. ISABELLE: Yes, I have another question. Is there a limit to the number of offences that a company may commit against the Food and Drugs Act, or may they break the law time after time, and the Food and Drug Directorate cannot do anything.

Mr. CHAPMAN: There is no limit in the act or regulations.

Mr. ISABELLE: So you could violate the act as many times as you wish.

Mr. CHAPMAN: Of course the courts are informed that this is a second or third violation, but again it is up to the courts to decide what the penalty must be.

Mr. ISABELLE: Under your authority, this is the fine. I mean, the court knows that if this is a second offence, then instead of $50 they probably fine them $75, but under your jurisdiction is any action taken against those companies who repeatedly violate the Food and Drugs Act.

Mr. CHAPMAN: As far as the Directorate is concerned, if we find that there are repeated violations, or we feel that there is a possibility of violations of the Food and Drugs Act, we do give these firms priority and they receive more attention than firms where we feel there is less likelihood of violation.

Mr. ISABELLE: Priority in inspection.

Mr. CHAPMAN: Priority in inspection and laboratory analysis of their products.

Mr. ISABELLE: In other words, you go after them?

Mr. CHAPMAN: I would prefer to say, sir, that we give priority to those firms or products.

Mr. MACKASEY: A supplementary question on this very point, Dr. Chapman; you would, however, if we had a system of licensing or registering these firms, then have a weapon by which you could decertify or take back their licence.

Mr. CHAPMAN: This is quite correct.

MR. MACKASEY: And your drug notification system, which you instituted, is simply a poor substitute for what you consider to be a constitutional problem?

Mr. CHAPMAN: Sir, I would not call it a poor substitute. We have found already that it is going to be I believe, extremely useful to have this data, but it is not a licence.

Mr. MACKASEY: I should not have used the words "poor substitute"; it is a bit misleading. It is a substitute for a licence. The ultimate action would be, if the Food and Drug Directorate could licence a firm, and as Dr. Isabelle suggested, they constantly violated your rule, to take the licence away and simply put them out of business.

Mr. CHAPMAN: This would certainly give us much more power.

Mr. MACKASEY: Now, certification, or registration, I believe is the word we have used in our last recommendation, would not give you quite as much power, but again you would have power.

Mr. CHAPMAN: If registration were a condition of sale, then it would give us approximately the same power.

Mr. MACKASEY: We have settled on drug notification instead, which does not give you this type of power.

Mr. CHAPMAN: That is correct.

Mr. MACKASEY: We should be recommending the ultimate in this Committee and if it is a constitutional problem, it is not our porblem; it is not your problem. Am I right in that?

Mr. CHAPMAN: This is a constitutional problem, as I understand it.

Mr. MACKASEY: But it is not our problem, or the Committee's problem; this is the problem of the justice department. In other words, we would be quite legal to recommend either registering or licensing rather than drug notification to obtain the result that Dr. Isabelle envisaged. It is only an observation, I agree.

Mr. CHAPMAN: Yes.

The CHAIRMAN: Of course, the Committee already saw fit to recommend, as you say, licensing, and the government have come back and said, well we required notification.

Mr. MACKASEY: I do not remember them ever coming back with anything; that is the trouble with Committee work. But we do agree that if one day we

woke up to the fact that logically the Food and Drug Directorate has come up with drug modification.

The CHAIRMAN: I think we should give ourselves a little bit of credit.

Mr. MACKASEY: Well, they may have notified you, but I never heard about it; that this was a direct result.

The CHAIRMAN: I should say that some of the recommendations that we have made have been carried out. I think you know the ones that I just recently tabled for the Committee members, a copy of our report on our one year study of clinical trials, which the government instituted at our request, and I think Miss Savard has copies of it, if you want it.

Mr. MACKASEY: When you table it, and I am not being disrespectful, and it is of such significance, how does the average member know of this.

The CHAIRMAN: I did not get it printed as part of the record, because it has nothing to do with the cost of drugs per se.

Mr. MACKASEY: Thank you.

Mr. ISABELLE: I will be through after this last question; after what Mr. Mackasey said, the only power that is within the ambit of the Food and Drug Directorate is blackmail. You blackmail the firms who have been violating the Food and Drugs Act repeatedly. You do not go after them; you just give them priority. You could send inspectors day after day to put pressure on them in order that they get discouraged; they fold.

Mr. CHAPMAN: I would not agree with your statement that it is blackmail. This is the same type of penalties that is applied in most federal statutes.

Mr. MACKASEY: But they can be prevented from selling the federal government.

Mr. CHAPMAN: I do not quite follow the question.

The CHAIRMAN: Mr. Mackasey means by removing them from the 74-GP-1b list on which you have a representative they can be prevented from government tendering.

Mr. CHAPMAN: That is correct.

Mr. MACKASEY: But you cannot prevent them from selling to the public; a poor guy like myself would have to take a chance. We are not blaming you, but there are two standards.

Mr. CHAPMAN: Over a period of seven years we have had five cases where there was a significant hazard to health. I gave you some figures: We now have an indication of some 17,249 different pharmaceutical products on the market; in addition to that, I think there are some 2800 products listed under the P or PM Act. The chance you are taking is very, very small indeed.

Mr. MACKASEY: Which should lead me to another question, if Dr. Isabelle does not mind. Why all the emphasis in the GP regulations if it is so insignificant.

Mr. CHAPMAN: I would prefer to talk about the over-all regulations, the Food and Drug regulations relating to drugs. Drugs do represent a potential hazard to health and unless the proper manufacturing facilities and controls are

exercised in regard to these products, a very serious situation could develop. This is the reason that we feel as strongly about the matter as we do.

Mr. MACKASEY: Thank you.

Mr. MACLEAN (*Queens*): A supplementary question; this is broadening the field probably, but should I infer from your last remarks and from the statistics that you have given, that in actual fact there is no danger to health from accidental poisoning from chemicals and things that are not drugs at all, and are not intended to be taken. I think that there are more deaths in the country from this cause than from drugs being mislabelled. It would seem to me that the accidental poisoning is a greater hazard to health than are drugs that get on the market that do not meet the Food and Drug requirements.

Mr. CHAPMAN: There is not the slightest doubt about this. Approximately 50 per cent of the accidental poisonings reported each year in Canada, are due to drugs; but these are due to severe overdoses of drugs, not to properly prescribed, or properly used drugs.

Mr. MACLEAN (*Queens*): It would seem to me that this a field to which more attention should be given—it is no doubt a very difficult problem.

Mr. CHAPMAN: I can assure you sir, that we are very much aware of the situation.

Mr. MACLEAN (*Queens*): I had a few supplementary questions a while back. Although they are not in proper sequence now, perhaps I might be allowed to ask them now. With regard to drugs that do not meet the potency requirements —I am thinking especially of vitamins—in analysing them is there any distinction made between drugs of which the active ingredient may be unstable and as a result it has a short shelf-life, if that is the term that is used, and ones that were improperly compounded in the first place. Can you distinguish between the two types?

Mr. CHAPMAN: This would be rather difficult. Of course, the end result is the same, whether the product has deteriorated or insufficiency of a particular vitamin was used in preparing the drug. It would be rather difficult to determine analytically whether the particular vitamin had been there or not.

Mr. MACLEAN (*Queens*): From one point of view at least I think it could be argued that if the drug was properly compounded in the first place, that that is not as great an offence as a company intentionally putting on the market something that is not what it is represented to be, and never was.

Mr. CHAPMAN: As I said before, it is not going to make very much difference in the long run. In the first case, it would indicate that the company was probably not exercising the proper controls during the manufacturing process; in the second case it would probably mean that they had not carried out the proper test to determine the stability of their product. Either that, or they allowed it to remain on the market for too long a period.

The CHAIRMAN: Any other questions on appendix V?

Mr. ISABELLE: I have a comment which appeared in the *American Business News*; it reads:

> The Food and Drug Directorate announced it is seeking compulsory annual legislation for all drugs available in Canada.

Has this been done, or is that what we were referring to just a little while ago?

Mr. CHAPMAN: We are not seeking compulsory registration of all drugs in Canada. I presume the reference must be to our new drug notification requirements.

Mr. ISABELLE: This was in 1965.

The CHAIRMAN: That was what our Committee recommended. Are there any other questions on this section. If not, perhaps we could pass to the summary of the appendices which is labelled: "Summary on Data on Drugs, Food and Drug Directorate."

Mr. CHAPMAN: Mr. Chairman, I think we have covered quite adequately everything in this summary. I have no further comments to make on it.

The CHAIRMAN: Fine. During the questioning on this I limited some of the discussion. Rather than jumping around I tried to do it in an orderly fashion. I think it was Dr. Brand who was questioning you on some of these and I insisted that we wait until we got to the specific appendix. Dr. Brand is not here today.

Mr. MACKASEY: Mr. Chairman, on a point of order; I know Mr. Forrestall and other members have indicated that they want to question extensively on this, which brings me back to this point. I would hate to see us break up and go away—this is now a public document—and then find that the document was unintentionally misleading. I have one or two questions about this which puzzles me and could again defeat the purpose of the explanation.

The CHAIRMAN: We will accept questions on it. I think Mr. Forrestall had questions on it too, or at least wanted to look at it.

Mr. FORRESTALL: Mr. Chairman, there are one or two questions I would like to ask with respect to the summary. I spoke to Dr. Brand and asked if he wanted me to follow through on one or two of them, but he commented that perhaps the point that he intended to get across to Dr. Chapman was well made the other evening. I do not think he would have pursued it today.

The CHAIRMAN: All right. Would you like to proceed, Mr. Forrestall?

Mr. FORRESTALL: Yes. If we could just go to the change in statement. This certainly if I can use the expression, "changes the water on the beans considerably". Dr. Chapman, you simply say that you presume the figure of 15 per cent was derived from the statement—no, I am sorry. I can only assume that this refers to the monetary value of the drugs produced by member companies. You draw that assumption from your further figures, based on the indications which you have had from returns from both the generics and members of the PMAC? Is that what you base the assumption on?

Mr. CHAPMAN: I base the assumption on two factors. A statement in the proceedings, page 97 which states:

> The Pharmaceutical Manufacturers Association Of Canada, a non-profit organization whose 57 members companies account for more than 85 per cent of the pharmaceuticals made and sold in Canada,—

We find, however, from our drug notification program that 12 per cent of the firms are members of the PMAC and they produce 5,408 drug products. There

are 375 other drug manufacturers, producing 11,841 drug products. Therefore, the statement made in the PMAC brief must relate to monetary value.

Mr. MACKASEY: Dr. Chapman, does it not relate to the percentage of what they consider to be prescription drugs; whereas your figures are also probably on a different basis. Are you talking about drugs in general which come under the Food and Drug Directorate?

Mr. CHAPMAN: I am talking about drugs in general.

Mr. MACKASEY: Yes, but they are not. They are talking about prescription drugs, if I recall the evidence.

Mr. FORRESTALL: This is the point I was making, Dr. Chapman, whether or not this is in fact—

The CHAIRMAN: May I have the proceedings.

Mr. CHAPMAN: It is No. 4, page 97.

The CHAIRMAN: I still do not think that the small line of non-prescription drugs would account for the difference. I think the difference is—as Dr. Chapman has said—that one group is talking about the number of firms and the other is talking about the percentage of actual sales. They are probably both right.

Mr. FORRESTALL: They are probably both right. But the fact remains there are more Volkswagens sold in Germany than there are Cadillacs, if that is not a too far stretched analogy. This is what I am concerned about.

Mr. CHAPMAN: There is no indication in this statement that this was referring only to prescription drugs. The statement is as exactly as I quoted it and it simply says pharmaceuticals, and when you talk about pharmaceuticals you are talking about drugs.

Mr. MACKASEY: What page are you quoting from, Dr. Chapman.

Mr. CHAPMAN: I am quoting from page 97.

Mr. MACKASEY: Are you quoting the brief as it appears in the proceedings or are you quoting the remarks of a witness?

Mr. CHAPMAN: This is a section which apparently is an abstract of the brief and the heading is: "Introduction." The first sentence is that which I quoted.

The CHAIRMAN: It was the brief which was printed.

Mr. MACKASEY: I have it here: "The PMAC at present and its 57 members produce about 85 per cent of the prescription drugs sold in this country." This is the brief.

Mr. FORRESTALL: This is the assumption that I have had and I think most of the members of the Committee were under that assumption notwithstanding the semantics which were used.

Mr. CHAPMAN: Thank you very much.

Mr. MACKASEY: This is very important because I think it would lead to a reissuance of another statistical table.

Mr. FORRESTALL: Or another brief we could go on ad nauseam with it.

The CHAIRMAN: In the same issue, the next paragraph starts off by stating:

> The prescription drug industry—

This might imply that they were actually talking about prescription drugs, but it does not actually say that.

Mr. CHAPMAN: Mr. Chairman, I should like to make it very clear that our references here are to all drugs—prescription and over the counter—all drugs sold in Canada.

The CHAIRMAN: You mean this is strictly on the basis of the returns of notification which you have received from all drug manufacturers in Canada?

Mr. CHAPMAN: All the drug manufacturers that have notified us.

Mr. FORRESTALL: I wanted to make sure that there was no misunderstanding about what the figures refer to. I understand the basis upon which you have made it. I still think the earlier analysis in terms of prescription drugs is possibly then quite accurate. It is not a misleading statement.

Mr. CHAPMAN: The statement in the—

Mr. FORRESTALL: The statement relating to the effect than two-thirds of the drug recalls by your Directorate are among the 15 per cent of companies in Canada who are—in the term here—purely generic.

Mr. CHAPMAN: No, sir. I still feel that that statement is misleading.

Mr. HYMMEN: Mr. Chairman, one other question: Fifteen per cent generic —are the 375 other drug manufacturers all termed as purely generic.

Mr. CHAPMAN: In my statement I very carefully put quotation marks around those words "purely generic." Those were the words which were used, they are not my interpretation and I would not wish to attempt to interpret them.

Mr. FORRESTALL: It did not come out too well on the photostat machine but you did say "quote" when you read it out to us.

Mr. CHAPMAN: Yes.

The CHAIRMAN: Are there any questions on either the statement or the summary of data.

Mr. MACKASEY: I have no question on the statement but perhaps someone else has, Mr. Chairman.

Mr. MACLEAN (*Queens*): I would like to try to understand the statement on recalls, convictions and hazards. On page 2 you have the quotation:

> Two-thirds of the drug recalls by the Food and Drug Directorate were among the non-PMAC companies producing 69 per cent of the drug products in Canada;—

Sixty-nine per cent of the drugs produced in Canada that refers to what? Is that 69 per cent of the kinds of drugs or is it 69 per cent of the total volume?

Mr. CHAPMAN: No, sir. This is 69 per cent of the dosage forms. If a particular drug is put up in a tablet of 100 milligrams and 200 milligrams that still is considered to be one dosage form. But if it were put up also as a solution or in a capsule that would be a different dosage form. So here we are talking about 69 per cent of the different dosage forms.

Mr. MacLEAN (*Queens*): Without any reference to the volume. There might be a million of one sold in the country and 10 in the other—

Mr. CHAPMAN: Yes, sir.

Mr. MacLEAN (*Queens*):—in a year, so that this does not relate at all to the total volume of drugs.

Mr. CHAPMAN: No, sir; it does not. Let me make it perfectly clear. I am not challenging the statement made by the Pharmaceutical Manufacturers Association of Canada. What I am doing is indicating that this does not relate to the actual number of drug products on the market.

Mr. MacLEAN (*Queens*): I see.

Mr. CHAPMAN: Of course, a small lot of drugs, if they are not properly compounded, could cause quite serious effects just the same as a very large lot of drugs if they were not properly compounded.

Mr. MACKASEY: Dr. Chapman, I know your impartiality with respect to these things and you represent the Food and Drug Directorate and you deal with the statistics as you see them. I understand this, and we do not have to belabour the point because I respect the role you have and it is a very unenviable one. But, when I read this statement I was not concerned about you or us, but about the fact that it is still too ambiguous and could create again an erroneous impression among those people who are uninitiated or uninformed. I do not pretend to be fully informed but we do have a little knowledge. It strikes me too much like apples and oranges. You have come to certain conclusions on page 2. If people want to do this—I know this is not your purpose—but there are enough statistics here to enable them to compare PMAC members to members of the industry who are non-PMAC members on statistics which are not limited to prescriptions only. This is not your fault. Mr. Chairman, I would like to be bold enough, through you, to put 6 or 7 or 8 questions—not now because I want to prepare them,—to Dr. Chapman which I think if answered would give me a statement which I could not criticize and then I would be quite happy to take the statistics as they fall. You see, the minute you introduce the word "prescription" you change the ratios at the top. It is basically prescriptions in which we are essentially interested in the general concept of things. But you are equally right and it is your concern in the Food and Drug Directorate with drugs in general. Our Committee has been concerned essentially with prescription drugs, reducing the cost of prescription drugs. This is why it is unintentionally misleading, in that we again have statistics on convictions. For instance, you mentioned 92 per cent of the convictions for breaking drug regulations were in this same group. I would like to know how many of these were breaking prescription areas against non-prescription areas. Ninety-two per cent sounds so alarming and can be used so gleefully by enemies of the generic firms. This thing may come down to a respectable figure if we were to break down what prescriptions are and what prescriptions are not. Of course, the same thing applies in reverse higher up. This is why I am afraid that again, statistically, we are making an error that statisticians should not fall into, in that we are not using the same basis for comparison.

The CHAIRMAN: May I ask you a question, Mr. Mackasey. I am a bit confused here.

Mr. MACKASEY: That is McLuhan's influence.

The CHAIRMAN: Are you suggesting that there is a difference in the safety standards of drugs for prescription and non-prescription items; that one should be more safe than the other.

Mr. MACKASEY: No, of course not. What I am saying is that when people outside this room take the statements and compare a segment of the industry that is specifically concerned with prescriptions to a segment of an industry that is not necessarily concerned strictly with prescriptions, then the figures become misleading.

The CHAIRMAN: If you would like to prepare those questions I will see that Dr. Chapman gets them. I think it is obvious that Dr. Chapman and his group probably will come back before the Committee once more.

Mr. MACKASEY: Mr. Forrestall brought out the fact that the word "prescription" is not in the records so Dr. Chapman would be perfectly valid in not placing it in here, but it is in the brief that was presented to us and it does make the 85 per cent quite conceivably extremely accurate just because the word "prescription" is in it, but inaccurate according to Dr. Chapmans' statistic because—

The CHAIRMAN: No, not more abrasive—

Mr. FORRESTALL: I do not think it alters the accuracy, Mr. Chairman, of either set of figures we are talking about. I think Dr. Chapman extended the basic conflicts that we had in our mind and what we were prepared to accept; and if Mr. Mackasey would prepare the questions I know I would be extremely interested. I would not want to give this to the Directorate or to anybody else to work out or to precipitate a battle of statistics between any groups of business interests in Canada at all.

The CHAIRMAN: I think that even if you accepted the figures as they are now, they could both be right because they are really related to two different things.

Mr. MACKASEY: You make the point better than I that the statistics could be used as seen fit, and still be accurate. It is a little like some of the evidence that we sometimes get about advertising from the detailmen; it is accurate as far as it goes, but it does not go quite far enough, and that is exactly what can happen here.

Mr. CHAPMAN: I would certainly be most happy to answer any questions that members of the Committee have. Would it be helpful if I tabled the data we have on the response to our drug notification requirements?

Mr. MACKASEY: Only if it could be kept in the Committee until such time as we can get our questions together. I want to be fair to the press. They interpret only what comes out of here and if it is ambiguous it will go to the press ambiguous. This is my problem.

The CHAIRMAN: Are there any other questions on the statement or on the summary of data on drugs? Does anyone want to discuss that in detail? If there are no other questions perhaps we could arrange to meet Dr. Chapman again and then recess. We have not really discussed the other statement on drug control in Europe at all.

Mr. MACKASEY: When are we going to meet? After orders of the day?

The CHAIRMAN: Today?

Mr. MACKASEY: Yes.

The CHAIRMAN: No, that is impossible.

Mr. MACKASEY: We are meeting Dr. Hilliard on Friday and there is another area I would have liked to go through with Dr. Chapman before that time.

The CHAIRMAN: I am afraid we just do not have the time unless Committee members are prepared to sit this evening.

Mr. CHAPMAN: We could be available, Mr. Chairman.

The CHAIRMAN: It is up to the Committee. I think Dr. Chapman and members of his department are going to have to come back anyway, perhaps in about a week or so.

Mr. MACKASEY: All right, we will see Dr. Hilliard first and Dr. Chapman afterwards.

The CHAIRMAN: As far as Dr. Hilliard's appearance is concerned, he is coming on Friday, February 3. There has been some suggestion that we meet in the Railway Committee room. I do not think that is really a good idea in that it is a terrible room for acoustics.

Mr. MACKASEY: What is wrong with this room?

The CHAIRMAN: This room will not be available to us. The only other room available is 209 which is slightly smaller than this, but I think it would be fine. Does anyone have any objection to that?

On Tuesday, one week from today, we are meeting with the Director of Investigation and Research (Combines Investigation Act) and other officials of the Combines Branch and, if it is possible, I was going to suggest that perhaps Dr. Chapman and members of his department could come back on Thursday, February 9, at one o'clock. Would that be suitable, Dr. Chapman?

Mr. CHAPMAN: Yes, as far as I am concerned.

The CHAIRMAN: Are there any other questions? We will adjourn until Friday at 9.30 a.m. in room 209, at which time we will hear from Dr. Hilliard.

Mr. MACKASEY: Do you feel, Mr. Chairman, that an hour and a half will give us time to explore this in detail or will we be in the same position as we are today?

The CHAIRMAN: I am not sure, but we do have authority, of course, to sit when the house is sitting if we want to go on. I somehow think that the hour and a half will be sufficient.

APPENDIX "A"

SUBMISSION

TO THE SPECIAL COMMITTEE

OF THE HOUSE OF COMMONS

ON

DRUG COSTS AND PRICES

ON THE SUBJECT MATTER OF

SALES TAX ON PHARMACEUTICALS

BY THE

CANADIAN DRUG MANUFACTURERS

Representing the Views of Canadian-Owned Companies

Submitted January 26, 1967

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Appendix I

Appendix II

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

I. *Introduction*

The Special Committee on Drug Costs and Prices is currently considering ways and means whereby the costs of medicines could be lowered in the near future under the proposed Medicare Program. One of the apparently simple ways of accomplishing this purpose would be the abolishment of the 12% Sales Tax on pharmaceuticals, which should reduce drug prices. It is believed that the reduction may be as much as 10¢ on the prescription dollar, considering the impact at the three distributing levels, namely manufacturers', wholesalers' and retail pharmacists' level.

II. *The dilemma of our government about the sales tax on pharmaceuticals*

The abolishing of Sales Tax on pharmaceuticals is recommended vehemently by several large manufacturers and also by the P.M.A.C. Even the Canadian Pharmaceutical Association strongly feels that ridding the public of this tax should be a welcome measure, since the sick person should not be taxed—his burden is already hard as it is.

The issue appears to be clear-cut on the surface. Even the Hon. Mr. Benson, Minister of Revenue, expressed willingness to consider the suspension of Sales Tax on pharmaceuticals, together with the Hon. Mr. Sharp, the Minister of Finance. Mr. Sharp said, however (Hansard—page 6094 Tuesday, June 7, 1966) "In my budget address I made clear that the Government is prepared to remove the sales tax from drugs, should this course be recommended by the Committee of this House which is concerned with the question of drugs and drug prices. The reason is that the Government would like to be *ASSURED* (italics and capitals are our own) that the benefits of a reduction in the tax would be passed on to the consumers; this is the only reason for our RELUCTANCE to move ahead now, before the report of the Committee has been presented."

The Hon. Mr. Sharp made a very wise statement, indicating his profound understanding of the subject of sales tax on drugs.

One matter is certain to us, that soon—probably after the recommendations of the Special Committee—our Government must take a definite stand on the sales tax on pharmaceuticals, and declare themselves. It appears that they have two possible courses of action:

1. Maintain the sales tax on pharmaceuticals as it is today;
2. Abolish the sales tax on pharmaceuticals as advocated by some associations.

It is the carefully considered opinion of CDM that BOTH OF THE ABOVE COURSES ARE WRONG, IMPRACTICAL AND LACK FARSIGHTED THINKING, and therefore THEY SHOULD NOT BE UNDERTAKEN. Here are the reasons:

1. If our Government DOES NOT yield to the pleas of stopping to tax the sick and does not remove the sales tax, it may find itself in an embarrassing position politically. It may easily become the butt of the frequently vile political criticisms, which it should avoid as much as possible;

2. If our Government DOES remove the sales tax on pharmaceuticals, in the belief that the savings would be passed on to the consumer, it may soon discover to its dismay that the manufacturers HAD NOT PASSED on the savings in their ENTIRETY, but only PARTIALLY, and all the consumer would save would amount to only 2-3¢ on the dollar.

They would quickly learn that the manufacturers would find many excuses for not passing on the sales tax reduction completely. Precisely this has happened already twice when the sales tax has been increased from 10 to 11% and from 11 to 12%—however the manufacturers increased their prices, not by one percent, but at least by 5-10%. The 1% increase in the Sales Tax TRIGGERED off a chain reaction, although previously the price structure was in balance. Increasing internal costs were then compensated by greater operating efficiencies within the business enterprise.

Our Government—and the Special Committee—has no reason to believe that this same chain reaction would not repeat itself, if and when the sales tax would be abolished, since HUMAN NATURE HAS NOT CHANGED SIGNIFICANTLY in the past three years, and we have grave doubts that it will in the next three years. Matters can also be aggravated by the fact that our Government has no legal control whatsoever over the drug firms, as to whether or not they pass on to the consumer the sales tax savings in their ENTIRETY. Our Government may discover to their disappointment that the entire drug cost savings plan on taxes BACK-FIRED, since the actual savings DWINDLED TO LITTLE and a formerly well-intentioned recommendation brought disillusion and bitterness in practice. Our Government now has given up some 19 million dollars in taxes, however the consumer received only pennies. Now he feels resentment against the shortsighted policies of our Government.

III. *An alternative (Third) course of handling sales tax on pharmaceuticals*

It is the opinion of C.D.M. that our Government should undertake a THIRD COURSE OF ACTION in dealing with the sales tax on pharmaceuticals.

Before this course would be discussed in detail, let us quickly review the implication of sales tax at the three levels of distribution, if the sales tax is retained under Medicare.

1. *Sales Tax at Manufacturers' Level*

This amounted to a total of 19 million dollars in 1965, or about 7% based on Sales. (Taxes are paid on the lowest level at which sales are made, provided at least 15% of customers purchase at that price—therefore tax remittances across-the-board are about 3-4% less than the maximum sales tax percentage. That is 11%—7%, or 12%—8%.) This means about 3.5¢ for each consumer dollar.

The abolishing of the Sales Tax is further complicated by the SIMPLE MECHANICS of its application. Our understanding is that only the prescription pharmaceuticals would be exempt from the tax, however, over-the-counter pharmaceuticals are still taxable (and also not covered by Medicare). Now, if a pharmaceutical company sells vitamins or antacid tablets, or any other medica-

tion over-the-counter, this is taxable. However, IDENTICAL medication could also be sold under prescription. Thus, a fairly large number of medications overlap in their classification and consequently our Sales Tax Auditors will spend a fair amount of time in deciding which medication belongs in what classification and should it be taxable or not.

2. Sales Tax at Wholesalers' Level

This amounts to about ½¢ for each consumer dollar, certainly a small amount at this level. The wholesalers are, however, extremely concerned about the abolishing of sales tax, since this would reduce their sales volume on pharmaceuticals by about 8% with a corresponding decrease in revenues, without any change in their overhead. In short, it may wipe out completely their own very small profits and would make their operation very difficult indeed. Soon this group would knock on the doors of our Government for subsidy in order to SURVIVE. In other words, the Government, in trying to solve the problem of lowering drug costs to the consumer, had just created another problem. The Government now has to go to the consumer and take back from him the savings on the sales tax, in order to keep the wholesalers alive with a subsidy. For the above reason the wholesalers are quite concerned to maintain the status quo with regard to sales tax on drugs.

3. Sales Tax at Retail Pharmacists' Level

Surprisingly, the Canadian Pharmaceutical Association advocates the removal of the sales tax, although they should have the least reason to do so, unless for other than humanitarian considerations. Besides, they should know better that the sales tax reduction will not be passed on in full to the consumer. We find it difficult to understand their attitude when they also request (with all justification) that all future payments on prescriptions to pharmacists be made on COST PLUS DISPENSING FEE basis. This method of remuneration is already practiced by many pharmacists. This being the case, Federal Sales Tax is NOT a factor in establishing the professional fee and under Medicare, at pharmacists' level, it does not exist.

We are therefore talking about a maximum of 3-3½¢ savings to the consumer for each prescription dollar, or about 10¢ per prescription (about $3.35 being the average Rx price in Canada today), should the sales tax on drugs be removed. The Hon. Mr. Sharp justly wonders will this REALLY BE PASSED ON TO THE CONSUMER FULLY, for if not, because he gets only 1-2¢ per consumer dollar or about 3-4¢ per Rx, then the ENTIRE TAX SAVING PROPOSITION ASSUMES A COMPLETELY DIFFERENT PROPORTION AND DIMENSION.

This being the case, we STRONGLY FEEL that our Government should take a third course in handling this matter. It is our opinion that if our Government cannot be certain about the outcome of eliminating the sales tax on drugs, it should *NOT ELIMINATE IT,* but *RETAIN* it, and *INSTEAD* embark upon a course of action about which it can be more CERTAIN AS TO ITS OUTCOME. This course of action would be the RAISING OF THE STANDARD OF OUR NATIONS' HEALTH by adopting definite measures, as described below.

IV. *National Health Fund and the setting up of a new Government Agency or an independent non-profit organization*

We suggest that our Government transfer the entire tax collected on drugs to a special fund, which can be called "THE NATIONAL HEALTH FUND" and distribute it at various levels to different groups, each contributing individually and collectively to a marked betterment in our nations health, according to a well-planned programme.

Simultaneously, a new Government Health Agency or an Independent Non-Profit Organization should be created—which would be different in scope and operation from the Food & Drug Directorate—and it would be dedicated to RAISE THE HEALTH STANDARDS OF THE CANADIAN PEOPLE.

Pherhaps the agency handling the National Health Fund could be compared to the CANADA COUNCIL, which promotes art in our nation, whereas this agency with the National Health Fund would raise the standards of our Nations' Health noticeably.

V. *The beneficiaries of this Health Fund*

The groups should be as follows:

(a) Public

(b) Pharmaceutical Industry

(c) Physicians

(d) Government Agencies on Health

(e) Research Centres

Let us now consider each level of assistance separately.

(a) *Aid to public*

We would envision the establishment of a Drug Research Institute, which body would assure that our nations' health is continually increasing. This Institute has been described in detail by Dr. Wright in his earlier Submission to the Special Committee on November 8th. (For details see Appendix I).

We would like to see the establishment of a FORUM or BOARD to which the various societies representing the chronically ill people, such as the Cystic Fibrosis Society, Arthritic and Rheumatic Society, Heart Group, Cancer Group, and so on, could turn to for financial and other assistance.

The Drug Research Institute would also disseminate OBJECTIVE and IMPARTIAL information to all physicians and thereby assure the use of MORE EFFECTIVE MEDICATIONS to the patients. This alone should substantially raise the health of our nation.

The MARKETING COSTS and EXTRAVAGANCES by some manufacturers could be reduced by providing more reliable and accurate information to physicians by this Institute. Undoubtedly, pharmaceutical manufacturers always have to incur marketing costs and undertake promotional activities, however, now, because of the regular and reliable medical data releases by the Drug Research Institute, they can afford to spend less.

Drug Research Institute would continually look for ways and means to find efficiencies in pharmaceutical manufacturing, marketing, research, quality control and thereby help the manufacturers to reduce the cost of drugs.

Therefore, this entire program would have a drug-cost reducing effect in several areas of our drug cost structure, and the savings could be passed on to the consumer, coming from other levels than the sales tax.

(b) *Aid to Industry*

Of course, the pharmaceutical industry would also greatly benefit by having a competent and well-staffed Drug Research Institute available at their service, just as the industry at large makes a good use of the Ontario Research Foundation today. Now the members of P.M.A.C., C.D.M., A.F.Q.P.P. or other drug manufacturers groups, could turn to this group to get assistance to solve their pharmaceutical problems, in the field of pre-clinical and clinical drug testing, drug safety and other evaluations—manufacturing, production, analytical and control problems.

The Drug Research Institute would also carry a very extensive technical library, which would be made available to the industry, together with a vast amount of technical information which the drug industry collects from all the major research centres and governmental agencies throughout the world. No single company alone would be capable of acquiring and storing this wealth of information which, in due time, could be gathered by this non-profit organization.

(c) *Aid to Physicians*

The physicians would be particularly thankful for having the Drug Research Institute, since it would keep them abreast on the medical advances—treatments and drugs alike—in an OBJECTIVE and AUTHORITATIVE MANNER. The perennial complaint of physicians has been to find sufficient time for reading medical literature on the latest medical advances, while attending to the care of their patients and maintaining their very busy practices. Now the Drug Research Institute would send out to all physicians free of charge, a reliable Drug Index, describing objectively the new drugs. Of course, physicians could be solicited for some contribution towards the cost of this book.

Now physicians are helped to evaluate better the use and application of modern potent medications and avoid the so-called "Therepeutic Nightmare".

Physicians could also write to the Drug Research Institute for detailed information on the side effects, contraindications, idiosyncrasies of medicines and discuss some of their professional problems.

(d) *Aid to Government Health Agencies*

It is quite conceivable that one of the beneficiaries of this Institute would be our own Food & Drug Directorate, which body is already expanding at a very rapid rate and may require the establishment of other agencies which would supplement its work. Besides, most of the drug records collected by the Food & Drug Directorate cannot be made available to the public, whereas records of the Drug Research Institute would be always available to all interested parties.

(e) *Aid to Research Centres*

Research Centres would also benefit from the Drug Research Institute, for more research scientists would be kept at home and our Universities would find an excellent training ground for their recent graduates. Eventually, internationally-known scientists would become attracted to the Drug Research Institute on a loan basis, and important scientific papers would be published.

The Drug Research Institute would also request voluntary submission on the pharmaceutical and medical research projects undertaken in Canada by the various research centres and universities and it could thereby coordinate developmental research in Canada and avoid duplication of efforts and expense.

The Drug Research Institute could also assist projects undertaken by the various Research Centres and Universities which, for some reason or other, could not be completed.

Similarly, if a new drug has been discovered by the Research Centre (or other government agency) the Drug Research Institute could make it available to the industry by working out suitable arrangements with one or several manufacturers.

Of course the measures outlined above are by no means complete, invariably the scope and the activities of this National Health Fund and Drug Research Institute would expand in time.

Should the Special Committee on Drug Costs & Prices tell the public that the removal of the Sales Tax would be a DUBIOUS WAY of lowering drug costs effectively and therefore, instead, they propose MORE EFFECTIVE AND MEASURABLE means to upgrade our nation's health, the public would likely accept their explanation with satisfaction. After all, the lowering of drug costs means the lowering of the EXTRAVAGANT, UNNECESSARY and UNJUSTIFIED COSTS, but certainly NOT COSTS PER SE.

VI. *Conclusion*

IT IS OUR BASIC CONTENTION THAT OUR CANADIAN PUBLIC VALUES ITS HEALTH GREATLY AND IS QUITE WILLING TO SPEND MORE WISELY THE FEW CENTS OF POSSIBLE SAVINGS PER PRESCRIPTION—OBTAINED BY REMOVAL OF THE SALES TAX ON DRUGS—IN GAINING AN ENLIGHTENED AND INTELLIGENT PROGRAM, WHICH WOULD RAISE ITS HEALTH STANDARDS SIGNIFICANTLY.

If the above arguments make sense to our Government and to the Special Committee on Drug Costs and Prices, then the sales tax on pharmaceuticals should not be removed but maintained, for it can be channelled towards the raising of our nation's health, as outlined in our Presentation.

APPENDIX I

DRUG INSTITUTE FOR CANADA

The Drug Institute for Canada is an original idea of Dr. George F. Wright, Professor of Chemistry at the University of Toronto, also technical consultant to C.D.M. He introduced this idea before the Special Committee on Drug Costs and Prices first on July 7, 1966 and discussed it briefly on November 8, 1966.

According to him, the Drug Institute for Canada would be made up of the FOUR SCIENCE PROFESSIONS, such as MEDICINE, PHARMACY, PHARMACOLOGY and CHEMISTRY. The objectives of this institute should be:

1. To examine the areas of therapy in which new drugs may or may not be needed
2. To regulate some preclinical and all clincial trials of a new drug
3. To solicit, receive and correlate all reports of side effects, contraindications 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.

The idea of the Drug Institute for Canada fits well into our CONCEPT which recommends setting up a NEW GOVERNMENT AGENCY, or alternately an INDEPENDENT NON-PROFIT RESEARCH ORGANIZATION, similar to the National Research Council.

Our concept goes BEYOND THE SCOPE of a Drug Institute. We envision, in addition, well-programmed activities to RAISE THE HEALTH STANDARDS IN CANADA, offering assistance at different levels, such as to the Public, to the Industry, to the Government Health Agencies, to the Physicians and to Research Centres. This new agency would continually communicate to these levels in an objective and authoritative manner and its store house of information and its research facilities are available to anybody. It would therefore operate in a different sphere than the Food and Drug Directorate, although it would COMPLEMENT its activities.

The Food & Drug Directorate is designed to PROTECT the PUBLIC in Health Matters, and it passes Laws to ASSURE SAFETY in medications and related matters. Its records are generally confidential, and the F.D.D. is unable to "approve or disapprove" officially medications, or carry out studies on behalf of private firms, because of its non-committal and regulatory nature. Nor can it assist companies or individuals in providing better medications or offer improved health standards. It can merely OBJECT to certain medications once they come to its attention and they find them to be unsatisfactory.

APPENDIX II

THE IMPACT OF SALES TAX AT THE THREE LEVELS OF DISTRIBUTION

(a) MANUFACTURERS' LEVEL

Medication "X"

Suggested Retail Price	1.00
less 40% (Retailers markup)	.40
Retailer's Cost	.60
less 16⅔% (Wholesalers markup)	.10
Wholesaler's Cost	.50
less 12% Sales Tax	5.5

But Manufacturers do not pay Sales Tax at the HIGHEST Level, but at the LOWEST DISTRIBUTORS SALES PRICE; therefor TAX ACTUALLY REMITTED IS NOT 12% but about 8% or 3.7 ¢ per Sales Tax Dollar.

If ALL Manufacturers would remit the Sales Tax COMPLETELY the saving would be about 3.7¢ per dollar at Manufacturers Level or about 11¢ per average Rx in Canada (about $3.35)

If Manufacturers REMIT SALES TAX ONLY PARTIALLY—assuming only ½ of the tax would be passed on to the consumer—then the saving would be about a nickel per Rx filled.

IS IT WORTH IT TO THE PUBLIC TO HAVE HIGHER HEALTH STANDARDS FOR A NICKEL PER Rx?

(b) WHOLESALERS' LEVEL

Wholesalers Selling Price of Medication to Retailer if Sales Tax RETAINED		Wholesalers Selling Price of Medication if Sales Tax ABOLISHED i.e. now medication costs him 3.7¢ less or 46.3¢	
Price to Retailer	.60¢	Price to Retailer	55.5¢
less 16⅔% (wholesalers mark-up)	.10¢	less 16⅔% (wholesalers mark-up)	9.2¢
Cost of Medication to Wholesaler	.50¢	Cost of Medication to Wholesaler	46.3¢

Now the Gross Margin of the Wholesaler dropped about 8% without a corresponding decrease in operating costs.

OR

Assuming that the Wholesalers volume is 60 million dollars per year, which represents about 20 million dollars in pharmaceuticals:

Sales	20 million $
less 16⅔% Markup	$3,333,000.
8% Loss in Markup therefore represents about	$ 260,000.

which is slightly less than THEIR ENTIRE NET PROFIT PER ANNUM.

How will the Wholesaler generate funds for normal expansions and satisfy their shareholders if he loses this REVENUE?

Therefore, wholesalers desparately need the monies they derive due to the presence of sales tax incorporated in our price structure.

(c) AT RETAIL PHARMACISTS' LEVEL

Since Pharmacists advocate under Medicare as their method of remuneration—Cost plus Professional Dispensing Fee—Sales Tax SAVINGS AT THEIR LEVEL IS NON-EXISTENT, therefore Meaningless.

APPENDIX "B"

SUMMARY OF DATA ON DRUGS, FOOD AND DRUG DIRECTORATE

During the hearings of the Committee numerous statements have been made about the quality of drugs sold under a generic name as compared to brand-name drugs, questions have been asked about imported drugs and the hazards to health of certain lots of drugs were cited. Furthermore the Food and Drug Directorate has been accused of remaining silent on drug quality or at best tending "to generalize and thus confuse further an already confused situation".

In view of the questions raised and with a sincere desire to clarify the picture as far as possible, I asked the officers of the Directorate to collate all the data which might have a bearing on this situation. They have provided me with the following information which I should be pleased to table.

(a) APPENDIX I—*Comparative Survey of Quality of Brand Name and Generic Drugs, Domestic and Imported, 1965.*

As the cover sheet on Appendix I indicates these data were compiled from the reports of the examination of 973 drugs selected by categories to permit a comparison between approximately equal numbers of products of each category containing the same active ingredient. The data include results of laboratory analyses only. The "generic" drugs are those which were sold under a generic name while the labels of the "brand-name" drugs carried, as you might anticipate, a brand name. This method of labelling does not necessarily bear any relationship to the size of the firm. The results indicate that of all samples, 10.4 per cent were unsatisfactory.

The comparison of brand name vs. generic and domestic vs. imported is as follows:

	% Unsatisfactory
Domestic	10.1
Imported	12.5
Brand Name	8.6
Generic	11.8

On the basis of these data, one would be justified in concluding that there is no significant difference between the four categories.

Figures for all drug samples analyzed during 1965 are as follows:

	Total	% Unsatisfactory
Drugs	1817	13.3
Vitamin Preparations	916	25.3
Total	2733	17.3

(b) APPENDIX II—*Drugs Analyzed for Department of Veterans Affairs, 1965 and 1966.*

These data were obtained on 72 samples of drugs analyzed in 1965 and to September, 1966 in the laboratories of the Directorate at the request of the

Department of Veterans Affairs. One sample only was found to be unsatisfactory, a lot of chlorpromazine hydrochloride tablets manufactured by Bell-Craig Pharmaceuticals, Toronto. The tablets were found to contain from 109.1 to 113.5 per cent of the declared amount of chlorpromazine hydrochloride. This lot was returned to the firm and placed under seizure by the Directorate.

As you will note most of these lots were produced by the so-called "generic drug" firms.

(c) APPENDIX III—*Drug Recalls Involving Food and Drug Directorate, June 1965 to January 1967.*

These recalls involved 35 products manufactured by 31 firms. They were instituted by both large and small firms. Other recalls undoubtedly were made during this period without the knowledge of the Directorate.

(d) APPENDIX IV—*Convictions Registered Against Drug Manufacturers, 1963 to 1966.*

It should be noted that these convictions included many cases of vitamin and mineral preparations which were low in potency or had excessive disintegration times. A number of firms were prosecuted for advertising their products for Schedule A diseases. Only two cases could be considered to constitute a significant hazard to health.

(e) APPENDIX V—*Instances of a Significant Hazard to Health Involving Pharmaceutical Products, 1959 to 1966.*

Our records have been reviewed to determine those instances over the past seven years in which pharmaceutical products presented a significant hazard to health and could be considered to be in violation of the Food and Drugs Act or Regulations. Only five such cases were found. These are described in Appendix V.

The following conclusions can be drawn from the data shown in Appendices I to V.

(i) There does not appear to be any significant difference between drugs sold under a generic name and those sold under a brand name. Similarly imported drugs appeared to be of the same general quality as domestic production.

(ii) The instances of a significant hazard to health involving the quality of pharmaceutical products is relatively rare in Canada, a total of five over a period of seven years.

APPENDIX I to Summary

Comparative Survey of Quality of Brand Name and Generic Drugs, Domestic and Imported, 1965.

The data in the attached table was compiled from our examination of reports on 973 brand name and generic drugs. These were selected to permit a comparison between approximately equal numbers of products in each group containing the same active ingredient. The data includes the results of laboratory examination only.

Comparative Survey of Quality of Brand Name and Generic Drugs, Domestic and Imported, 1965.

	Domestic			Imported		
	Total Samples	Unsat.	% Unsat.	Total Samples	Unsat.	% Unsat.
Brand Name	459	37	8.1	49	9	18.4
Generic	426	53	12.4	39	2	5.1
Total Samples—Brand Name and Generic	885	90	10.1	88	11	12.5
	Total	Unsat.	% Unsat.			
All Samples	973	101	10.4			

APPENDIX II to Summary

DRUGS ANALYSED FOR DEPARTMENT OF VETERANS AFFAIRS

	Product	Lot No.	Manufacturer	Satisfactory	Unsatisfactory
February 1965	Cortisone Acetate Tablets U.S.P. 25 mg...	40582	Bell-Craig Pharmaceuticals, Toronto.....		X
"	Cyanocobalamin Injection U.S.P. 1000 μg per cc.....	16208	Bell-Craig Pharmaceuticals, Toronto		X
"	C. T. Hydrochlorothiazide 50 mg.....	40547	"		X
"	Meprobamate Tablets U.S.P. 400 mg.....	40572	"		X
"	Meprobamate Tablets U.S.P. 400 mg.....	40573	"		X
"	Pentabaribtal Sodium Capsules U.S.P. 1½ grains.....	2538	"		X
"	Propantheline Bromide 15 mg.....	301	Paul Manoy Laboratories, Toronto		X
"	Nikethamide Injection BP.....	1429	Matthews & Wilson Limited, England		X
"	Injection of Cyanocobalamin B.P., Anhydrous Vitamin B_{12} 1000 μg per ml.....	1924	Matthews & Wilson Limited, England		X
"	C. T. Chlorpromazine HCl U.S.P. 100 mg.	287	Paul Maney Laboratories, Toronto		X
March 1965	Secobarbital Sodium Capsules 1½ grains....	2635	Bell-Craig Pharmaceuticals, Toronto		X
"	C. T. Chlorpromazine HCl U.S.P. 25 mg..	321	Paul Maney Laboratories, Toronto		X
"	C.C.T. Aminophylline Compound Tablets.	284	"		X
June 1965	Meprobamate Tablets U.S.P. 400 mg.....	5104	Bell-Craig Pharmaceuticals, Toronto		X
"	Meprobamate Tablets U.S.P. 400 mg.....	5072	"		X
July 1965	Pentobaribital Sodium Capsules 1½ grains..	5510	Bell-Craig Pharmaceuticals, Toronto		X
"	Ferrous Gluconate Tablets 5 grains.....	5114	"		X
"	Ferrous Gluconate Tablets 5 grains.....	5122–1	"		X
July 1965	C.T. Hydrochlorothiazide 50 mg.....	5118	Bell-Craig Pharmaceuticals, Toronto		X
"	C.T. Hydrochlorothiazide 25 mg.....	5123	"		X
"	C.C.T. Ephedrine Compound.....	5120–1	"		X
"	C.C.T. Ephedrine Compound.....	5120–2	"		X
"	Cortisone Acetate Tablets.....	5132	"		X
"	Chlorpromazine Tablets 100 mg.....	5003	Bell-Craig Pharmaceuticals, Toronto		X
"	C.T. Chlorpromazine 100 mg.....	5028	"		X
"	C.T. Chlorpromazine 25 mg.....	40367	"		X
"	C.T. Chlorpromazine 25 mg.....	40365	"		X
"	Propantheline Bromide Tablets 15 mg.....	423	Paul Maney Laboratories, Toronto		X
September 1965	C.T. Meprobamate 400 mg.....	5133	Bell-Craig Pharmaceuticals, Toronto		X
"	C.T. Meprobamate 400 mg.....	5070	"		X
"	C.T. Meprobamate 400 mg.....	5144	"		X
"	C.T. Meprobamate 400 mg.....	5134	"		X
"	C.T. Meprobamate 400 mg.....	5141	"		X
"	C.T. Hydrochlorothiazide 50 mg.....	5146	"		X
"	C.T. Calcium Gluconate 10 grains.....	5148	"		X
"	S.C.T. Phenylbutazone 100 mg.....	433	Paul Maney Laboratories, Toronto		X
October 1965	C.C.T. Aminophylline Compound.....	5147	Bell-Craig Pharmaceuticals, Toronto		X
"	C.C.T. Ephedrine Compound.....	5150	"		X
"	S.C.T. Probanthine 15 mg.....	466	Paul Maney Laboratories, Toronto		X

APPENDIX II to Summary (*concluded*)

Month	Product	Lot No.	Manufacturer	Satisfactory	Unsatisfactory
October 1965	Chloramphenicol Palmitate	01372	Lukas Pharmaceuticals, Toronto (Distributed by Unipharm Limited)	X	
"	Tetracycline HCl Capsules 250 mg	2008	Lukas Pharmaceuticals, Toronto (Distributed by Unipharm Limited)	X	
"	Tetracycline Oral Suspension 60 cc	141	Lukas Pharmaceuticals, Toronto	X	
December 1965	Tetracycline Suspension 60 ml (Decycline) 125 mg per 5 ml	291-H	Desbergers Limited, Montreal	X	
"	Chloramphenicol Capsules 250 mg	1758	Lukas Pharmaceuticals, Toronto	X	
"	Tetracycline Suspension 60 cc 125 mg per 5 cc	2034	Lukas Pharmaceuticals, Toronto	X	
"	Chloramphenicol Palmitate Oral Suspension, 60 cc, 125 mg per 4 cc	2010	Lukas Pharmaceuticals, Toronto	X	
January 1966	Tetracycline Capsules B.P. 250 mg	2014	Lukas Pharmaceuticals, Toronto	X	
"	Promazine Tablets B.P. 25 mg	3852	Noco Drugs Limited, Toronto	X	
"	Chlorpromazine HCl Tablets 25 mg	40365	Bell-Craig Pharmaceuticals, Toronto		X
"	C.T. Chlorpromazine 25 mg	40366	"	X	
"	C.T. Chlorpromazine 100 mg	5028	"	X	
"	C.T. Chlorpromazine 100 mg	5079	"	X	
"	Chlor-Propanyl Tablets 100 mg (Chlorpromazine HCl)	287	Paul Maney Laboratories, Toronto	X	
February 1966	Neomycin Sulphate Tablets U.S.P., 500 mg	891-JL	Empire Laboratories Limited, Toronto		
"	Propantheline Bromide Tablets U.S.P. 15 mg	546	Paul Maney Laboratories, Toronto	X	
March 1966	Meprobamate Tablets U.S.P. 400 mg	6010	Bell-Craig Pharmaceuticals, Toronto	X	
"	Meprobamate Tablets U.S.P. 400 mg	6011	"	X	
"	Tetracycline Capsules B.P. 250 mg	JL-215	Jules R. Gilbert Limited, Toronto	X	
"	Erythromycin Tablets B.P. 100 mg	220	"	X	
"	Hydrochlorothiazide Tablets B.P. 50 mg	105-KB	Desbergers Limited, Montreal	X	
"	Hydrocortisone Acetate Tablets 20 mg	40566	Bell-Craig Pharmaceuticals, Toronto	X	
May 1966	C.T. Chlorpromazine 100 mg	5198	Bell-Craig Pharmaceuticals, Toronto	X	
"	C.T. Chlorpromazine 100 mg	5290	"	X	
"	Phenylbutazone Tablets B.P. 100 mg	6060	"	X	
"	Phenylbutazone Tablets 100 mg	6029	"	X	
"	Cyanocobalamin Injection U.S.P., 5 cc, 1000 µg per cc	6806	Bell-Craig Pharmaceuticals, Toronto	X	
June 1966	Ephedrine Compound Tablets	6049	Bell-Craig Pharmaceuticals, Toronto	X	
"	Ephedrine Compound Tablets	6050	"	X	
"	Ephedrine Compound Tablets	6049/2	"	X	
"	Aminophylline Compound Tablets	6051	Bell-Craig Pharmaceuticals, Toronto	X	
September 1966	C.T. Prednisolone 5 mg	6184	Bell-Craig Pharmaceuticals, Toronto	X	
"	S.C.T. Promazine 50 mg	6187	"	X	

APPENDIX III to Summary

Drug Recalls Involving Food and Drug Directorate
June 1965 to January 1967.

Product	Company	Date	Reason
Muralin Suspension	Nadeau Ltd., Montreal	June, 1965	Low Potency
Cogentin	Merck Sharpe & Dohme, Montreal	July, 1965	Some Bottles Labelled Hydrodiuril
Enteric Coated A.S.A. Tablets	B.C. Stanley Drugs, Vancouver	October, 1965	Excessive Disintegration Time
Vitality V.P.	Vitality Products, Vancouver	October, 1965	Low Potency
Mineral Oil	Pharmo Products, Toronto	October, 1965	Contained Isopropyl Alcohol
Jintan Needles	Standard Surgical Supply, Calgary	January, 1966	Containers Did Not Maintain Needle Sterility
Tetracycline Capsules	Lucas Pharmaceuticals, Toronto	January, 1966	Contained Chloramphenicol
Soluspan Injection	Schering Corporation, Montreal	February, 1966	Ineffective Preservative
Ideal Syringes	J. F. Hartz Co., Toronto	April, 1966	Improperly Graduated
Neo Cholex	Bell Craig, Toronto	April, 1966	Adverse Reaction
Diphtheria Toxoid	Connaught Labs., Toronto	May, 1966	Possible Toxicity
Tolbutamide Suspension	Horner, F.W., Montreal	May, 1966	Now Drug
Germaform	J. F. Hartz, Toronto	June, 1966	Mislabelled
Protamine Sulfate Injection	Eli Lilly & Co., Toronto	June, 1966	Expiry Date Excessive
Ampicillin Biodiscs	British Drug Houses, Toronto	July, 1966	Potency in Excess of Label Claim
Carmine Red	Various Companies	September, 1966	Salmonella Contamination
Boplant	E. R. Squibb, Montreal	December, 1966	Adverse Reaction
Diethylstilbestrol Tablets	Alpha Drug, Montreal	"	Recalled by U.S. Supplier
Cobaltyl Ampoules Cobaltyl Tablets	Laboratoire Welcker, (Address)	"	(1) Evidence obtained that drug might not be safe under the conditions of use recommended.
Homavite Tablets Caley Compound	W. E. Saunders, London, Ont.	"	(1) "
Calvital	Laboratoires Marois, Montreal	"	(1) "
Neolil Suspension Vonacillin Solution	Stevenson Turner & Boyce, London, Ont.	"	Low Potency
Liver Extract Injectable	British Drug Houses, Toronto	"	Pyrogen Contaminated
Roncovite Tablets Roncovite MF	Hoescht, Montreal	"	(1) Evidence obtained that drug might not be safe under conditions of use recommended.
Chorionic Gonadotrophin Injectable	Norwich Pharmacal Co., Paris, Ont.	December, 1966	Possible Pyrogen Contamination
Catalyfer	J. M. Marsan, Montreal	"	(1) Evidence obtained that drug might not be safe under the conditions of use recommended.
Pepcoban Injection	E. L. Stickley, Hamilton	"	(1) "
Iros Tablets	Dymond Drugs, Brampton, Ont.	"	(1) "
Cobalt Iron	Barlowe-Cote, Quebec City	"	(1) "
Co-For	Lab Species, Trois Rivières	January, 1967	(1) "
Pentothal Sodium Suspension	Abbott Labs, Montreal	January, 1967	Did Not Deliver Effective Amount of Medication.

APPENDIX IV to Summary

CONVICTIONS REGISTERED AGAINST DRUG MANUFACTURERS, 1963 TO 1966.

Firm	Date	Product	Violation	Penalty
Gauls Herb House Fort William, Ont.	June/63	Herbal Remedies	Advertised as a treatment for Schedule A Diseases (Sec. 3)	Fine $350
Empire Laboratories, Toronto	April/64	Vitamin Drops	Low Potency (Sec. 10(3))	Fine $250
Barlow-Cote Cap-Rouge, Quebec	June/64	Triparnol and Trifluorpromazine	New Drugs (C.01.302)	Fine $50 plus 50 percent of cost
G.E.M. Drugs, Toronto	June/64	Vitamin Tablets	Low Potency (Sec. 9(1))	Fine $300
Charles C. Cummings, Toronto	Sept./64	Vitamin Tablets	Low Potency (Sec. 9(1))	Fine $200
Empire Laboratories, Toronto	Sept./64	Lobeline Sulphate Tablets	Exceeds Dosage Limits (Sec. 9(1))	Fine $100
Bell-Craig Ltd., Toronto	Oct./64	Ferrous Sulphate Tablets	Disintegration and High Potency (Sec. C.01.016 and Sec. 10(2))	Fine $75
Canada-Duphar, London, Ontario	Oct./64	Promazine Solution	Low Potency (Sec. 10(3))	Fine $200
Ultravite Laboratories Toronto	Oct./64	Vitamin Tablets	Low Potency (Sec. 9(1))	Fine $25
Canadian Nutritional Products, Toronto	Jan./65	Vitamin Tablets	Low Potency (Sec. 9(1))	Fine $300
G.E.M. Drugs, Ottawa	Feb./65	Vitamin Tablets	Low Potency (Sec. 10(3))	Fine $100
Metro Drug Ltd. Montreal	June/65	Minavite Tablets	Disintegration (Sec. D.01.015)	Fine $200
Sun-N-Health Products Montreal	Nov./65	Garlic Capsules	Advertised as a treatment for Schedule A diseases (Sec. 3)	Fine $150
Zirin Labs. Ltd., Montreal	Dec./65	Dymasol (Dimethyl Sulfoxide)	New Drug (Sec. C.08.002)	Fine $100
Sun-N-Health Products Montreal	Jan./66	Vitamin E Preparations	Advertised as a treatment for Schedule A Diseases (Sec. 3)	Fine $300
Penslar Co. Ltd., Windsor	Feb./66	Cold Tablets	Disintegration (C.01.015)	Fine $50
Stylecraft Products Ltd., Vancouver, B.C.	Feb./66	Phillips DMSO (Dimethyl Sulfoxide)	New Drug (C.08.002)	Fine $500
Charles E. Frosst, Montreal	May/66	Frosst "692" Tablets	Distributed as a sample (Sec. 14(1))	Fine $100
Lukas International (Canada) Ltd. Toronto	May/66	Chloramphenicol Capsules	Incorrectly Described Not tested for identity (Sec. 9(1) and C.01.051)	Fine $2,000
Metro Drug Ltd., Montreal	May/66	Stilbestrol Tablets Minavite Liquid	Manufactured under unsuitable conditions. (C.01.051)	Fine $300
Zirin Labs. Ltd., Montreal	June/66	Vee Pee Solvent (Dimethyl Sulfoxide) Diisopropylamine	New Drugs C.08.002	Fine $150
C. E. Jamieson & Co. (Canada) Ltd., Windsor	July/66	Vitamaster Twin Tablets	Disintegration and Low Potency (C.01.015 and 10(3))	Fine $75
B.M.C. Laboratories (Martin Van Ular) Montreal	Aug./66	Diazepam	New Drug (Sec. C.08.002)	Fine $500
Harry D. Reid Agencies Ltd., Toronto	Aug./66	Allimin Tablets	Disintegration & Not tested for identity (C.01.015 and C.01.051)	Fine $150
Jules R. Gilbert Ltd., Toronto	Nov./66	Diethylpropion Tablets	New Drug (Sec. C.08.002)	Fine $300

APPENDIX V to Summary

INSTANCES OF A SIGNIFICANT HAZARD TO HEALTH INVOLVING PHARMACEUTICAL PRODUCTS 1959 to 1966

(a) In the fall of 1959, Charles E. Frosst and Co., Montreal increased the size of their 50 mg. Dicumarol tablets (bishydroxycoumarin, an anticoagulant), in order to facilitate breaking the tablets in half to permit a dose of 25 mg. Between January and March, 1960, the firm received eleven complaints that the product was not as effective as in the previous dosage form. An investigation revealed that the reformulation of the tablet had decreased the availability of the therapeutic agent. Increased solubility was achieved by providing a finer dispersion of the ingredients. The offending lots were recalled by the company and physicians informed of the change. Since the firm had acted in a responsible manner and the improper formulation removed from the market no legal action was initiated by the Directorate.

(b) In July, 1963, a physician brought to our attention that a product labelled as Dicumarol (bishydroxycoumarin) manufactured by Empire Laboratories, Toronto, Ontario, was not giving the expected results on several of his patients. Laboratory examination revealed that the active ingredient was not as shown on the label but was 4-hydroxycoumarin. The firm was immediately contacted and it was learned that they had already initiated a recall of the lot since a routine analysis to determine stability had indicated low potency. They were unaware of the mislabelling at that time. When the recall had been completed 70,000 tablets were destroyed under Food and Drug Directorate supervision.

(c) During the summer of 1965 it was found that Stylecraft Products Ltd., Vancouver, British Columbia, were selling a solvent consisting of dimethylsulfoxide (DMSO) for therapeutic purposes. This chemical was a new drug according to the definition in the Food and Drug Regulations. This firm had not made a submission to the Directorate on this product. Therefore, the product was removed from the market by seizure action and the firm prosecuted. A fine of $500.00 was assessed by the Court.

(d) In March, 1966, an investigation by the Food and Drug Directorate revealed that capsules labelled as Tetracycline and sold by Lukas International (Canada) Ltd., Toronto, were chloramphenicol. Immediate recall action was initiated by the company at the instigation of the Directorate. Physicians and pharmacists who had received these mislabelled capsules were informed of the situation. It was found that the firm had not carried out the proper analytical controls on the product. Legal action was, therefore, initiated and the firm was fined $2,000.00.

(e) In June, 1966, it was found that J. F. Hartz Co. Ltd., Toronto, had mislabelled a strong germicide as a mild antiseptic. The product was immediately recalled from the market and the firm was sent a formal warning.

APPENDIX "C"

IN CONFIDENCE

SOME OBSERVATIONS ON DRUG CONTROL IN EUROPE

Introduction

During October and November, 1965, three members of the Directorate's staff visited phamaceutical companies, manufacturing associations and control agencies in Italy, Switzerland, Germany, France, the Netherlands, Belgium, England, Denmark and Sweden. The purpose of this mission was to learn about drug control as presently carried out in these countries. The following brief report covers a few observations on the present situation.

Special Situation in Canada with Respect to Drug Imports

We believe that Canada finds itself in a special situation with respect to control over drug imports. Unlike many European countries and, for that matter, also the United States, Canada imports both bulk drugs and pharmaceutical dosage forms from a far greater number of foreign suppliers. Our 1964 survey showed that during this year bulk drugs and formulated dosage forms from over 30 different countries and from more than 300 different sources came to this country from abroad. We manufacture only a minor fraction of the bulk drugs we consume.

Some General Comments on Drug Control in European Countries

In the European countries—excluding those within the communistic sphere of influence—most of the drugs used in a given country are manufactured in this country and controlled by governmental agencies in this country. Whatever drugs are imported—and some countries actively discourage the importation of pharmaceutical dosage forms—will be subject to quality control as well.

The frequency and thoroughness of these controls vary. In some countries they appear to be quite good while in others much room is left for improvement. On the whole, it is our impression that drug control in Europe is improving. In most countries drug registration has been in effect for some years and has resulted in reducing the number of pharmaceutical specialties on the market considerably. Detailed compositional data (active and inactive ingredients), analytical methodologies and their experimental verification in government laboratories, are integral parts of the registration of drug products.

In Belgium, Holland, Denmark and Sweden, effective drug control is to some extent, at least, due to the strength and status of the profession of pharmacy. In these countries strong pharmaceutical associations are powerful competitors of the pharmaceutical industries. Both small and large pharmacies produce—individually and collectively—all types of products, including parenterals, suppositories, pills, tablets, capsules, etc. Special fees and a certain percentage of their sales are used to support a central laboratory for the analysis and certification of both raw materials (bulk drugs) and pharmaceutical dosage forms.

In Canada, very few medicaments are compounded by pharmacists on any appreciable scale, and neither the beneficial nor adverse effects of this special

pharmacy-pharmaceutical industry relationship need concern us. Yet we should note there are some who believe it does contribute to high standards of drug quality and to lower drug prices as well prevailing in these countries.

Pharmaceutical Manufacturers' Associations

In most of the European countries there are well organized and influential manufacturing associations. In a few countries they represent the larger drug manufacturers, while in others they represent the whole industry. The relationship between the Health Ministries and these associations appears to vary in different countries. In some, it is a particularly close relationship but, in others, they appear to carry out their respective activities independently of one another.

Practically all European drug manufacturers' associations are in favour of drug patents. We believe it can be said that they all are well aware of recent trends to stricter drug laws in all countries, particularly in the areas of new drugs, inspection and quality control.

In a few countries, they had been particularly active in trying to improve manufacturing facilities and controls in the industry.

Investigational Drugs

Of special interest to us was the finding that no country in Europe has legislation to control the use of investigational drugs. In the United Kingdom, investigational drugs are handled in a manner similar to that of the F.D.D. The Medical Assessor for the Committee on Drug Safety, feels that there is considerable merit in requiring prior review of the data before permitting the drug to be used in clinical investigation.

Reporting of Adverse Drug Reactions

There are only two countries in Europe who are attempting to carry out WHO's request to compile and report adverse drug reactions to WHO. The United Kingdom is the only country who has set up a workable system to collect and compile adverse drug reactions; a start has also been made in Germany. Other countries are thinking seriously of ways and means to set up a system but, to-date, have made very little progress.

Withdrawals of Drugs

Estimates given regarding the frequency of withdrawals of drugs from the market because of discrepancies between composition and label claims, ranged from about 5-8%. Such recalls are made known to the professions and we learned that companies both small and large have been so implicated.

Fees for Registration in Sweden

There are several other legislative measures available in these countries preventing the accumulation of drugs from getting out of hand. Thus, drug registration is not free. A manufacturer or distributor pays a fee for each pharmaceutical dosage form he wishes to market and for annual renewals. Applications for drug registration are reviewed very critically in every respect, including chemical, pharmacological, toxicological and clinical evidence for safety and efficacy, and a fee is charged even for an application that is rejected.

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Drug Combinations and Analytical Methods

Preparations based merely on different combinations of known ingredients are generally frowned upon, and products purported to contain active drug complexes or associations are accepted in some countries only if it is demonstrated that the clinical and therapeutic efficacy of such products is superior to that of their individual constituents. It should also be noted in this connection that only drugs meeting the requirements of the law and demonstrated to be safe and effective for the purposes claimed come within the jurisdiction of prevailing social security or national health insurance schemes. As already indicated, analytical methods for each product is a pre-requisite for registration, and such methodologies are not only reviewed but experimentally tested—and often improved—in the government control laboratories.

Registration and Analytical Control

Particularly effective integration of registration and laboratory control appears to have been achieved in some countries. The composition, including both active and inactive ingredients, of all products marketed are filed systematically, and cross-references permit their technical staff to locate quickly all preparations containing a given active ingredient. Thus, the composition of and methodologies for related products can be conveniently ascertained.

Registration and Inspection

In most of the European countries, registration of a product also means inspection of the manufacturer's premises to determine that the product to be registered can be made in accordance with good manufacturing practices. In fact, income from drug registration constitutes for some of these countries an important budgetary aspect in the operation of their national drug control laboratories.

The Common Market and Drug Legislation

Economic co-ordination of the European Common Market countries has, by now, affected quite markedly the policies of European pharmaceutical industries. ECM-committees are at work harmonizing the multitude of regulations which now exist with regard to drug registration and trade practices. Although there are some who believe that on certain issues agreement will be most difficult to reach, e.g., requirements for new drugs, definition of experts and standardization of pharmaceutical education, all common market countries are committed to adopt essentially uniform legislation on drug registration by 1968. This means that by then free movement of drugs should begin within these important trading areas.

Collaboration Within Common Market Countries

The close collaboration of the common market countries in many spheres of activity has also led, generally, to greater interest in drug plant inspection and pharmaceutical quality control.

Inspectors in European Countries

In Germany, as well as the Benelux countries, France, Denmark and Sweden, there is a small corps of qualified inspectors operating. Although it is

apparent that they do not carry out inspections in the same manner we do, their scrutiny of manufacturing facilities and controls is a pre-requisite to registration.

Inspection by Foreign Inspectors

Most European countries, including the United Kingdom, are not in favour of inspections by foreign governments. They would like to see all countries accept each other's inspections. This should be the goal to strive for, but it will be some time before we can be assured that inspections do mean the same thing for all countries.

Inspection Guide

We were unable to obtain an Inspection Guide similar to our own in any of the countries we visited. In France, such a guide was being prepared and was to be ready for distribution last year.

In Sweden, drug plant inspection began in 1964 and a Swedish inspector is to go to other European countries for further training. It was gratifying to learn that our Inspection Guide and personal discussions of Dr. C A. Morrell, former Director of the Food and Drug Directorate, with Dr. Hans Hellberg, Director, State Pharmaceutical Laboratory, Stockholm, were instrumental in initiating this programme. The Senior Dutch inspector, and also a Senior Swiss official, visited our laboratories last year to learn more about our inspection procedures and to study drug control in Canada.

Preparation of the European Pharmacopoeia.

It should be pointed out that the common policies being pursued in Europe with regard to drug trading, are also accompanied by common patterns in drug standardization. Considerable work is being done in the Common Market countries as well as in England and Switzerland on the compilation of the European Pharmacopoeia. A number of committees have been set up and are functioning. Their major objective is the establishment of more sensitive and selective techniques of analyses and specifications for drugs marketed within these important trading blocks. A British scientist, Mr. H. Grainger, whose headquarters are located at Strassbourg, is directing this project. About 100 monographs for drugs have been agreed to.

Nordic Pharmacopoeia

Further to the north, five other countries—Denmark, Sweden, Norway, Finland and Iceland, issued recently the so-called Nordic Pharmacopoeia and thus extended their traditionally close relationships in social and cultural affairs to problems concerning drug legislation, quality control and trade. A visit to the Danish Pharmacopoeia Laboratory (Director, Dr. K. Ilver) showed what tremendous an amount of planning and effort was expended to produce this reference text of 4 volumes published in the Danish, Finnish, Norwegian and Swedish language. It is an excellent piece of work kept up-to-date by means of addenda in loose-leaf form. Three chemists assist Dr. Ilver in this continuing project. In addition to the development of pharmacopoeial standards these people are also trying to establish tests and specifications for medical supplies, such as plastic bones, sterile cotton, syringes, surgical dressings, catgut, medicine droppers, etc.

Products meeting official requirements and referred to as Medicine Utensilia will then be recognized by their MEDU-label.

Drug Control in the United Kingdom

Drug Control in the United Kingdom is quite different from that exercised in other European countries. It is based on a number of different Acts, but control over manufacturing facilities and analytical procedures is carried out only to regulate the marketing of medicinals sold under the Therapeutic Substances Act (Licenced Drugs) and of new drugs approved by the Dunlop Committee. Of all the European Free Trade Association (EFTA) countries, the United Kingdom is now the only one that does not require registration of pharmaceutical specialties.

Proposed Changes in Drug Laws in the United Kingdon

An intensive study has been conducted in the United Kingdom for the past four years on their existing drug laws and determined efforts are being made to bring them more in line with those of other countries of the world. There has been public demand for an independent assessment of the safety of all drugs placed on the market (both home-produced and imported) and also for an assurance of the purity of these drugs. Fundamental points in the proposed scheme are that all medicinal products supplied to the public should be subject to scrutiny. In addition to the sampling and testing of drugs, provision should be made for registration of drugs, inspecting and licencing of premises in which drugs are manufactured, compounded or stored, and that all imported drugs should also be controlled. The establishment of a Licencing Authority to co-ordinate the work of a central laboratory and subsidiary regional laboratories, as well as to oversee all the operations, is envisaged.

Need for Stricter Control of Bulk Drugs

To appreciate the trend toward stricter bulk drug control, one must realize that it is difficult to assign with certainty the source of an impurity to a particular compound in a complex pharmaceutical formulation. Whereas an impurity in a bulk drug may often be recognized with ease by an experienced chemist, its detection in a formulated product can be a major analytical task. Massive quantities of bulk drugs made in different countries and often produced by different methods of synthesis are coming into our country and it is essential that they be thoroughly tested for identity and purity.

Limitations of Existing Pharmacopoeial Standards

There is at present concern amongst analytical chemists that even pharmacopoeial standards cannot always be relied upon to guarantee that a product is free from impurities which may be toxic. Admittedly, conventional specifications are inadequate to characterize fully the potent and complex drugs now being produced. Isomeric configurations, for example, are not always distinguished on the basis of classical tests. Frequently, compounds closely related in structure to the parent drug are simultaneously produced during synthesis with the result that small amounts of impurities, which may be toxic, contaminate the final product and escape detection by accepted assay methods. Progressive drug firms are making use of more refined techniques over and above those recom-

mended by pharmacopoeial standards, in order to detect impurities in products they manufacture or buy elsewhere. The B.P. Commission, aware of the problem on the basis of pertinent and authenticated case reports in recent years, is now also taking a close look at their monographs from this point of view. The analyst must now not only think in terms of estimating the content of pure substance but also in terms of tests to limit the content of impurities. Recently, the British General Medical Council and the Pharmaceutical Society formed a joint committee to collect Chemical Reference Substances for such studies, and pertinent data for a number of pharmaceuticals were received.

We found through our visits that some of the companies exporting drugs to Canada would not meet our requirements. Yet, there were others far superior to many of our own. Thus, both reliable as well as sub-standard pharmaceutical manufacturers export products to this country. Our regulations require that such drugs and pharmaceutical dosage forms be tested for identity, purity and potency either abroad or in Canada and if such testing is done solely abroad, test for identity must still be performed in Canada.

Certificates of Analysis

Continued vigilance by the Food and Drug Directorate in the area of drug importation is imperative, for we found that there are many European companies who do not have proper production facilities and, applying merely patent specifications, fail to achieve the same accuracy and precision of analytical quality control as the original manufacturer.

Drug Exports

There exists a distinct lack of control of drugs destined for export. Governments feel that the quality control of drugs is primarily a national responsibility. Some are prepared to provide certificates similar to our own, i.e., documents which confirm that a given product is marketed in their country but are devoid of any reference to the potency, safety and quality of any particular batch. Only the Danish government, we learned, is prepared to issue certificates of analysis for specific lots of registered drugs if requested to do so by foreign governments.

Some Additional Observations

This report is but a brief account of general impressions and observations. It should be pointed out that Canada's industrial accomplishments and the Directorate's efforts, as a drug control agency, are well known in Europe. Many of the manufacturers we interviewed employ foreign relations experts who are thoroughly familiar with our legislation. Our Food and Drugs Act and our Trade Information Letters are studied, and our scientific contributions in the field of drug methodology are appreciated beyond the borders of our country. It was gratifying to see and hear all this first-hand for we felt that what we saw and heard was genuine.

M. G. Allmark
L. Levi
R. Ferrier

Ottawa
January, 1967

APPENDIX "D"

EXAMINATION OF TRIFLUOPERAZINE TABLETS MARKETED IN CANADA

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Ottawa—Canada.

Purpose of Investigation

This study was undertaken following submission of a Brief to the Special Committee on Drug Costs and Prices of the House of Commons by Smith, Kline & French/Montreal, in which products of different companies were compared as to cost and quality.* Its purpose was to determine the degree of physicochemical equivalency existing between dosage forms of corresponding label claims and to assess the extent of pharmaceutical quality control exercised by different manufacturers in the formulation of these preparations.

Scope of Investigation

At present four pharmaceutical companies manufacture Trifluoperazine Tablets B.P., each marketing their products under a brand name as shown in the following tabulation.

Company	*Trade Name*
Smith, Kline & French	Stelazine
Mowatt & Moore	Clinazine
Paul Maney Laboratories	Triflurin
Jules R. Gilbert	Triperazine.

Sixteen official samples representing all dosage levels currently produced by these manufacturers were obtained and analyzed in the Pharmaceutical Chemistry Division of the Food and Drug Directorate for drug content and content uniformity. Seven unofficial samples (specimens) were examined likewise, and tests for disintegration time carried out using one sample from each manufacturer.

Methods

1. *Assay for Trifluoperazine Content (1)*

Twenty tablets were taken at random from a bottle of 100, weighed accurately and analyzed as described in the British Pharmacopoeia (1).

2. *Determination of Content Uniformity (2,3)***

The test which demonstrates the extent of potency variation existing between individual tablets of a given lot or sample was carried out as follows.

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*Minutes of Proceedings and Evidence, No. 13, Thursday, October 27, 1966; pp. 939-969.

**Content uniformity tests are specified for a restricted number of pharmaceutical dosage forms in the U.S.P. and N.F. Trifluoperazine is not included in these compendia.

After performance of the assay for trifluoperazine content each of the eighty tablets which remained from a given lot was weighed individually. Three groups of tablets were selected containing the lightest, medium weight and heaviest tablets, respectively. Six tablets of practically identical weight from each of these groups were then assayed individually for trifluoperazine content. Exceptions: Lot No. 735; Paul Maney (4 tablets only) and Lot No. J6626; SK & F (24 tablets).

3. *Determination of Disintegration Time (4)*

By means of this test, information is obtained concerning the relative ease with which tablet formulations break up under controlled experimental conditions simulating *in vivo* environment. Food and Drug Regulations specify that plain coated tablets—and all trifluoperazine tablets presently marketed in Canada belong to this class—must disintegrate within 60 minutes (30 minutes in simulated gastric juice and 30 minutes in simulated intestinal juice).

Experimental Results

Analytical data are shown in Figures 1-16 and summarized in Tables I-VII.

They demonstrate that—

1. Currently marketed brands of trifluoperazine tablets B.P. appear to be formulated in terms of trifluoperazine base by all manufacturers.

2. With the exception of one lot (Clinazine 10 mg., Mowatt & Moore Lot No. 6-3K; N.H. & W. Sample No. A54148) all currently marketed products met label claims.

3. Potency variations between individual tablets were smallest in lots manufactured by Paul Maney Laboratories and largest in lots manufactured by Jules R. Gilbert. The Food and Drug Directorate has informed the latter company of results obtained with their products.

4. All tablets tested for disintegration time met the requirements of the Canadian Food and Drugs Act and Regulations.

Literature Cited

1. British Pharmacopoeia, The Pharmaceutical Press, London, W.C.1. 1963; pages 847 and 848.

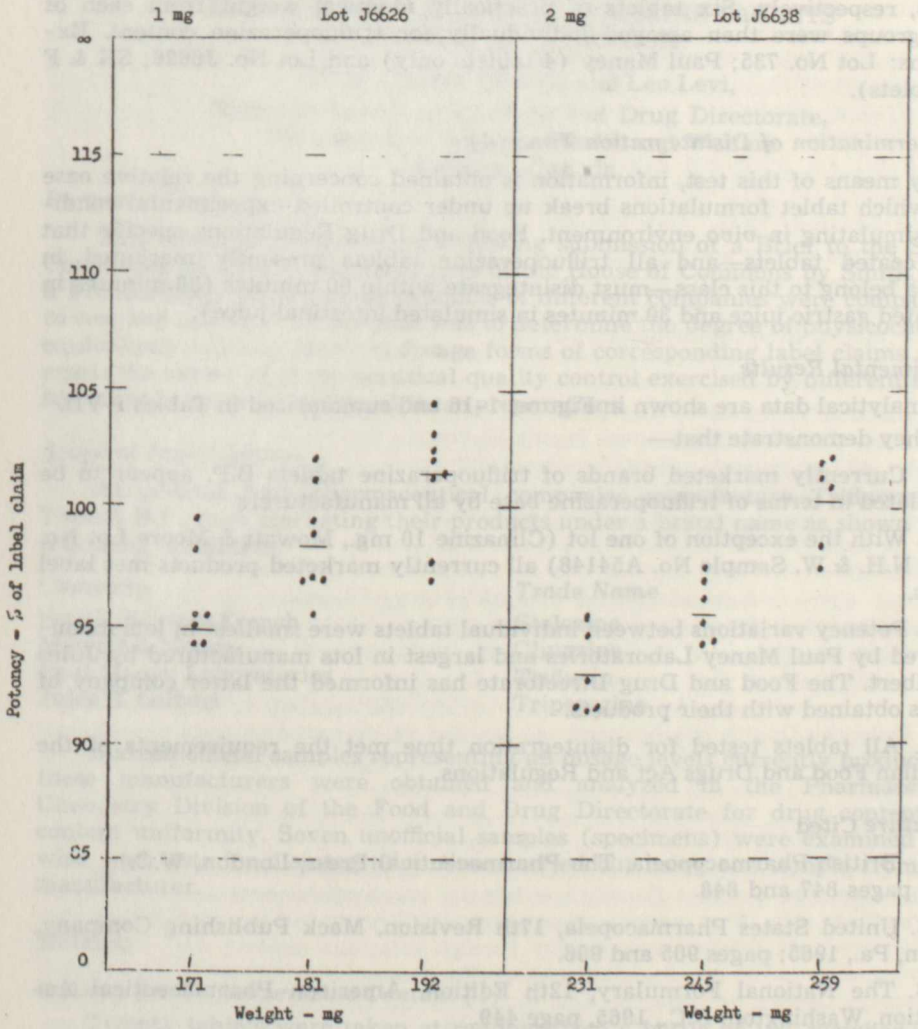
2. United States Pharmacopeia, 17th Revision, Mack Publishing Company, Easton, Pa., 1965; pages 905 and 906.

3. The National Formulary, 12th Edition, American Pharmaceutical Association, Washington, D.C., 1965, page 449.

4. Official Method issued by Food and Drug Directorate, DO-25, 1965.

Fig. 1

STELAZINE - SMITH KLINE & FRENCH

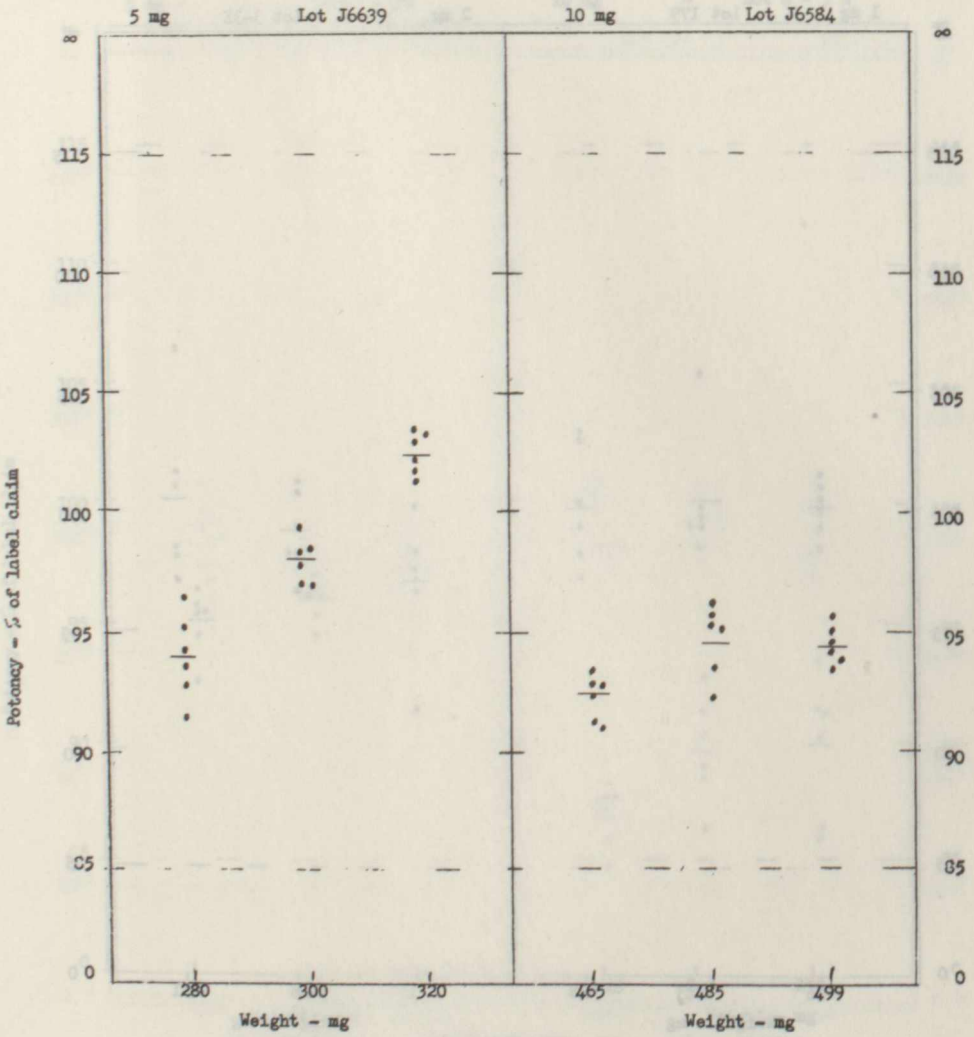


98.4	Average Potency	96.4
99.9	B.P. Assay	98.7
3.91	Std. Dev. (Individual Tablet)	3.53

Note: 1. Potency expressed as % base relative to numerical value on label.

Fig. 2

STELAZINE - SMITH KLINE & FRENCH

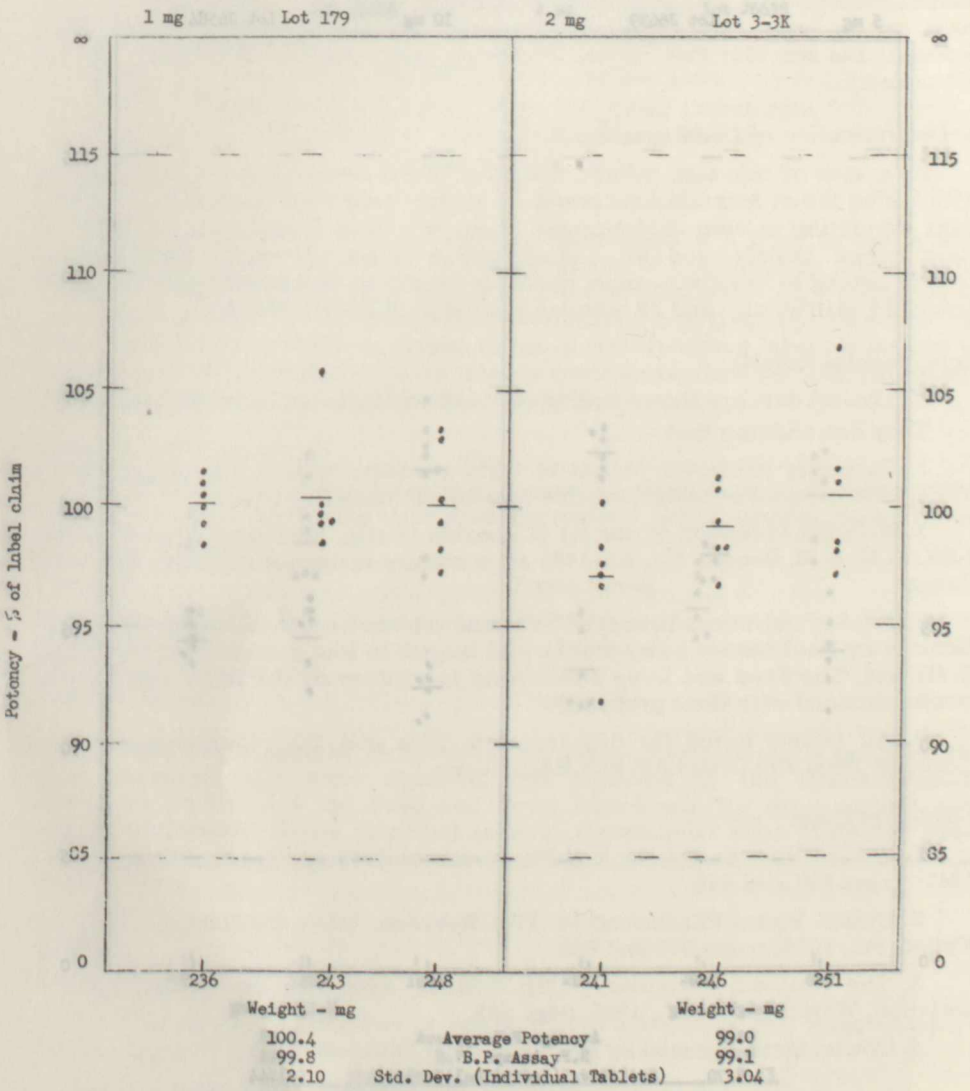


98.2	Average Potency	94.1
99.9	B.P. Assay	96.4
3.70	Std. Dev. (Individual Tablet)	1.44

Note: 1. Potency expressed as % base relative to numerical value on label.

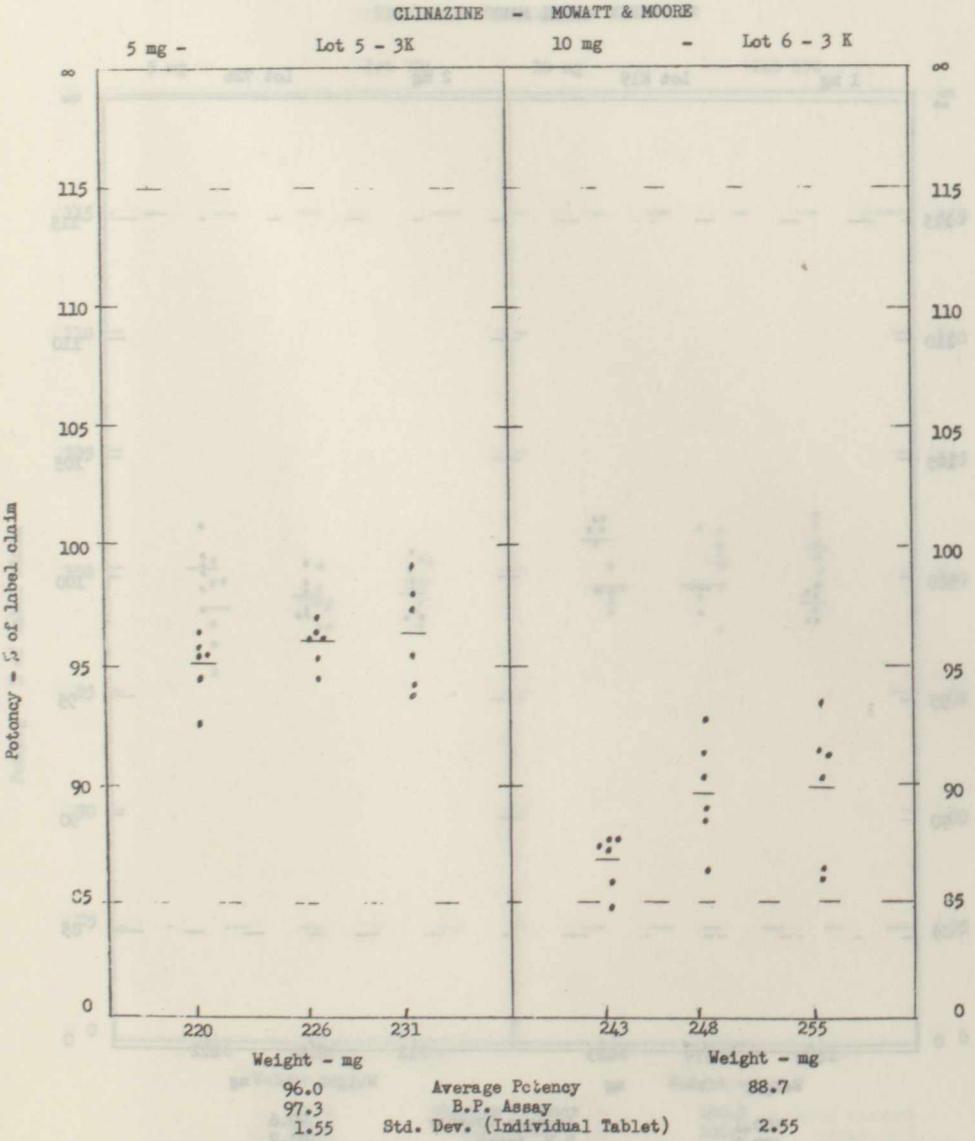
Fig. 3

CLINAZINE - MOWATT & MOORE



Note: 1. Potency expressed as % base relative to numerical value on label.

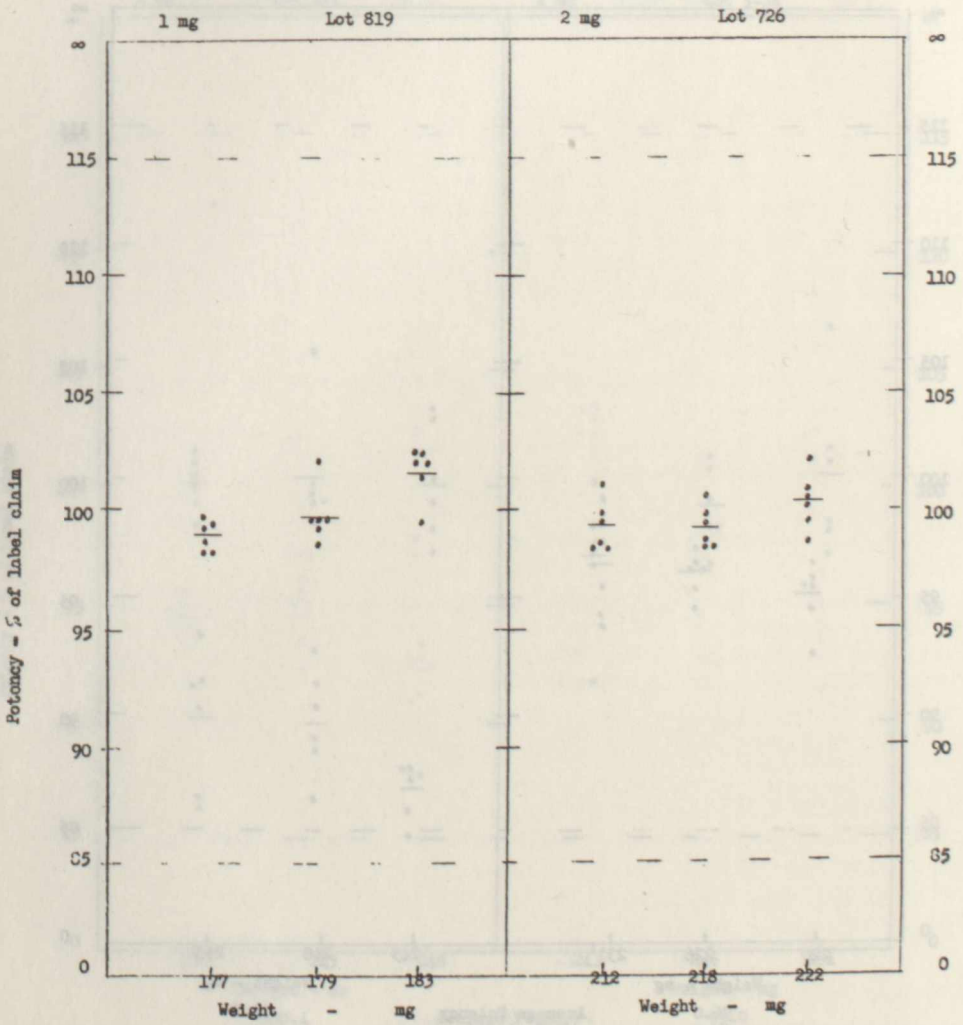
Fig. 4



Note: 1. Potency expressed as % base relative to numerical value on label.

Fig. 5

TRIFLURIN - PAUL MANEY



100.1	Average Potency	99.6
199.8	B.P. Assay	101.2
100.6	Mfr. Assay	101.5
1.51	Std. Dev. (Individual Tablet)	1.14

Fig. 6

TRIFLURIN - PAUL MANEY

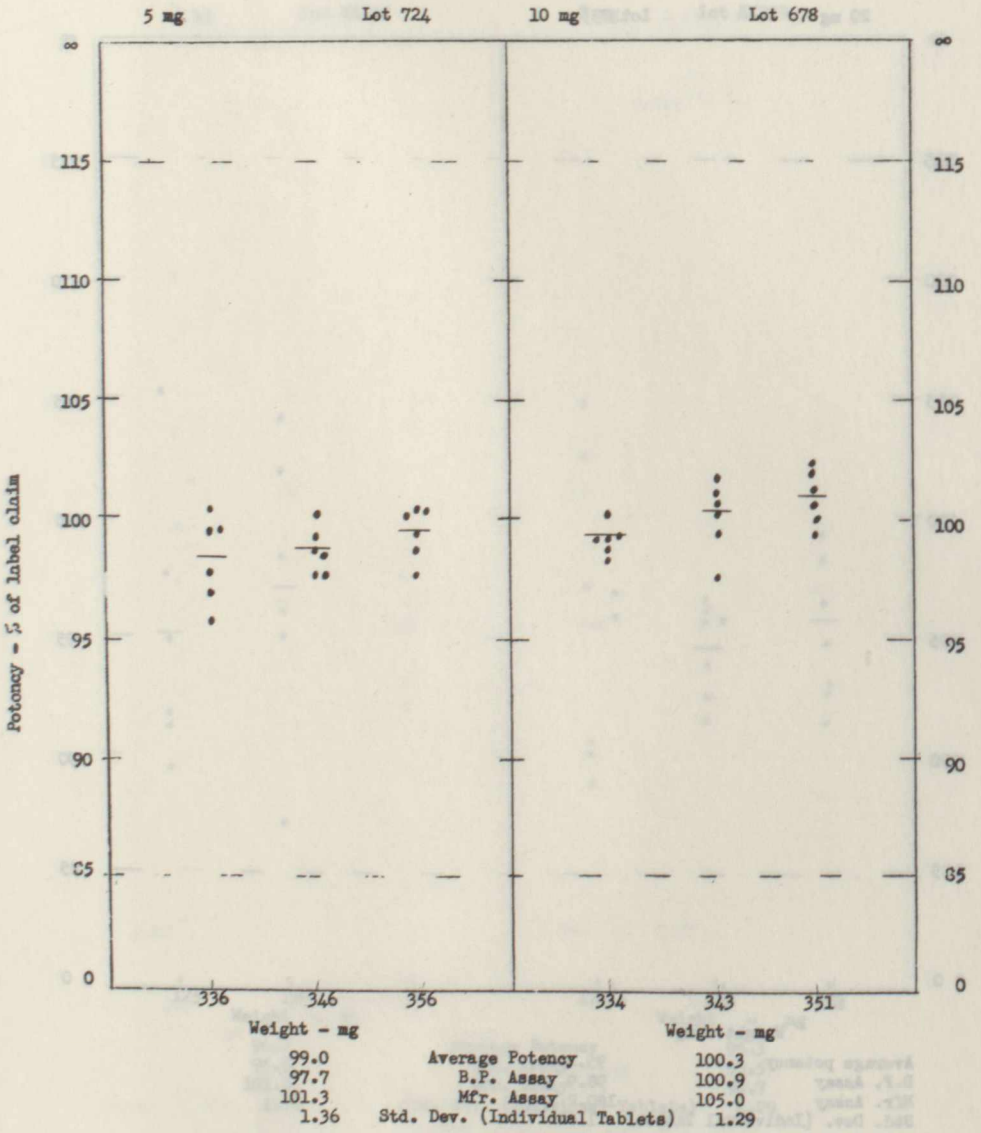
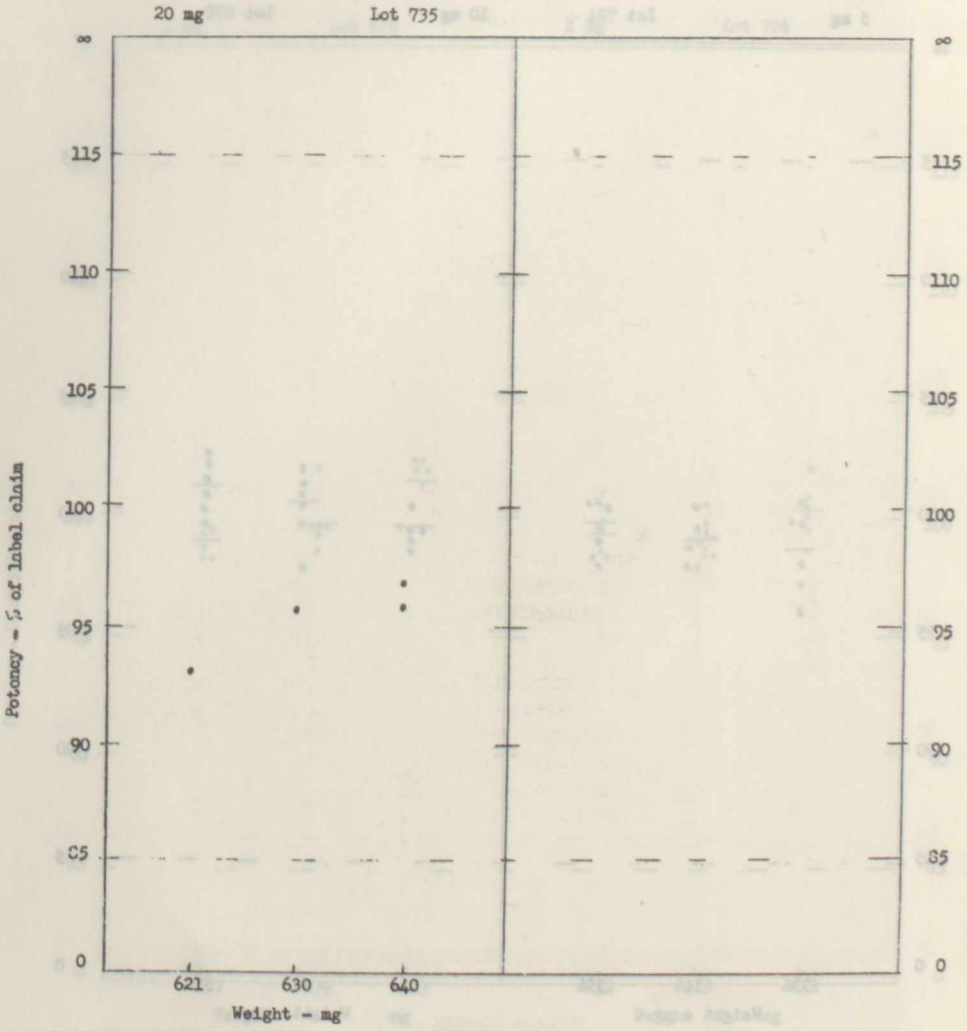


Fig. 7

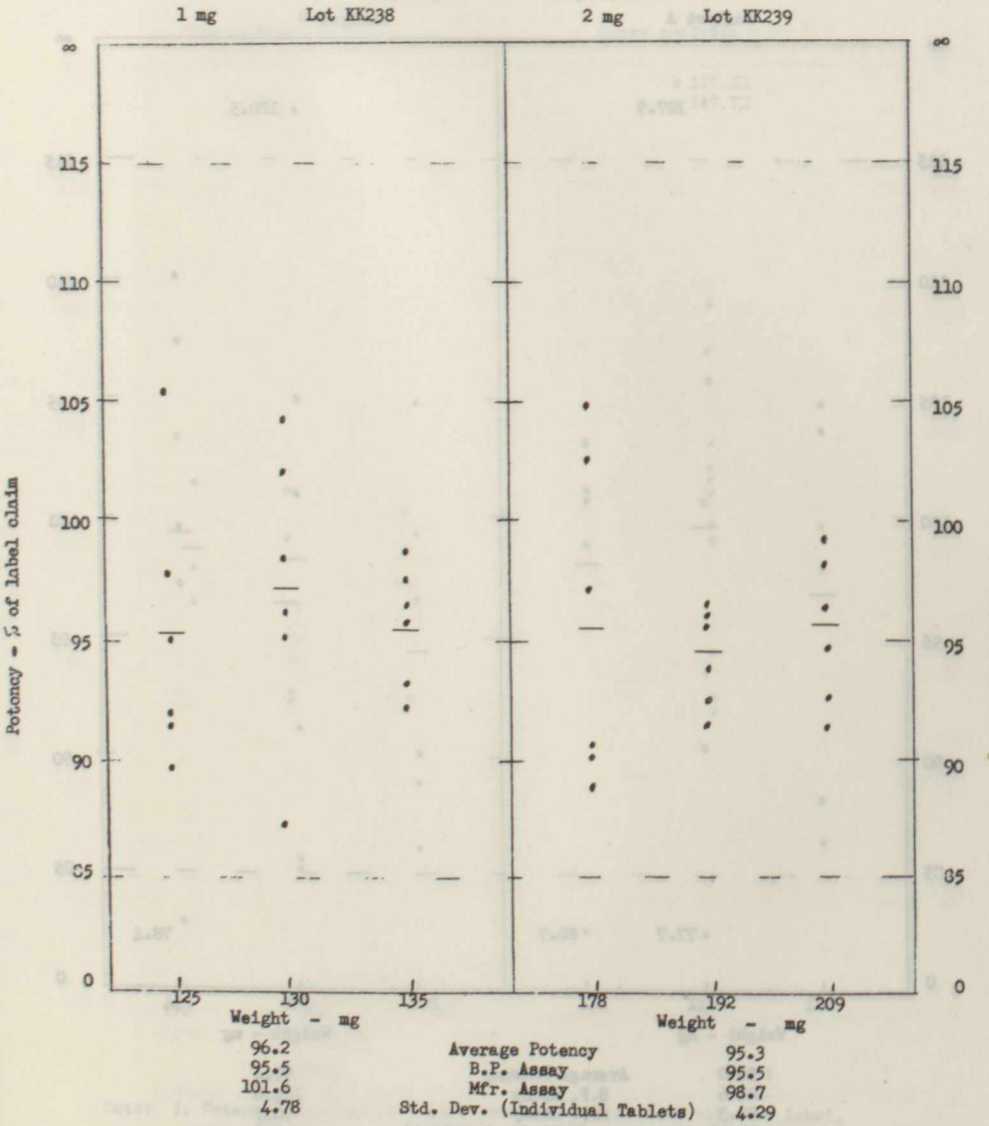
TRIFLURIN - PAUL MANEY



Average potency	95.2
B.P. Assay	98.9
Mfr. Assay	100.2
Std. Dev. (Individual Tablet)	1.62

Fig. 8

TRIPERAZINE - JULES R. GILBERT



96.2	Average Potency	95.3
95.5	B.P. Assay	95.5
101.6	Mfr. Assay	98.7
4.78	Std. Dev. (Individual Tablets)	4.29

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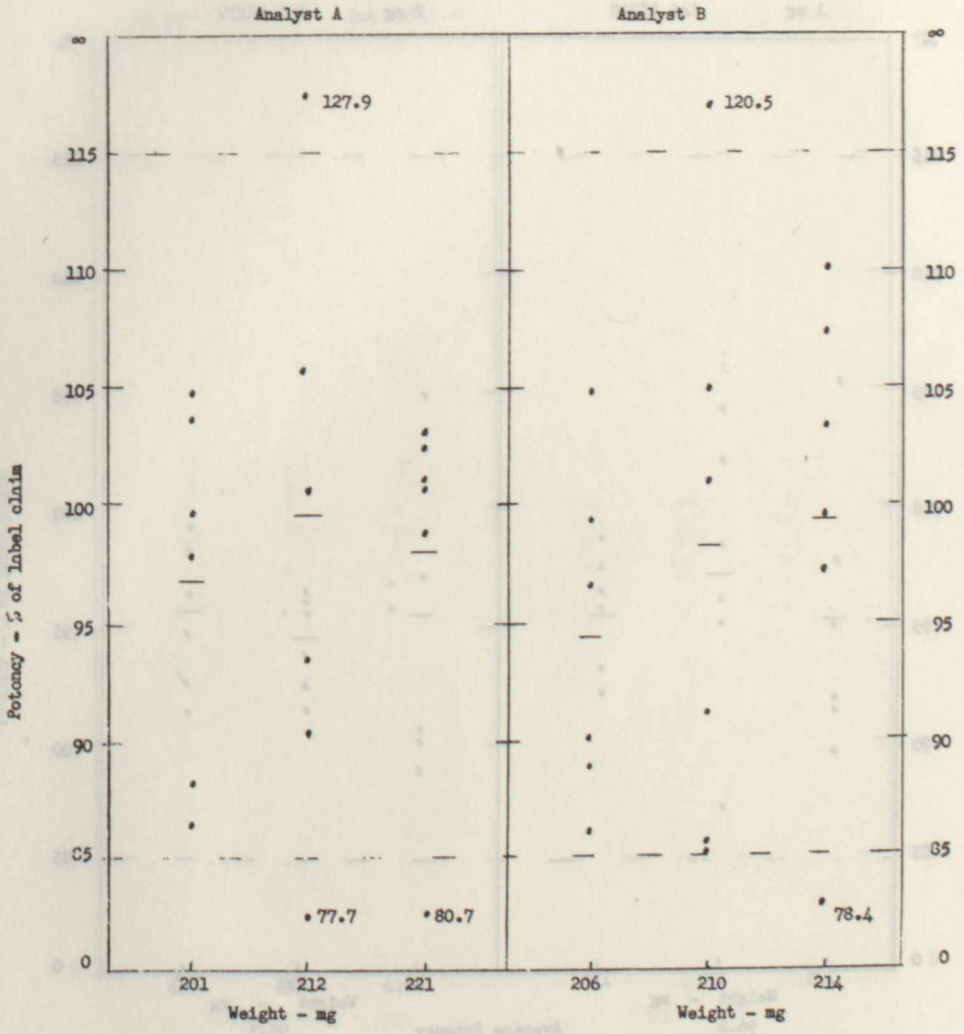
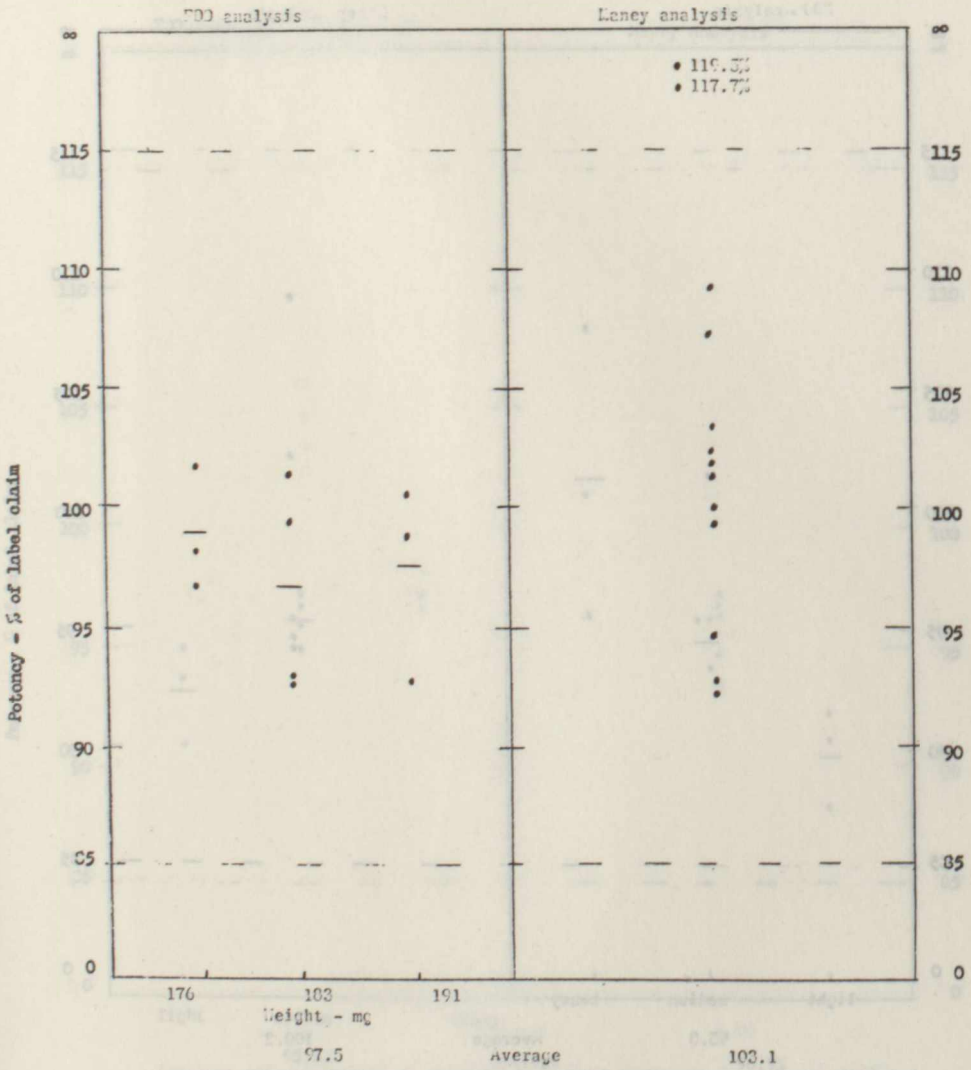
Fig. 9

TRIPERAZINE - Jules R. Gilbert
5 mg Lot KK235



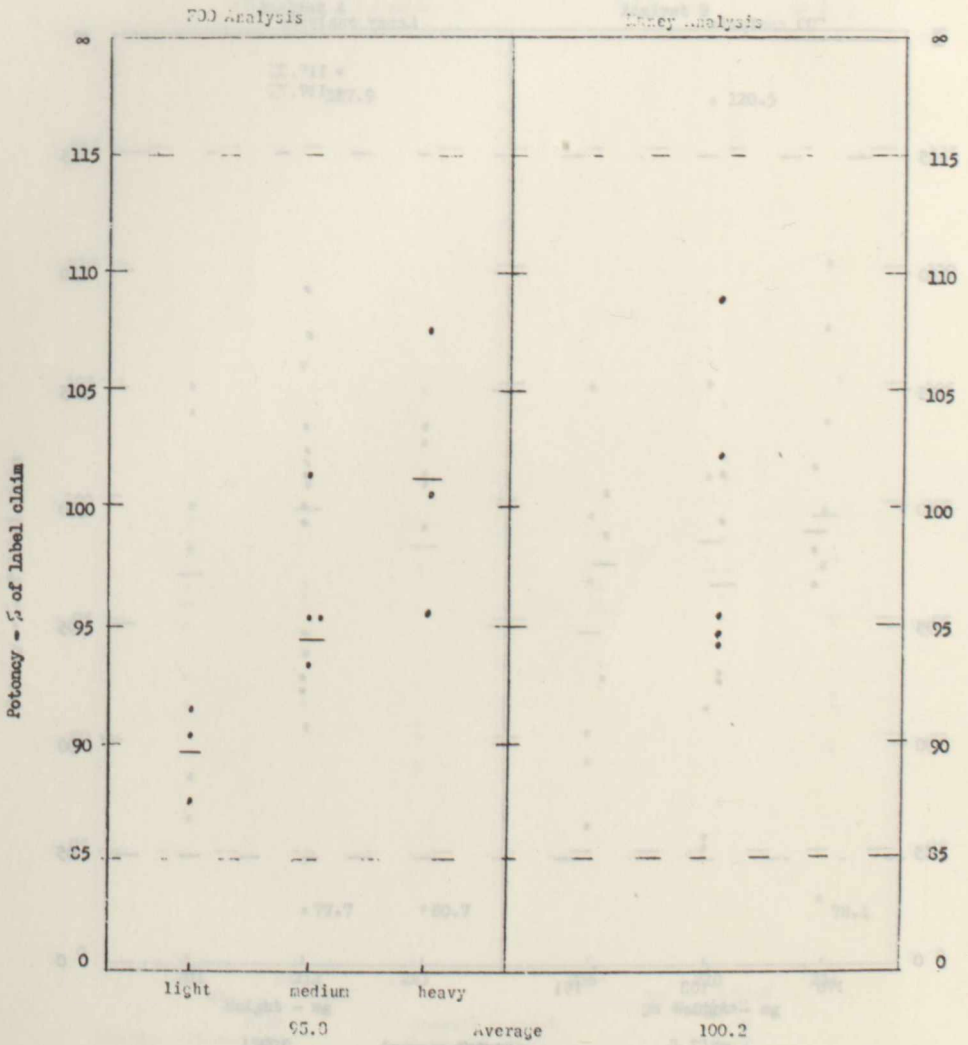
98.0	Average Potency	97.4
104.6	B.P. Assay	104.6
98.3	Mfr. Assay	98.3
11.22	Std. Dev. (Individual Tablet)	10.6

Stelazine - SKF Fig. 10
1 mg Lot F-1166 (E-976)



Note: 1. Potency expressed as % base relative to numerical value on label.
2. Tablets chosen for TDD assay according to weight classification.

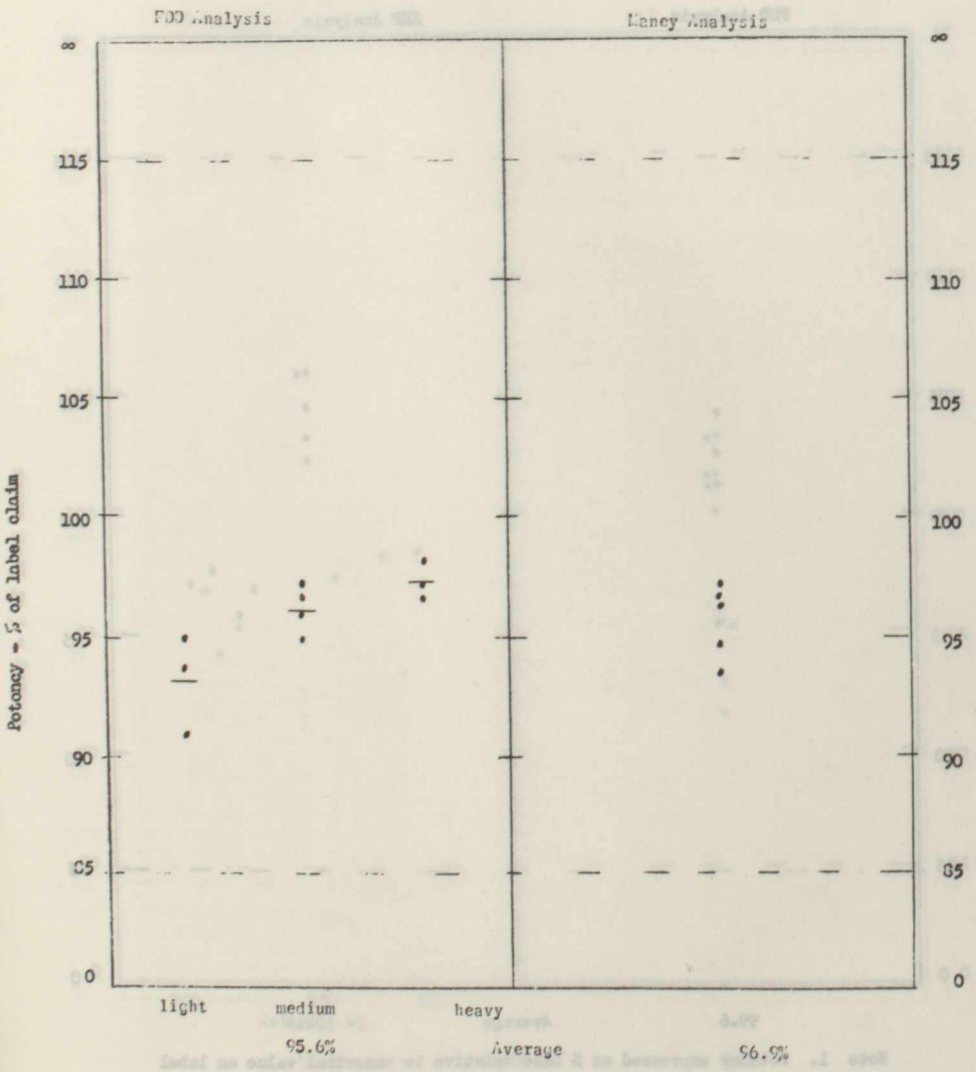
Fig. 11



Note: 1. Potency expressed as % base relative to numerical value on label.
2. Tablets chosen for FDD assay according to weight classification.

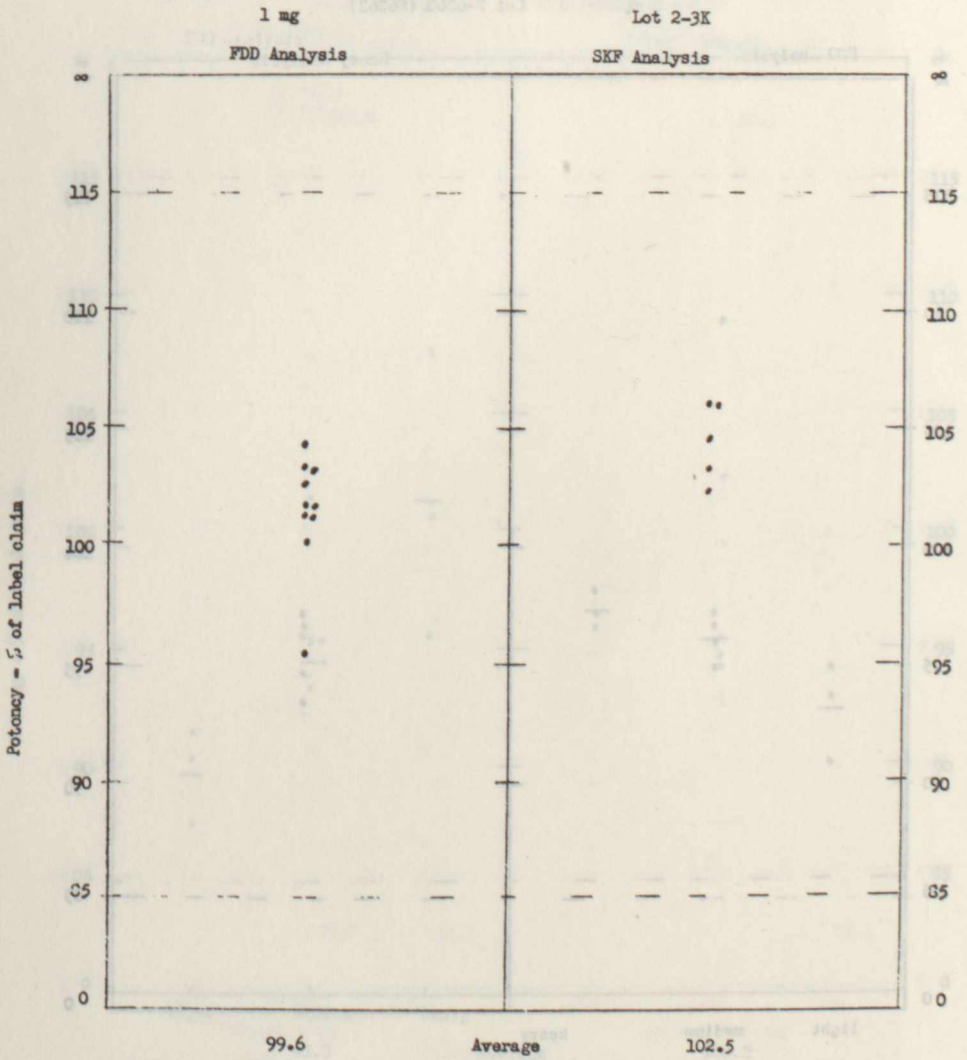
Stelazine tablets - SKF
5 mg Lot F-6363 (F6362)

Fig. 12



Note: 1. Potency express as % base relative to numerical value on label.
2. Tablets chosen for FDD assay according to weight classification.

CLINAZINE TABLETS - MOWATT & MOORE Fig. 13

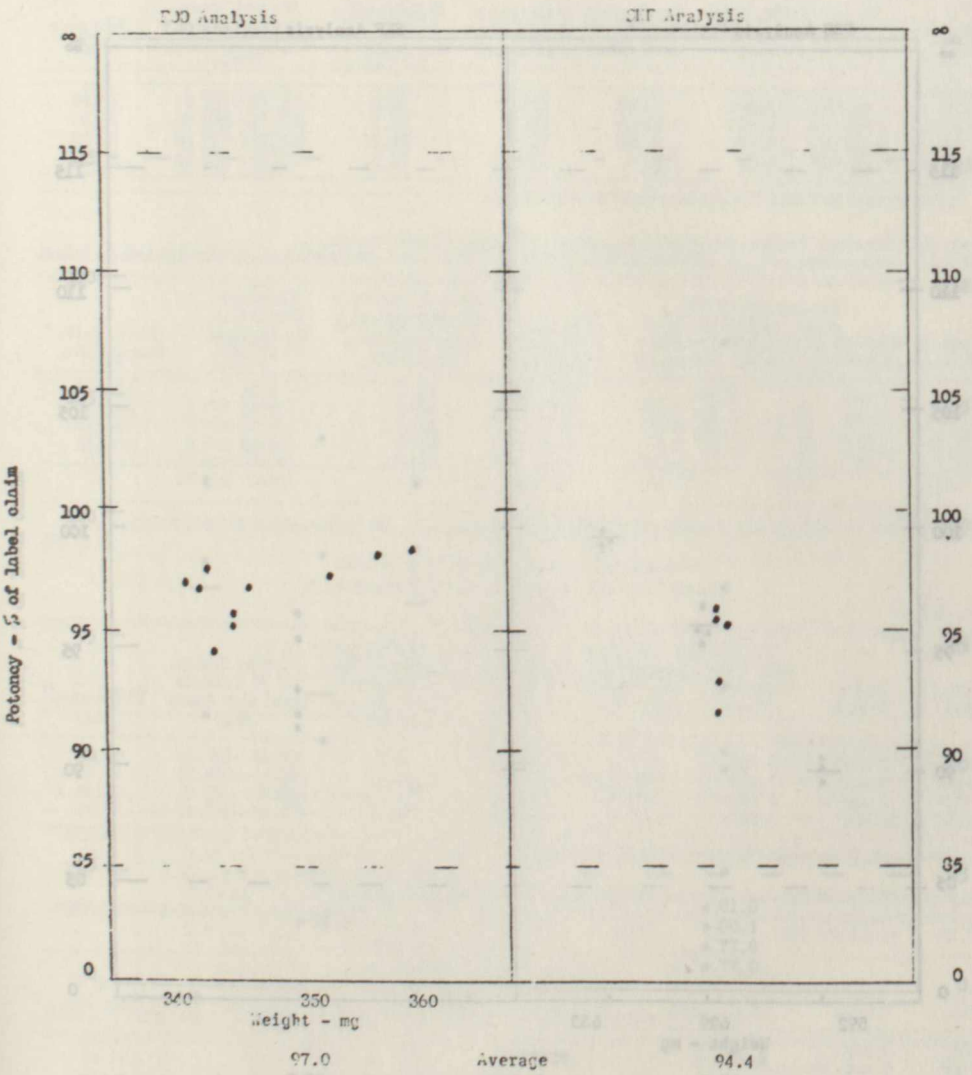


Note 1. Potency expressed as % base relative to numerical value on label
2. Tablets selected at random for assay.

Fig. 14

Trifluorin Tablets - Paul Maney

10 mg Lot 73/

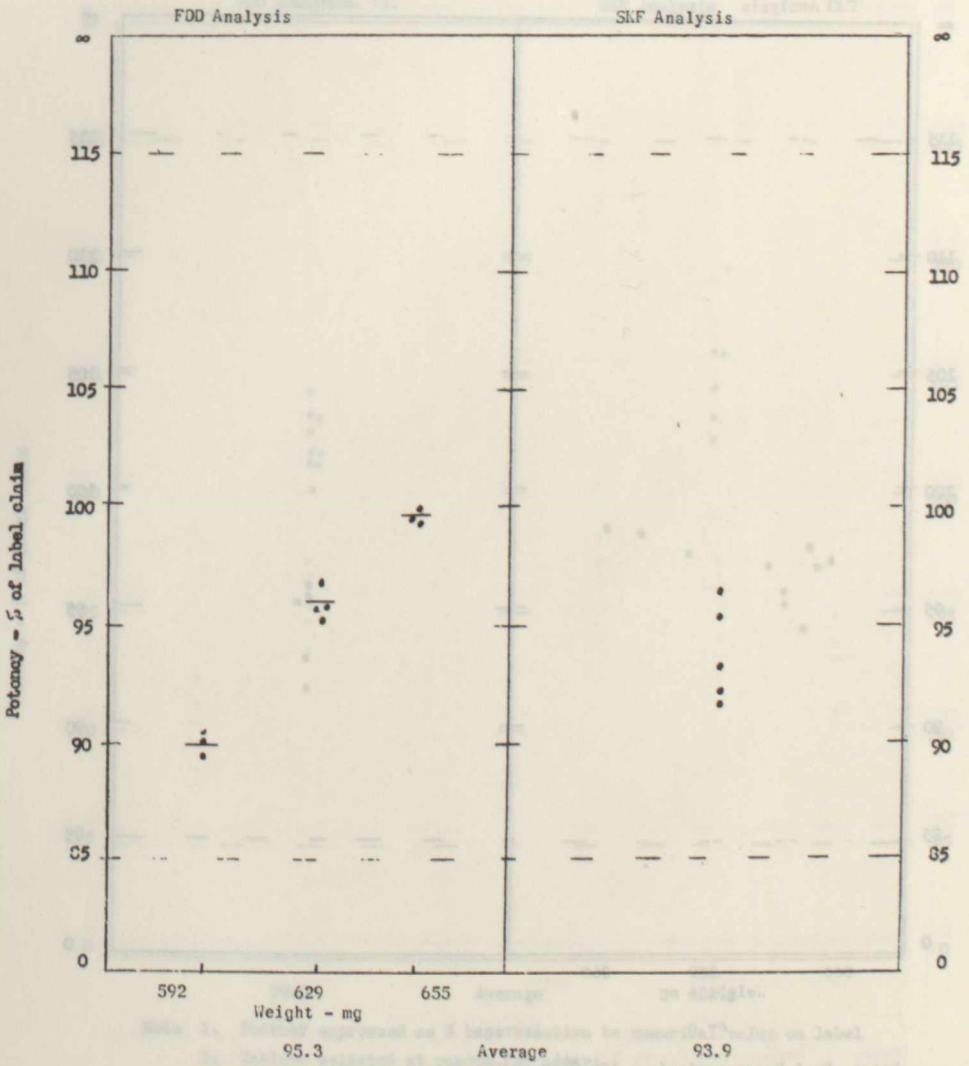


Note: Paul Maney analysis - 100.0% by B.P.

Triflurin Tablets - Paul Maney

Fig. 15

20 mg Lot 741

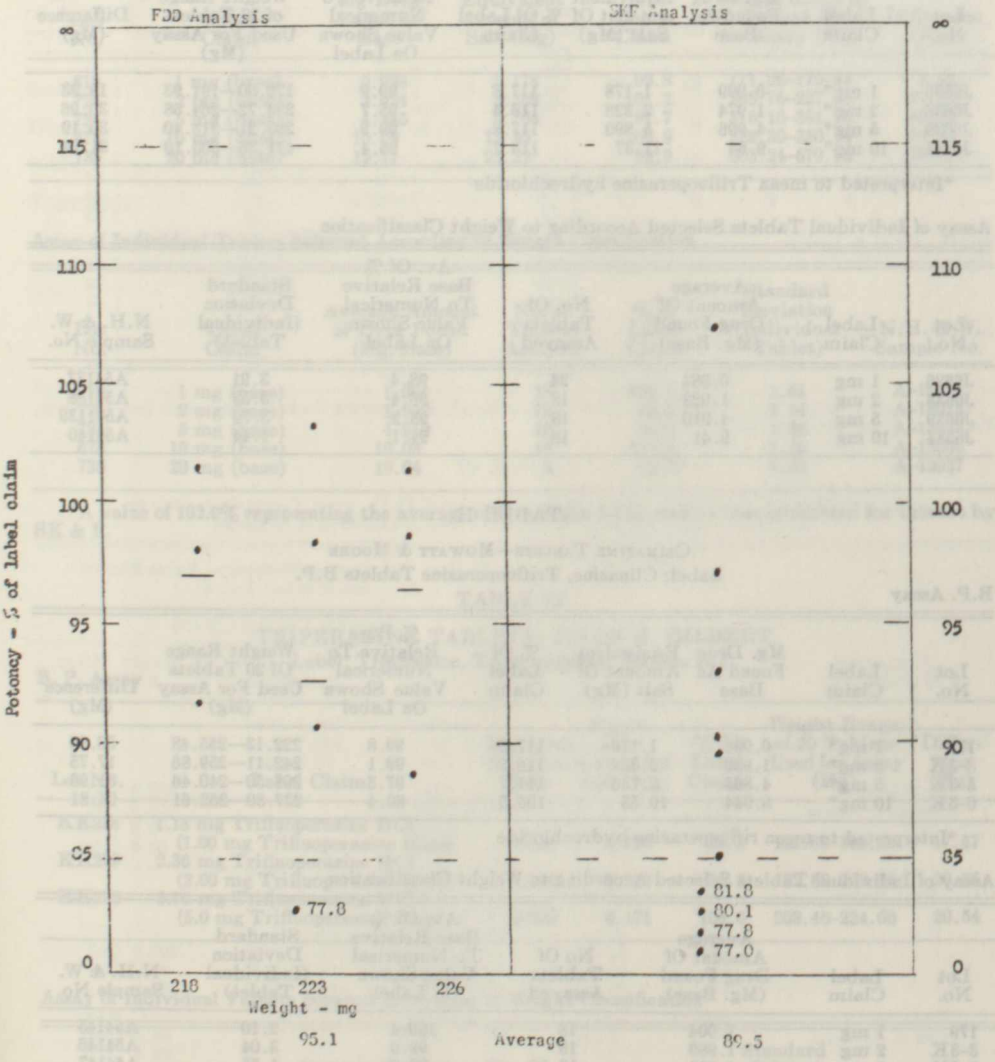


Note: 1. Tablets chosen for FDD assay according to weight classification.

2. Paul Maney analysis - 102.1% by B.P.

Trifluoperazine tablets - Gilbert

2 mg Lot 605 Fig. 16



Note: 1. The average % of label claim as determined by the Harnock-Hersey laboratory was 103.3%.

2. Percentage of label claim expressed as salt relative to numerical value on label. Label claim- "Each tablet contains 2mg Trifluoperazine Hydrochloride B.P."

TABLE I

STELAZINE TABLETS—SMITH, KLINE & FRENCH
Label: Stelazine Tablets, Trifluoperazine Tablets B.P.

B.P. Assay

Lot No.	Label Claim	Mg. Drug Found As Base	Equivalent Amount Of Salt (Mg)	% Of Label Claim	% Base Relative To Numerical Value Shown On Label	Weight Range of 20 Tablets Used For Assay (Mg)	Difference (Mg)
J6626	1 mg*	0.999	1.178	117.8	99.9	172.00—191.93	19.93
J6638	2 mg*	1.974	2.328	116.4	98.7	233.72—264.68	30.96
J6639	5 mg*	4,996	5.890	117.8	99.9	283.21—313.40	30.19
J6584	10 mg*	9.64	11.37	113.7	96.4	471.36—503.10	31.74

*Interpreted to mean Trifluoperazine hydrochloride

Assay of Individual Tablets Selected According to Weight Classification

Lot No.	Label Claim	Average Amount Of Drug Found (Mg. Base)	No. Of Tablets Assayed	Av. Of % Base Relative To Numerical Value Shown On Label	Standard Deviation (Individual Tablet)	N.H. & W. Sample No.
J6626	1 mg	0,984	24	98.4	3.91	A54137
J6638	2 mg	1.928	18	96.4	3.53	A54138
J6639	5 mg	4.910	18	98.2	3.70	A541139
J6584	10 mg	9.41	18	94.1	1.44	A54140

TABLE II

CLINAZINE TABLETS—MOWATT & MOORE
Label: Clinazine, Trifluoperazine Tablets B.P.

B.P. Assay

Lot No.	Label Claim	Mg. Drug Found As Base	Equivalent Amount Of Salt (Mg)	% Of Label Claim	% Base Relative To Numerical Value Shown On Label	Weight Range Of 20 Tablets Used For Assay (Mg)	Difference (Mg)
179	1 mg*	0.998	1.179	117.9	99.8	222.13—255.48	33.35
3-3K	2 mg*	1.982	2.337	116.9	99.1	242.11—259.86	17.75
5-3K	5 mg*	4.865	5.736	114.7	97.3	208.50—240.46	31.96
6-3K	10 mg*	8.944	10.55	105.5	89.4	237.80—262.61	24.81

*Interpreted to mean rifluoperazine hydrochloride

Assay of Individual Tablets Selected According to Weight Classification

Lot No.	Label Claim	Average Amount Of Drug Found (Mg. Base)	No Of Tablets Assayed	Av. Of % Base Relative To Numerical Value Shown On Label	Standard Deviation (Individual Tablet)	N.H. & W. Sample No.
179	1 mg	1.004	18	100.4	2.10	A54145
3-3K	2 mg	1.980	18	99.0	3.04	A54146
5-3K	5 mg	4.800	18	96.0	1.55	A54147
6-3K	10 mg	8.87	18	88.7	2.55	A54148

Analytical results submitted by SKF
Lot No. 3-3K—106.6% of label claim (average of five single tablet assays)
Lot No. 5-3K— 95.9% of label claim (average of ten single tablet assays)
Lot No. 6-3K— 89.6% of label claim (average of ten single tablet assays)

TABLE III

TRIFLURIN TABLETS—PAUL MANEY
Label: Triflurin, Trifluoperazine Tablets B.P.

B.P. Assay

Lot No.	Label Claim	Mg Drug Found as Base	Equivalent Amount of Salt (Mg)	% of Label Claim	Weight Range of 20 Tablets Used for Assay (Mg)	Difference (Mg)
819	1 mg (base)	0.998	1.178	99.8	171.26–179.84	8.58
726	2 mg (base)	2.024	2.388	101.2	205.76–227.28	21.52
724	5 mg (base)	4.885	5.764	97.7	316.16–361.70	45.54
678	10 mg (base)	10.09	11.90	100.9	320.30–350.74	30.44
735	20 mg (base)	19.77	23.32	98.9	603.24–679.75	76.51

Assay of Individual Tablets Selected According to Weight Classification

Lot No.	Label Claim	Average Amount of Drug Found (Mg. Base)	No. of Tablets Assayed	% of Label Claim	Standard Deviation (Individual Tablet)	N.H. & W. Sample No.
819	1 mg (base)	1.001	18	100.1	1.51	A–13034
726	2 mg (base)	1.992	18	99.6	1.14	A–13035
724	5 mg (base)	4.950	18	99.0	1.36	A–13033
678	10 mg (base)	10.03	18	100.3	1.29	A–13036
735	20 mg (base)	19.04	4	95.2*	1.62	A–13037

*A value of 102.0% representing the average of five single tablet assays was submitted for this lot by SK & F.

TABLE IV

TRIPERAZINE TABLETS—JULES R. GILBERT
Label: Triperazine, Trifluoperazine Tablets B.P.

B. P. Assay

Lot No.	Label Claim	Mg. Drug Found as Base	Equivalent Amount of Salt (Mg)	% Of Label Claim	Weight Range of 20 Tablets Used for Assay (Mg)	Difference (Mg)
KK238	1.18 mg Trifluoperazine HCl (1.00 mg Trifluoperazine Base)	0.955	1.126	95.5	122.83–140.50	17.67
KK239	2.36 mg Trifluoperazine HCl (2.00 mg Trifluoperazine Base)	1.910	2.252	95.5	172.80–202.35	29.55
KK235	5.90 mg Trifluoperazine HCl (5.0 mg Trifluoperazine Base)	5.230	6.171	104.6	203.46–224.00	20.54

Assay of Individual Tablets Selected According to Weight Classification

Lot No.	Label Claim	Average Amount Of Drug Found (Mg Base)	No. Of Tablets Assayed	% Of Label Claim	Standard Deviation (Individual Tablet)	N.H. & W. Sample No.
KK238	as above	0.962	18	96.2	4.78	A–13032
KK239	as above	1.906	18	95.3	4.29	A–13031
KK235	as above	4.900	18	98.0	11.22	A–13030

TABLE V

POTENCY VARIATION OF TABLETS PRODUCED BY DIFFERENT MANUFACTURERS

Manufacturer	Official Sample (Lot No.)	Dosage Level (Base)	No. of Tablets Analyzed	Standard Deviation (Individual Tablet)*
Paul Maney	819	1 mg	18	1.51
	726	2 mg	18	1.14
	724	5 mg	18	1.36
	678	10 mg	18	1.29
	735	20 mg	4	1.62
Mowatt & Moore	179	1 mg	18	2.10
	3-3K	2 mg	18	3.04
	5-3K	5 mg	18	1.55
	6-3K	10 mg	18	2.55
Smith, Kline & French	J6626	1 mg	24	3.91
	J6638	2 mg	18	3.53
	J6639	5 mg	18	3.70
	J6584	10 mg	18	1.44
Jules R. Gilbert	KK238	1 mg	18	4.78
	KK239	1 mg	18	4.29
	KK235	1 mg	18	11.22

*Data courteously supplied by Dr. D. F. Bray, Head, Biometrics Section, Research Laboratories, Food and Drug Directorate.

TABLE VI

COMPARISON OF ANALYTICAL RESULTS OBTAINED BY F.D.D. WITH THOSE OBTAINED BY OTHER MANUFACTURERS FOR OFFICIAL AND NON-OFFICIAL SAMPLES

Brand and Manufacturer	Lot No.	Dosage Level (Base)	% Base Relative to Numerical Value Shown on Product Label — Found in Laboratories of: Food and Drug Directorate	Paul Maney	Smith, Kline & French
Stelazine Smith, Kline & French	F-1146	1 mg	97.5 (10s)**	103.1 (13s)	
	J-5525	2 mg	95.8 (10s)	100.2 (5s)	
	F-6363	5 mg	95.6 (10s)	96.9 (5s)	
Clinazine Mowatt & Moore	2-3K	1 mg	99.6 (10s)		102.5 (5s)
	3-3K*	2 mg	99.0 (18s)		106.6 (5s)
	5-3K*	5 mg	96.0 (18s)		95.9 (10s)
	6-3K*	10 mg	88.7 (18s)	88.6 (?)	89.6 (10s)
Triflurin Paul Maney	819*	1 mg	98.8 (B.P.)**	100.6 (B.P.)	
	726*	2 mg	101.2 (B.P.)	101.5 (B.P.)	
	724*	5 mg	97.7 (B.P.)	101.3 (B.P.)	
	678*	10 mg	100.9 (B.P.)	105.0 (B.P.)	
	735*	20 mg	98.9 (B.P.)	100.2 (B.P.)	102.0 (5s)
	734	10 mg	97.0 (10s)	100.0 (B.P.)	94.4 (5s)
	741	20 mg	95.3 (10s)	102.1 (B.P.)	93.9 (5s)
Trifluoperazine Jules R. Gilbert	605***	(salt) 2 mg	(salt) 95.1 (10s)		(salt) 89.5 (10s) 92.4 (10s) 103.3 (10s)****

*Official Sample.
**Method of analysis included in brackets—e.g., B.P. designates British Pharmacopoeia, 1963 Edition, 10s indicates assays of ten individual tablets.
***Specimen obtained several months prior to this survey and formulated in terms of the salt—label claim: "Each tablet contains 2 mg. Trifluoperazine Hydrochloride B.P."
****Result obtained by Warnock-Hersey Lab., as reported by SK & F.

TABLE VII

DISINTEGRATION TIMES OF DIFFERENT BRANDS OF TRIFLUOPERAZINE TABLETS

Product		Lot No.	Disintegration Times (Minutes)						Average Value (Minutes)
Stelazine	10 Mg.	J6584	12	12	13	13	13	14	13
Clinazine	10 Mg.	6-3K	8	8	9	9	9	10	9
Triflurin	10 Mg.	678	15	15	16	16	16	18	16
Triperazine	5 Mg.	KK235	2	2	3	3	3	3	3

May 19, 1965.

APPENDIX "E"

Dr. R. A. Chapman,
Director,
Food & Drug Directorate,
Department of National Health & Welfare,
Tunney's Pasture,
OTTAWA, Canada.

Dear Doctor Chapman:

Further to our conversations in your office on Thursday, May 13th, I would like to detail the reasons why we feel it is important that trifluoperazine should continue to be treated as a "new drug".

In spite of the fact that trifluoperazine had been used widely throughout the world for several years, the Canadian Food and Drug Directorate found it necessary to question the possible teratogenicity of this agent in December of 1962. You will recall that we were then able to provide specific follow-up of our previously recorded investigational cases, and, subsequent to further intensive investigation, published a report from our Medical Department in the C.M.A.J. of February 16th, 1963. We have subsequently followed up all cases of pregnancy associated with the use of trifluoperazine which have been brought to our attention.

Pigment deposition has recently been reported with chlorpromazine and other phenothiazines. In the United States, our Company has circularized all physicians to call this rare reaction to their attention and has revised its Prescribing Information accordingly. Special animal and clinical studies have been undertaken. In Canada, we have initiated specific follow-up studies of certain patients receiving trifluoperazine. While this reaction occurs primarily in chronic refractory cases requiring high, long-term dosage, there is still much to be learned regarding the maximum dose, chronic vs. intermittent therapy, possible dietary and therapeutic incompatibilities.

More recently, instances of prolonged extrapyramidal symptoms have been reported in the literature, and these are being studied.

We feel that it is our responsibility, as the supplier of trifluoperazine, to follow up all instances of any side effect attributed to this drug with whatever medical and technical resources are required.

You will recall, too, how important this type of activity proved in the tranylcypromine experience of last year. At that time, SK&F took the initiative, in co-operation with the governments concerned, in warning physicians around the world. The subsequent documentation of world-wide cases submitted to you for study points up the extensive medical and technical resources which are required to investigate and deal with such a problem. When it was found desirable to limit distribution of the drug, this was carried out promptly and efficiently.

Part of our discussion in your office dealt with the opinion expressed by a member of your Department that trifluoperazine might not still be considered a new drug. Apart from the fact that this was only the expression of an opinion, we can visualize circumstances under which an old drug could be reclassified as a "new drug". One reason might be a change in knowledge about its use or potential side effects. Another might be the appearance of an additional manufacturer, which could have the following implications:

(1) It has been well-documented that minor chemical and formulation changes can have important effects on the toxicity, as well as the efficacy, of a number of drugs.

(2) Although manufacturing standards are starting to be applied, there are still great differences in the approach to drug manufacture and distribution to different suppliers. The quality, calibre and number of staff, medical and technical back-up, and relative concern for corporate reputation are some of the factors involved.

(3) As in the case of trifluoperazine, the primary manufacturer might be voluntarily continuing extensive studies on an old drug which you would wish to see continued after the entry of a new manufacturer. Your wishes in this respect could only be effected by reclassification as a "new drug", since the new manufacturer would probably not voluntarily co-operate in the primary supplier's programme, even if he had the facilities. On the contrary, economic and technical factors could well dictate modification of the primary manufacturer's existing programme.

In suggesting that trifluoperazine be firmly classified as a "new drug", I can assure you that Smith Kline & French is anxious to continue providing the Directorate with the type of information required by the spirit as well as the letter of the regulations, in our own interest as well as that of the public safety. Such a ruling would not interfere with the grant of licenses to other manufacturers, but would ensure that they, too fulfilled the responsibilities inherent in the distribution of such a potent therapeutic agent.

We have investigated your thought that trifluoperazine might appear in the next issue of the U.S.P. To the best of our knowledge, it will not.

Yours very sincerely,

Andrew J. Moriarity, M.D.,
Director of Research & Development.

AJM:jh

Tunney's Pasture,
Ottawa 3,
June 11, 1965.

Dr. Andrew J. Moriarity,
Director of Research and Development,
Smith, Kline and French Inter-American
Corporation,
300 Laurentian Boulevard,
Montreal 9, P.Q.

Dear Doctor Moriarity:

I have delayed replying to your letter of May 19 in order that I might give the fullest consideration to the points that you set forth in support of your suggestion that Trifluoperazine should continue to be treated as a new drug.

You will meanwhile be aware of the discussion which took place in Parliament on June 4 and 7 in relation to this drug. This discussion dealt with certain matters, including a compulsory licence under your patent, which were raised by you in the discussion which took place between us on May 13, last.

You will, of course, appreciate that we must reach an opinion on the status of a drug in accordance with the regulations and, moreover, it must be one that we could reasonably support in court in the event of any issue being raised.

To support the view that this is a new drug, it would be necessary to show that it has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada its safety and effectiveness for use. The drug has been on the Canadian market for a number of years and, according to our information, has been extensively used for the purpose for which it is recommended. The information accompanying this drug sets out information which the physician should have in prescribing it. This includes information with respect to contraindications or side effects. This is not unusual in the case of any potent drug but we are not able to say that it is of such a character to affect the evidence furnished regarding its safety and efficacy.

If the dangers associated with the use of this drug at this time were sufficient to continue it in new drug status because of lack of evidence of safety and efficacy, it would follow that consideration would need to be given to whether the notice of compliance should not be revoked and the drug returned to investigational status. We are not satisfied that this action is required and are therefore of the opinion that the drug is no longer a new drug because of the length and quantity of experience of use in Canada to establish its safety and efficacy.

You will appreciate that in expressing this view, I express no opinion as to what the status might be of this drug when manufactured by another manufacturer either pursuant to agreement with your company or pursuant to compulsory licence. The notice of compliance issued to your company would not necessarily govern or apply to a new manufacturer and there are many factors which could bring this drug into new drug status when manufactured by some other company, or even by your own company for new formulations or

conditions of use. My opinion, therefore, is directed solely to the status of the drug as currently manufactured by your company and does not relate to its status if manufactured by someone else.

You indicated that in respect of new drugs, different records are required than in the case of drugs that are not in new drug status. You also indicated that additional information might be available depending upon whether a drug was a new drug or not. We have examined this aspect of the matter and point out that whether a drug is in new drug status or not, there is a clear requirement on the manufacturer of that drug to have adequate facilities and controls. This includes the keeping of records respecting hazards and other matters which, while differently phrased, are not unlike the type of information which the manufacturer is required to keep regarding a new drug. I distinguish here between the type of records required of a drug in investigational status and a drug in respect of which a notice of compliance has been issued. In the latter, it does not appear to me that the kind of records required of a new drug differ substantially from those required of any drug.

I think the above indicates the position taken by the Directorate that Trifluoperazine is not regarded as a new drug. You will also see that this is the view expressed by the Minister in her statement to Parliament under date of June 7th.

If there are additional points which you think should be considered, I should be very glad to hear from you. Meanwhile, this will set forth the position of the Directorate with respect to this drug.

Yours sincerely,

Original Signed by,
R. A. CHAPMAN
R. A. Chapman,
Director

REC/RAC/EG

PHARMACEUTICAL MANUFACTURERS ASSOCIATION OF CANADA

1110 Gilling Building, 141 Laurier Avenue West, Ottawa 4, Ontario

June 16, 1966
Honourable A. J. MacEachen,
Minister of National Health and Welfare, House of Commons,
Ottawa 3, Ontario.

Dear Mr. MacEachen:

My colleagues and I in PMAC are disquited by the delay in the implementation of the recommendations contained in the Hilliard Committee Report.

When Dr. Eloise Jones raised the issue of the present administration of compulsory licensing in the House of Commons, she said she did so as a "matter of urgent public importance" under Standing Order 26 of the House. There was no dissent from this statement, and the Hilliard Committee was established. The

report of that Committee underlines the importance of effective regulation of the licensed manufacture of potent drugs.

The Food and Drug Act, in our view, gives you, as Minister of National Health and Welfare, the power to establish and enforce such regulation. An amendment to the Regulations to further define the expression "New Drug" may be required, but our legal advisers tell us that the Governor in Council has the authority to do so under the existing legislation and that an amendment to the Food and Drug Act would not be required.

On behalf of the Association, I would, therefore, urge that all of the Hilliard Committee recommendations be implemented, and in particular, that the definition of "New Drug" as contained in the Regulations be amended to include a drug not currently in "New Drug" status, if, with prolonged use, new or more serious or more frequent side effects develop.

When you tabled the report in the House of Commons, our Association immediately issued a statement of support and I would like to quote the following passage: "The Committee's recommendations will, if properly enforced, strengthen the administration of the patent act as it affects pharmaceuticals, and this in turn will encourage responsible drug manufacturers to continue their increasing investments of research money in Canada's medical future." Further, I stated on behalf of the Association that the report is "a major stride forward in the continuing struggle to keep unsafe drugs from being made and sold to the people of Canada."

PMAC representatives met with officials of the Food and Drug Directorate and explained to them just how important we feel that these recommendations are. Dr. Hilliard has made it clear—and we agree with him—that his Committee's proposals constitute a vital defence of the public interest in the matter of drug safety. We are surprised and disturbed to discover that members of the FDD seriously doubt that your Department has the legal authority either to act effectively under existing regulations or to establish new regulations under which the specific recommendations of Dr. Hilliard and his associates could be carried out.

We want to emphasize that in no circumstances do we question the good faith of the members of your Directorate. What we do question is the legal basis for their doubt.

The crucial issue is the extent of the Minister's authority, as the Minister of National Health and Welfare, to declare as a "New Drug" a product that has been accepted as no longer "new." We gather that FDD doubts that it has the legal powers to re-classify such a product and here we feel FDD is in error. I understand that the FDD plans amendments to the present regulations that would call for re-classification when, to quote the Hilliard Committee, a drug "is to be manufactured or produced by a method or process that is substantially different from the method or process currently being used in Canada." However, the FDD believes that the Hilliard Committee recommendations for the re-classification of a drug cannot be put into effect without an amendment to the Food and Drug Act when "if with prolonged use, new or more serious or more frequent side effects develop."

Yet, unless the Directorate is prepared to make such a re-classification, when a second manufacturer is licensed to produce a potent drug product the control exercised over his activities will be quite rudimentary. He is not required to meet the same pharmacological, toxicological and clinical standards as the original manufacturer, nor is he required to carry out the toxicity and mislabelling reporting that are considered essential for a "New Drug."

Further, in its recommendation No. 7, the Hilliard Committee stated: "... no manufacturer shall market any drug unless he has available a product brochure containing complete information on the indications, contraindications, precautions, dosage and side effects, as well as a resume of the pharmacological and clinical studies carried out on that drug." Unless a second manufacturer has to prove product equivalency according to the "New Drug" requirements, the validity of any physicians' information copied from the literature of the original manufacturer must be highly questionable.

The decision whether to issue a compulsory licence lies with the Patent Commissioner; the Directorate can only inform the Commissioner about the adequacy of an applicant's manufacturing facilities. Unless the product for which a compulsory licence has been issued is treated as a "New Drug" it will be distributed without regard to the many and complex questions of drug safety that were defined by the Hilliard Committee.

In these circumstances, we feel strongly that failure to redefine a "New Drug" according to the criteria laid down by the Hilliard Committee constitutes a failure to carry out the intentions of a committee set up by your predecessor to consider the public safety implications of uncontrolled compulsory licensing.

Dr. Chapman stated to the Parliamentary Committee on the Cost of Drugs the other day that the definition of a "New Drug" is "a matter of judgment." The factors influencing judgment can change, and to consider the FDD absolutely bound by past decision could prove extremely hazardous. Past decision in an area of advancing scientific knowledge surely cannot be immutable.

I would suggest to you, finally, that the legal powers of the Minister to issue necessary new regulations in the interest of public safety are very widely defined in Section 24 of the Food and Drug Act. It is stated that: "The Governor in Council may make regulations for carrying the purposes and provisions of this Act into effect, and, in particular...may make regulations...(o) respecting:

(i) the method of preparation, manufacture, preserving, packing, labelling, storing and testing of any new drug, and

(ii) the sale or the conditions of sale of any new drug, and defining for the purposes of this Act the expression 'New Drug.' "

To sum up: the report of the Hilliard Committee underlines the importance of effective regulation of the licensed manufacture of potent drugs. The Food and Drug Act, in our view, gives you, as Minister of National Health and Welfare, the power to establish and enforce such regulation.

It is our fervent hope that you will.

We would welcome an opportunity to meet with you at your convenience to discuss the matter further.

Yours sincerely,

Wm. W. Wigle, M.D., C.M.,
President.

25520—11½

June 24, 1966

The Hon. Allan MacEachen,
Minister of National Health & Welfare,
Brooke Claxton Building,
Tunney's Pasture,
Ottawa 3, Ontario.

Dear Mr. MacEachen:

Further to my letter of June 16th I can now tell you that the legal representatives of the Association had a useful meeting with Dr. Chapman, Mr. Allmark and Mr. Curran at which time it became apparent that my letter had been written as a result of a misunderstanding as to the position of the Food and Drug Directorate relative to the Hillard Committee Report.

It has now been decided to explore further the legal and scientific matters involved in the implementation of the recommendations and further meetings will be held between the legal and scientific representatives of the Association and officials of the Directorate. Therefore, this matter is to be adjourned pending these further meetings and there is no need to reply to my letter of the 16th at this time.

Yours sincerely,

Wm. W. WIGLE, M.D., C.M.,
President.
Wm. W. Wigle, M.D., C.M.,

cc: Dr. R. A. Chapman

HUME, MARTIN & ALLEN
BARRISTERS AND SOLICITORS
110 CHURCH STREET
TORONTO 1, CANADA

July 12, 1966

Mr. R. E. Curran,
Barrister & c.,
The Food and Drug Directorate,
Ottawa, Ontario.

Dear Mr. Curran:

Further to the meeting held in your office on the 23rd of June, 1966, it was agreed that I would set down my views with respect to a few matters discussed at that meeting relating to the power of the Governor-in-Council to make regulations under The Food and Drug Act.

It is my understanding that some of the recommendations of the Hilliard Committee Report would require amendment of or new regulations in order to effectively implement that report. It is recommended that a manufacturer who has been granted a compulsory licence on a new drug must forward a New Drug Submission to the Directorate but that it was felt by the Department of Justice

that under the present regulations the Food and Drug Directorate does not have the authority to redefine a product which is "not a new drug" so as to give it new drug status if certain injurious side effects occur over a period of use.

It is further my understanding that the Department of Justice felt that the present Food and Drug Act does not permit retroactive reclassification of a drug.

If I have correctly stated the problem, may I say that I am of the opinion that the present statute would authorize the making of any regulations which the Governor-in-Council deemed necessary for the due carrying out of the purposes of the Act.

The former statute only permitted the making of regulations with respect to specific headings. It is significant that the 1952 statute permits the Governor-in-Council to make regulations "for the carrying of the purposes and provisions of the Act into effect". There follow some particular headings in Section 24 but these particular headings are specifically stated *not* to restrict the generality of the general power to make regulations.

If, therefore, the Governor-in-Council deems it necessary to make a regulation redefining an old drug as a new drug for the purposes of carrying the provisions of the Act into effect, it is my opinion that Parliament has empowered the making of that regulation.

There is legal authority for the proposition that a Court will not substitute its opinion for that of the Governor-in-Council unless a particular regulation under a statute is so completely irrelevant to the subject matter of the statute that it would be impossible to argue its necessity. It is my opinion that a Court would not interfere with nor declare invalid any regulation deemed necessary by the Governor-in-Council for the carrying of the Act into effect, particularly if the recommendation arose from a report such as the Hilliard Committee Report.

It is further significant that in 1962 additional headings were included in Section 24; including a heading relating to defining the expression "new drug" It may well be argued that the 1962 amendment was not necessary as the general power of making necessary regulations is unrestricted provided it relates to the purposes of the statute.

If, therefore, it is necessary to implement the recommendations of the Hilliard Committee and to redefine an old drug as a new drug, it is my opinion that the necessary regulations would be within the competence of the Governor-in-Council and would be valid. The power to make regulations being unrestricted and Section 24 (1) (o) (II) containing specific authority to make a definition of a "new drug", it is my view that it is only necessary for the regulation to be passed by the Governor-in-Council, in which event the regulation has the sanction of Parliament. I also include the power to make a retroactive reclassification if the Governor-in-Council deems it necessary in the public interest for carrying the purposes and provisions of the Act into effect. If a drug has been on the market and suddenly shows effects not previously detected, it would seem to me to be a matter of extreme public interest that the drug be reclassified as a "new drug" for the normal procedure of administering the Act and protecting the public interest.

It was suggested at the meeting that there were other procedures that could be adopted but I believe that a direct approach to the problem is more satisfactory as a regulation would be published for all to read and understand.

I trust that my comments will prove of some assistance and am

Yours very sincerely,

FRH/PC

F. R. Hume (facsimile)
CC to Gordon F. Henderson, Esq., Q.C.
Mr. G. J. Gorman
Dr. W. W. Wigle

DEPARTMENT OF JUSTICE

Ottawa 4, September 23, 1966.

R. E. Curran, Esq., Q.C.,
Legal Adviser,
Department of National Health and Welfare,
Brooke Claxton Building,
Tunney's Pasture,
Ottawa 3, Ontario.

Re: Definition of "new drug"

Dear Sir:

208719

I refer to your letter of July 21, 1966, with which you enclosed a copy of a letter to you from Mr. F. R. Hume, Q. C., Counsel for the Canadian pharmaceutical Association.

After carefully considering the arguments raised in Mr. Hume's letter, I find that I am still of the opinion that the Governor in Council has no authority under the Food and Drugs Act to make a regulation to include in the definition of "new drug" an old drug if previously unknown serious adverse reactions develop from its use.

Mr. Hume's opinion appears to be based in large part on the general regulation making power given to the Governor in Council by the introductory words of section 24 of the Food and Drugs Act. I do not think that that general power is of any assistance in this case because, speaking generally, such a general power does not give any authority to define a word or expression for the purposes of an Act. You will appreciate that the power to define a word or expression for the purpose of an Act is, in effect, the power to extend or restrict the operation of the Act. In the case of the Food and Drugs Act, the Governor in Council would have had no authority to define the expression "new drug" if it had not been specifically given by paragraph (o) of subsection (1) of section 24.

The authority to define the expression "new drug" given by paragraph (o) is a very broad one. However, it is not without limits and, in particular, does not authorize the Governor in Council to include in the definition of new drug a drug

that does not have something about it that is new. I do not think that the fact that previously unknown adverse reactions develop from the use of an old drug gives that old drug the necessary quality of newness.

The possible consequences of a regulation of the kind in question should also be kept in mind. One result of it could be that a person lawfully selling an old drug one day could, without this knowledge, be in contravention of the new drug regulations the next day for selling the same drug. A regulation having that result would have to be carefully considered by this Department from the standpoint of the Bill of Rights.

Yours truly,

(SIGNED) D. S. Thorson
Assistant Deputy Minister.

October 20, 1966.

Mr. Frederick R. Hume, Q.C.,
Messrs. Hume, Martin & Allen,
Barristers and Solicitors,
110 Church Street,
Toronto 1, Ontario.

Re: Definition of "new Drug"

Dear Mr. Hume:

As I advised you, I forwarded a copy of your letter of July 12 to the Department of Justice in order that they might give consideration to the points which you raised.

This has been and the Department of Justice advises that they do not feel the opinion already given can be altered. They point out in particular that while the authority to define a new drug is broad, the definition must imply at least something that is new in order to bring a drug into that status. The very fact that certain adverse reactions might be reported in connection with an "old" drug does not of itself give to that drug the necessary quality of newness.

There is, of course, an additional matter that is pointed out and this relates to the situation where if reported adverse reactions automatically brought an old drug into new drug status, a person could without knowledge contravene the provisions of the Act by selling such drug in the same way as he may have sold it over a previous lengthy period. This you will appreciate, could involve the bill of Rights.

I am grateful for the interest you have shown in raising the matters that you did and I hope this will indicate that they have been given very careful consideration. You can be assured, of course, that the situation you raised is not one that will be overlooked because there are other ways of dealing with a drug which is suddenly found to produce hitherto unreported adverse reactions.

Yours very truly,

R. E. Curran,
General Counsel.

October 21, 1966

R. E. Curran, Esq., Q.C.,
Department of National Health & Welfare,
Legal Division,
Ottawa, Ontario.

Dear Mr. Curran:

Thank you for your letter of October 20th.

I note the opinion expressed by the Department of Justice and will pass copies of your correspondence on to my clients.

Yours very truly,

HUME, MARTIN & ALLEN
Per: F. R. Hume

APPENDIX "F"

PHARMACEUTICAL MANUFACTURERS ASSOCIATION OF CANADA
1110 Gillin Building, 141 Laurier Avenue West, Ottawa 4, Ontario

January 9, 1967.
Mr. A. M. Laidlaw,
MacLaren, Laidlaw & Corlett,
30 Metcalfe Street,
Ottawa 4, Ontario.

Dear Mr. Laidlaw:

During the course of our appearance in front of the Parliamentary Committee on Drug Costs and Prices on Thursday, November 24th, you requested certain facts and figures which we were unable to supply at the time. I have since given you this information on the telephone and the present letter is to confirm that conversation.

1. You requested me to give you the history of prescription prices in Canada.

According to the surveys conducted yearly by the Canadian Pharmaceutical Association in all provinces, the average prices of prescriptions to the consumer were as follows:

1941 — 0.87
1946 — 1.14
1949 — 1.38
1954 — 2.28
1959 — 2.98
1965 — 3.32

It should be noted that during those years, the operating costs of the pharmacists have increased so that the cost of ingredients in 1949 constituted a larger percentage of the price to the consumer than in 1965. The therapeutic efficacy of the products has increased considerably, of course.

2. You asked if the products used by the Dominion Bureau of Statistics to establish the prescription index were purchased by brand names or by generic names.

I am informed that DBS uses three therapeutic classifications of drugs in what it calls a "basket of goods". These are: antibiotics, sedatives and hypnotics, and ataractics.

The antibiotics are: Tetracycline 250 mg., 16 caps. Penicillin G 500,000 i.u., 12 tabs.

The tetracyclines surveyed contain six brand names and one generic name.

The penicillins surveyed consist of three brand names.

The sedatives and hypnotics are: Phenobarbital ¼ gr., 100 tabs. Secobarbital Sod ½ gr., 24 caps.

We are told that all brands and generic names of these drugs are surveyed.

The ataractic is: Meprobamate 400 mg., 50 tabs.

The actual products surveyed contain seven brand names and no generic names.

3. You wanted to know what proportion of the yearly research budget of our member companies constituted clinical research. The figures supplied to us by 37 of our 58 members for the year 1965 indicated that the proportion is 23.2%; the actual figures are:

Total out-of-pocket research expenditures: (85.4 % of which is spent in Canada), 9,544,479.

Clinical Investigation (including medical Department), 2,204,825.

Total sales of packaged human pharmaceuticals (37 compagnies), 125,054,386.

It is interesting to note that these companies' research expenditures represented 7.6% of sales in 1965. Comparable figures for Japan are, 5.1% of sales; United Kingdom, 4.2% of sales; and the United States, 9.6% of sales. Despite criticisms to the contrary, the Canadian pharmaceutical industry has nothing to be ashamed of in the research field.

Please do not hesitate to call on us should you require additional information.

Very sincerely yours,

Guy Beauchemin.
Executive Vice-President.

APPENDIX "G"

GOWLING, MacTAVISH, OSBORNE & HENDERSON
Barristers & Solicitors
Patent & Trade Mark Agents
116 Albert Street, Ottawa 4, Canada

January 12, 1967.

Dr. Harry C. Harley, M.P.
Chairman,
Special Committee of the House of Commons on
Drug Costs and Prices,
Parliament Buildings,
West Block,
Ottawa, Ontario.

Dear Dr. Harley:

Re: Submission of Micro Chemicals Limited, Gryphon Laboratories Limited and Paul Maney Laboratories Canada Limited to The Special Committee of The House of Commons of Canada on Drug Costs and Prices.

As you know we are the Solicitors for Hoffmann-La Roche Limited in patent matters in Canada and we have been asked by our client to write to you commenting on the references made on pages 30 and 31 in the brief of the above submission concerning the Statement in the Reasons for Judgment of the Supreme Court of Canada in Hoffmann-La Roche Limited vs. Bell-Craig Pharmaceuticals Division of L. D. Craig Limited, (1966) S.C.R. 313 as follows—

> "Such royalty should also be commensurate with the desirability of making food or medicine available to the public at the lowest possible price consistent with giving to *the inventor*—not the patentee—reward for the research leading to the invention."

The words "to the inventor" can of course be narrowly interpreted and this problem has always been apparent both to our client and to ourselves in dealing with the compulsory licence applications that have been made in respect of Roche patents under Section 41 (3) of the Canadian Patent Act.

Before the British Patent Statute was amended in 1949 the British equivalent of Section 41 (3) read exactly as the Canadian Section 41 (3) now reads and the question of the interpretation of the words "to the inventor" arose in the Case of re Glaxo Laboratories Limited (1941) 58 R.P.C. 12 at pages 16 and 17 where it was held—

> "At the Hearing, Mr. Lloyd Jacob referred to the direction in Subsection (3), that "in settling the terms of such Licence and fixing the amount of royalty" or other consideration payable, the Comptroller 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." He suggested that this direction requires me to make any royalty that I may fix

> under the Licence payable not to the Patentees but to the original inventor. I do not, however, so read the Subsection. Where the inventor and original Patentee has entirely disposed of his interest in the Patent, it would, I think, require a clear direction in the Act before it could be held that any royalty payable under a Licence granted under this Subsection, or any part of that royalty, should be paid to the inventor. And the Subsection does not so provide. The provision in question merely gives directions as to the considerations to be taken into account in settling the terms of a Licence and fixing the amount of royalty or other consideration payable thereunder, and for that purpose takes the case where the inventor is still the Patentee and so entitled to the royalties under the Licence. It is not, in my view, intended to give the inventor an interest in the Patent which he would not otherwise possess."

It is apparent, therefore, that the interpretation placed on the pertinent words of the British Statute was not consistent with what is suggested by Micro to have been the interpretation of the same words in the same section in Canada by the Supreme Court of Canada.

In the above brief and orally before the Parliamentary Committee when the above brief was presented, a great deal was read into the statement of the Supreme Court of Canada that does not actually exist. The statement stands isolated in the judgment without preceding or subsequent explanation of what it was intended to mean. In fact, the interpretation of the said words was not even before the Supreme Court of Canada in the case involved.

During the hearing of that case in the Exchequer Court of Canada, it was conceded by Counsel on behalf of Bell-Craig Limited that the words "to the inventor" should not be narrowly interpreted. At that time Counsel for Bell-Craig said as follows:

> "Your Lordship was asking me at the end of yesterday afternoon about the position I took with regard to the use of the word inventor in section 41 (3). May I put my position in this way. The word must, I submit, be read the way it stands as inventor, as it is in the section, except where, as in this case, the inventor has assigned his invention to somebody else who becomes the patentee; and in my submission the patentee is entitled, by virtue of the assignment, to that reward for research leading to the invention to which the inventor would have been entitled but for the assignment. That is in my submission the way in which the patentee gets into the picture."

The reasons for judgment of the Exchequer Court of Canada in the said case are found in (1965) 2 Ex. C.R. 266 and the President of the Court who wrote the reasons commented on the fact that the interpretation of the said words was not an issue before the Court in a foot note found at page 292 of the Report.

Our Firm acted as Solicitors for Hoffman-La Roche Limited, both in the Exchequer Court of Canada and in the Supreme Court of Canada in the said case. At no time during the appearance before the Judges of the Supreme Court of Canada was any reference made either by Counsel or by the Judges to the interpretation of the said words.

As mentioned, the statement of the Supreme Court of Canada is without any explanation as to the thought behind it and it cannot be said that the controversy was "settled by Mr. Justice Abbott". If it has in fact been settled, then obviously a great injustice has been read into the Section which was never intended to be there. The justification for the interpretation made to the Committee by Counsel who appeared for Micro before the Committee was made on the basis that the Canadian subsidiary owning the patent had not itself done any of the research involved. This would mean that the costs of research would only be recoverable in the country where the research was conducted. This would certainly make the price of drugs prohibitive in such a country, particularly in countries the size of Canada or Switzerland.

Yours very truly,

R. G. McClenahan

APPENDIX "H"

HOFFMANN-LA ROCHE LIMITED
1956 Bourdon Street, St. Laurent, Montreal 9, P.Q.

January 10, 1967

Dr. Harry C. Harley, M.P.
Chairman,
Special Committee of the House of
Commons on Drug Costs and Prices,
Parliament Building,
West Block,
Ottawa, Ontario.

Dear Dr. Harley,

Your Committee will probably recall that much of the testimony of Roche, both in its written brief and verbal answers was directed to explaining the problem and the importance of the scale of and increase in the capital required for the distribution and servicing of drugs.

Our main point has been that no matter who supplies the goods or services which the public requires, whether it be the State itself, the larger international drug companies, or the smaller national companies, such as those who describe themselves as "Canadian-owned", the growth of drug consumption has posed and continues to pose this fundamental problem.

In the discussion which Roche had recently with the Sainsbury Committee in the U.K., Roche pointed to the acceptance by the U.K. Government in a White Paper published in 1961 that the nationalised industries, providing coal, electricity, gas, water etc. must require the consumer to provide, in advance, in the prices it currently pays for those commodities or services, the capital required for the future expansion of their supply.

The reality and importance of this problem was, in Roche's view, perhaps the only significant point to emerge from the appearance before the Committee on November 24th, 1966, of the "Canadian-owned" manufacturers, whose views apparently were mainly those of Mr. Dan.

You will probably recall that in the course of our own verbal explanations to the Committee we suggested that it was unrealistic to believe that small local concerns could adequately supply the public with the greater part of the drug it needs. Mr. Dan's submission seems amply to confirm that, hence "several of our members will merge. . . probably with a substantial public participation".

Mr. Dan also suggested that the "Canadian-owned" may introduce new drugs. But, as we have explained, launching any new drug necessarily involves having available, in advance, a national organisation of men and money for the launching. And all that would necessarily have to be covered in the price of the drug.

In Roche's opinion therefore, the public will merely be deceived if too much credence is given to claims by whomsoever they may be made, that drugs can be

generally supplied to the public otherwise than in the pattern that now exists, or for the most part, at the levels of price that now exist.

Nor is it realistic to believe that the larger international companies can be replaced by the smaller socalled "Canadian-owned" manufacturers. At any rate, Dr. Wright of Empire seemed to accept that even if positive and substantial action were taken to this end, 15 years would elapse before the "Canadian-owned" manufacturers could wholly supply the market.

We think perhaps some brief comment by Roche may assist the Committee, in regard to the somewhat involved argument of Mr. Dan about "Primary, Secondary and Tertiary Markets". This is relevant to the other main point of the Roche testimony, namely that the drug industry is likely to remain internationally organised if only because disease and ill-health are international. Regardless of the ethical problem for any individual "nation", as to whether it should or should not pay other nations for their research, know-how etc., and whether that payment should be secured by adequate patent protection, Mr. Dan's "invention" of these three separate types of market is naive and illogical; as doubtless the Committee realised.

The naivety is perhaps very simply seen by trying to apply Mr. Dan's propositions to the industry as it exists today. Apparently the only markets which would clearly be "Primary" for Roche, and the other major Swiss concerns, would be Switzerland itself, and probably the U.S.A. But the markets in the rest of the world, including that of the U.K. would hardly seem to qualify as "Primary". For most of the German and British concerns, it seems likely that only their domestic market would qualify as "Primary" by Mr. Dan's tests, if such words in them as "most" may be relied upon. Apparently the costs of research would only be recoverable from Primary Markets. This would certainly make the price of drugs, in those markets, quite prohibitive.

It is not true, as Mr. Dan writes on page 6 of his Oral Submission, that the sales in other countries, which he calls Secondary Markets, are "usually small". The British and German concerns would certainly have only a minor part of their sales in Primary Markets, and the overwhelming part in Secondary and Tertiary Markets.

The "passionate pleading" of Roche hardly seems to be destroyed by these rather weird notions. In fact the pleading was only that it be realistically faced that all consumer patients everywhere in the world must contribute to drug research, though some, of course, may often, in practice, contribute more than others. Possibly the consumers in the U.S.A. have in fact contributed most, as they have tended to do to other international burdens in recent years.

Yours very truly,

Hoffman-La Roche Limited
C.A. Nowotny
Assistant Secretary

OFFICIAL REPORT OF MINUTES

OF

PROCEEDINGS AND EVIDENCE

This edition contains the English deliberations and/or a translation into English of the French.

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Translated by the General Bureau for Translation, Secretary of State.

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

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966-67

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 31

FRIDAY, FEBRUARY 3, 1967

WITNESS:

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

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

25607—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

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

and

Mr. Brand,
Mr. Clancy,
Mr. Côté (*Dorchester*),
Mr. Enns,
Mr. Forrestall,
Mr. Goyer,
Mr. Howe (*Hamilton South*),
Mr. Howe (*Wellington-Huron*),
Mr. Hymmen,
Mr. Isabelle,
Mr. Johnston,
Mr. MacDonald (*Prince*),
Mr. Mackasey,
Mr. MacLean (*Queens*),
Mr. O'Keefe,
Mr. Orlikow,
Mrs. Rideout,
Mr. Roxburgh,
Mr. Rynard,
Mr. Tardif,
Mr. Whelan,
Mr. Yanakis—24.

(Quorum 10)

Gabrielle Savard,
Clerk of the Committee.

MINUTES OF PROCEEDINGS

FRIDAY, February 3, 1967.
(44)

The Special Committee on Drug Costs and Prices met this day at 9.40 o'clock a.m., the Chairman Mr. Harry C. Harley, presiding.

Members present: Messrs. Brand, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), MacDonald (*Prince*), Mackasey, MacLean (*Queens*), O'Keefe, Orlikow, Tardif (10).

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

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

The Chairman welcomed Dr. Hilliard, Chairman of the Special Committee appointed in 1965 by the Minister of National Health and Welfare to consider problems involved in the compulsory licensing for the manufacture of new drugs. Dr. Harley expressed his regrets for having omitted to invite, at the same time, the two other members of the above Committee.

Dr. Hilliard explained the background of his report as it appears at pages 146 to 150 of the Committee's Minutes of Proceedings and Evidence.

The Committee considered the Hilliard report, paragraph by paragraph, and questioned the witness as they went along.

Mr. Laidlaw also asked questions.

On behalf of the Committee, the Chairman thanked Dr. Hilliard for his appearance.

At 11.00 o'clock a.m. the Committee adjourned to 9.30 a.m., Tuesday, February 7, 1967.

Gabrielle Savard,
Clerk of the Committee.

25607—1½

EVIDENCE

(Recorded by Electronic Apparatus)

FRIDAY, February 3, 1967.

The CHAIRMAN: Gentlemen, I see a quorum. I would like to start the meeting; we have only an hour and a quarter before the bells ring this morning.

We have with us this morning Dr. Hilliard from Toronto, who I am sure you are all familiar with by reputation; his report has been referred to many times in the Committee hearings to date. Dr. Hilliard is not here to present a brief; he is here to answer any questions or queries you might have concerning his report. It is a pleasure to have Dr. Hilliard with us.

I should say that Dr. Hilliard's position is physician in chief of the Toronto Western Hospital, and, of course, chaired what is now called the Hilliard Committee which brought its report into the Minister on July 8, 1965. For those who want a copy of it in front of them, it has been reprinted as part of our proceedings of Thursday, June 16, 1966, Minutes of Proceedings and Evidence, No. 4, page 146. It was also reprinted in the P.M.A.C. brief.

The meeting is open for discussion and questions.

Dr. IRWIN HILLIARD (*Chairman, Physician-in-Chief, Toronto Western Hospital*): Mr. Chairman, may I make an apology. In flying over this morning I realized that I had been the chairman of the committee because I knew least about it, and here I am before a group of very knowledgeable people who know much more about the whole matter than I do without my two lieutenants. I really think it would have been preferable if we had thought to ask Professor Gowdey and Dr. Gaudry to be here this morning as well. If I muff some of the questions that they would answer quite easily, I can only apologize and say that I was busy and did not think clearly about what you might require in this Committee this morning. With this apology, Mr. Chairman, I will be glad to attempt to answer any questions you might ask.

The CHAIRMAN: The Chairman takes full responsibility for the other omissions. I invited Dr. Hilliard at the request of several of the members of the Committee, and I must say that it never crossed my mind until this morning that we should have also included the other members of your Committee. I apologize to them in absentia. Mr. Mackasey?

Mr. MACKASEY: To give Dr. Hilliard a chance to familiarize himself with the informal atmosphere of these committees, perhaps he would like to explain to us before we get into detail, the philosophy behind the report.

Dr. HILLIARD: Very briefly the fact is, that we had a good directorate with fairly clear cut ideals and a good administrative set-up. The Food and Drug Directorate was responsible for the public safety as far as drugs were concerned and they were doing a good job. As we got to know them and discussed matters with them we realized in greater detail how seriously they took their respon-

sibilities. This was obvious, and it did not seem necessary to set up any other committee or organization to do the job which they were established to do.

However, with this premise it became obvious that they had to be informed. As we studied the compulsory licensing procedures, we realized, to our horror, that there were many loopholes; that they might not be informed, and that the public would be in considerable danger. We also felt that regulations should be made that would allow them, in any dangerous situation, to bring the drug under consideration into the same category as new drugs, so that the safety of the public would be ensured.

I should say, too, Mr. Chairman, that I am not clear on how many recommendations have been implemented; I know some have. I realize the difficulty in implementing others of them.

Mr. MACKASEY: Dr. Hilliard, as a layman on this thing and new to the whole industry and the problems, although since I have been on the Committee I have learned a little bit, something has puzzled me, particularly terminology. Do you think the terminology—new and old—is really a very accurate one in this whole concept; should we not be searching for better terminology?

Dr. HILLIARD: That is a very good question. The more I studied this, the more convinced I was that this was poor terminology. When does a drug not become new? It was used primarily to make use of the very good regulations which have already passed with regard to new drugs. The Committee fell in line with the nomenclature, and I see this gets us into some difficulty.

Mr. MACKASEY: It might get you into some, but I think it gets the Food and Drug and all of us into even deeper problems. As I read some of the literature concerning opinions expressed by the Department of Justice—again, I am not a lawyer—it seems to me that they fall into the trap, if I may use that expression, of precisely what you are saying in sticking to a concept of "new" that I do not think is really applicable to the Food and Drug Directorate.

Dr. HILLIARD: You will notice, Mr. Mackasey, in the recommendations, that we were not thinking of how they would be implemented. Some of them are not applicable because of the varied differentiation between new and old drugs. We thought it should be left to those who make the laws to know how to tie the recommendations into the legal framework. We realized that new recommendations would have to be brought in.

Mr. MACKASEY: If I recall, Dr. Hilliard, one of the problems—just as you have mentioned—of the Department of Justice, while sympathetic to the implementation of some of your recommendations, comes back to the definition of what is new and what is old. This is why I value your opinion on whether we should not find better expressions, even within the Food and Drug Directorate.

Dr. HILLIARD: I would be heartily in support of that.

Mr. MACKASEY: Mr. Chairman, I do not know how you want to proceed on this. Do you want to go paragraph by paragraph with the report, or do you want to start with the recommendations?

The CHAIRMAN: Perhaps it would be best to have any general questioning first and then go into each heading of the report.

Mr. MACKASEY: Then I will pass, Mr. Chairman.

Mr. O'KEEFE: Just one question, Dr Hilliard. It has been said that it is impossible for a government agency—in this case, I suppose, the Department of Health and Welfare—to completely protect the Canadian public in connection with impure drugs or even dangerous drugs. Is this really so, that it is impossible?

Dr. HILLIARD: If one would take "impossible" in its correct meaning, this is true. We know that drugs such as phenacetin and aspirin, which are not controlled at all, can kill people. So it is impossible to make all drugs completely safe for all people.

Mr. O'KEEFE: I was not thinking particularly of drugs like aspirin, but other dangerous drugs. I understand they are not inspected when they come into Canada, at least not every batch is inspected. Should that really be impossible?

Dr. HILLIARD: The committee tells us we could get a lot nearer to it if we followed some of the recommendations, considering drugs such as you mentioned coming under the regulations of new drugs. We felt that this would tidy it up very neatly.

Mr. O'KEEFE: But even with the old drugs, doctor, do you not think it is a rather frightening thought for an ordinary layman to realize that he is not being protected, or his family is not being protected by the proper government agency, and that they have been told it is impossible to have this done? I do not accept the word impossible there, and I was hoping you would not.

The CHAIRMAN: You mean, every batch of every drug?

Mr. O'KEEFE: Yes; if it is dangerous, I think it should be inspected; that seems obvious to me.

Dr. HILLIARD: I think the difficulty sometimes is that the danger is not in the drug but in some impurity which may have come into it. It really would require a much larger organization to carry out this kind of inspection. I am sure this Committee has come to the conclusion, as our committee did, that really safety lies in the character and the commitment of the people making the drug, as much as it does in the machinery that produces them, and in the inspection that we carry out.

Mr. O'KEEFE: Do you think it is safe for us to rely on that commitment?

Dr. HILLIARD: No; I think we should have other safeguards as well.

Mr. O'KEEFE: Thank you, Mr. Chairman.

The CHAIRMAN: I think perhaps recommendation No. 10 deals with that to some extent, under imported drugs. Are there any other general questions of Dr. Hilliard? If not, perhaps we should go on to—

Mr. MACKASEY: I do not know if my question would fall under a general heading, I do not mind not bringing it up now if it will fall under a clause. But reading Dr. Hilliard's statement by Dr. Chapman—I am trying to get my hands on it—I notice there, a resistance to the Hilliard report; or maybe I sense one; that may be a better expression. Are you familiar with Dr. Chapman's statement, of the Food and Drug Directorate?

Dr. HILLIARD: No, I am not.

The CHAIRMAN: You are referring to the statement Dr. Chapman made just the other day.

Mr. MACKASEY: Well, Mr. Chairman, this is for you to rule on, and I will go by your ruling. On page 8 of Dr. Chapman's brief there is a definite reference to recommendation No. 5; now, would you prefer that I ask my question when we come to No. 5?

The CHAIRMAN: Yes, I would think so.

Mr. MACKASEY: That is fine; I will do that.

The CHAIRMAN: I was just noticing that some of the numbering seems to be absent.

Mr. HOWE (*Hamilton South*): Mr. Chairman, this is an extremely general question. In the Committee report that I am looking at, on page 147, I come to the words compulsory licence down near the bottom of the page at paragraph No. 1; on page 148 I find paragraph No. 2; and at page 149 I find paragraph No. 7.

The CHAIRMAN: I was just saying that there are many numbers missing.

Mr. HOWE (*Hamilton South*): I am sorry, I did not hear; I was too busy deciding that for myself.

The CHAIRMAN: I think we will just go by the headings rather than refer to the numbers.

Mr. HOWE (*Hamilton South*): Are there simply numbers missing, or are we missing several paragraphs of information that we should have?

Mr. MACKASEY: I have the Hilliard report here, and if I see that we jump one, or vice versa, I will point it out to you.

The CHAIRMAN: I think the report is complete; it is the numbering that seems to have gone awry.

Mr. HOWE (*Hamilton South*): The report is complete as printed and the error is in the numbering?

The CHAIRMAN: Yes, as far as I am aware.

Dr. HILLIARD: Mr. Chairman, my I make one comment. This was sort of an implied general question. We found that the Food and Drug Directorate, and those who were working with us, were most helpful and most co-operative; this was also true of Mr. Michel the Commissioner of Patents. I do not think we could have produced a report in this detail if it had not been for, not only their co-operation, but their sympathetic approval of what we are trying to do.

Mr. MACKASEY: Yes, I am certain that they are working toward the same end that you are, and that is to increase safety. But in their brief they imply that certain of your recommendations can be arrived at by other ways and means.

Dr. HILLIARD: Yes; I realize that we did not really take into consideration, maybe, the easiest way to do it, and I can see we are putting a lot of hard work in the Food and Drug Directorate.

Mr. MACKASEY: We will see when we get to that clause.

The CHAIRMAN: Is it the wish of the Committee to move down on the report and discuss compulsory licence? Do you have a question Dr. Brand?

Mr. BRAND: No; I will leave it until later.

The CHAIRMAN: Are there any questions under that section of compulsory licensing?

Mr. MACKASEY: Excuse me, Mr. Chairman, are you going down one by one?

The CHAIRMAN: We are at compulsory licensing; I think we will just forget the numbers completely. The report begins at page 146.

Mr. HOWE (*Hamilton South*): Compulsory license is on page 147.

The CHAIRMAN: Yes, that is correct; the report began on page 146.

Mr. MACKASEY: In the statement under compulsory licence, I would just like to read this to you, Dr. Hilliard:

> Compulsory licensing for the production of a drug and its implications relevant to the protection of the public were discussed at some length. This subject of licensing was considered important as the committee feels that patents are valuable in stimulating research and development in the field of drug therapy.

We have heard a lot of controversy on this; certain witnesses have expressed a contrary opinion. Would you like to elaborate a little further there?

Dr. HILLIARD: The committee was unanimous in feeling that patents had a value. We realized that, as a committee, we had to take into consideration the importance of drugs to people as well as their cost. We were not as concerned about cost of drugs as this Committee certainly is. We felt that to give not only credit, but some financial remuneration for research done seemed a very logical way in our modern society and we felt that this should be protected to some extent by the use of patents.

Mr. HOWE (*Hamilton South*): To the same extent it is now, Dr. Hilliard.

Dr. HILLIARD: I think, Mr. Chairman, the Committee is probably aware of the fact that in the last 15 years there have only been ten compulsory licenses given and one could argue that the reason there were not more was the threat of compulsory licensing. This is true, but we really did not have any strong criticism of the patenting laws as applied to drugs as long as there was the loophole that the cost would not become a difficulty for the people.

Mr. MACKASEY: As long as—

Mr. ORLIKOW: May I ask you a question, Dr. Hilliard? Did your Committee look at the—if you did not do any studies on your own with regard to cost —evidence presented to other groups, such as the Kefauver Committee in the United States, and the Restrictive Trade Practices Commission in Canada, both of which came to the conclusion that patents have been and are being used to keep the price of very important prescription drugs at a quite high level?

Dr. HILLIARD: We realize that they sometimes were misused in this regard.

Mr. ORLIKOW: No; I would just like to get it clear, so that in fact you were really concerned only in terms of principle; that there should be nothing done to inhibit the development of new drugs. You did not really look at the implications in terms of cost, did you?

Dr. HILLIARD: I think that at least one other member of the commission was very aware of the Kefauver Report and both of them were more knowledgeable on this point than I am.

Mr. MACKASEY: Again, this is a point of clarification. Your report does not mention costs, of course, and I may have led the Committee into the cost field. The area I had asked you to comment on, and which you did, was the statement that patents are valuable in stimulating research and development in the field of

drug therapy. Judge Thorson, who appeared before us, as a very knowledgeable witness a few weeks ago, in discussing patents and compulsory licensing, expressed the opinion that the compensation to the innovator was a mere pittance. This was his expression and I thought quite objectively he made the statement that—this I think is a fair comment, Mr. Chairman, since you say, stimulate research—that the amount of research done in Canada should be taken into consideration when royalties are being established. Have you any comment on that?

Dr. HILLIARD: Well, certainly in my own department, both in Toronto and Saskatoon, we had support for research, clinical trials, and so on, from drug companies. I had the impression that they would like to do more of it in Canada, and it certainly would help clinical departments a great deal if we did have this support and were able to carry out our own trials rather than taking results from the United States. It is not that Canadians are any more susceptible to drug allergies than anybody else, but it is a matter of pride, I think, that we should do our own trials and I think that those to whom we had talked felt that having a chance to make it sort of their product, partly by patent and partly by name, and so on, added prestige to their company, and it was more than just the financial remuneration.

The CHAIRMAN: Could I ask you a question, Dr. Hilliard. You said, we would like to do more research. Do we have the staff in Canada to do the research; do we have the people?

Dr. HILLIARD: It is hard to answer a question like that. We could have the people if we had the finance. In other words, we are losing people to the United States because they have the finance and we do not. By finance I do not mean just for the payment of the people doing the research but for the building of research space. I have three scientists I would like to bring to Toronto but I cannot because we have not the space and because we have not the money to build the space. Does that answer you?

Mr. MACKASEY: It is sort of the chicken and the egg process.

Mr. HOWE (*Hamilton South*): Mr. Chairman, Mr. Mackasey said that we were inadvertently led into the price field by him. I think that we were led into the price field by the government in their terms of reference to begin with, so to pursue it along the lines which—

The CHAIRMAN: Well, Dr. Hilliard's point was that they did not really take the aspect of cost into consideration in their report at all.

Mr. HOWE (*Hamilton South*): Well, then I would like to ask some leading questions, if I may. Taking into account that we are dealing with prices do you not think that name brand companies are over-protected by patents at the expense of the consuming public, in the drug line, when it has been shown in this Committee that generic drugs are just as safe, as far as public consumption is concerned. The Food and Drug Administration have proven this fact, certainly to my satisfaction. Do you not think that this is providing them with an over-protection?

Dr. HILLIARD: I think there are many ways of influencing people, Dr. Howe. I am not sure that changing the patent law is the most persuasive way of doing it.

Mr. HOWE (*Hamilton South*): I do not understand what you mean by influencing people, Dr. Hilliard.

Dr. HILLIARD: I, for example, I do not think that the pharmacists or the medical professions or, the buying groups, like the hospitals, and so on, bring enough pressure to bear on the large companies to reduce their prices. I think that this is probably a way in which we can be more successful than, or as successful, as doing away with the patent system, although I would agree, that the generic names is something that we all are working toward.

Mr. HOWE (*Hamilton South*): Do you not think that part of this is due to the overbearing influence of the PMAC group that has the money to educate people and doctors, and pharmacists, along this line.

Dr. HILLIARD: I think we all share the blame, Dr. Howe.

Mr. MACKASEY: Including doctors.

Dr. HILLIARD: I said, "we", as doctors.

Mr. ORLIKOW: What pressure can you bring on the pharmaceutical manufacturers except the threat, and the carrying out of the threat, of buying generic products, as an alternative. What other pressure can you bring on them?

Dr. HILLIARD: Well, not buying drugs very much; I do not know, but I would think that where you have large groups like the hospital commissions and the government, and so on, there must be ways in which they can influence the drug companies.

Mr. ORLIKOW: Yes, but the obvious way is to buy somebody else's product.

Dr. HILLIARD: That is correct.

Mr. ORLIKOW: But if a patent has got the product tied up how can you buy another product?

Dr. HILLIARD: Well, I think we really feel that most of the drugs are tied up by patents. I do not think this is as serious a threat, probably as you would imply.

Mr. HOWE (*Hamilton South*): Dr. Hilliard, may I just interject, seeing I was interrupted when I was given my time to be heard. Are we not as doctors all buying drugs with our patients money?

Dr. HILLIARD: The point I was making is that so often we send the prescription and the patient to a pharmacy and never say there are several brands of this, you might get the more reasonable one. At least I very seldom think seriously of the cost of the preparation. I am sure other doctors are much better at it than I am; but when we think of the cost of drugs, many of us feel that drugs, except for a very small proportion of the population, are not an expensive item because they should not be used very long, and that we should be careful to prescribe the right drugs for the right condition and having done this, we stop short of thinking well, could they get this a more reasonable way.

Mr. HOWE (*Hamilton South*): Could you not accept the possibility of a Canadian formulary of equal quality drugs as determined by the Food and Drug administration as being a system that could conceivably lower the price of drugs considerably without decreasing the quality of drugs that patients are receiving?

Dr. HILLIARD: I actually had one or two suggestions which included that, Dr. Howe, but that was not in my report.

Mr. MACKASEY: Mr. Chairman, there have been certain statements made in the last ten minutes along the lines of how or what. Is it not a fact, Dr. Hilliard, that under the present law there are at least several ways to bear on the prices the first one being the issuing of compulsory licenses? Are compulsory licenses issued only in particular cases by the government to protect the Canadian consumer against a monopoly? Is this not the philosophy behind compulsory licensing?

Dr. HILLIARD: That is so, yes.

Mr. MACKASEY: Then, do we not also have the Restrictive Trade Practices Commission, in case there is price fixing? So it is wrong for any member of the Committee to say that we have no ways and means of protecting the public.

Dr. HILLIARD: I assumed that the Restrictive Trade Practices Commission were active in this field, I quite agree.

Mr. MACKASEY: Then, you would agree that out of the study you have done on compulsory licensing these things have been issued—there are ten in number—and if I recall the evidence they are issued to provide competition, healthy competition, for those companies, those innovators who have the field to themselves, and who, in the opinion of the courts, represent a threat to the public in so far as costs are concerned?

Dr. HILLIARD: Correct.

Mr. MACKASEY: Now, perhaps, Dr. Hilliard, you might tell us why your committee was ever set up in the first place, because I think this is an important point here.

Dr. HILLIARD: Officially, or theoretically or practically?

Mr. MACKASEY: Well, I mean—

Dr. HILLIARD: I do not recall the details but I understood there was an application for a drug particular which concerned one of the members of parliament, because it might, if not properly prepared, be dangerous to the people that wou'd be using it. It was in light of this drug being manufactured under a compulsory license or by some special agreement without adequate control that brought the matter to the atention of the house.

Mr. MACKASEY: Adequate control by the person obtaining the right to produce this drug through the medium of compulsory licensing? Was the concern with the innovator or with the copier that led to the events of establishing a committee report.

Dr. HILLIARD: The copier.

Mr. MACKASEY: So, at least in some areas, there is a distinction between the brand and the generic firms, or let us get into the innovator-copier area, which is not quite consistent with what we were talking about a few moments ago.

Mr. MACLEAN (*Queens*): It seems to me that on occasion we do not see the woods for the trees. Surely the question is not so much whether an innovator by having a new drug patented therefore gets more for its manufacture and its sale than might be the case if it were not patented. Surely the question is whether this money, this extra money, these extra charges on the users of drugs, are going to research which is the purported justification for the higher price, and for the purpose of patents to begin with. I think it is completely wrong to state that merely because a copier might be able as a freeloader to produce some drug

cheaper than a patented drug that therefore this is morally right and completely beneficial to mankind.

Take a case which may not be a very good illustration. The benefits which have accrued, it would seem to me, from the discovery of penicillin are so vast that the entire cost of all drugs probably that are sold in Canada would not begin to compare with the benefits which have accrued from the use of penicillin and the thousands of lives that have been saved—if there is any benefit in being alive, sometimes the cost of living is so high that, as a witness said, we wonder if it is worth it sometimes. Surely, if the extra price involved actually goes to more research which advances the pharmaceutical research throughout the world and thereby produces from time to time new drugs which are highly beneficial to mankind the price which is being paid is certainly not too great. The question boils down to whether the extra charges fall fairly on the people who bear them.

Dr. HILLIARD: Yes, Mr. Chairman, I think the committee felt very much along the lines that Mr. MacLean has indicated. We felt that if this was used as a deterrent to the high cost of drugs, our responsibility was to make sure that it was safe; but we felt that the responsibility for deciding whether the price of a certain drug which had been developed with a lot of research and time and effort just was not the responsibility of the committee.

Mr. ORLIKOW: May I just ask one supplementary question, Mr. Chairman, at this point. Is it not right, Dr. Hilliard, that penicillin is a pretty poor example because it was developed without any patents and the British government made all the information available to anybody who wanted it?

Dr. HILLIARD: It is only in part true. As you know, it had to be sent to our wealthy neighbour to the south of us to really exploit its development; that it required a large amount of money to make it available in the way in which it was.

Mr. ORLIKOW: But you did not have the one company monopoly with a patent that you had in the other antibiotics which have been used since then?

Mr. MACKASEY: Dr. Hilliard, do you know how long penicillin lay on the shelf because people would not spend the money to develop it?

Dr. HILLIARD: Thirty years, was it?

Mr. MACKASEY: Do you think a lot of lives could have been saved in those 30 years if private industry had had an opportunity to afford to develop penicillin?

Dr. HILLIARD: That is true, although I think the reason it stayed there was that somebody did not look at it with an inquiring mind.

Mr. MACKASEY: Yes, but who could that someone have been? As Mr. Orlikow mentioned, who had the possibility at the time, 30 years earlier or during that time?

The CHAIRMAN: I think it was first discovered in 1928. I think that was the date.

Mr. MACKASEY: And it was put on the commercial market when—which is Mr. MacLean's point after all.

Dr. HILLIARD: I was thinking of 1926, but 1928 was about the time.

Mr. MACKASEY: Then only because private industry realized the possibility and were ready to spend a million dollars to commercialize it.

Mr. BRAND: No, that is not correct. I cannot agree with this. That is not historically correct, Mr. Chairman. Correct me if I am wrong, Dr. Hilliard. Is it not true that as far as penicillin is concerned its value was not recognized until Dr. Florio, I believe, recognized its possibilities.

Dr. HILLIARD: The point I was making was not just the discovery but the developing and production and so on. This is an expensive part of modern drug development.

Mr. BRAND: Oh, I agree with this. I got the impression from the questioning that nobody wanted to put any money into developing it so it lay there for so many years. I just do not think that this is true.

The CHAIRMAN: I would also say it is probably a poor example and it is now one of the cheapest drugs that is available.

Mr. HOWE (*Hamilton South*): Mr. Chairman, supplementary to that very point, if sufficient public money had been made available to develop these drugs, rather than by development of private enterprise, does this not indicate that drugs, such as in the case of penicillin, insulin, and so on, would be much cheaper to the public rather than by the competition of private enterprise.

The CHAIRMAN: I think insulin itself is still a patent drug and royalties are still paid to the University of Toronto. I am sure of that.

Mr. HOWE (*Hamilton South*): I do not think there is any royalties being paid on insulin.

The CHAIRMAN: I am afraid there is. They are payable to the University of Toronto.

Mr. BRAND: I am afraid I will have to agree with the Chairman because I know it is true that royalties are still being paid to the University of Toronto.

Mr. HOWE (*Hamilton South*): This is a rather unusual political situation.

The CHAIRMAN: We are getting into cross issues here. Mr. MacLean, do you have anything further?

Mr. MACLEAN (*Queens*): I do not think I have anything more to say, except that I started out by saying that I thought penicillin was a poor example. Suppose as a result of research, some new drug is developed that is effective in stopping completely some now incurable disease, surely whether the required dosage is going to cost $4 or $5 is a small item if it is going to save a life. That, of course, does not relieve the Committee from it responsibility of making sure that there are not excessive prices to begin with, and secondly, making sure, as far as this is possible that the cost of drugs fall fairly on the users. It seems to me that the key problem in the cost of drugs is the fact that the buyer does not have a choice. If a drug is necessary, he has to have it, and some people cannot afford it. To me, this is the main problem so far as the price of drugs is concerned.

Mr. HOWE (*Wellington-Huron*): I was rather interested in the suggestion that the committee was impressed by the willingness of the Commissioner of Patents to work closely with the Food and Drug Directorate. In discussing this with Dr. Chapman there came up the question of whether the staff was adequate in the Food and Drug Directorate to look after all the work that was brought before them and whether there was much of a backlog in their work, or if there was quite a period of time between the application and granting of licences. Could you go into that, Dr. Hilliard?

Dr. HILLIARD: Not directly. I know when we suggested frequent inspections they pointed out there was a limited staff and that they would give precedence to new companies or companies preparing new drugs but that there was a limit to what they could do in one year. I did not get the impression that there was any undue delay because of the priority that was given to some of the matters brought out in the report.

Mr. HOWE (*Wellington-Huron*): This question was discussed in the brief that we have before us from the Alberta government indicating that there probably was not enough staff in the Food and Drug Directorate. We sometimes feel that the person who discovers a new drug has a monopoly in the field. During the period when he has a monopoly we know that drugs are at a certain price and then all of a sudden they drop. I was wondering if you could comment on whether, if there was more staff and more adequate facilities in the Food and Drug Directorate, that period would be shortened?

Dr. HILLIARD: Common sense would say that it probably would but I have no statistics on it.

Mr. HOWE (*Wellington-Huron*): As I say, this is a recommendation in the brief by the province of Alberta.

The CHAIRMAN: I should point out that you are referring to a brief that the Committee has not considered.

Mr. HOWE (*Wellington-Huron*): It came up before, that they could, I will not say, be more efficient but probably more expeditious in their examination of the licensees if they had more adequate staff. Do you feel that there are areas where there might be a shortening of time between the application and the granting of the licence?

Dr. HILLIARD: I do not know, Mr. Howe, really. I know that they are pressed from comments they made when we increased their responsibilities but I do not know exactly to what extent this has delayed in any way the granting of licences.

Mr. HOWE (*Wellington-Huron*): I think it would be interesting to find out from the Food and Drug Directorate—

The CHAIRMAN: Yes. They will be back before the Committee.

Mr. HOWE (*Wellington-Huron*): —the average time it takes before the licences are granted.

The CHAIRMAN: Are there other questions, Mr. Howe?

Mr. HOWE (*Wellington-Huron*): That is all. Thank you.

Mr. BRAND: Yes; Dr. Hilliard, I would like to ask a few very general questions. They are related I suppose to the recommendations in your report, sir, but some of them perhaps you will not want to answer, which is quite all right.

Since we are discussing the cost of drugs, do you feel, Dr. Hilliard, in your wide experience as a physician that you can separate quality of drugs from cost of drugs? In other words, can you prescribe on cost alone, or must quality always be a consideration?

Dr. HILLIARD: I would think quality is the major consideration.

Mr. BRAND: And frankly a lot of the discussion we have had in the Committee has been on the quality of drugs. Do you believe that all the drugs on the

Canadian market right now are of quality sufficient to ensure therapeutic effectiveness? Coul you say this without fear of argument?

Dr. HILLIARD: That sounds like a legal question, Dr. Brand?

The CHAIRMAN: A very leading question.

Mr. BRAND: I will rephrase the question.

Dr. HILLIARD: I would reply that I do not think there would be anyone in this room who would be willing to guarantee the quality of all the drugs in all the drugstores in Canada at this moment.

Mr. BRAND: I was thinking, of course, of just prescription drugs at the moment. You did mention a few minutes ago that a lot of us do not say to the patient that there are several different brands of these drugs that he can get, some cheaper than the others. Would you say that you can be absolutely sure of every one of these brands on the market?

Dr. HILLIARD: I would not know enough about it, but I would expect the pharmacist would be able to indicate where two preparations were of the same standard of quality; I would not certainly know, Dr. Brand.

Mr. BRAND: Then you have to depend to a large degree on the pharmacist.

Dr. HILLIARD: Yes.

Mr. BRAND: This, of course, goes back to the report and you refer to the Food and Drug Directorate to a great degree. Do you believe that their methods or their facilities, and I am thinking particularly of their methods of testing drugs, are adequate to ensure the therapeutic effectiveness of drugs on the market today?

Dr. HILLIARD: Dr. Brand, the more I got to know about the Food and Drug Directorate, the higher my regard became for their methods of control. I thought they were doing an excellent job.

Mr. BRAND: I agree with this statement but it does not quite answer the question.

Dr. HILLIARD: You said there was one question I did not need to answer exactly. I will take that one.

Mr. BRAND: Let me rephrase the question. Since most of the testing done by the Food and Drug Directorate would include such things as testing the active ingredient in a pill and the disintegration of the pill and perhaps a little testing in simulated gastric juice, do you think this method is sufficient from your own experience, and we will forget about the Food and Drug Directorate for the moment. Do you think there is any advantage to doing blood levels *in vivo* testing of drugs prior to putting them on the market.

Dr. HILLIARD: Oh, I think the clinical trials are very important. I think this is part of the information that they insist on having before recommending a drug for use. We thought that regulations laid down for new drugs, Dr. Brand, covered this and you probably have them there.

Mr. BRAND: I did not think it had, as a matter of fact, that was why I asked the question. In fact, I am sure it does not.

Dr. HILLIARD: It depends on how you read the words "clinical safety and efficacy". This has to be provided and I assumed that, although—I think, Mr. Chairman, if the Food and Drug Directorate are coming before you again, this might be a good time for this to be asked.

The CHAIRMAN: Yes, we could ask them directly.

Mr. BRAND: Dr. Chapman made some rather strong statements as a result of doing the—

The CHAIRMAN: I do not think that blood levels came into it, as I remember.

Mr. BRAND: I beg your pardon.

The CHAIRMAN: I do not think we discussed clinical tests.

Mr. BRAND: Well, this is exactly the point, is it not? He stated that he took issue with a paper by Mr. Searle and Dr. Pernarowski on phenylbutazone. He said he disagreed with the results of this completely.

The paper was on 23 different brands of phenylbutazone and the Food and Drug Directorate tested one of them but did not of course do any blood levels or anything of this nature, and on the basis of this, felt that the drugs were safe for use.

The CHAIRMAN: But Dr. Pernarowski had not done any blood levels either.

Mr. BRAND: That is not correct; I am afraid he did.

The CHAIRMAN: At least they were not in the report then, as I remember it.

Mr. BRAND: I would be very happy to get you a copy of the report, Mr. Chairman, to show you that in fact they did. He was one of the subjects himself; I had the opportunity to speak to him just the other day to confirm this point. You see what I am getting at Dr. Hilliard. They test them in certain ways but not the clincial efficacy and yet they will allow a drug to go on the market. The clinical testing is not done by the Food and Drug Directorate, but has been done by the large manufacturers before they approach the Food and Drug Directorate. This does not hold true necessarily with compulsory licensing. Some of the smaller firms may not do any blood levels or clinical trials with their drugs. Some of them do, admittedly, but some do not. We may have the analogous situation of a drug with the same amount of chemical, if you want to use that word, in the pill that appears on the shelf and yet the actual therapeutic effect of the drug may be entirely different. This brings me to my next question. Do you believe there is such a thing as generic equivalency?

Dr. HILLIARD: I suppose that is the nearest thing we have at the moment.

Mr. BRAND: To what?

Dr. HILLIARD: To having exactly the same comparison from one drug to another.

Mr. MACKASEY: May I ask a supplementary question? This brings me to a paragraph in your letter to Judy LaMarsh, of July 12, expressing your misgivings of this slight differentiation between the generic and the brand. This is the point Dr. Brand has made; this difference—I should not say, you have minimized it, which is the basis or the crux of the whole Hilliard report.

Dr. HILLIARD: I do not have that paragraph right before me.

Mr. MACKASEY: I will read it after Dr. Brand is through, because I intend to come to it anyway.

This is of course my interpretation, it may not be yours Dr. Hilliard. In your letter you say:

> It was a shock to the members of the committee to find the heavy responsibility put on the Commissioner of Patents. Many of the newer

drugs are so complicated in their formulae that part of the products, the isomers, might not be active therapeutically, though chemically pure, and some dangerous impurities may not be sufficient in amount, in small samples, to be detected.

The even greater worry to the committee was this much larger area of drugs produced under agreement. The Food and Drug Directorate are not informed ahead of time and no inspection is required, although it might occur in the course of time. Samples of the new product prepared by the new company—

Now we are talking about the company that obtains permission and a compulsory licence.

—are now being analysed.

This is the point Dr. Brand was getting at.

Dr. HILLIARD: I think Dr. Brand's point was a little more than that. They analyse it, but they do not insist on clinical trials and it has to do with efficacy. Is that not right, Dr. Brand.

Mr. BRAND: Yes, that is right.

Dr. HILLIARD: I understand that they do take the sample and make sure of the chemical purity, but as you pointed out the isomer may not be as active as originally thought.

Mr. MACKASEY: The point I am trying to make is that nobody as yet proved to my benefit in this Committee that you can copy anything precisely. What bothers me is, how important is the fact that there must be some areas of difference between the original product and the product produced under compulsory licence, or for that matter produced by a competitive brand?

The CHAIRMAN: For the guidance of the Committee I would like to say that the letter under discussion is reproduced on page 144.

Mr. BRAND: I have had recent information, Dr. Hilliard, on the testing being done on various brands of prednisone. Some of them, apparently, say a 5 mg. tablet, with an actual clinical trial and testing the blood levels obtained, show that there is a wide variation in the time it takes to produce the blood level with these different brands, and also in some instances, less than 2 mg of the drug is actually going into the blood stream, and in some 5 mg. There is a wide variation, though they all assay out in pure chemical terms as being 5 mg of the active ingredient.

Dr. HILLIARD: I think, Mr. Chairman, Dr. Brand's point is a very good one. I think we do need facilities in Canada for drug testing, particularly the clinical trials, opposed to the biochemical ones, which are so much more simple. One would hope that, as a result of the work of this Committee it would be possible in Canada to do a great deal more clinical testing of drugs, through research departments in medical schools.

Mr. HOWE (*Hamilton South*): Mr. Chairman, may I ask Dr. Brand a question with regard to this. He has made a lot of rather nebulous statements about efficacy of absorption of drugs. I wonder if these facts could be produced to the Committee, because firstly we are considering price, and your intimation is that there is a direct ratio, between the less efficient drugs and the price of drugs. If this is so, I would like to see these figures, because I think this is an important

consideration and if we are dealing with facts this should be taken into account when we make our recommendations as a Committee.

Mr. BRAND: Mr. Chairman, through you to the gentleman on my left, I will say, I will be very happy to provide such information for tabling if you so wish. There are many well-known papers on this subject including some by Ernest Shain, Max Sadove of Chicago, and many others. I would be very happy to table these, which would show exactly the point I am trying to make. As I pointed out in a Committee meeting, I obtained from one of the witnesses the statement that the Food and Drug administration of the United States, recognizing this problem, has already $4 or $5 million for setting up a type of program which will carry out proper clinical testing, to test the therapeutic efficiency of drugs. I agree with my hon. friend that this is a very serious problem and one which should be of very great concern to the Committee. Furthermore, I think Dr. Hilliard has agreed with me already that quality is of prime importance when you are prescribing drugs, not just the cost, but quality, despite the fact that the government has already pointed out that they buy on cost alone and they have given that evidence before this Committee, as you know, Mr. Chairman.

The CHAIRMAN: Cost alone subject to their being on the government list and meeting the specifications of 74-GP-1.

Mr. BRAND: On the chemical purity of the drug, and that is the point, Mr. Chairman.

Mr. MACKASEY: Could I read another paragraph to strengthen your point. I do not know where it appears in the Committee, but I know where it appears in the Hilliard report. Perhaps Dr. Hilliard with Dr. Brand's permission might comment. It is a simple statement. It says:

> More and more drugs are being produced by synthetic processes of increasing complexity. Because of the number of steps involved and the need for proper care at each intermediate step, it has become essential that adequate quality control procedures be established and carried out at all levels of the manufacture or synthesis of the chemical involved. It is not sufficient any more to perform a simple test on a finished product.

I think this was the point Dr. Brand was getting at:

> It is not sufficient any more to perform a simple test on a finished product.

And this bothers me:

> In many cases such tests would not disclose the presence of potentially dangerous by-products or impurities or even chemical isomers which should be removed from the desired material if at all possible.

And then finally—and this is what I would like someone to analyse:

> Minor changes in process may perhaps lead to quite different contaminants in finished products and these contaminants may be toxic and may even be missed by routine chemical analysis.

Do I gather from this, or do I get the wrong conclusion, doctor, that these minor changes in process could be the minor changes in process of the copier of the original method employed by the innovator. Am I right there?

Dr. HILLIARD: This is what we were worried about.

Mr. MACKASEY: Are you still worried about it?

Can I repeat it then:

> Minor changes in process may perhaps lead to quite different contaminants in finished products and these contaminants may be toxic and may even be missed by routine chemical analysis.

Dr. HILLIARD: I think Dr. Roger Gaudry was the one most familiar with this aspect and he had certain examples, which he brought before the committee, which concerned us.

Mr. MACKASEY: I am not trying to be unfair to the copiers. How can we possibly under the pretence of dropping cost permit such a situation under compulsory licence? I am not against compulsory licence per se. I am against the Department of Justice permitting someone under compulsory licence.

Dr. HILLIARD: Frankly, Mr. Chairman, this is what concerned us. When we took a look at it, we did not realize that this had been functioning in Canada for these years, and we felt we did not have the direction to discuss whether this should be continued or terminated. What we were trying to do is to make it as safe as possible. We did consider Dr. Brand's question of insisting on clinical trials of all the variations and we felt that, although it was very reasonable and certainly beneficial, it was not possible in Canada until we had a greater extension of our research facilities. To put something in, which at this time could not be implemented, did not seem reasonable.

Mr. MACKASEY: What you are saying, in conclusion, is that as long as we do grant compulsory licence as long as necessary as some brake on prices there will constantly be the problem of minor changes in process leading to contamination. What your report has done, realizing that this is inevitable, is to try to minimize it?

Dr. HILLIARD: That is right.

Mr. HOWE (*Hamilton South*): The intimation is that the cheaper drugs, the copier, the generics, are necessarily the drugs that are less effective. Is this the intimation? Is this factual; is this suggested or can any make of drug be less efficient than another, clinically?

Dr. HILLIARD: We did not imply that the copier was necessarily the cheaper one. All we meant was, when you innovate, when you start a new production line in a different circumstance, you run into certain dangers, which have to be safeguarded.

Mr. HOWE (*Hamilton South*): No, you said that it did not necessarily mean that the copier was the cheaper one. I ask, is the copier necessarily the less effective one, the more dangerous one?

Dr. HILLIARD: He might have a better preparation.

Mr. HOWE (*Hamilton South*): That is my point. So it can be either way. There is no direct ratio or relationship between the price of the drug and the efficacy of that same drug, necessarily?

Dr. HILLIARD: Not necessarily, but we all know that one way to reduce a price is to reduce control and some of the very careful analysis that should go along with it.

Mr. HOWE (*Hamilton South*): But Mr. Chairman, it was shown in the PMAC brief that this is a very small portion of the cost of the drugs, so I do not think it

really enters into it. There are many other factors. If my memory is correct, the control of the drug was either a half of one cent of the 37½ cents that the manufacturer received out of a prescription dollar. This is a pittance. This is not important. I hardly see this as a genuine means of lowering price in many instances to only 10 per cent of the brand name drug. Certainly this 90 per cent is not used up in quality control; therefore, my question is: Are you intimating that there is necessarily a genuine relationship between the price of drugs and the quality, or efficacy, the clinical effectiveness of this drug?

Dr. HILLIARD: I do not think I implied that, Mr. Chairman.

Mr. HOWE (*Hamilton South*): I just wanted to make sure that that implication was not there, because again this is important in their consideration.

Mr. MACKASEY: Mr. Chairman, I think I agree with Dr. Howe. To clear it up I would like to say that Dr. Hilliard is not here to worry about costs. I understand that your report was set up to make sure that drugs which are reproduced by compulsory or voluntary licence would be as safe as or safer than that of the innovator. This leads me to the next paragraph in which you refer to the minor changes in process which lead to contamination. Then you say in the next paragraph, which again bothers me:

> Chemical producers with insufficient staff and technical facilities may either be unaware of or tend to ignore these problems—

Now, the problems which you have just mentioned are contamination. You go on to say:

> Chemical producers with insufficient staff and technical facilities may either be unaware of or tend to ignore these problems, or may be unable to institute the necessary control procedures which will ensure a standardized product which is safe when used according to direction.

It seems to me that we should have at the disposal of the Canadian people some way of making sure that an institution that obtains a voluntary or compulsory licence does not fit into this last section, and I will reread it:

> —or may be unable to institute the necessary control procedures—

Why would not an institution be capable of instituting the necessary control procedures?

Dr. HILLIARD: I think Dr. Gaudry was aware of some companies that were on the whole producing the simpler products and might be quite safe and efficient in their production. They might want, through a compulsory licence, to prepare more complicated ones and this would be the worry of the committee, that they would not have adequate staff for the new drugs which they are copying, rather than the ones which they have been doing quite safely.

Mr. MACKASEY: Would you draw the Committee's attention to your recommendations which would prevent this?

Dr. HILLIARD: The committee felt that in treating these drugs prepared by the companies under compulsory licence, they should be treated as carefully as a new drug. This is in essence what they say. They made the three points of chemically, that they were prescribed properly and the information was available. It really boils down to taking as careful a look at it as they do with a brand new preparation coming on the market.

Mr. MACKASEY: This is equally true of those who get the voluntary licence?

Dr. HILLIARD: Yes.

Mr. MACKASEY: I am falling into the trap of compulsory licence, the voluntary licence—

Dr. HILLIARD: Which is the largest, of course.

Mr. MACLEAN (*Queens*): Mr. Chairman, I have a supplementary question. Is not the crux of the whole thing that copiers, whether they are compulsory licensees or voluntary licensees, should be prepared to prove that their product is, as a result of clinical tests, at least as effective as the product they are copying and they should not be able to put a product on the market as a licensee which might not pass clinical tests?

Dr. HILLIARD: I think that is true.

The CHAIRMAN: If I may ask a question: Going back to Mr. Mackasey's question of a moment ago about the risks of having an impure product on the market and you say this is a risk in your clinical knowledge. Have you ever seen this happen, a new product came on the market and it obviously had some impurities or there was something wrong with the product?

Mr. HOWE (*Hamilton South*): Mr. Chairman before Dr. Hilliard answers that, what do you mean by "new product?" Do you mean a copy product or do you mean—

The CHAIRMAN: A copy product, but not a new product.

Dr. HILLIARD: I do not have the details here, but they could be furnished if the Committee so desires.

The CHAIRMAN: I would point out to the Committee that we only have 10 minutes left and we might make our questioning brief.

Mr. A. W. LAIDLAW (*Legal Counsel for the Committee*): I wonder if I might ask Dr. Hilliard a question regarding his recommendations with respect to the compulsory licencing provision of the Patent Act. I have been told that as a result of your report, Dr. Hilliard, there is very close collaboration at the moment between the Commissioner of Patents and the Food and Drug Directorate, but it is on an informal basis and I believe the Commissioner of Patents writes the Food and Drug Directorate when an application for a compulsory licence is made. The Food and Drug Directorate then replies. I am wondering whether your recommendations here do not, in effect, take away from the Commissioner of Patents his present sole discretion with respect to issuing a compulsory licence and transfer that onus to the Food and Drug Directorate. I understand that the Commissioner is very jealous with respect to his prerogative rights under the Patent Law as it stands at the moment, and he feels that he can ask the Food and Drug Directorate what he wants, but he does not necessarily have to follow any advice given by the Food and Drug Directorate. Are you really in fact recommending, sir, that the authority of the Commissioner of Patents be changed by law and either transferred in total or in part to the Food and Drug Directorate?

Dr. HILLIARD: You have put that very well, Mr. Laidlaw. I would expect that a lawyer would put it down that way. Wes, we thought there would need to be some revision of the Patent Act.

At the moment, legally the Commissioner of Patents has full responsibility. Let us assume that he feels he should grant the licence, although the Food and Drug Directorate have recommended against this, and some of the drug comes on the market and within a month, it has to be given over to the Food and Drug Directorate and they check it, and they find that it is not standard or even dangerous; the Commissioner of Patents has really put himself in a very awkward position. I would think that although it does, in a sense, detract from his sole responsibility, nevertheless he runs a very serious danger to his reputation, if he proceeded contrary to the advice of the Food and Drug Directorate. Therefore, although he has full legal responsibility, I think he would feel—and I think any Commissioner of Patents would feel—a moral responsibility to pay very careful attention to the recommendation of the Food and Drug Directorate.

Mr. LAIDLAW: Then by law you think there should be a shared responsibility between the Commissioner and the Food and Drug Directorate with respect to these doings.

Dr. HILLIARD: I think this would make it easier.

Mr. LAIDLAW: The only controversy on this is that there have been complaints I believe when compulsory licences have been issued in the past—these 10 or 14 licences—that it takes some time to issue from the time the application is made. The Commissioner has told me that this time varies between six months and 3½ years, between the time of application and the time the licence is granted. By introducing the Food and Drug Directorate, by law, also to participate in this decision, I am wondering whether or not this would extend the length of time before the licence is granted to such an extent that no one would apply for compulsory licences, with the consequent result that prices could not be reduced by the issuing of a licence.

Dr. HILLIARD: I would not think this was really necessary. One of the dangers of our modern world, with telephones and so on, is the lack of communication. I think, if one considers a drug company preparing to produce a product and it would take quite some time to get the machinery and the know how and so on, that it is during this stage they could also be going through the procedures of getting their licence and accreditation with the Food and Drug Directorate. I really cannot see any undue delay unless, as was suggested by Mr. Howe, they did need a few more people in their department, and I am sure we would all be in favour of that.

Mr. LAIDLAW: Thank you, Dr. Hilliard, that is all I have, Mr. Chairman.

The CHAIRMAN: Mr. Mackasey.

Mr. MACKASEY: To supplement what you just finished saying, and I am only going by memory, but I think somewhere you implied that there was a possibility of firms obtaining compulsory licences or, for that matter, selling drugs for a considerable period of time before the Food and Drug Directorate catch up with them. Is that in here?

Dr. HILLIARD: I do not recall, but certainly in the past it has occurred that they have not caught up with them for some time.

Mr. MACKASEY: Is it possible at all theoretically? Surely it could not be possible for those who are applying for a compulsory licence to do this?

Dr. HILLIARD: No; this would be in the secondary group where a threat of compulsory licence caused a secondary supplier to be tied in with the primary producer.

The CHAIRMAN: I think Dr. Chapman said that this was not now possible under the new notification program.

Mr. MACKASEY: Excuse me, Mr. Chairman, but it certainly is. It is quite possible under the notification program. Mr. Allmark is bowing his head that I am right and this will not go on record. All the notification of drugs does is enable the Inspector of the Food and Drug Directorate eventually to catch up with those who put drugs on the market without notifying the Food and Drug Committee, and this could still take months. There is no fool proof method other than registering or licensing.

The CHAIRMAN: I think we might go into that when the Food and Drug people are before us.

Mr. BRAND: I would just like to ask Dr. Hilliard two very short questions. Do you think it is about time, in view of the importance of the drugs on the market to the consumer, that the Food and Drug Directorate are separated into a food testing branch and a drug testing branch, with a pharmacologist rather than just a chemist overseeing the operations. Do you think pharmacologists perhaps in a sense have a little more to offer on the therapeutic effect of drugs?

Dr. HILLIARD: I think it should be a combination. In certain drugs, the chemical side is the important one and in certain others it is the pharmacological, and I think they would have to be tied in. It seems neater to have them separate, but it is very hard to separate them.

Mr. BRAND: Do you think it would be a good idea to have some pharmacologists around there though?

Dr. HILLIARD: I do not know whether they have, or have not, but I think, as you point out, the whole testing is both in the biochemical and the pharmacological field.

Mr. BRAND: Thank you.

Mr. MACLEAN (*Queens*): I have one brief question on recommendation 5, for clarification. We have not come to it yet, but might I be permitted to ask a question. It reads:

> That the definition of a new drug be amended to include a drug not currently in new drug status if it is to be manufactured or produced by a method or process that is substantially different from the method or process currently being used in Canada; or if with prolonged use, new or more serious or more frequent side effects, develop.

That is perfectly clear as it stands, but surely is it not the case that the statement is not as broad as it should be? Are there not cases where it is not a matter of new side effects being developed by the prolonged use of a drug, but that new side effects are discovered that were always there, but were unsuspected, such as was the case with thalidomide?

Dr. HILLIARD: Yes; I think as Mr. Mackasey has pointed out, it is unfortunate to use the term "new drugs". If a drug has been on the market 10 years and you want to re-evaluate it, I am sure that when this is put into legal terms there is a clearer way of saying the drug which is developing side effects should be

re-evaluated in the same way that a new drug would be; this would make it clearer to me.

Mr. MacLEAN (*Queens*): Is it not wrong to use the words developing side effects; side effects were always there but were not realized.

Dr. HILLIARD: Disclosing and—

Mr. MacLEAN (*Queens*): Discovering—

Dr. HILLIARD: Exhibiting new side effects.

Mr. MACKASEY: Well, are we finishing up now, Mr. Chairman, or are we going on?

The CHAIRMAN: That is up to the Committee; as far as I am concerned we are ending.

Mr. MACKASEY: Well, the biggest area has yet to be investigated. Could it be possible then, in view of the fact that the Food and Drug Directorate will be here to talk about the Hilliard report, if we are not satisfied, Dr. Hilliard would come back, because I do not think we ever got to the main point of your brief.

There is an area, for instance, where you stress the desirability and the necessity of literature.

Mr. HILLIARD: Yes.

Mr. MACKASEY: This is a little contrary to some of the expressions here that all literature is bad. We have had this said in the Committee. You are recommending more information—and I am just jumping around through it briefly—and the availability of information is one of your recommendations; notificaton, identification, and an area on imported drugs, Mr. Chairman, all must be passed over and ignored because of a shortage of time.

The CHAIRMAN: We will take into consideration what you have said, Mr. Mackasey.

Mr. MACKASEY: I do not think we are doing justice to perhaps the most important report that has come before us in years. I just do not think we have had time to do justice to it.

The CHAIRMAN: We could sit this afternoon while the house is sitting, but I doubt whether we would get enough Committee members to make a quorum.

Dr. HILLIARD: Mr. Chairman, I would be glad to come back, and if so, I would like to have Dr. Gowdey and Dr. Gaudry with me; I think they would add quite a bit to the discussion.

The CHAIRMAN: That is fine. Gentlemen, there is one other piece of information I have, but perhaps I should put it on next meeting.

The meeting is adjourned until Tuesday when we have the Director of Investigation and Research, (Combines Investigation Act), before us, at 9.30 a.m.

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966-67

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 32

TUESDAY, FEBRUARY 7, 1967

THURSDAY, FEBRUARY 9, 1967

WITNESSES:

Mr. David H. W. Henry, Q.C., Director of Investigation and Research (*Combines Investigation Act*); Mr. F. N. MacLeod, Senior Combines Officer, Combines Branch; Mr. R. M. Davidson, Officer in charge, Merger and Monopoly Section, all of the Department of the Registrar General, and Mr. Michael Sheldon, of Montreal, Assistant to the General Manager, Smith Kline & French/Montreal.

From the 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. L. Levi, Chief, Pharmaceutical Chemistry Division; Mr. A. Hollett, Director, Bureau of Operations; Dr. R. C. B. Graham, Division of Medicine and Pharmacology.

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

27609—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

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

and

Mr. Brand,
Mr. Clancy,
Mr. Côté (*Dorchester*),
Mr. Enns,
Mr. Forrestall,
Mr. Goyer,
Mr. Howe (*Hamilton South*),
Mr. Howe (*Wellington-Huron*),
Mr. Hymmen,
Mr. Isabelle,
Mr. Johnston,
Mr. MacDonald (*Prince*),
Mr. Mackasey,
Mr. MacLean (*Queens*),
Mr. O'Keefe,
Mr. Orlikow,
Mrs. Rideout,
Mr. Roxburgh,
Mr. Rynard,
Mr. Tardif,
Mr. Whelan,
Mr. Yanakis—24.

(Quorum 10)

Gabrielle Savard,
Clerk of the Committee.

CORRECTIONS (English copy only)

PROCEEDINGS No. 26—Tuesday, December 13, 1966

Cover page—*Representing Jules R. Gilbert, Ltd:* Mr. Jules R. Gilbert, Ph.G., B.S., *Ch.E.* of Toronto.

Page 1696—Add comma after had not been, 5th line of par. 1 of Mr. Gilbert's evidence.

Page 1697—6th line—*Triperazine.*

Page 1699—5th line—*74*-GP-1 regulations instead of *47*-GP-1

Page 1703—7th line—*Chlorodiazepoxide* instead of echlorodiazopoxide.

—19th line—Mr. GILBERT: Where is Morrell right now?

Page 1704—29th line—certain *inequities.*

Page 1705—3rd line from the bottom—*Rhone* Poulenc

Page 1707—38th line—*forty* million units instead of "quarter of a"

Page 1710—37th line should read: He has responsibility and I think he is caught *between* three *millstones*:

Page 1712—10th line—the *knowledgeable* physician

Page 1716—20th line should read: Has a better product in their *stock,* they will not put it out until the *life* of that

—8th line from bottom: In other words, *if you have four*

Page 1719—32nd line—*compulsory*

Page 1720—18th and 19th lines: I may only be *95 per cent correct*

Page 1721—6th line—delete "it" after I am doing.

Page 1726—7th line—but the decision is *theirs.*

Page 1728—28th line should read: patents have been *set* aside,

Page 1729—5th line—add comma after patent.

Page 1730—7th line—the law controls it in the way *it* decides...

Page 1733—2nd line—*generic*

18th line—*knock*

24th line—You have *substituted* gifts...

Page 1734—30th line—*when* they get beyond a certain point...

Page 1744—3rd line—*endurance*

—27th line—substitute *two* patents for ten

Page 1747—7th line—to assess carefully the *real* value

Page 1749—13th line—question of *mg.* equivalent

Page 1750—last paragraph: add "*a*" after visiting, in the first line.

Page 1750—14th line: *Furodantin*

Page 1756—last paragraph, 5th line *Also,* it is...

25609—1½

MINUTES OF PROCEEDINGS

TUESDAY, February 7, 1967.
(45)

The Special Committee on Drug Costs and Prices met this day at 9.50 o'clock a.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Messrs. Brand, Enns, Forrestall, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), Hymmen, Isabelle, MacLean (*Queens*), Orlikow, Rynard (11).

In attendance: From the Department of the Registrar General: Mr. David H. W. Henry, Q.C., Director of Investigation and Research (Combines Investigation Act); Mr. F. N. MacLeod, Senior Combines Officer, Combines Branch; Mr. R. M. Davidson, Officer in Charge, Merger and Monopoly Section. Mr. Michael Sheldon, of Montreal, Assistant to the General Manager, Smith Kline & French/Montreal.

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

Agreed—That a report entitled "The Cost of Pharmaceuticals and Medicines in Canada, 1961-1965" copies of which have been distributed to the Members of the Committee, be printed as an appendix to this day's proceedings. (*See Appendix "A"*)

Agreed,—That a letter dated January 27, 1967 from the Honourable Minister of National Health and Welfare to the Chairman of the Committee be printed as an appendix to this day's proceedings. (*See Appendix "B"*)

The Chairman called Mr. Henry who introduced the officials accompanying him.

Mr. Henry went through the statement which had been previously distributed to the Members. He was questioned on some of his remarks. Mr. Sheldon was invited to comment on some information contained in the above statement which concerned Smith Kline & French/Montreal.

Agreed,—That the statement of Mr. Henry be printed as part of the record.

On motion of Mr. Isabelle, seconded by Mr. Brand,

Resolved,—That a per diem allowance be paid to Dr. Irwin Hilliard who has been called to appear before this Committee on Friday, February 3.

Mr. Henry was questioned. He was assisted by Messrs. MacLeod and Davidson who also supplied information to the Members.

Mr. Blakely commented on cost allocation.

Mr. Henry was further questioned.

The Chairman thanked the officials for the information supplied to the Committee.

At 12.40 o'clock p.m. the Committee adjourned to 1.00 p.m., Thursday, February 9.

THURSDAY, February 9, 1967.
(46)

The Special Committee on Drug Costs and Prices met this day at 1.20 o'clock p.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Messrs. Forrestall, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), MacDonald (*Prince*), Mackasey, MacLean (*Queens*).

In attendance: From the 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. L. Levi, Chief, Pharmaceutical Chemistry Division; Mr. A. Hollett, Director, Bureau of Operations; Dr. R. C. B. Graham, Division of Medicine and Pharmacology.

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

The Chairman called Dr. Chapman who was questioned.

Mr. Allmark also answered questions asked by Members.

Dr. Levi gave information on the investigation carried out on bulk chemicals.

Mr. Hollett explained how the regulations governing radio and television commercials can be applied.

Dr. Chapman was further questioned.

On behalf of the Committee, the Chairman thanked the officials of the Food and Drug Directorate, and at 2.45 p.m. the Committee adjourned to 9.30 a.m. Tuesday, February 14.

Gabrielle Savard,
Clerk of the Committee.

EVIDENCE

(Recorded by Electronic Apparatus)

TUESDAY, February 7, 1967.

The CHAIRMAN: Gentlemen, I see a quorum. We will start our meeting this morning.

Before we begin with our witnesses today, there are two matters I would like to bring to the attention of the Committee. First, I have received 24 copies of a report entitled: The Cost of Pharmaceuticals and Medicines in Canada, 1951 to 1965, which is really an updating of portions of the report "Provision Distribution and Cost of Drugs in Canada" that was prepared for the Royal Commission on Health Services—the Hall Commission—in 1963. There is a great deal of fact and figure about drug prices in this, and I think the best thing to do would be to have it printed as part of the record, and you will also get a copy in the mail today. I am sorry, it has been sent within the last day or so. Is it agreed that it become part of today's record?

Some hon. MEMBERS: Agreed.

The CHAIRMAN: There also is communication from the Minister of National Health and Welfare, the hon. Mr. MacEachen, forwarding to us two resolutions passed by the National Pensioners and Senior Citizens' Federation. I suggest, rather than read it, that it he made part of today's record. It deals with some assistance for old age pensioners for drug provision and also asks for an inquiry into hearing aid costs. Is it agreed that this become part of today's record?

Mr. HOWE (*Hamilton South*): Is it applicable to the drug prices, do you think?

The CHAIRMAN: Not really, they want a government inquiry into whether drug prices are justified, which is what this inquiry is doing, and whether some system would be devised where they could be made available free, when necessary, to those in the low income group.

Mr. HOWE (*Hamilton South*): Drugs?

The CHAIRMAN: Yes.

Mr. BRAND: Not hearing aids?

The CHAIRMAN: Drugs, and they inquire also about hearing aids in a later resolution.

Mr. BRAND: As long as it is applicable to our terms of reference, because we are getting so cluttered up with—

The CHAIRMAN: The first one certainly is, and the other one is part of the letter. Is it agreed?

Some hon. MEMBERS: Agreed.

The CHAIRMAN: We have with us today, Mr. Henry, who is the Director of Investigation and Research, Combines Investigation Act. He has with him, two members of his staff and I think I will call on him to introduce them. Mr. Henry has prepared a statement which has not been in your hands very long—probably just since this morning—I have discussed this with him and decided that the best thing to do is to go through it very rapidly and cover the major points in it. Mr. Henry?

Mr. DAVID H. W. HENRY Q.C. (*Director of Investigation and Research (Combines Investigation Act) Department of Registrar General*): Thank you, Mr. Chairman. Gentlemen, I have with me, on my right, Mr. R. M. Davidson, and on his right, Mr. F. N. MacLeod. Mr. Davidson's specialty is economics; Mr. MacLeod is a lawyer who did the major part of the work on the Green Book, which, as you know, is the basic book of data that was prepared as a result of the inquiry under the Combines Investigation Act that we undertook about 1960.

Before I make my statement, I know members of the Committee will fully understand this but perhaps for the record I should say that I am speaking here as Director of Investigation and Research, a statutory officer, making what contribution I can to this difficult subject; I am not speaking for the government or making any announcement of government policy, as you understand.

Now, again, before I get into the text of what I had proposed to say, I would like to point out that I am making one assumption here in my remarks, and that assumption is that it is the purpose or the object of this study to attempt to find a way to reduce the prices of drugs. My remarks are made in that context.

I am also making another assumption, and that is, that I regard as completely paramount the necessity of making sure that Canadians receive drugs of high quality, drugs which are safe, and drugs which are effective. Anything I say has borne that in mind, and as I say, to me that is paramount; it is not even an issue in this debate; I do not think anybody would quarrel with this point.

So, my object today, if I may put it very briefly, is to try to clarify for the members of this Committee the issues, as I see them, arising out of the great mass of material that has been placed before you. I am seeking to reduce them to their simplest terms so that, through the mass of detail, it may be possible to determine exactly what the issues are with which this Committee has to grapple, as I see them, and I hope that you will find this helpful. I have attempted to make this an objective analysis—this is always the approach we take in the combines branch with the sole purpose of seeing how this problem, of what we generally regard as the high cost of drugs, may be met.

Now, gentlemen, my basic contribution in this matter is contained in the so-called Green Book, that is as far as data are concerned. You are familiar with the Green Book and I need say no more about it except that it contains the data that we were able to find at the time of the inquiry, and, of course, is valid as of 1960. I can say this. I think there is no real difference in the basic facts concerning this industry as between 1960 and now. There have been changes in the data, but it is my view that there is nothing of significance to the purpose of this inquiry. In other words, the Green Book, I think, points up the trends, and the data may be used as an analysis just as much as current up to date data.

One thing I might mention is that there has been a recent increase in research, attributable, as I see it, to the government's incentive program that

perhaps has taken place since the Green Book was prepared. Members of the industry may also say that the change has taken place in the law with respect to the setting of a royalty for a compulsory licence. I do not see that as a change in the law, but nevertheless since royalties are now smaller it may be that some individuals consider compulsory licences are a little easier to get.

Apart from those things, gentlemen, I think the basic data in the Green Book and the implications that can be drawn from that, are completely valid now.

Now, I have been asked to deal with patents and research; that is what I am concentrating on today. On page 2 of the paper, which I understand you now have, and which I sent over yesterday, I have tried to set out the problem, and perhaps you would not mind if I read the paragraphs that deal with that.

As I see it, the problem is effectively stated by that portion of the terms of reference of the Committee which reads:

> 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.

In further defining the problem the following points may be considered. (a) The price of patented drugs in Canada is too high, and I emphasize the word "patented". This fact has been determined by two commissions (Restrictive Trade Practices Commission and Hall Commission). The prices of patented drugs have been described as among the highest in the world if not the highest. For the purposes of this Committee's work, however, it is necessary only to make the point that the prices of patented drugs are higher than they need be. (b) The high level of such prices is attributable primarily to lack of effective price competition. This is likewise the finding of the two commissions; this is also the view of one professional economist who has appeared before this Committee and it is a view that I personally share.

Apparently the problem is created and aggravated by certain characteristics of the industry. I made a brief survey of some relevant industry characteristics, which I will not read through, but I will say briefly that we are relying in Canada on the private enterprise system to get our supplies of drugs. Under such a system manufacturers, distributors, and retailers all seek to make profits, which is perfectly proper; that is the way the system works. This system, in the drug field, is subject to certain statutory controls, which is not unusual because there are other industries which are also subject to statutory controls.

Now, drug manufacturers do two things. They manufacture and they import. As I will say later, they rely very heavily on imports; notwithstanding that they also carry on manufacturing activities. As there is no developed fine chemicals industry in Canada the basic drugs are mainly imported. In many cases final dosage forms are imported. The manufacturing activity in Canada is largely a matter of converting bulk drugs into dosage forms and packaging and marketing them. By converting, I do not mean merely, necessarily, just a mechanical operation, because compounding is also included in my expression "converting".

Now, I said something about the size of the employment group here. It is well known, there is something like 10,500 employees in the industry at the

manufacturing level. I merely want to point out that on the basis of DBS figures, recently received, 4,500 of those employees are actually employed on manufacturing itself; the remaining 6,000 are on activities that you would not call manufacturing. We have the DBS definition of manufacturing here, if you wish me to read it.

There is a footnote on page 3A, incidentally, which is designed to help avoid falling into the trap which may come out of statistics used to indicate the amount of imports; I am not going to say anything more about that because this can be read and discussed later if necessary. (The footnote follows):

3A

*The P.M.A.C. brief to this Committee states, at page 287 of the Minutes of Proceedings and Evidence, No. 5, June 23, 1966, that approximately 83 per cent of prescription products sold in Canada were manufactured here, the remaining 17 per cent being imported. As the Hall Commission has observed, meaningful statistics as to the proportion of drugs imported and those manufactured in Canada are not available. Where competition does not operate as in the case of patented drugs, the large differential between cost of production and selling prices of such products seriously distorts available statistics on the industry in Canada. To take an example, a drug is imported into Canada from a parent company, almost in a ready-to-sell condition, for $3.88 (see page 16). Packaging expenses of 24¢ bring the total factory cost of up to $4.12. It is sold by a Canadian subsidiary for $63.51. When this is translated into general statistics this becomes imports into Canada $3.88, value of sales by Canadian company $63.51. This, in turn, becomes the basis for a statement that 94 per cent of the drugs sold in Canada are produced in Canada. But in so far as our example is concerned, production in Canada is virtually nil. It is obvious that if total figures include many examples like this, they do not provide a reliable indication of drug manufacturing in Canada.

Now, on page 4, I am still finishing up the discussion of the characteristics of this industry. Perhaps all I need to say is that this industry is a large international industry, comprising mainly very large international firms whose economic and commercial policies tend to be determined—quite properly—on the basis of maximizing the profitability of the world wide operations of the international firm. These policies do not necessarily coincide with the best development of the Canadian economy and the Canadian branch of the firm. Just as an indication of that approach I have referred you to a comment in the Hoffmann-La Roche brief.

The industry is characterized by relatively high profits and by limited economies of scale; I do not think there is any dispute about that.

The industry is highly protected and there are high barriers to the entry of newcomers who might inject new and more vigorous competition. The high barriers to the entry of new competitors are the result of patents, trade marks, the tariff, the anti-dumping laws, the very intensive and costly program of marketing and promotion, and the requirements of the food and drugs laws.

Those, gentlemen, I put in there just so you will understand what we are talking about when we talk about this industry being protected.

Although this is a research-based industry, relatively little research has been, or is as yet being done in Canada. I am not overlooking the fact that there has been some increase since the government's incentive programs were instituted. I am also not overlooking the contribution of some Canadian firms, and I may say this in passing—if I may be permitted to do so—that I have seen one plant, because I was offered the opportunity to do so, at the time we were preparing the Green Book. I have seen the Ayerst, McKenna and Harrison plant, and at that time it was supervised on the research side by Dr. Roger Gaudrey an eminent Canadian scientist whose reputation, of course, is well known to all of you. I, as a layman, was impressed by that operation; I know this company has made progress in the development of new drugs, particularly the drug premarin—is that right? I know what is in premarin, but the name sometimes escapes me.

I would like you to understand that I recognize this, and I mention this company because I actually have seen its plant. Of course there is also outstanding work being done by Connaught Medical Research Laboratories which is not a commercial institution, and I point that out to indicate that advances are made outside the commercial field as well. There is no need for me to elaborate on the work of the Connaught Lab.

Now, those, gentlemen, are structural characteristics; could I say a word about price characteristics in this industry? Everybody, I think, understands the basic idea that in the marketplace, supply and demand determines price. I would like to read, however, two or three paragraphs on page 5, if I may.

In this industry, on the demand side, the demand for ethical drugs is determined largely by the incidence of sickness and the writing of prescriptions by doctors. Demand is said to be inelastic in that the requirements of patients for drugs do not rise proportionately or fall proportionately according to the change in price, but are dictated by the necessities of illness and the choice of the physician.

In these circumstances price tends to be set at what the traffic will bear —that is an expression which I will be glad to explain, it has a meaning in economics.

The price of patented drugs rarely appears to rise even with increasing costs or increasing demand; likewise, there is no downward pressure on prices which tend to remain level for a particular patented drug throughout the life of the patent. Price therefore does not tend to have any identifiable relation to cost and does not, as it would in the case of a competitive product, tend to approximate cost of production but rather tends to be considerably above it.

On the supply side competing supplies of a drug are limited by reason of the barriers to the entry of new producers able to manufacture the same products; notwithstanding that profits and prices are high, few newcomers have in fact entered the field of competition with the established firms on a substantial scale.

Price competition during the life of the patent is found only in limited circumstances, notably in sales to institutions and governments. Instead, competition takes the form of product differentiation which requires inordinately large sums to be spent on promotion of a particular firm's product, usually by its brand name, primarily to the physicians who make the selection at the time of prescribing for the patient. Competition is therefore cost-increasing rather than price reducing. The more intense the competition, the higher costs are driven.

There being no downward pressure on price there is no downward pressure on cost with the result that pressures within the firm for more detailmen, more advertising, etc., tend to be inflationary, and resulting high costs are used to justify high prices.

Mr. Chairman, those are some basic facts about this industry which I think are sound and which I think are probably not open to too much dispute. Now, my next paragraph is perhaps important; it is entitled "the Solution". I am not giving the solution, gentlemen, but I am trying to point out here at this stage what the choices appear to me to be. Now, these are basic choices; they are not water-tight compartments; it is quite possible that there will be variations of these, but I suggest that these are the basic choices.

First, preserve the status quo. This I believe is the net effect of representations by the industry. By preserving the status quo I mean that the drug industry will be regarded by the Committee as requiring statutory protection for its own sake in order that it may manufacture and do research in Canada behind a protective wall of patents, trade marks and other protective devices. This choice will not result in lower drug prices to the patient; indeed, it is this protection which has produced current price levels. To preserve the status quo, therefore, requires rationalizing or justifying the present level of prices and this the industry does by stating that it is subject to extreme competition; that its costs are irreducible; that research is costly; that it needs protection if it is to exist in Canada, and that, in any event, the patient can afford the prices of the drugs because his standard of living is high.

Now, basic choice No. 2 is direct control, and perhaps I should say that there may be variations of this which we might generally call government intervention.

But direct control is the extreme end of the stick. The imposition of price control would presumably have the immediate result of lowering the price of the drug to the selected level by law. Price control was used in wartime under conditions of national emergency. In the absence of such an emergency direct price control is a device which normally falls within the jurisdiction of the provinces and is not available to the federal authorities or parliament. Moreover, the imposition of direct controls immediately calls for the extension of such controls to different levels of trade and ultimately to the allocation of raw materials and other resources themselves. In addition to an extensive network of such controls, it is axiomatic that the results lead to economic inefficiency because administrative action is not a satisfactory substitute for market forces in the allocation of resources and the development of efficient industries; it is also an impairment of the private enterprise system.

Now, the third basic choice is the development of price competition. This is the device recommended after mature consideration by the two commissions and by one professional economist who has appeared before this Committee. It is, in my view, the soundest remedy and will also be effective.

Let me say at once that if a program to encourage price competition on ethical drugs is soundly planned and applied with determination, there is no question in my mind that the price of drugs will be reduced.

Such a program, however, in my opinion, requires several measures to be adopted as a package.

Some package proposals are before this Committee in one form or another (by the two Commissions and by a professional economist, Doctor English). I need here say only that it should be clearly understood that items which are alone intended to reduce cost, for example, the removal of the sales tax, cannot be expected to work unless downward pressure is at the same time placed on the price of the product to force it to come into as close approximation as possible with the cost of its production. I will shortly give you an illustration of the difference between behaviour of the price of patented drugs in this respect and the price of unpatented drugs, the latter tending to approximate cost of production under the pressure of competition; the former bearing no real relation to cost of production at all because of the absence of pressure on price.

The point I am making is very simple; it is insufficient to reduce the manufacturer's cost by eliminating, for example, some of his costs of promotion, research costs, and so on, without placing pressure on price because price being what the traffic will bear, reduction in costs will merely result in a larger mark-up at the same price. If that does not happen in the immediately short term, it will happen, gentlemen, over the long term. I can refer you to an example of how this is likely to work, taken from an actual case of a trade marked product made by one of the leading firms, which is reported in my annual report for 1964, page 31. I have that report with me—I will not get it out just now, gentlemen—but the substance of it is, to put the matter shortly, we managed to get the price of the imported product down somewhat by having a new value for duty placed on it by national revenue.

An hon. MEMBER: The cost.

Mr. HENRY: The cost of the imported product, because this was simply an imported product resold by the Canadian company. Having produced this result, we were told by the company it was not their intention to reduce the price in any event. That is the matter of it in a nutshell. This is just an example of how reducing the cost does not necessarily bring about a reduction in price. That is in the annual report for 1964.

Now, I would like to read the next paragraph if I may. If as a result of a package remedy downward pressure is brought to bear on price, then it is an inevitable economic result that the firms, once price begins to move towards cost of production, will seek to reduce and minimize their cost. At this stage costs which were previously thought to be irreducible are suddenly found to be capable of reduction; the firm is forced to seek a greater degree of efficiency, to eliminate wasteful operations and expenditures, and, in short, to streamline the operation to its most economical and efficient level. It is possible that some firms may be unable to face this kind of competition. If so, they will have to retrench or may even be eliminated, but those who remain will be the healthy firms. Some reduction in the number of firms or number of products in this industry may possibly take place, although not inevitably, but this would, I suggest, be to the advantage of the industry as a whole and certainly to that of the nation. Some people, gentlemen, like to call this process rationalization, a word which I think you have often heard, and the object of rationalization is to produce a healthy and efficient industry.

I think the next paragraph is important. I should also point out that in my view it is central to any program of injecting price competition into the industry

that the monopoly at present afforded by the patent system be substantially weakened. I will discuss this further in a moment. But I say, in passing, gentlemen, that I do not use the word "monopoly" here, in any sense of an epithet; it is simply a statement of fact that a patent gives a monopoly.

It should also be recognized that any proposal to inject price competition calls for action at three major levels—the manufacturer's level, the retail level, and the patient's level (which effectively means the level of the physician). I mention the physician merely so that it will be borne in mind that no matter how much opportunity for price competition may be made available, unless a physician has confidence in the source of the drug and in the measures taken to ensure the purity, safety and effectiveness of the product he would not prescribe it for his patient. It is therefore important that along with any package of measures adopted, full attention be given to the necessity of building up confidence on the part of the physician in competing products available so far as safety, quality and effectiveness are concerned. In the absence of such confidence, a downward pressure on drug prices cannot, in my view, be achieved. This is primarily the role of the Food and Drug Directorate which must be supplemented by arrangements for the provision of reliable, objective information about drugs available, which, primarily of course, is for the information of the physician.

Patents. Perhaps I might just read the paragraph on page 11 which indicates an important point.

In the first place, it is the high cost of patented drugs with which we are concerned. As I have said earlier, what is here meant is that the price is higher than it need be. This is demonstrated by reference to (a) The price to institutions and governments. (b) Prices of the same drug in other countries. (c) The price in Canada charged by newcomers. (d) The price of unpatented drugs or drugs on which the patents have expired. (e) Extreme examples in the Green Book of disparity between laid-in cost and ultimate selling price.

As a matter of fact, one or two of those examples are given later in this paper; so we need not look at the Green Book.

In the second place, patents have no relation to quality. Industry submissions would have us believe that only a patented or trade marked drug carries the assurance of high quality and safety. This is simply not the case. Assurance of quality depends upon, firstly, the controls exercised by the Food and Drug Directorate, and secondly, the integrity of the particular manufacturer. The patent, however, confers no guarantee of quality, nor is it an essential condition of quality; otherwise a serious situation would arise when the patent expires or is declared invalid.

The third point which I would like to make is that one must not make the mistake of talking about the price of drugs as if there is one uniform pricing practice. In this connection an important distinction must be made between patented and unpatented drugs.

Unpatented drugs are very much like other commodities such as hardware, clothing, food or the like. Subject only to the Food and Drug regulations being complied with, they may be manufactured, distributed or sold by anyone. They are freely available at all stages of production.

A firm may manufacture an unpatented drug right through from the basic chemical to the final dosage form, it may buy the chemical and carry on from

there, it may buy the dosage form in bulk and package it or it may buy the dosage form fully prepared and simply put its own label on it. Whenever the selling price of the dosage form is high in relation to the cost of manufacture or of procuring the drug for resale, so that there is an opportunity for a seller to make a profit, additional firms will enter the field. This will put pressure on prices and they will fall. If they fall too far, some firms will be forced out of the field and prices will probably rise. Eventually the situation will level out and prices will tend to stabilize at the level at which an efficient producer can make a profit. This is typical of the private enterprise system and is the situation which obtains in respect of any commodity which is in free supply where there are few barriers, either natural or artificial, to the entry of new firms into the field.

That paragraph says, substantially this: The selling price in the case of an unpatented drug which is subject to free competition in the market, is directly related to the cost of production. Competition ensures that that relationship is maintained. One need only look at the way prices behave on unpatented drugs to understand how this works.

The pricing of patented drugs is entirely different. When a new drug is discovered and patented the owner of the patent normally becomes the exclusive seller and sets whatever price he sees fit on the drug, subject to the principle of what the traffic will bear, which I mentioned before. The evidence that we obtained in our inquiry indicates that the price set almost never bears any relation to the cost of production but is many times higher. There are reasons for this, which the industry, of course, has, and can explain.

The point that I am making is, and it is only a simple point, that we are not dealing with products the price of which is set by competition as that term is ordinarily understood and certainly not the kind of competition that exists in the case of unpatented drugs.

I put some figures here, without taking you through all the words, dealing with the original penicillin G which was not patented. Originally, as you will see at the bottom of page 13, the going price has dropped from $2,300 in 1947 for one billion international units, to $33 in 1959; and since then it has gone still lower. It is a commodity in free supply and it has a going market price just as copper, gasoline, or any other similar commodity. The last price noted on January 27 is $19.50 to $20.00 for potassium penicillin and $21.50 for procaine penicillin.

The prices of dosage forms of a non-patented drug have reflected the reductions in the cost of the basic drug. I give an example that Mr. Gregory of Ayerst, McKenna and Harrison referred to in evidence before this Committee, just indicating to you, that that particular dosage form drug dropped from $9.85 in 1950 to $1.50 in 1959. Mr. Gregory simply referred to a vial of penicilin but it would appear to be the dosage form referred to on page 162 of the Green Book because the figures are the same. The $1.50 is the list price. Assuming that the discount to the druggist is 40 per cent off list, a druggist would pay 90c. This would include sales tax of approximately 9c so that the net return to the company would be 81c. Since this is a rather sophisticated dosage form, involving the preparation and sealing of a sterile solution, it is difficult to see how the price could fall much lower. Another illustration of the low price of penicillin is the one million international unit vial of crystalline penicillin powder. The most recent general drug price book appears to list this dosage form at prices from 55c

to 65c. This means that the net return to the drug manufacturer on this dosage form is about 30c to 35c.

Now when we turn to patented drugs the situation is quite different. The last day I was here, expecting that I might be called, there was considerable discussion about the drug stelazine and we may take it as an example of a patented drug. Stelazine is Smith, Kline and French's trade name for trifluoperazine dihydrocloride. At the time we obtained information in our inquiry in 1960 Smith, Kline and French was importing stelazine tablets from its parent company in the United States. The prices paid for 1,000 tablets were:

1 mg. size	$1.15
2 mg. size	$1.32
5 mg. size	$1.80
10 mg. size	$3.10

I have here Smith, Kline and French's list prices and prices to hospitals if the Committee wants full details but for the purposes of illustrating the situation, I shall refer only to one size, the 50 tablet package of 2 mg. tablets. The list price, i.e., the suggested retail price, was $6.25 and the price to hospitals was $3.20. Prices to the trade were list price less 40 per cent which would mean that the price to the trade was $3.75. This would include sales tax so the return to the company, i.e., price to the trade less sales tax, would be $3.38. Now if we put this on the basis of 1,000 tablets we arrive at the following figures: *

Cost of 1,000 tablets	$ 1.32
Return to company if tablets sold to hospital	$ 64.00
Return to company if tablets sold to trade	$ 67.60
Price to consumer	$125.00

Special prices were quoted on quantity sales to hospitals. If a hospital bought 5,000 tablets the price was $37.60 per thousand and if it bought 25,000 tablets the price was $33.84 per thousand.

According to the price book, which incidentally is the same as the figures we had in the Green Book in 1960—in other words, the prices have not changed —the return to the company on the tablets it sold to the hospitals is $64.00, based on the cost of $1.32; the return to the company on the tablets it sold to the trade is $67.60 and the price to the consumer, which of course as you know is the list price, is $125.00. Then there are some special prices quoted to hospitals on quantity sales. Smith, Kline & French recently stopped publishing suggested list prices, but as of June 1965 it would appear the price on this product has not changed.

Another example is trancopal made by Winthrop. This is also an imported drug as was stelazine. The reason these examples are chosen, gentlemen, is that you can get the invoice cost to the manufacturer in Canada. That is the price he paid for it; he simply imports the drug and pays for it, so you know what it costs him in clear terms. On trancopal, we have some more figures as well, indicating that the factory cost is a little more than the cost of the imported drugs. A thousand tablets of 100 mg. cost $3.88 to bring into Canada; then there is

* See Green Book page 201.

packaging 10 cents, packaging labour 7 cents, factory overhead 7 cents, total factory cost $4.12. Then again we have price to hospitals in quantity $57.16; regular price to hospitals $63.51, price to retailers $70.50, and suggested retail price $117.50. That is the spread between the company's selling price and what it costs the company to bring in the drug, which is only bringing it in, not manufacturing in Canada—it is simply importing it, paying an invoice cost and then packaging it which, as you will see from these figures, is a relatively small expense.

All I am trying to do here, gentlemen, is to explain that there is a large spread between the manufacturer's cost of the drug, whatever that may be, and the price at which it is sold. That spread has some significance because in that spread there is room for some form of economies in distribution if people other than the manufacturers or their competitors can have the opportunity of getting that drug. This is the reason why we show this disparity as well as to show you that patented drugs are priced in a completely different manner from unpatented drugs.

Mr. HOWE (*Hamilton South*): May I just interject a question. Are these imported as the final dosage form, or imported as the raw chemical? Does any manufacturing take place, other than simply bottling, distributing, on these two that you selected?

Mr. MACLEOD: Our information is that these are imported as tablets in bulk.

Mr. HOWE (*Hamilton South*): But in the final dosage form.

Mr. MACLEOD: That is correct; that is our information.

Mr. ORLIKOW: I would assume, Mr. Henry, that when they buy this either from their parent company, or from some company that manufactures basic drugs, the seller is including in this price of $3.88, what he considers a fair part of the cost of original research.

Mr. HENRY: That is quite possibly so, Mr. Orlikow. I know that there is somebody here from Smith, Kline & French, but let me say that, practices vary in this respect. Some firms, according to our studies in 1960, in fact charged some proportion of cost of research in the price of the drug that is imported into Canada, so it is quite conceivable that when we bring a drug in and pay the invoice cost, that is also in part in payment for research that has been done abroad. Other companies work on a different basis. They have a contract between the company in Canada which is buying its research from the company abroad and presumably makes a payment to the company. There are different methods and I cannot tell you exactly what the situation is in this case.

Mr. BRAND: Mr. Chairman, I would just interject, I do not think you are right that stelazine is brought in in tablet form. I think that is actually entableted in Canada. I am almost sure that evidence was brought before us.

Mr. HENRY: I am certainly open to correction, but the main point is that we are not aware that there is any other cost; we have no other figures of other cost, which is to be added to the $1.32. We had figures in the other case.

Mr. ENNS: This is a point of order; there are witnesses here from the firms involved. Is there anything out of the order in having them confirm or deny?

The CHAIRMAN: These are figures as of 1960?

Mr. HENRY: Yes. The cost figures are in 1960—the price figures, of course, are checked against the current price list and they have remained the same.

The CHAIRMAN: In 1960, was stelazine imported in bulk or in finished form?

Mr. MICHAEL SHELDON (*Assistant to the General Manager, Smith, Kline & French/Montreal*): I did not work with Smith, Kline & French in 1960 and I am afraid I do not know the facts as they were then. All I can say is that at present we manufacture stelazine in Canada and we do most of the chemical synthesis in Canada, so there may have been a change, but my impression is we have always actually done the manufacturing here.

Mr. MACLEOD: Our information from Smith, Kline & French, as of April 13, 1960, was that they imported trifluoperazine dihydrocloride which is the basic drug. They imported it in capsules, two forms of capsules and they imported it in tablets 1 mg, 2 mg, 5 mg and 10 mg at the prices set out in the Green Book and reproduced in the statement which Mr. Henry is making.

Mr. RYNARD: Mr. Chairman, surely we do not have to go back in this Committee seven years to have a report brought in. This seems to me to be wrong. Do we not have anything that is up to date and modern, instead of quoting a figure of seven years ago in a world that is going as fast as ours. That does not seem to me to be right.

The CHAIRMAN: Mr. Henry has already told you that this is based on the 1960 report.

Mr. RYNARD: Why base it on that?

The CHAIRMAN: Because those are the only figures available to them.

Mr. RYNARD: This is a fact finding Committee of today, not seven years ago.

The CHAIRMAN: The point he made earlier is that these were the only figures he has.

Mr. RYNARD: I realize that.

Mr. HENRY: Perhaps I should explain. We, of course, concluded our inquiry, which is a formal inquiry, under which we exercised formal powers against drug companies to obtain returns of information from them under the powers conferred by the statute. This is a formal inquiry, which was terminated at the time. We do not have access to any up to date figures without starting a new inquiry. I think it is quite obvious that we, having made our contribution back in 1960, really have no particular business to conduct a new inquiry on this matter. My position on it is that I assume that the necessary figures, that is, current data, that this Committee would work with, would be produced before this Committee by the drug manufacturers. This is why at an earlier stage I was very firm in explaining to Dr. Harley that I am not able to produce any new figures beyond what is in the Green Book and therefore they should be sought from the companies themselves, which is the only proper thing to do; and I entirely agree that we are here working on the basis of some earlier figures that we had.

Mr. RYNARD: Mr. Chairman, I just want to add that that puts it in the right perspective.

Mr. HOWE (*Hamilton South*): Have you any reason to believe that there has been any change in the basic facts now, from what you quoted from 1960.

Mr. HENRY: No, sir.

Mr. HOWE (*Hamilton South*): Does a similar situation exist. In other words, this $1.32 has not suddenly gone up to $30 or $40.

Mr. HENRY: I have to tell you that I do not know what the laid in cost is now and I am not able to furnish the actual figure because we have not obtained anything beyond the $1.32; it could be more now.

Mr. HOWE (*Hamilton South*): But there is no reason to believe that it has gone up to $30 or $40?

Mr. HENRY: There is no particular reason why it would go up anywhere near $64.

Mr. RYNARD: But still we do not know.

Mr. HENRY: This, sir, is a matter that can be easily checked.

Mr. ORLIKOW: Mr. Chairman, I suggest the proper procedure is that if any of the companies mentioned here or mentioned in the Green Book feel that the department has done a disservice to them, that the Committee will be very happy to have them come here and bring their records, their figures, and show how they have been misrepresented. And of course they would be subject to questioning by the Committee and by the committee's accountant and counsel.

The CHAIRMAN: Of course, you will also find, if you work back from the wealth of information this Committee already has, we probably already have this information.

Mr. BRAND: Mr. Chairman, may I point out that I believe the province of Alberta is coming before us soon and they have a very comprehensive list of pricing, which is considerably different from some of these here.

Mr. HENRY: Mr. Chairman, could I just add one more thing. The figures that are here were valid in 1960, and I have no reason to believe that the principle has changed. The date may change; that is perfectly true, and as I say, we are neither omniscient nor are we dogmatic about these matters and it certainly would be fair to make sure that the current figures are before the committee. I have no quarrel whatever with that. I just do not have them, nor do I feel I could go out to get them, the way I could in 1960, but all figures that are here were valid in 1960. Our information about the importation of stelazine was from Smith Kline & French. The letter that Mr. MacLeod has read, was given to us by Smith, Kline & French about the importation of stelazine and we assume we can accept what the company told us.

Mr. ORLIKOW: And we can also assume, I suggest, Mr. Chairman that if Smith Kline & French decided to manufacture in Canada, rather than import as they were doing in 1960, they did it because they could do it at least as chap and probably cheaper than they were importing or they would have continued to import.

Mr. HENRY: This may be, Mr. Chairman, but do you understand why we have chosen these figures. It is just a simple illustration of a drug that is imported and the only cost you have is the invoice price. There is no need for a

sophisticated cost accounting performance to throw a lot of cost into this. It just is a simple importation of drug at a price which is then marked up from $1.32 to $64.00. It is as simple as that and that is the only point I am trying to make.

Mr. HOWE (*Hamilton South*): You do not know whether on that $1.32 there was a profit to the parent company?

Mr. HENRY: No, I do not know. All I know is that that is the price they paid; also I do not know if they had a packaging cost, such as was the case in the Trancopal where we did have knowledge of packaging costs and we added them in to show them. Whichever way you look at it, gentlemen, the main point I am making is that, as of 1960, some drugs were being imported and you can identify the cost because of the invoice price. Then, you can see the mark-up on that when the sale takes place to hospitals. All we are saying is that first of all this is the way patented drugs are priced, and, secondly, surely within that spread there must be somebody in Canada who can distribute cheaper than that.

Mr. HOWE (*Hamilton South*): Do you have any comparable figures equal to this on the so-called and I quote "generic firms". We are very hesitant to use this word in this Committee. Is there any way you can acquire this because as a rule these are not imported in dosage form, so you cannot get the true comparable figure.

Mr. HENRY: Mr. Chairman, when we go away from here I would be glad to see whether our data would allow us to produce this from the Green Book. I cannot tell you just for the moment although Mr. MacLeod will look while I am going on with this and if we can find it immediately we will let you know. I am not sure that we have taken such an analysis of a generic drug firm as such.

Mr. MACLEOD: I do not think we have. Scattered throughout the Green Book in various places there are bits of information which we have obtained from so-called generic houses. I will see if I can put my hand on one but it will take a little time. Basically what we obtained from generic firms was the prices that they paid for various drugs, some in bulk form, some in finished form and these are mentioned at various places in the Green Book.

The CHAIRMAN: Shall we return to the brief?

Mr. HENRY: When we get through the paper we can come back to this and cover the ground, because I would like the Committee to have it all in perspective.

On page 17, perhaps we could go down to the middle of the page because the others are just an elaboration on the same theme.

The question may be asked: What happens when the patent on a drug expires? There are very few examples of this because most of the important drugs have been discovered and patented within the last seventeen years and the patents have not yet expired. However, there is a recent example in England where Pfizer's patent on Terramycin (i.e. oxytetracycline) recently expired. Pfizer's selling price to druggists for one hundred 250 mg. capsules was 111 shillings and 9 pence or $16.76. Around April 1966 Imperial Chemical Industries started producing and selling oxytetracycline under the trade name Imperacin. Its price to druggists for one hundred 250 mg. capsules is 37 shillings or $5.55, that is one-third of Pfizer's price. Pfizer's price has since been reduced and the

last information which I have is that it is now the equivalent of $12.58. Thus the situation is that as soon as the patent expired another firm entered the field and reduced the price of the product by two-thirds. The original patentee then reduced its prices by 25 per cent. Later I will have some final figures on that. Members of the Committee will, of course, know that Imperial Chemical Industries is one of the major companies of the world. It produces a line of pharmaceuticals, including the widely used anaesthetic Fluothane, which are sold in Canada by Ayerst, McKenna and Harrison. It sells oxytetracycline under a brand name. It cannot be disparaged, by being referred to as a fly-by-night operator or as a generic name firm, although I think it might be called a copier if I can put it that way because I have seen that expression used; I understand what it means and I think in this context I.C.I. is a copier.

To summarize, the pattern of pricing of patented and unpatented drugs differs in at least two important respects:

(a) prices of unpatented drugs are governed by the cost of manufacturing the drug; prices of patented drugs are not;

(b) prices of unpatented drugs fluctuate, almost always following a general downward trend as costs of manufacture decline; prices of patented drugs usually remain fixed and unchanged for years.

There are one or two other things in here. There was a question raised by Mrs. Rideout who is not here so perhaps we could leave this to be read in due course. It is about a vial of penicillin which has dropped in price. The only point I wanted to make is that this is an example of the trend in unpatented drugs but not patented drugs.

There is constant, intense price competition. This, of course, is the reason for the $1.50 price of the vial of penicillin referred to by Mr. Gregory. I don't suppose Mr. Gregory intended the price reduction which he quoted to be an example of trends in drug prices. It is not. It is an example of trends in prices of unpatented drugs. No similar situation exists in respect of patented drugs. And since many of the more widely used drugs are patented, prices of such drugs are not subject to the kind of price competition which results in "price wars" and lower prices.

There is no precise formula which we can apply to a particular price for a patented drug and determine if it is high and, if so, by how much. But it may be helpful if, going back to one of the examples which I cited and eliminating sales tax, we state the question in this way: Are prices reasonable when a bottle of tablets which are manufactured, packaged and labelled ready for delivery to the consumer at a cost of $4.12 are sold to the trade at $63.51 and resold by the trade to the consumer at $105.85? Exact figures vary from one drug to another and even from one dosage form of a particular drug to another dosage form of the same drug, but the example I have given is not untypical of the situation in respect to the pricing of patented drugs. Prices to the trade and to the consumer bear no meaningful relation to the cost of production. I suggest that looking at it in this way puts the matter in perspective.

I would like to take you over, if I may, to page 20 which is referring to the patent system. I do not want to bore the Committee with a description of how the patent system works in relation to drugs because that has been very competently done by others.

Patent systems throughout the world have a common economic objective which is expressed in statutory form. The Patent Act creates a temporary monopoly of the patented product or process for the inventor with the object of encouraging invention and innovation and of making the fruits of inventiveness available in due course to the public at large. The grant of a patent to the inventor or his assignee gives him the power to prevent others from making, using or selling the patented product or process.

Patents relating to food and drugs are placed in a special category. In the first place, the Act provides that in the case of an invention relating to substances prepared or produced by chemical processes intended for food or medicine, the patent does not include a patent on the substance itself except when prepared by the particular process described. Any person, therefore, is free to produce, import or sell the same drug so long as it is not made by the patented process. The inventor is however protected to the extent that the onus is on a newcomer to show that the drug he makes, uses or sells is not made by the patented process.

This is both with respect to the subject matter of the patent and also for the provision of the grant of a compulsory licence which is capable of being used for or intended to be used for the preparation or production of food or medicine. As you know, the Commissioner of Patents is the official who grants the licence and he also fixes the royalty.

I think the Committee is aware, the industry considers royalties fixed under this provision are inadequate.

I might say that I thought it would be useful if I put in a few words at the middle of page 21 in which Mr. Justice Abbott of the Supreme Court of Canada has described how Section 41(3) works on the assessment of royalty. Of course, all hon. members who know his background will recognize that he is fully experienced in financial and business affairs and matters relating to the public interest from the standpoint of the Government of Canada. I think he can be regarded as one who is well able to pronounce on this subject. At any rate, this is his version of it which now is the law.

> "In my view the purpose of s. 41 (3) is clear. Shortly stated it is this. No absolute monopoly can be obtained in a process for the production of food or medicine. On the contrary Parliament intended that, in the public interest, there should be competition in the production and marketing of such products produced by a patented process, in order that as the section states, they may 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'."*

At the bottom of the page—perhaps I might read the paragraph. Thus, the usual patent protection has not been granted in the case of drugs. Remember you cannot get a patent on the product itself. To put the matter in simple terms the patent is on the process—that is different from other patents. Second, the monopoly is not the usual patent monopoly in that a compulsory licence can be ontained almost as of right—not quite. Then, of course, the patent system is preserved because a royalty must be paid under the licence.

*Hoffmann-LaRoche Ltd. v. Bell-Craig Pharmaceuticals Div. of L. D. Craig Ltd. [1966] S.C.R. 313 at 319.

The industry in the P.M.A.C. submission refers to this as discrimination; I prefer to suggest that parliament has recognized the important principles of public policy involved, and it has weighed them—this, after all, is the art of government—weighing up different and perhaps, conflicting principles of public policy—and has decided that, in this particular case, the immediate welfare and interest of the general public is paramount and the private interest of the industry, and the more speculative advantage to the public of added research incentives, is to be subordinated in this case. An exception is therefore made to the general pattern of the act in the case of food and drugs. It does not answer the question to say that the section is not in harmony with the general philosophy of the patent system. It is an exception to it and one can quite frankly say so.

It is a noteworthy fact that the patent system is an expensive way of stimulating inventive activity in Canada. Something less than 5 per cent of all patents issued in Canada are issued to residents of Canada; the remaining 95 per cent are issued to non-residents. While statistics in the field of drug patents are not available, it was the opinion of the Commissioner of Patents when he appeared before the Restrictive Trade Practices Commission that the percentage of drug patents issued to Canadians is considerably smaller than 5 per cent.

It might be pointed out that tax incentives and grants can be applied by the government on a much more selective basis than patent incentives. In other words, tax incentives and grants can be made available only to the firms which are actually willing to do research. Patent incentives, on the other hand, are given equally to those who are prepared to do research in Canada and to those who are not.

In other words, if we are thinking in terms of how to induce research in Canada all I am saying here is the patent method is a shotgun method which is not aimed at research by itself but to government incentive programs. The commissioning of projects is aimed at the people who are prepared and willing to do the work.

I do not think I need to take you through the next paragraph except to mention that compulsory licences have not been sought in any significant numbers although perhaps there is a slight upturn in the last two or three years. The point I make at the bottom of page 22 is that in many cases it is apparently uneconomical to manufacture in Canada the basic drug covered by the patent. This may be the reason why there are no compulsory licences sought to manufacture basic ingredients in Canada, because it is uneconomic as witness the fact that existing firms import most of their active ingredients. Note the statement in the PMAC brief that states:

> It has not proved economically feasible to develop a pharmaceutical chemical industry itself, primarily because of limited size of the Canadian market.

Now, there is our position on the manufacture of basic drugs. We are still mainly importers of the basic drugs, dependent upon the people who make them abroad.

Therefore competition has not developed through compulsory licensing for manufacturing. The alternative stimulus to competition, namely, the importation of drugs ranging from the basic chemicals to final dosage forms, has not, in fact,

been given an opportunity to work in the Canadian market by reason of the fact that the Commissioner of Patents has taken the view that he is not authorized to issue a compulsory licence for import under section 41(3) of the Patent Act.

So, owing primarily to the patent monopoly, importation of lower priced drugs has been prevented. This is one of the reasons, gentlemen, why, when one looks abroad and sees low priced drugs we ask why can we not get these in Canada, the answer is if it is a patented drug then the patent prevents it.

It is, I suggest, clear that drug patents are the major contributing cause to the high price of drugs by reason of the restraint placed on competition by the patent monopoly. The Restrictive Trade Practices Commission has recommended, accordingly, that drug patents be abolished; the Hall Commission has recommended that, as the first step, authority be given to issue compulsory licences for import and that total abolition of patents on drugs be held in abeyance.

I think, as a practical matter that the suggestion of the Hall Commission is a practical one in the circumstances because if you abolish patents on drugs you then are certainly impairing the patent system with respect to a particular group of commodities in the economy. But if you merely licence imports you are still preserving the system—it is true you are weakening the system, but you are still preserving it because the licensing of the import carries with it the right to get a royalty. If we assume that that royalty can be computed in an adequate way to give a proper and fair return to the owner of the patent, then you have preserved the patent system. This is a very important aspect; you have given some return to the person who owns the patent who of course, as you know, is not always the inventor as a result of giving the compulsory licence. If you abolish the patent then, of course, you wipe that all out. I am suggesting to the Committee that there is a way out on this point, assuming that the Committee considers that something ought to be done to the patent system. It is not initially necessary in my view to abolish patents on drugs. The same result could be obtained in my view by taking the lesser course, which I think will work, and you still are not open to criticism that you have, so to speak, obliterated this area of patent protection in Canada.

As I say, I think the Hall Commission's recommendations are very practical in that respect. I would expect that if you granted compulsory licences for import that the net result would be that imports of drugs now reaching the market would be made from their cheapest source—Gentlemen, I am on page 24. I think if I may just read this page it is as clear as I can put it—which in all likelihood would turn out to be the parent companies abroad. In other words, I am not suggesting that all the drugs which come in from abroad are going to come from unknowns. This may be quite minimum. The fact is that once the pressure is on the established companies to get their prices down they are not going to let this Canadian market go. They are going to come in here and, as I see it, we will be getting the same drugs or many of them at a lower price but imported. This is one possible result. I have put in here—just for you to think about—a short quote from the Hoffmann-La Roche brief:

> The mischief for Roche lies not so much in what business would actually be lost to copiers but what happens to the price level as a result of their entry.

In other words, one more point, I think, to be made, gentlemen, is that this device would reduce prices.

It is of course accepted and understood that the Food and Drug Directorate would provide a program of quality and safety control to ensure that any imported drugs meet necessary standards. It is my understanding that this should present no insuperable problem provided the resources are made available. One must bear in mind that the task becomes one only of degree because the Food and Drug Directorate at present apparently quite satisfactorily manages the task of supervising imports of non-patented drugs and drugs upon which the patents have expired. The proposals of the Directorate for improving their capacity for the control of imported drugs—which Doctor Chapman explained to the Committee the other day—will obviously facilitate any step up in the program that might be necessary to take care of drugs imported under compulsory licences.

Moreover, such a program would be facilitated if the Food and Drug Directorate is involved in the decision by the Patent Commissioners to grant or withhold a compulsory licence to import as suggested by the Patent and Trademark Institute of Canada, and as is implicit in the Hilliard Report.

An adequate program of quality assurance of this kind should satisfy physicians that drugs imported subject to such supervision may safely be prescribed.

However, again I emphasize, gentlemen, that that is up to the physician.

Now, research. As the Committee is well aware, the international drug industry is a research-based industry. Substantial and continuing research is necessary for the discovery and development of new and improved medicines. Such research is costly and the cost must be borne by someone.

Research has several important functions which justify it. It produces new drugs; it produces improved products; it produces new and improved processes for manufacturing the products. These functions represent added cost to the industry. Research, however, may also produce a greater efficiency of operation and to the extent that this is the case it can be cost decreasing. There is, however, another type of research aimed merely at product differentiation which, although a competitive activity, does not necessarily produce new or improved products or achieve greater efficiency but is at the same time cost increasing.

No one can question the importance of research in the development of our economy. In the context of this Committee's inquiry, however, the important considerations are—in which directions it shall be encouraged; does it contribute to innovation and efficiency; what alternative vehicles are available to get it done; and who is going to pay for it?

The patent system is designed as an incentive to invention and therefore to research leading to invention. There is no question that inventiveness in general terms is stimulated by the patent system. No doubt this is true in the case of some highly industrialized countries such as the United States. The proposition is not, however, necessarily true universally. In the case of the drug industry the patent system does not appear to have promoted significant invention in Canada. It also does not appear to have promoted significant drug research in Canada.

It is significant that the increase in actual research in Canada in the pharmaceutical field during the past three years has in fact coincided with the

development of the government's incentive program to encourage research and development through tax incentives and direct contracts for research projects. It is a fair conclusion that the patent system as an incentive in the drug industry has historically been ineffective in Canada.

The research referred to by the industry as contributing to the cost of the products is mainly done outside Canada. There is of course, as a matter of economics, no reason why a Canadian firm should not purchase its research elsewhere. Indeed, as a matter of sound economics, it should weigh up whether it can more cheaply and efficiently do its own research or purchase it elsewhere. It nevertheless must be paid for. Moreover, the cost of much unfruitful research—in the sense that it produces no bonanza drug for the firm—must be borne along with the cost of successful research efforts.

When the cost of research is paid for commercially it must be recovered by the company in the price of the product. Perhaps that simple basic proposition is all I need to say. However the paragraph goes on to say that it is open to foreign suppliers who wish to charge for research to recoup the cost they have incurred, including the cost of research, when selling the product in Canada.

The above mentioned paragraph reads thus:

"While this is not necessarily true in the short term, it must be true of all costs in the long term if the business is to survive. In the case of finished drugs imported into Canada for sale, the cost of research, or a contribution with respect thereto, may also be recovered by the royalty on the patent or by the repatriation of profits earned by the Canadian subsidiary. However, it is open to each foreign supplier to recoup whatever costs he has incurred, including the costs of research, when he sells his product in Canada."

It is not obvious why Canada should provide any special measures to guarantee that foreign suppliers should be able to recover any particular costs by any particular method in Canada.

The Committee might also consider whether it is necessarily to be accepted that, where research has been carried on outside of Canada and where the drug would obviously have been produced in any event for world markets whether or not the Canadian market was available, the foreign firm, as a matter of economics, is required to obtain any contribution that is labelled research from the Canadian market. I suggest that the only economic necessity for such a firm is to recover the cost of its research and other continuing overhead actually incurred in Canada, just as to be viable in Canada it need only earn a reasonable return on its investment in Canada. I was talking about paying for research commercially and on page 28 I say:

"The other major mode of paying for research is through government subsidies, incentive programs and the like."

Of course there are institutional programs as well, and I take that as read. Where such programs are adopted the cost of the research is borne by the tax payers at large and that portion of the cost is therefore spread over a much wider group; when the cost is borne commercially and passed on in the price of the drug, it is ultimately borne by the smaller group of patients.

If substantial drug research is to be undertaken in Canada and actively encouraged as public policy, the Committee I think must consider how the cost of that research is to be borne. If it is to be borne by the people who use the drug, it

will be charged to them in the price of the drug over the long term. If research can be purchased more cheaply abroad, then, assuming properly competitive conditions, this would decrease the cost to Canadian companies.

Either way it is essential that the pressure of price competition be continually brought to bear on the companies in order that all their costs, including that of research, may be minimized through the achieving of the greatest degree of efficiency in the organization and administration of research programs and staffs and the avoidance of unnecessary and wasteful research expenditures. Moreover, I suggest that only sharp price competition over the long term can effectively achieve such economies.

It is also important for the Committee to bear in mind that whether or not research will be done in Canada commercially will depend upon whether it is economically attractive to do so. This fact is well pointed up in the Hoffmann-La Roche brief at page 777 of the Minutes of Proceedings and Evidence, No. 11, October 20, 1966. If—as I do not believe to be the case—the development of research in Canada will be hindered by a more flexible patent policy as recommended by the two Commissions, then the Committee must very carefully weigh the extent to which Canadians can be asked to pay the cost of that research as reflected in the price of drugs, through greater patent protection.

Gentlemen, I ended this paper by attempting to define for the assistance of this committee what semed to me to be the fundamental issues arising out of this matter of patents and research. I worked this over quite carefully and I hope you will not mind my reading it. The Committee has the task of weighing broad principles of public policy and perhaps making a choice between conflicting principles. This requires that the board underlying issues be identified and examined carefully. What is really required is a consideration of the social cost and benefits of alternative arrangements for supplying drugs to the Canadian market.

Perhaps the first* fundamental issue emerging in this Committee's proceedings is whether a drug manufacturing industry ought to be preserved in Canada in its present form. To do so requires continuation of the present protective devices which the industry considers necessary to its viability, but which deny Canadians access to less costly supplies of drugs. To remove significant elements of that protection (as by extending compulsory licensing to imports, or by abolishing drug patents) should lower the prices of drugs reaching the Canadian market but may well shift some sources of supply to plants abroad. It is possible that some Canadian drug manufacturers may become distributors to a greater extent than they are now. Manufacturing would then tend to concentrate on those products which Canadians can produce most efficiently. The issue may perhaps be stated thus: Ought drug manufacturing in Canada as such be preserved and the social cost of protecting the industry paid for by patients through the price of drugs? I suggest to you this is the first basic issue in this whole study.

The second issue is whether research in the field of drugs is to be encouraged in Canada. It may well be cheaper for Canadian firms to acquire their research abroad, particularly through their parent organizations. Assuming it is

*This does not overlook the matter of safety and purity which is not an issue—it is obviously paramount.

desirable to do research in Canada as an end in itself, the social cost may be borne by patients through the price of the drug, through subsidies and incentives to research under government programs or by institutions and the public at large if research is channelled into universities and other institutions who might be called upon to bear a greater share of research in this field. The issue may be stated, therefore thus—Is research in the pharmaceutical field to be encouraged in Canada and, if so, is the social cost to be paid by the patient or the public at large or a combination of the two?

To the extent that these social costs are to be borne by users of the drugs, that cost must be built into prices of the drugs and the public must be made aware that the high price of drugs is the price they pay for the preservation and stimulation, as a matter of public policy, of drug manufacturing and research in Canada. Those, as I see them, are the issues before this Committee, Mr. Chairman.

The CHAIRMAN: Thank you vey much, Mr. Henry.

Gentlemen, before we proceed with the questioning, is it agreed that the complete statement prepared by Mr. Henry be printed as part of today's record?

Agreed.

The other day we passed a resolution authorizing the Committee to pay Dr. Hillard for his travelling expenses; we neglected to also pass a motion that he be paid a per diem allowance for that day, Friday, February 3. Is it agreed that we do so?

Mr. ISABELLE: I so move.

Mr. BRAND: I second the motion.

Motion agreed to.

The meeting is open for questioning.

Mr. BRAND: I am sorry I did not have this brief about a week ago, so that I could have an opportunity to annotate it a little more thoroughly. It is a pretty lengthy brief.

Mr. HENRY: I must apologize too. I had my problems.

Mr. BRAND: I understand this. I just want you to understand why I will be fumbling a little bit trying to remember all the various portions of the brief.

You made quite a thing out of the fact that penicillin, not being patented, was the reason why the price went down so quickly. Is that right?

Mr. HENRY: Yes. What I have said is that the behaviour of the price of penicillin is characteristic of the behaviour of a drug which is operating in a free market and in this case an unpatented drug.

Mr. BRAND: You also made the statement that Connaught Laboratories was not a commercial institution. You are aware that insulin was patented.

Mr. HENRY: That insulin was patented?

Mr. BRAND: Yes, the process.

Mr. HENRY: Yes, the patent, I think, being held by the Connaught Laboratories.

Mr. BRAND: That is correct, and they have benefited from the revenues in the University of Toronto.

Mr. HENRY: Oh yes, decidedly.

Mr. BRAND: What about cortisone. That was a patented drug. What has happened to the price of that? Do you have any figures on that?

Mr. MACLEOD: We did not do an extensive study on cortisone.

Mr. BRAND: I am a little curious you did not when it is a patented drug in which the price has tumbled spectacularly over the past few years. I am a little curious why you would not use a patented drug as an example as well.

The CHAIRMAN: That would have been in 1960. Would cortisone have come down in price by that time?

Mr. BRAND: Cortisone was down considerably by 1960. As a matter of fact if you look at page 50 of the Green Book, you will see that you talk about it there. I am a little curious why you did not go into it here.

Mr. MACLEOD: The reason that we did not go into it is that starting out we set a field that we thought we could cover. We took two—the antibiotics and the tranquillizers then known.

Mr. BRAND: Nevertheless is it not a fact that the price of cortisone, the patented drug, has dropped remarkably since its inception.

Mr. MACLEOD: That is quite true and there are certain reasons for that.

Mr. BRAND: Could you give me some of the reasons for this. I am curious; in view of the fact that the free market forces brought down the price of penicillin it surely is valid to discuss then what forces brought down the price of cortisone, which was a patented product.

Mr. MACLEOD: I believe there are at least two: improved methods of production. In the early phases it had to be extracted at great costs from certain glands, which probably you know a great deal more about than I do; and further when certain progress was made in making it, it was found that the companies making it had to go to other companies to get related patents to use in the process. In return these other companies were licensed, so that the patents for the cortisone were widely spread and you will find as a fact that it is now produced by a number of companies, so that you have a number of companies competing to supply this particular drug to the market.

Mr. BRAND: This is the only reason then that the price would come down.

Mr. MACLEOD: I must emphasize, and it is probably quite obvious, that I am not an expert on cortisone but I mention that those reasons appear to be some of the reasons which have brought the price of cortisone down: reduced costs of production and the fact that a large number of companies hold patents in this field so that the drug is relatively—

Mr. BRAND: You made the statement that reduced cost of production brought down the price of the drugs. Somewhere in this I recall Mr. Henry saying that the prices of drugs stayed the same despite the changes in production. Is that correct.

Mr. HENRY: This is the general pattern, Dr. Brand, certainly as we understand it.

Mr. BRAND: It is not absolutely true.

Mr. HENRY: Obviously, one can find exceptions.

Mr. BRAND: On page 50 of the Green Book you make the statement of methods of production were improved by Merck and Upjohn and the cost was reduced. That flies in the face of your other contention to a degree, does it not.

Mr. HENRY: No propositions are absolute and if you would like us to attempt to analyse why these things happen in the case of particular exceptions, I will be very glad indeed to do so. I do not have the answers here. But if it is important—

Mr. BRAND: I think it would be important in view of the fact of the recommendations about the patent laws. What do you think would have happened to cortisone if there were no patent protection, as was suggested initially by the Restritive Trades Practices Commission?

Mr. HENRY: In what respect. You mean what would have happened to the price?

Mr. BRAND: Yes, what would have happened to the production of the drug. Do you think this would have mitigated against production of the drug?

Mr. HENRY: I do not know. I do not see why it should. It certainly has not with penicillin, for example.

Mr. BRAND: Penicillin was not discovered by a drug company, was it?

Mr. HENRY: No.

Mr. BRAND: But a lot of these other antibiotics were, were they not?

Mr. HENRY: Yes.

Mr. BRAND: I believe on pages 49 and 50 of the Green Book you point out a lot of these that were developed by the drug companies; there is quite a list here, as a matter of fact.

Mr. HENRY: Yes.

Mr. BRAND: Developed and patented by Parke, Davis & Co. Ltd., this chloromycetin, chloramphenicol; American Cyanamid marketed aureomycin developed and patented and so on. I will not read through the list. There is quite a large list here.

Mr. HENRY: There is no question about that, Dr. Brand.

Mr. BRAND: You say on page 27:

> It is not obvious why Canada should provide any special measures to guarantee that foreign suppliers should be able to recover any particular costs by any particular method.

Take the patent system in the United States as it is now. You are suggesting in your brief, correct me if I am wrong, that they can recover their costs of research somewhere else, but in Canada they do not have to. I wonder if that is a valid assumption. You are suggesting, perhaps, that a copier could produce

a drug cheaply because he would not have any of the costs of research or development, but then you would expect these companies to bring in their drugs, as you say at page 27 of your brief:

> In the case of finished drugs imported into Canada for sale, the cost of research, or a contribution with respect thereto, may also be recovered by the royalty on the patent or by the repatriation of profits earned by the Canadian subsidiary.

Mr. HENRY: Yes.

Mr. BRAND: Despite this background of extra costs you would expect them to compete with the copier who has no such background of costs.

Mr. DAVIDSON: They do not really have extra costs in Canada, Dr. Brand. Basically the great majority of Canadian companies are copiers. In some cases the copier copies from an affiliated company abroad and in other cases the copier copies from a non-affiliated company abroad, but their costs are not necessarily different in Canada.

Mr. BRAND: Well, let us go into something just a little different. Let us bring the car industry into this because it is the free market forces that govern. If it is your belief that it will work so well, why does it not work in the automotive industry? I am a little curious. Why do we not have cheaper cars in Canada? If the cars are designed in the United States, why should we pay for the design? Why can we not have cars here made by copiers?

Mr. DAVIDSON: I think one reason is that only three or four significant automobile companies have control over the whole industry. This is a great deal more significant than the control a company would have if it had 50 competitors.

Mr. BRAND: Do you have to have 50 competitors before you get this free flow you are talking about?

Mr. DAVIDSON: No, you do not have to have 50; it depends on the industry. The economies of scale in the automobile industry are very important and therefore, it is very difficult for a firm to enter the automobile industry on a small scale. This makes it unrealistic to contemplate small Canadian companies starting up to produce automobiles. The economies of scale in the industry are far too great.

Mr. BRAND: Do you suggest that this is not necessarily true in the drug industry?

Mr. DAVIDSON: Yes; that is right.

Mr. BRAND: As far as quality control and things of this nature are concerned?

Mr. DAVIDSON: Yes; that is right.

Mr. BRAND: You make a few other statements in your brief which I question just a little bit. In referring to the Food and Drug Directorate on page 24, you make a lot of what I would consider unwarranted assumptions which are not in accord with the evidence that was presented before this Committee. In particular, on page 24 you state:

> It is of course accepted and understood that the Food and Drug Directorate would provide a program of quality and safety control to

ensure that any imported drugs meet necessary standards. It is my understanding that this should present no insuperable problem provided the resources are made available.

This is not quite what was presented to us. The fact, as pointed out by Dr. Chapman, is that there was a moratorium on any improvement in the Food and Drug Directorate which was stretched out for 12 years. Other problems came up such as the fact that there is no battery of pharmacologists. This is not a simple problem at all; it is a very serious one.

Mr. DAVIDSON: Yes, I understand that.

Mr. BRAND: You make it sound much too simple here, in my book.

Mr. HENRY: It may well be that I make it sound much too simple. The point is, of course, that I am unable to pass a judgement on what the Food and Drug directorate can do and, as I have pointed out at the very beginning, the safety, the quality and the effectiveness of the drug are paramount. I can only go to the extent of saying that the question of quality control, if I can call it that, the safety control over the imported drug, no matter where it comes from, is a matter that has to be left to the Food and Drug directorate. If they cannot do anything about this, if they say to you, it is impossible for us to allow imports of drugs from abroad because we cannot possibly tell whether or not they come from proper sources and can be safety prescribed, then, of course, I think the exercise comes to an end as far as importation is concerned. However, I do not understand that the Food and Drug directorate takes that position.

An hon. MEMBER: They certainly do not.

Mr. BRAND: Well, they do in my view, certainly.

Mr. HENRY: Well, I have a different view, Dr. Brand, and this is as far as I can go because I cannot speak for them. The only person who can deal with this point is Dr. Chapman or somebody from his department.

Mr. BRAND: Let us assume for a moment—and I notice that you do not necessarily agree with this now—that we did away with drug patents completely in this country; where would this place Canda in relationship, say, to the United States which has a patent system?

Mr. HENRY: In what way, Dr. Brand? Do you mean—

Mr. BRAND: Would this interfere at all with—

Mr. HENRY: —that we square off with each other?

Mr. BRAND: Well, yes. We have been doing that lately and I am sure there is no reason why we should not do it again.

Mr. HENRY: Yes. Well, there might be some name-calling. I think that that is point No. 1.

Mr. DAVIDSON: I think it is important, Dr. Brand, to recognize that particular patent systems vary from country to country around the world and in fact there is one area, right now, where we do not grant patents; whereas the United States, on the other hand, does, in the area of the development of new plants. We do not give any patents on that and the United States does, and they presumably are prepared to live with this difference.

Mr. BRAND: Am I wrong in feeling from your brief, taking it as a whole, that you feel we would be a lot better off just to bring the drugs in and forget about research?

Mr. HENRY: No, I do not feel that way at all. Provided Canada is prepared to pay the social cost of supporting research in Canada, I think this would be a good thing.

Mr. BRAND: Do you mean the Canadian government?

Mr. HENRY: Provided Canadians are prepared to pay the social cost. As I say in the brief, the cost has to be extracted from somebody and, at the moment, it is being extracted from the patient, if I can simplify it. You could, however, place part of that burden on the taxpayer generally by shifting the cost or part of the cost to the government or to the institutions, endowed institutions, and this sort of thing. You could spread it around. You have various choices here and perhaps one way of putting it is, it can be a little easier on the patient if general drug research is financed by a device which will spread the cost over a larger group, because all taxpayers in the long run will benefit because ultimately all taxpayers get sick. I think medically that is probably sound. Would you appreciate my point if I said that to encourage research in Canada for its own self requires you to consider the means by which it will be paid. Let us assume, and I am quite prepared to say it that it is a good thing to do—

Mr. BRAND: You go into that in your brief as well.

Mr. HENRY:—then how do you pay for it? This is my main point and, of course, one of the biggest issues I have raised.

Mr. BRAND: You feel it is better to spread it among all the taxpayers rather than just out of the—

Mr. HENRY: I think it would help your problem in connection with the high cost of drugs. If the companies are right and costs have to be "high" because research is costly,—and I am using that word "high" with quotes around it—then, of course, you are taking a chunk of that out and causing taxpayers at large to support it. You can have research, whether it is commercially feasible or not, induced by incentives of a more selective kind, as I explained in the brief, that is, you can direct your research incentives to the people who are actually prepared to do the research. As Hoffmann-La Roche says in its brief, you do not just do research because it is nice to do it from some country's national pride; you do it as a company because it is commercially profitable to do it there. If it is not commercially feasible as far as their policy is concerned they presumably would do it somewhere else. Ayerst, McKenna, on the other hand, does the research as I understand it for their parent and the rest of their world-wide network in Canada. The ball happened to bounce that way, probably for historical reasons. The point I am getting at is that the company must make its own choice and the basic choice as far as a company is concerned is going to be commercial consideration, is it profitable to do it? The companies say it is only profitable if you give continued protection and allow the present price levels to prevail. I say, well, if you agree with that argument the question is then, do you feel the patients should be the people who pay for this or should you stimulate research in some other way and perhaps spread the cost wider. If you weaken the patent protection as I suggest and as the

Hall commission does, as a first step by compulsory licensing of imports, then your research incentives will have to come from the government. Research can still be done by people who are prepared to do it. You do not just blanket out research because you discourage them by not giving them patent protection. Some companies may not do it, other companies may; this will depend in part on the incentives given.

Mr. BRAND: The fact still remains that the amount of money put into research in Canada right now is pretty minuscule.

Mr. HENRY: Yes, I use that in relative terms, relatively small, and I do not think anybody would suggest otherwise. Also, bear in mind that the PMAC in their brief say it is completely unrealistic to expect that Canadian research, research in Canada, will produce the major part of our drug requirements in the future. In other words, in the foreseeable future we are going to depend very largely on imports. Whether it is the basic ingredients, or the dosage form does not matter; that is the choice of each company in the process of doing business. We are going to go on being importers and, as I have said before, the Food and Drug Directorate are dealing with imports all the time.

Mr. BRAND: You would obviously accept the premise that you would have to spend many, many millions of dollars on the Food and Drug Directorate and on research before—

Mr. HENRY: Not many millions, no.

Mr. BRAND: You realize, of course, that the Food and Drug Directorate are using the facilities of some of the major drug manufacturers now in order to do some of their work, and therefore they would have to reduplicate their own facilities, I presume, or such facilities themselves.

Mr. HENRY: Dr. Brand, it may be that I should not say this, but at one time I had an investigation made into this very point. Obviously I cannot commit another department, but at the time it was our understanding that an expenditure of $4 million on Drug inspection facilities would deal with the problem as we see it. Please, do not overlook the fact that this figure could be different now, but it was only a year ago that we made this estimate of what the social cost would be of stepping up the quality control, if I can call it that, of imports, bearing in mind that imports are coming in now. All you would be dealing with is imports of patented drugs, many of which will be coming in from the parent firms.

Mr. BRAND: I think you are suggesting that we increase the staff sufficiently so that every drug that comes in can be tested, using the present methods. It is my contention, of course, that these lists are not adequate, and you would have to spend many more millions in order to make an adequate type of examination. For instance, Dr. Chapman did not indicate to this Committee that the type of tests they are doing is absolutely adequate. Some of them are being done in the universities. I think the Canadian Association of Medical Colleges, or some such organization, has recommended the expenditure of many, many millions of dollars for research in universities and this has been said in the house many times. Dr. Rynard knows the figures better than I do at the moment.

Mr. HENRY: Dr. Brand, this depends really on how the problem shapes up in actual practice. I, of course, cannot comment beyond what I have because I am

not competent to do so, but you must remember that there is a tendency to think in terms of all sorts of drugs, coming from unknown and suspect sources, flooding Canada. I do not see this happening at all. Indeed, I do not think the Food and Drug Directorate would permit this. I think what will happen is, if you will follow out what is generally presented in these suggestions of mine, that there will be the threat of cheaper drugs from various sources. The threat will come from the fact that smart Canadian purchasers—wholesalers or the smaller manufacturers—will look for alternate supplies. In the first place they will look for supplies of the drugs that, for example, show a marked difference between the Canadian price and the price abroad. You may remember that Dr. Howe put a list of 48 drugs or something of that sort down—

An hon. MEMBER: It was 56.

Mr. HENRY: Yes, it was 56. Those were particularly picked because there was a considerable spread between the price in England and the price in Canada.

Mr. HOWE (*Hamilton South*): There was a little selectivity there.

Mr. HENRY: I understand that. The fact is, though, that it illustrates the point where you have a drug in that position and the patent protection is lessened because it is easy to get the licence. Then, of course, the Canadian importer—he may be a large drug wholesaler who wants to get the cheapest drugs possible and he would be prepared to compete—may select some of these drugs and say that he can get these cheaper in Italy and go over and do it. These are not suspect drugs; he gets them from reliable sources. If he is a manufacturer, he can get drugs now. There are manufacturers who are operating under compulsory licences right now and voluntary licences who are having no difficulty whatever in getting the basic raw materials for the drug and whatever is necessary to put it into the dosage form. These are available on the market and there seems to be no problem about safety.

Mr. BRAND: I just have one more question at this time. I emphasize that. You made no mention at all in your brief of the cost of drugs at the drugstore level, the retail level. We certainly have some evidence of some wide disparity in charges at the drugstore level, some of them being just fantastically different in the prices charged for the same drug. Have you any thoughts on this?

Mr. HENRY: Dr. Brand, I said in my statement, that I had been asked to talk about patents and research, but I went out of my way to emphasize that I think action must be taken at the retail level as well as at the manufacturing level—I think it is quite unfair—

Mr. BRAND: How? This is the point. This is what bothers me.

Mr. HENRY: I have not anything more than half formed thoughts on this at the moment. I did not come prepared to discuss it but may I put it this way? I think there can be very little quarrel that the drug distribution system in this country at the retail level is a high cost system. Part of this is due to the nature of our geography but we go about distributing drugs by having a multitude of small retail stores—in cities they are usually in reasonably expensive properties—the retailer is not able to make ends meet on his pharmacy work; he is a professional man who has to turn to straight merchandising of unrelated products in order to make ends meet. You have, therefore, what might be termed an

uneconomic operation, generally speaking, as far as prescription work is concerned. The pharmacist is not making a huge profit. Am I right about this that the pharmacist is having trouble? The evidence that he is having difficulties making ends meet on his pharmaceutical work—his compounding—is that he has to turn to other sources of revenue. I may be wrong about this figure, but I thought I read the other day that only one-third of the average business of the pharmacist goes into pharmaceutical work. Mr. Davidson says it is less than a third. Therefore, if this is right, here is a very large proportion of this professional man's business being carried for him by something that has nothing to do with his profession.

That is one thing. It may be—I am not producing a solution here, I am just throwing out some thoughts; things that have been going through my mind because this, I think, is probably going to have to be the next step in the exercise at some stage—that it may be possible to devise a more efficient system of pharmaceutical distribution. The hospitals do this, for example, through the hospital pharmacy as far as patients are concerned, as you know. Whether some system could be devised, shall we say, by combining pharmacists in dispensing centres in a city where the costs could be localized in one set of premises, whether it could be done or not, I do not know. I see this as a way of cutting down the costs. You could then have a round the clock service, for example. You would have two or three centres in a large city with quick and efficient delivery services. This is the sort of thing that might be possible because I do not think the present system of operating a retail pharmacy gives any scope at all for the pharmacist to reduce his costs at the moment.

Mr. BRAND: Yet there are examples across the country where pharmacists have done this.

Mr. HENRY: Yes.

Mr. BRAND: And have done it very successfully without the difficulties that seem to be inherent in your statement about the trouble they are having keeping alive in business.

Mr. HENRY: Right.

Mr. BRAND: For example, there is one in Winnipeg who charges cost price plus a dollar professional component and has done exceedingly well and fills about 800 prescriptions a day. There is another one in Vancouver who does up to 2,000 a day.

Mr. DAVIDSON: I think Dr. Brand, that may be where the solution lies. The trouble has been that the retail pharmacy trade has been one in which there has been very very little price competition and that can be accounted for, in part, by the fact that, as was indicated in the PMAC brief, most drug manufacturers price maintained their products at the retail level before resale price maintenance was prohibited under the Combines Investigation Act. It has taken a long time—the people in the trade have become used to this method of operating which de-emphasized the price appeal—for a few mavericks to decide that their best interest lies in narrowing the margins.

Mr. BRAND: Do you have any real evidence that the druggists are in trouble, economically?

Mr. HENRY: Only the figures we have in this Green Book and I have not personally checked the recent ones that Mr. Turnbull probably put before the Committee. I am not suggesting that they are in real trouble. What I am saying is that they are not making high profits and they are all relying on something in addition to pharmacy to keep their operations going. What I am talking about here is the basic structure.

Mr. BRAND: You are sure they must rely on other things such as cameras which have a much lower mark-up than drugs?

Mr. HENRY: This may be.

The CHAIRMAN: I think that was a long last question, Dr. Brand. You talked about four more things. You opened up a whole new subject.

Mr. HENRY: I wonder if I could complete this because I think it is very important. As I said, this may be the next round, but the starting point at the moment apart from the structural problems which are very basic and very underlying, are, of course, the things that may be done to interject some price competition at the moment. Some pharmacists, as you will have observed, have been competing. This was starting at the time we had our inquiry and just from general observation without any study being made, it is our impression that it has increased. You also have a movement on the part of the pharmaceutical profession generally to try to adopt the cost plus a fee method of charging. As has been explained, this probably will increase the cost of the lower priced prescriptions but decrease the cost of the higher priced ones; but it has this virtue that if the pharmacist does adopt a cost plus a fee method, you can identify what the drug cost him. If the manufacturers' price to the druggist is reduced, you have made the first step. On top of that goes the professional fee which may or may not be supported by some form of legislation. Then, of course, you have the problem of collusion under the Combines Investigation Act if they do get together to agree what the fee should be for prescribing the drug. There is a problem here, let me put it that way.

If the pharmacists adopt a system such as this and I understand the majority now in Ontario—well over 50 per cent—are doing it, you have been able to isolate the cost of the drug as long as he does not throw into that price—the cost of that drug—a lot of things like overhead and so forth. If he takes the cost of his overhead and other costs of his business out of his fee, the way a professional man normally does, then you see you can isolate the cost of the drug that was supplied by him by the drug house and you have part of your problem or rather part of your solution advanced because you can see then what is happening, much better than you can now.

On the other hand, it is important not to allow the pharmacist to get into the position where the cost becomes fixed and there is some understanding that they will not cut that; and the fee becomes fixed so there is no competition on the fee. Then you have eliminated competition and that is the very point I made in the Green Book at the very end when I attempted to place an appropriate element of responsibility for the whole situation on the pharmacist.

I have no solutions, as yet, Dr. Brand; I am sorry I cannot contribute more at the present time on that.

Mr. RYNARD: I was very intrigued with the brief Mr. Henry presented. As a matter of fact, it is quite a brief until you read the last of it and that softened the whole thing. I was interested in two or three points. First, he hoped that he would build up a multiplicity of drug manufacturers across Canada who would bring down the price of drugs to the people. Is this statement correct?

Mr. HENRY: Not necessarily, sir. You do not necessarily have a multiplicity of drug manufacturers; indeed,—

Mr. RYNARD: You were going to open up the field of competition by having more people going into the manufacture—

Mr. HENRY: That is right and manufacturers as such may be reduced. Indeed, the industry says there is over-extension in this respect. There are too many manufacturers here and this is what gives rise to the idea that possibly some rationalization, as some people refer to it, is necessary.

Mr. RYNARD: You mean in Canada now we have too many drug manufacturers?

Mr. HENRY: First of all, the industry says that. I am not necessarily saying that. Certainly, we have a lot of drug manufacturers and we do not have concentration in really a few hands except for some of the important patented items; but it is not so much the idea that you proliferate manufacturers as to get a good distribution system going. As I said in the paper, if you place the pressure which I suggested on price, you may eliminate a number of manufacturing operations in Canada. Some manufacturers may go out of business; this is quite possible and this is what has to be faced. Naturally this is unpalatable for those who are selected by economic forces, but this happens. It has happened in a number of industries.

As a matter of fact when the automotive parts plan was put in, the parts people were extremely sensitive about this because they thought they were going to be eliminated. This always happens when you have a new streamlined idea, but the whole purpose there was to bring in free trade, to cut down the barriers and get a good free trade movement of goods going, back and forth across the border. Here we are suggesting you open up freedom of trade by a somewhat different device, namely, cutting down some of this patent protection and as I said, without completely emasculating the patent system, because you still preserve the patent and give the patent holder a royalty on it.

Now, what you may have in addition is a change in the character of the operation of the manufacturer because he may become more of a distributor. He may import from his parent company more of that he now tries to manufacture in Canada. He will manufacture in Canada the things he can do best. There are some drugs where if you look at the price list, you will see that the Canadian price is better than the other prices. If we can manufacture at a better price in Canada that is the kind of drug we should be concentrating on. That is the kind of drug you may ultimately be able to export because you can do better in Canada than other people can.

On the other hand, in some products other people can do better than we can as far as efficiency and price are concerned and, therefore, if you want to seek the less costly drugs you go to those sources. Some manufacturers, therefore, may have to drop some of their activities in manufacturing and they may have to

import more and become distributors. You may have more distributors springing up, or you may have the existing wholesalers simply going abroad for their sources of supply to, shall we say, the United Kingdom, for the drugs that Dr. Howe has put down on his list, where they are cheaper.

Mr. RYNARD: Really, Mr. Henry, you are suggesting something but you do not know what the end outcome may be.

Mr. HENRY: You cannot tell with any precision what the outcome may be. You one perfectly right.

Mr. RYNARD: That is the point I wanted to make. You do not know what would happen with this brief that you have presented, if those ideas were carried out.

Mr. HENRY: I have had to speak in generalities because—and I think Mr. Davidson would agree with me,—you cannot predict with certainty what is going to happen to company A, company B or company C. All you can say is that on the basis of economic experience, the following things are likely to happen.

Mr. RYNARD: I wonder if you are sure they are likely to happen. Let us follow the one where you have a multiplicity of drug manufacturers, finally competition becomes pretty severe and what do you end up with? Just the same thing that you do with the motor cars. You end up with the three big ones. Then they fix their prices pretty well across the country. In the long run, you end up worse than when you started.

This is one thing that could come from the suggestion that you are making. I believe that in Italy, for instance, they have a lot of drug manufacturers and yet their prices are dearer there than they are in Great Britain, as I understand it.

Mr. DAVIDSON: It may depend upon the individual drug.

Mr. RYNARD: I am taking the average.

Mr. DAVIDSON: It depends on how the calculations are made, Dr. Rynard.

Mr. RYNARD: How do you mean, the way the calculations are made?

Mr. DAVIDSON: Sometimes people have taken simply an average of prices and not taken the quantities that were sold at these prices and have concluded that if you simply take an average of prices you are higher or lower than somebody else.

Mr. RYNARD: You admit that this does happen?

Mr. DAVIDSON: I think our experience is that where there is a multiplicity of suppliers the prices are low.

Mr. RYNARD: Well, of course, this is what you have admitted yourself you have taken certain drugs. I am just stating a fact, and you have done the same thing in your brief, so it if it applies to your brief, it applies to this, that drugs are dearer in Italy. Then, the other thing that I wanted to come to is this. I am a little bit disturbed by our becoming a group of copy cats, because you say, we could have research here but it is going to cost us a lot of money. Either the state has to pay for it or the individual has to pay for it. How much is this going to cost us? What really are you recommending here?

Mr. DAVIDSON: It depends on how much we want to do. We are copy cats just now because we do not do any—

Mr. RYNARD: Well, let me ask you this. Do you believe in keeping on that copy cat to its logical conclusion?

Mr. DAVIDSON: I think that Canadian research resources are limited and should be devoted to the area where they are likely to be the most productive.

Mr. RYNARD: You mean that you would produce the drug that you could produce and leave all the others to be produced outside the country and imported?

Mr. DAVIDSON: That is right.

Mr. RYNARD: How many drugs do you think you would manufacture in Canada on that basis?

Mr. DAVIDSON: I would not have any idea at this point.

Mr. RYNARD: Would it not be very few? Would it not be the same as the motor car industry?

Mr. DAVIDSON: The motor car industry is quite different because there are so many barriers to entry of new producers. It is not difficult to get into the drug industry unless there are artificial barriers to entry.

Mr. RYNARD: Well, it is different because we pay a hundred million dollars for that privilege. I am wondering where the logical conclusion of all this would go. Would we lose all the keen young fellows who want to go into this type of research, across the border? It costs us between $25,000 and $50,000 to educate them. I think this is something we have to face up to. Are we going to be a country or are we not? This copy cat stuff does bother me a little. In the long run what may appear cheap today may be very dear tomorrow. This is one thing that I feel is pretty pertinent. Are we going to be a nation or are we not? Are we going to stand up and protect the young fellows that we are putting through school, and we have a bright group of young researchers, or are we going to allow them to cross the border, just because we want to manufacture what we can best do here? With a 70 per cent efficiency in production compared to the Americans you can easily see where we are going to end up. This is the fact that bothers me about all this.

Mr. HENRY: I think the point is well taken. As I tried to emphasize in the brief, the task of this Committee is one of weighing up social costs against social benefits. The drain of human resources to another country is certainly a social cost, in terms of building up our own research resources in Canada. What I have suggested is that research is not simply going to be eliminated because more price competition develops. The research may be re-directed into different channels. Research may be called forth by, and can be called forth by, government incentives. This is what I am getting at.

Of course, you cannot guarantee that when you undertake some sort of a program like this that some people are not going to get hurt. This is impossible to guarantee. No one would ever think of doing it; so you must think in terms of broad social benefits as against social costs. The social cost at the moment is that there seems to be a problem in this country as far as the patients are concerned: The general public thinks the cost of drugs is too high. There seems to be some

evidence to support that. I am assuming that that is the first task of this Committee. What I have tried to do is to suggest to you here how you can reduce the price of the drugs. I say you can do that, and I say you must weigh against that what may happen and then decide which is the more important in the public interest.

Mr. RYNARD: Mr. Henry, would it be fair then to assume that probably the state could assume some of the cost of the drugs to the individual and in that way they would be paying some of it.

Mr. HENRY: It would be another means, would it not?

Mr. RYNARD: This would still keep you in the field of private enterprise.

Mr. HENRY: Well, there are several means, Dr. Rynard. For that matter, the state could form a crown corporation and manufacture drugs here in Canada to supply the needy, or the hospitals or others. Many devices involving state intervention can be thought of once we get on that route. You will recall that state intervention was one of the three basic choices that I think you have. I called it direct control but then I elaborated by saying that this may include a number of other things.

Mr. RYNARD: Would you agree that there should be incentives applied so that those people who are operating in Canada and yet doing a great amount of their research in the United States, for instance, would find it more favourable by your incentives on research to do it right here in Canada? Would that not be the best way out?

Mr. HENRY: Well, it is quite possible, and this is, of course where—

Mr. RYNARD: You have people with experience, people with know-how. Why would this not be the ideal way to do it?

Mr. HENRY: You mean have them come into Canada?

Mr. RYNARD: Yes, certainly. Give them an incentive to do it right here.

Mr. HENRY: You would have to attract them here, Dr. Rynard.

Mr. RYNARD: With your incentive and research?

Mr. HENRY: That is right.

Mr. RYNARD: Then you would keep your young men that you have educated right here working in Canada.

Mr. HENRY: All right. Then what you are saying is that you direct your incentives towards the companies who will do research. Right now your patent system is scattering them across everybody whether they do research or not.

Mr. RYNARD: Yes, but could we not also work this patent system by saying when you have recovered your research costs, and the accountants could very easily look into this, and they have all been added up, why then could not the patent be removed? Is this not a very simple way of handling this without this conglomeration that we seem to be going through in this brief?

Mr. DAVIDSON: It might be possible but it is certainly not likely to be simple because it is impossible to allocate research costs to particular drugs. You have a big lab. You have 100 Ph.D.s, all of them working part time on one project or some of them working full time on it. It is impossible to allocate the—

Mr. RYNARD: Parke, Davis were able to do that very well on chloramphenicol. I saw their figures. If they can do it on one drug, they can do it on another.

Mr. DAVIDSON: They can attempt this. I think probably Mr. Blakely could comment on the feasibility of something like that.

Mr. RYNARD: I would feel that they could. I would feel that this would be a very fair way of treating it. It does nothing to stop the research; they have recovered their research, and if you give the incentives you will bring in those people and they will do it right here in Canada. You say you have to subsidize them. What better way to subsidize them and keep our young, smart researchers right here operating in Canada and build a nation. This is my feeling.

Mr. HENRY: That is a very interesting thought, Dr. Rynard. On this basis, the life of the patent would vary according to the length of time it takes to recover the research costs.

Mr. RYNARD: That is exactly right.

Mr. HENRY: The difficulty here, of course, is that you probably would find that this would become unacceptable in view of the fact that the patent system generally works on the basis of a term, and this is agreed to. I think Mr. Laidlaw can tell me just how far I am right or wrong on this, but this is generally the pattern that is settled in the international conventions that are participated in by various countries from time to time. You have, your proposal, an uncertain term for the patent depending on what kind of figures the cost accountants throw in for consideration. Perhaps Mr. Blakely could tell us about this but it is my impression that just as you have five economists, you have five different opinions the same as lawyers; if you have five cost accountants you may have five different opinions. I am not quite sure how that would work. There is a problem there. It is an interesting idea.

In Canada the compulsory licensing provision is designed to give some return on research. That is what Mr. Justice Abbott said in dealing with this. In England, it is different. It is to give an appropriate advantage to the owner of the patent—you have a different system there—not only to cover his research but to give him an advantage because he is the owner of a valuable thing. I see some difficulty in this, but on the other hand, it is an intriguing idea because it is directed exactly at your problem.

Mr. RYNARD: Maybe we could hear from Mr. Blakely because I understand that they can project costs pretty well if they have done the proper research. They would know approximately how long it would take to recover this.

The CHAIRMAN: I would just like to ask one question, Mr. Rynard. Who and how would you pay for the drugs that did not produce a product that was marketable?

Mr. RYNARD: This over-all picture would have to be taken into account when we said what it would cost to do one job. You have also other research and this certainly would have to be taken into consideration. There is no question about it. But you would do that if it were a government agency. All the research would not succeed so you are going to pay for it one way or another. There is no difference whether it is private or public.

The CHAIRMAN: Do you wish to make a comment Mr. Blakely?

Mr. BLAKELY: I would say that in my opinion while it may be possible to do just this, I would agree that it would not be simple. There would be considerable opinion required. You have a very considerable degree of allocation and I believe, as Mr. Henry suggested, that you could probably or you will get several different opinions as to the precise method of cost allocation, depending on the number of opinions you seek out. I am afraid there would be some considerable difficulty. I believe that in fact, this is the very point which the manufacturers themselves have made to us. I recall at an earlier meeting when this very subject was being discussed, that is the determination of costs of specific drugs, they themselves indicated that this is an extremely difficult problem.

Mr. RYNARD: Mr. Henry, just one more question on this: Could the patent law not be arranged so that as soon as those research costs are recovered in general the patent law would then run out?

Mr. HENRY: Yes, as a matter of law I am sure this could be done. I would think that the problems that would be created by attempting to administer this might make it unworkable. That is the only point. I think it would be more complicated really than what we are suggesting. It would be better to take a standard period. Somebody has made this suggestion. I think it was when I was here last day Mr. Dan made a point about this. You take a period of three years, for example, and simply put a three-year period on the patent and let the patent expire. That would be a far simpler way. That period might be determined by what you might call the average period of time over which the companies are likely to recover the costs.

Mr. RYNARD: Then this could be re-arranged as you see how it works out.

Mr. HENRY: Yes: rather than trying to do it differently for every company, I think it would be better to make it clean cut and simply take a short period. I think that is better.

Mr. HOWE (*Hamilton South*): Mr. Chairman,—

Mr. ORLIKOW: Mr. Chairman, on a point of order, before Dr. Howe begins; I think it is better that I do this now before he speaks so that no one can say it is a partisan matter. I want to raise the point of order, just not for today. It is now a quarter to twelve. We are not likely to reconvene this afternoon on the basis of past practices. I just think, Mr. Chairman, that it is not very good business to permit one member—and I am not being critical of Dr. Brand; I am being a little critical of you, Mr. Chairman—to have thirty minutes, I think Dr. Brand took forty minutes,—because obviously there are members here who are not going to have an opportunity to ask questions.

I do not have very many questions today because I happen to agree substantially with the views which Mr. Henry presented. I think though, Mr. Chairman, that we should have a rule, I do not care whether it is ten minutes or fifteen minutes or, whatever the Committee members think is fair, and we should adhere to it.

The CHAIRMAN: I agree with you, but the problem is that you get into an area and the question runs on and on and you say one more question, and you may end up asking about four. This is my responsibility, except that we have

done this in the past and it has not been too successful. Everybody complains that they were cut off just where they were getting to the point.

Mr. ORLIKOW: Well, they can come back, Mr. Chairman, if we have time.

Mr. HOWE (*Hamilton South*): On this point of order: I am not going to ask a question and I do not want this taken out of my allotted time. I think it depends on the length of the answers how long a person is questioning, and some of our answers—and this is not criticism—have been long today which explains in part the forty minute longevity of Dr. Brand—

The CHAIRMAN: It was thirty minutes; I timed it.

Mr. HOWE (*Hamilton South*): Well, that clock is running a little fast then, Mr. Chairman, it was about forty minutes.

May I start on mine and if the answers are not too lengthy, I am sure I will restrict mine to fifteen minutes, but that again depends on the length of the answers.

The CHAIRMAN: I thought you said you only had a few questions.

Mr. HOWE (*Hamilton South*): Well, I said, it depends on the length of the answers. Some of this is a bit repetitive because the questions were not covered just in exactly the way that I had intended them to be, and I did not like to interject supplementary, so, will you bear with me in any repetition there may be.

With regard to research, do you think there is any tie-in between the obviously inadequate amount of medical research funds provided by the government, which has been subject to so much criticism lately, that has pushed research into private enterprise where it should not be.

Mr. HENRY: I do not really have any comment about that. What I am really saying is that research all over the world is done to a very large extent by private enterprise. I think, and perhaps the industry will correct me on this, that there is an expenditure for world wide research of $400,000,000 at the moment and maybe a little more. It may have gone up to $450,000,000, or something of that order. Now, this is done by private enterprise and, of course, there could be subsidies involved. The United States—I can recall hearing Dr. Cook quite recently, who is an eminent English professor, a consultant to the British Government, giving a dissertation on research in Britain and in the United States. It was his opinion, for example, that the major part of world research in this area will be done by the Americans, but it was his opinion that there must be co-operation between the three groups, industry, government and the medical profession, in doing research. How much of this ought to be by government incentives and whether the present government incentives are adequate, I really could not say. All I am saying is that if research is to be paid for, not by the patients through the cost of the drug, then the obvious answer is to increase the government incentives.

Mr. HOWE (*Hamilton South*): But, is it not rather ludicrous that private enterprise makes money and receives profit out of social problems as universal as Canadians' health.

Mr. HENRY: Well, this of course—

Mr. HOWE (*Hamilton South*): This is a philosophical question but—

Mr. HENRY: Yes, quite. It is a matter of opinion, but we, at the moment, have the free private enterprise system for this, and the only way to lose that of course, is to adopt some other system which would be—

Mr. HOWE (*Hamilton South*): Well, I am going to ask you about a system which I think is conceivably possible. What do you think about a Canadian formulary system with the drug firms tendering to drugstores for the sale of their product on a purely price competition basis which you in your brief says that within the PMAC group XX there is no price competition but merely advertising competition. This could conceivably eliminate the advertising competition which would drop approximately 30 percent of your prescription dollar, and certainly on a tender basis it has been proven that drugs can be sold at a much cheaper rate than we are now paying. Even at the present price of manufacture these can be sold much more cheaply. Could this conceivably be a system that would look after some of the problems that you have mentioned?

Mr. HENRY: Who buys the drugs, Dr. Howe?

Mr. HOWE (*Hamilton South*): The drugstores buy the drugs from the manufacturer.

Mr. HENRY: Yes, on the basis of a national formulary which in effect identifies the products?

Mr. HOWE (*Hamilton South*): It equalizes products that have been approved by the Food and Drug administration which has to be given more staff and, shall we say, more power to put, or not put, this particular brand on the formulary list depending on their qualifications.

Mr. HENRY: Correct. Well, I agree with the idea of the formulary list for various purposes, where the hospitals do this, and so forth. This has definite advantages in that is educates; it shows the, shall we say, the drugs that are adequate for the purpose, but I question whether for ordinary purchases by pharmacists you could by this alone get the kind of price competition on patented drugs that would be necessary.

Mr. HOWE (*Hamilton South*): Would this not even cut down some of the costs of your retail drugstores in that he would not have to stock twenty different brands but only one.

Mr. HENRY: Yes, this would cut down his cost; this is true.

Mr. HOWE (*Hamilton South*): So this would cut it at the retail level as well.

Mr. HENRY: Yes, but then, of course, you do eliminate certain other drugs. I think you eliminate some drugs that some physicians may wish to prescribe; that is all I am getting at.

Mr. HOWE (*Hamilton South*): They could be a drugstore B instead of a drugstore A and selling for a much lower price.

Mr. HENRY: That is true, and of course, it is possible then for the less frequently required drugs—you have a different distribution system; you might have to go back to the wholesaler that, rather than carrying it on the pharmacy shelf, but then a good deal of that is done now anyway.

Mr. HOWE (*Hamilton South*): Well the commonest drugs sell more commonly.

Mr. HENRY: However, this would be a step in the right direction, Dr. Howe.

Mr. HOWE (*Hamilton South*): Thank you. There was one thing that I asked of the two drug companies that came here and that was to give me prices f.o.b. their factory that were going to Canada and going to other countries. I specifically asked Frossts about—what is their penicillin—falapen—which they do export and I asked their prices f.o.b. their factory that were going to be sold in Canada and that were going to be sold in other countries. I have yet to receive a reply and I was wondering if you had any answers to this.

Mr. HENRY: I do not think we have this information. No, we do not; no, we only have the price list. Sorry, Dr. Howe, we do not have this information.

Mr. HOWE (*Hamilton South*): I am trying to get my questions finished in time, Mr. Chairman.

When I brought forth my 56 English drug prices which you referred to I was given about an hour and a half very lengthy complicated mathematical answer which involved a basket of 56 drugs here and in England, and multiplied by a factor that was approximately two, which referred to pay scale; in other words, how many hours did a person have to work in England to buy this basket of drugs there, and a basket of drugs here, rather than on the straight dollar basis. Do you think this is a fair way actually of figuring costs.

Mr. HENRY: No.

Mr. HOWE (*Hamilton South*): The reason I asked you was by the same token one should be able to buy a Ford car in India for about $400. Did you figure that this was just the use of figures to confuse and confound rather than state facts?

Mr. HENRY: No, I think that what happened here is that Dr. Briant was presenting his figures from a different standpoint. I do not find this comparison useful because it does not get to the root of the problem which is to get the price of drugs down. Now, if a drug is one-third the price in England that it is in Canada, it gets you nowhere to talk about the number of man hours that went into this and the real cost of producing that; the plain fact of the matter is that on simple economics if you can buy in England at one-third the price you can very probably bring it into Canada and still sell it cheaper. You are only interested in the absolute dollars comparison.

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

Mr. HENRY: Therefore, I would actually regard the analysis that you speak of as not helpful to the situation at all except as an attempt to explain to Canadians why they should not be too put out about the cost of the drugs because the standard of living is high and they can afford to pay for them.

Mr. HOWE (*Hamilton South*): I have two more questions. Number one, on page 30, you say:

> Ought drug manufacturing in Canada as such be preserved.

And yet you state that the Canadian industry is essentially a copier. May I ask why is there any necessity to preserve? What is there to preserve?

Mr. HENRY: Well, there is manufacturing going on in this country, Dr. Howe. Indeed, there are many people who think that to have a manufacturing industry of any kind in Canada is an end in itself. I am simply reflecting the fact that there may be members of this Committee who feel that way.

Mr. HOWE (*Hamilton South*): Yes, but this is small.

Mr. HENRY: Yes, well it is small. It is not a large industry.

Mr. HOWE (*Hamilton South*): No; so therefore it is not one of the more fundamental isues, simply because of the fact it is small.

Mr. HENRY: Yes, that is correct. I may say that. I have attempted to find out what the real arguments are for having a manufacturing industry in Canada for drugs in its present form and I have not received very good answers on this. I threw the question out, I might say, in a discussion which took place where a number of manufacturers were present as well as a number of academics. I am not quite sure what the argument is except that for nationalistic reasons it is a good thing to have a drug manufacturing industry in Canada. Now, this may be so, it may appeal to some people. But, all I say is that if this is to be the position taken by this Committee, then it is going to cost money to Canadians as it is costing them right now. That is my point. I personally am of the general view that, after all, we have gone beyond attempting to build a secondary manufacturing industry in Canada now; we have got over the hump; we are a secondary manufacturing nation. We are not particularly strong in the drug field, perhaps, but the point is we are grown up.

We are grown up and I think it is generally accepted that we are required to rely on less protection and this is the general thrust, the general thrust, without talking about specific industries, of the discussions in the Kennedy Round, and this is a world wide approach to the matter; that you let the barriers down and you begin to have more trade because that helps everybody. Now, in one sense the proposals that I am making on the drug industry are just that, if you let the barriers down, you will have more imports coming in, and as a matter of fact if this industry wants to export, they are never going to export on the basis of the prices they are charging in Canada. If they want to export what they ought to do is to start concentrating on the things that they can produce cheaper in Canada and then they can export to the foreign countries; but they will never export a product that is priced so high in Canada that it is away out of sight as far as England is concerned. This is just a vain hope, and you just cannot arrange these matters unless, of course, they are going to export on a two price system, charging foreigners less than they are charging Canadians in order to get into the market abroad.

Mr. HOWE (*Hamilton South*): Well I asked you that question.

Mr. HENRY: Well, I am not sure if that fully answers your question but I—

Mr. HOWE (*Hamilton South*): You may not want to answer this. Why have these recommendations of yours not been implemented by present or past governments? Is it because these governments have been afraid to face private industry? You do not have to answer that; it answers itself.

Mr. BRAND: Might I point out that the report came out in 1963 and if you said the present government it would be more accurate.

Mr. HENRY: A number of things have happened to that report, as you know; there have been studies made of it, including that of this Committee.

Mr. HOWE (*Hamilton South*): That was intentionally political.

The CHAIRMAN: It is recognized as such and ruled out of order.

Mr. MACLEAN (*Queens*): The last paragraph on page 27 reads as follows:

> The Committee might also consider whether it is necessarily to be accepted that, where research has been carried on outside of Canada and where the drug would obviously have been produced in any event for world markets whether or not the Canadian market was available, the foreign firm, as a matter of economics, is required to obtain any contribution labelled research contribution from the Canadian market.

Are you suggesting that the Committee should even consider the possibility of Canada being a free rider as far as the benefits of medical research that takes place in the rest of the world is concerned, and not pay any economic price for the tremendous advantages that are available to Canadians as the result of research carried on in other countries. And looking at the reverse side of the coin, if a Canadian company happened to embark on some form of research that looked very promising, but still very costly, but they were willing to take the chance and put up a great deal of money to do their necessary research, and then came up with a successful drug, should they be required to recoup their costs from the Canadian market only, although their drug was used all over the world with tremendous benefit to mankind?

Mr. DAVIDSON: I think there are a couple of considerations in connection with this payment by Canada for research. One thing is that a good many people who invest in Canada and who start a business here, invest both capital and know-how and they take their return on the results of their research investment and their know-how in the profit on the subsidiary, the profit that the Canadian subsidiary makes, and that is profit on capital they have invested and it is also a return on the know-how they have invested in the Canadian market. I think the point which is made at this stage in the brief is that there is not any obvious reason why a particular form of return on the investment in capital or in know-how should be provided for. It is up to the companies to make whatever return they can on either their invested capital or their invested know-how.

Mr. MACLEAN (*Queens*): Yes, but you are talking about their economic investment in the country. What about the return on research that culminated in a successful drug?

Mr. DAVIDSON: What I am suggesting is that in the case of most industries, most foreign firms which come into Canada, do not depend upon a royalty payment under patent for a return on the know-how that they give to Canada. They come in here with their capital, their techniques, the results of their research, with their new products and they expect to get a return on their whole operation by means of the repatriation of the dividends of the Canadian subsidiary company.

Mr. MACLEAN (*Queens*): What you are saying is that large companies can recover their cost of research without being protected by patents?

Mr. DAVIDSON: That is right. The Canadian market is a profitable market for them to sell in, and it is because it is a wealthy market and they are making money on their whole activity here, and part of the return they make is a contribution to research. Part of it is a contribution to the management of the parent company.

Mr. MACLEAN (*Queens*): Why do they bother to patent drugs, then?

Mr. DAVIDSON: Because it gives them a great deal of protection on the price in Canada. It makes it much easier for them to make a return.

Mr. MACLEAN (*Queens*): That is exactly my point. I think that the return on their capital investment, their know-how and everything else might go down the drain if the product was not patented, at least for a period.

Mr. DAVIDSON: A great majority of the industries depend really only on the tariff protection they get in Canada; they do not ask for additional protection from competition, whereas this drug industry depends very heavily for protection from competition on measures other than the tariff, namely, the absolute barrier to imports provided by the patent system.

Mr. MACLEAN (*Queens*): I wil leave that.

On page 23 we find:

> —the Hall Commission has recommended that, as the first step, authority be given to issue compulsory licences for import and that total abolition of patents on drugs be held in abeyance.

Could you say in about one minute what you think the effect on the Canadian pharmaceutical industry would be if this recommendation were brought into being?

Mr. HENRY: That is, that we have compulsory licensing for imports?

Mr. MACLEAN (*Queens*): Yes.

Mr. HENRY: I think what would happen is that the Canadian distributors to start with would seek to purchase the drugs in the cheapest markets and bring them into Canada and they would only do this if it was cheaper to buy abroad. The point is that they would have the opportunity to get them at the cheapest source, and this might displace some manufactured products; that is, products manufactured in Canada, because this may not be the cheapest source. Therefore, you may have some what of a rearrangement, more importing and less manufacturing. In other words, a shift in the character of the activities in the industry.

Mr. MACLEAN (*Queens*): On page 8 you spoke of the desirability of introducing into the economics of pharmaceuticals price competition. It would seem to me that this is a special market that is not expandable indefinitely, as some markets might be, and that in a free for all stituation and the devil take the hindmost, the competition is going to be for a bigger and bigger slice of a fixed market, rather than an expansion of that market. You may persuade a family that it is to their advantage to have two automobiles instead of one, but it is kind of hard to persuade someone that he should have two shots of penicillin if he needs only one. Would you not be apt to get the situation that prevails in Italy, I believe, where the cost of drugs generally are higher than they are in most European countries?

Mr. HENRY: I do not know if the Italian drug prices are higher than most European countries; what do you say the answer to that economic problem is, Mr. Davidson?

Mr. DAVIDSON: I think it depends on how you measure the price. There are those who argue that the prices are lower in Italy and those who argue they are higher; therefore, without carefully examining the measurement, I would not know the answer.

Mr. MACLEAN (*Queens*): Is it impossible to get figures which are really comparable of the prices of drugs in Italy and in some country where there are patents?

The CHAIRMAN: The steering committee have in their possession figures from Switzerland, Germany, United Kingdom, Italy, United States in three different centres. We are now trying to establish that these are truly comparable. The figures that are here, and exactly what they represent is something that the steering committee are trying to find out, but as far as I am aware they are comparable and we have certain numbers of tablets at list price. This will be available to members of the Committee probably within a week or 10 days.

Mr. MACLEAN (*Queens*): On page 6 of the brief there is this statement:

> The more intense the competition, the higher costs are driven. There being no downward pressure on price there is no downward pressure on cost with the result that pressures within the firm for more detailmen, more advertising—

This would lead me to believe that your contention is that there is an optimum position where there is some competition, but not complete open freedom for as many enterprises as wish to take the notion to get into the drug business; that you can have too many firms trying to scramble for a limited market, and thus put prices up.

Mr. HENRY: Mr. MacLean, this is not a question really of the number of competitors. This point that I am dealing with at the top of page 6 is a description of what happens where you have competition taking place because this industry is characterized by competition, on some element other than price.

Now, with the price tending to remain stable for patented drugs, competition takes the form of selling, to put the matter briefly, and there is a much more vigourous campaign of selling in order to get the product across to the physician, because price adjustments do not seem to make a difference in sales with these particular drugs. In other words, demand is inelastic. What I am describing here is when you have a price which tends to be stable, then the firms, in order to push their products, as we all know they do, and they compete very vigourously to do this, will do so on the basis of promoting the brand name of the patented drug and this is cost-increasing, because they have to have more detailmen out. We have one detailman man for every 10 physicians or something of that order. You have to have more literature. All I am saying is that costs tend to fill in that gap. Is that not so, Dr. Brand?

Mr. BRAND: Including all the different firms together, not a single firm.

Mr. HENRY: Detailmen?

Mr. BRAND: Yes, you are giving the wrong impression there.

Mr. HENRY: My parenthetical comment is probably ill-considered, I do not know.

Mr. BRAND: I agree.

The CHAIRMAN: Mr. Orlikow, you are next.

Mr. ORLIKOW: Mr. Chairman, I do not have too many questions. There have been a number of questions by Committee members worrying about the change of patent laws or the import provisions that the drug companies might have difficulty.

The Kefauver committee brought out the fact that in the United States the drug companies were earning a percentage in relation to their invested capital—which is the only real way of looking at the earnings of a company—of twice as much as industry as a whole. In your studies did you look at this type of question?

Mr. HENRY: Mr. Orlikow, in the Green Book I think we did put down some figures about the comparative profit ratio. I do not want to go any farther than to say that this is a profitable industry and the profits of this industry in Canada are higher than average. At the moment I do not think figures I have seen support anything more precise than that. I know that the PMAC has a series of figures which indicate they are not at the top in profit ratio, but perhaps third or fourth.

Mr. ORLIKOW: But their figures were not based on investment, but on the percentage of sales.

Mr. HENRY: Yes.

Mr. ORLIKOW: Is it not true, Mr. Henry, that even where a copier gets into the business, by the time he does get into the business the original company has taken out at least its share of the original research costs?

Mr. HENRY: This may well be, and I certainly would not dispute this, because I think at the moment one of the problems which faces this industry is the very rapid obsolescence of a particular drug. This is a problem for them and ought not to be minimized. Therefore, I think you will find that they have to recover as much as they can in the first few years of operation. At any rate, they can expect that after that, other drugs will replace the one on which they are attempting to recover their costs. Whether they in fact are able to do it within three years, I do not know.

Mr. ORLIKOW: Mr. Henry, I ask this question because the matter has been raised today. I know you are not an expert in this field, but you may have come across an answer to this question in your studies. A number of members here seem to have equated research done in drugs in universities with the research done by private companies. Is it not true that to a large extent the research done in universities is basic research, and that a very large percentage of the research done by drug companies is what they themselves call "development" which is really changing the form of a drug or combining two drugs so they have what they call a new product which can be sold?

Mr. HENRY: Yes, I think that is basically right. That is my understanding. I just want to add one thing on the industry's behalf and that is, some of the work done in the universities may have been commissioned by drug firms.

Mr. ORLIKOW: That is true, but universities, and I am sure medical colleges, are not any different from other departments of universities. Universities are pretty loath to do research, the benefits of which will be derived by a particular company which will be tied up in a patent. That is not the same as if the company does it and asks for confirmation or checking of the results; but universities do not want to work for a particular company and this is very understandable.

Mr. HENRY: I am sorry. I do not know what their attitude is on that.

Mr. ORLIKOW: I would like to come back to this question; as I followed your brief, one of your basic proposals is that we permit much freer importation of drugs than we have in the past. Dr. Rynard was a little concerned about this. I gather what you are saying in that suggestion is that some businessman: a drug wholesaler, a drug distributor, some new company, would bring in only those products which he felt he could sell cheaper than if he bought it from a Canadian manufacturer, or the Canadian distributor, or the retailer buying it from the Canadian manufacturer or distributor, will do it. If it proved right, there would be a saving to the consumer; if it did not prove right they simply would not bring in the drug?

Mr. HENRY: That is correct. They only import it from another source if it is cheaper to do so.

Mr. ORLIKOW: I wonder if in your research you came across cases where if this is done, the present supplier, manufacturer or distributor, in order to keep the business meets the competition by reducing his price?

Mr. HENRY: Well, I have not come across such a case at all, Mr. Orlikow, but I do recall the reaction of one businessman to this, namely, Mr. Dan who, as I have mentioned before, was giving evidence the day I was here expecting to be called. He said that if imports took place—he was asked what would happen—he expected the price would go down. He was then asked, "What are you, as a Canadian businessman, going to do?" He said, "Why I would have to get my price down to meet it". Now, that seems to me to be the reaction of a Canadian businessman, who, I think, is running a reasonably successful business, as far as I know, and I would expect that is what any businessman would say. Of course, as Hoffmann-La Roche says in their brief that is the very thing that they are worrying about; the fact that if imports take place the price level will go down.

Mr. ORLIKOW: Or if a copy, or a generic product comes up, they are going to have to do something about meeting the price?

Mr. HENRY: Well, if it is a competitive product—I mean I do not care whether it is a product of a copier or whether it is generic—I simply say if it is something that the physician is prepared to prescribe, no matter how you identify it, if the patient can get that in accordance with the prescription at the cheaper price, then he presumably will get that—at least he has a choice, and that, Mr. Orlikow, would produce the downward pressure, I quite agree.

Mr. ORLIKOW: I want, in a moment, to ask you to give us some illustrations of the things which you summarized on Page 11, which you have not done because it is from the Green Book; but many people on the Committee, and I am sure some of the press people, may not have looked at the Green Book for some time. Before I do I would just like to ask you a few questions with regard

to the question of retail drug prices, which you mentioned. I think it is highly unlikely that in the forseeable future we are apt to get the kind of dispensing through some kind of government or co-operative arrangement which you mentioned. Would you not agree, that really, if the consumer thinks the price of prescription drugs is too high—and I bought some in Ottawa last week which shocked me, coming as I do from Winnipeg, I must admit—he has the right and, indeed, the responsibility to ask for prices? In other words, to look for competition?

Mr. HENRY: To shop around?

Mr. ORLIKOW: To shop around.

Mr. HENRY: Yes, I think the consumer has this obligation if he wants to get the best price.

Mr. ORLIKOW: There is a company in Wninipeg which has made things very uncomfortable for the status quo in recent years. I was not here, I think I was sick, but there was a man here from Vancouver who has done a similar thing, and if there is overcharging at the retail level and if the druggists are not acting as a combine, and I presume your organization will watch them as closely as it watches anybody else—and it should?

Mr. HENRY: That is right.

Mr. ORLIKOW: If the consumer is worried, then he should be shopping around.

Mr. HENRY: Yes, I think the consumer has to make his choice but, of course, he has to have a choice in the first place; and all this is directed towards is ultimately producing a choice for the consumer.

Mr. ORLIKOW: I do not know whether you looked at this when you were doing your study. If the doctor were to write the prescription, not with the brand name, but with the generic name, so that the druggist has the opportunity to use a cheaper product, not equanil but some other form of meprobamate, there could be a savings to the consumer. Did you look at that at all when you were making your study?

Mr. HENRY: Well, yes, we were aware of the problem. I am not at all sure that that can be put quite as simply as that. I think the physician, after all, should be in control of the prescription that he issues, to the extent that if he wishes to prescribe a particular product he should be at liberty to do that. If his choice is to prescribe it by a brand name, I think he should do so.

Mr. ORLIKOW: Oh, I thought I had made that clear. Of course, if the doctor writes a brand name that is it; but if the doctor were to write the generic name there would be some flexibility. I am sorry.

Mr. HENRY: Well, I think that is taken for granted, is it not? I had exactly this happen in my own home last week. We had some sickness in the family and our physician was in: he went to the telephone and he ordered a prescription from the druggist. He first of all ordered prednisone; he simply gave the dosage he wanted and he called it prednisone. He also ordered tetracycline in those terms and he gave the dosage he wanted and then the third prescription that he ordered was for me, and it was something he called Actifed which is a trade name; so there you are, he used both methods without any discussion

with me at all and what the druggist sent us, I do not know, because it simply came in the druggist's own package.

Now, I would say the druggist can fill the generic name prescription in whatever way he thinks will meet the needs of that prescription. If he has a choice on that basis then, of course, he has a price choice. If there are three choices of tetracycline, at three different prices, it is up to the druggist to pick it out. If I as a patient happen to know that, I can go and find out from the druggist which is the choice and I can ask for it; it seems to me it is as simple as that.

Mr. ORLIKOW: Mr. Chairman, I do not think I have used up the small time that I suggested. On page 11, Mr. Henry, you talk about patent drugs and you say that the price is higher than it needs to be and you say this is demonstrated by reference to the prices to institutions and governments. I wonder if you could give us a brief example of that? I know it is all in the Green Book, and so on, but some of us have not looked at the Green Book.

The CHAIRMAN: Could we bypass it; that one is well recorded in our own documents when we had the government purchasing people before us? We have much material on that which is right up-to-date; and the same for "B" part, "C"—

Mr. ORLIKOW: In the light of the time Mr. Chairman, I will forgo that.

Mr. HENRY: Well, I can very briefly refer you to this. The prices to institutions and governments are shown, for example, in the set of figures that I gave you later on. You will find most of this right there, as one example, on Page 16. Then, the same drug in other countries—well you have Dr. Howe's list—that is probably good enough for that, and thirdly, the price charged by newcomers—I think that in the Hoffmann-La Roche brief—this is just picking something out of the air I think Hoffmann-La Roche put down the prices that are being charged by some of their licensees for some of their products, and indicated those prices were lower than their own prices. That is an example for you. A price of unpatented drug—well I gave you one when ICI had decided to produce tetracycline at one-third the price of Pfizer, and the examples from the Green Book are already on pages 14 to 16.

Mr. ORLIKOW: Mr. Chairman, I draw it particularly to your attention because this brief on page 17 gives the figures on librium. It so happens that Dr. Howe last week suggested that I start taking this drug and I resent having to pay at the price of $4,400 a kilo when the product is costing the company only $450 a kilo to produce.

The CHAIRMAN: Is that before or after a Committee meeting?

Mr. ORLIKOW: After a Committee meeting and today is not any different, Mr. Chairman.

Mr. BRAND: Can I just interject and ask, perhaps the hon. member if it is librium that Dr. Howe had ordered and not the other drug put out on compulsory licence which apparently is cheaper?

Mr. ORLIKOW: Well, I can assure Dr. Brand that I am looking into that myself.

Mr. BRAND: Thank you very much.

Mr. ORLIKOW: I think that is all for now, Mr. Chairman.

The CHAIRMAN: Mr. Howe?

Mr. Howe (*Wellington-Huron*): Do you feel, Mr. Henry, that there are too many drug manufacturers in Canada?

Mr. HENRY: That is not my opinion necessarily, Mr. Howe. I think that those who are closer to the situation, mainly the manufacturers themselves, think that there are too many manufacturers; and this may well be true. I am not sure that one can say, on any objective test that this is so. I would say this though, I think there would be a tendency for there to be more drug manufacturers in the economy than might be necessary, because this is a relatively high profit industry, and this will attract people in to get some of those profits; you have this price structure, you see, so that anybody who is manufacturing a competing product tends to price up to what the big firms may be charging, or something of that sort. It may well be that what the industry says is correct. If this is so, then the proposals that I am making, by the exercise of economic forces, would probably reduce them somewhat, or instead of being eliminated from business, they may simply change the character of their operation. They may concentrate more on buying the drugs somewhere else and distributing them.

Mr. HOWE (*Wellington-Huron*): In other words, this is such a profitable business that there are too many people in it?

Mr. HENRY: No. If there are too many people in the business it is because it is profitable. They are attracted in.

Mr. HOWE (*Wellington-Huron*): In their words, it is a very profitable business?

Mr. HENRY: It is, yes, I certainly think it is.

Mr. HOWE (*Wellington-Huron*): I believe the reference to this committee is to find ways and means of reducing drugs. On page 9 you make the statement:

> If as a result of a package remedy downward pressure is brought to bear on price—

What is a package remedy?

Mr. HENRY: Well, I first of all started out by saying that I think you cannot expect to accomplish the result by doing one thing which might reduce cost. Now, I picked out one thing that is being discussed in the committee, I know, that is taking off the sales tax. I do not think that is sufficient; that is what I am getting at. You must do something on the other side as well; that is, the patent side, which is what I would call the supply side. You must, to my mind, bring pressure to bear on price. It is true, I suppose if you took the sales tax off, immediately everybody would reduce their price list by roughly 10 per cent. This is not necessarily so, but presumably there would be some social pressure on them to do it. This would largely be dissipated in the course of time. I mean, if it was immediately apparent that some companies dropped their prices by the amount of the sales tax, this is fine; you would see it for a while, but it would be dissipated, as new drug products came on the market we would forget all about that, we would be back where we are.

Similarly if you reduce the cost of promotion. It has been suggested that perhaps there could be something done here. Incidentlly I might say that Mr. Hume did not, in my view, accurately reflect the tenor of the combines act when he said that he did not think that this could be done in collusion because there is a provision in the combines act that says people may agree on limiting advertising. And I think this industry could do the same as anybody else, if they want to, which could be doubtful.

The point is that suppose you somehow get the advertising costs down; that does not mean the prices will come down unless you get some pressure on the price. Do you see what I mean? You can eliminate some costs. I gave you that little example from my annual report because it happened to be a handy one, where we were able to get the costs down on the tariff, and this did not produce any result on the price. We were told the company just was not going to produce a reduction in its price. Therefore when I speak of a package, I am speaking in the broad sense of saying, first of all get some pressure on the price, then anything you can do to relieve the pressure, the upward pressure of costs, is all to the good, that is going to help. And the packages that are being suggested by other people, involved the tariff of course, as well.

I make no particular suggestions about that because I think that you should consult the Department of Finance on that; but two commissions, and I think Dr. English, when he was here, all said that it would be useful to consider the reduction of sales tax, possibly the tariff; the dumping duty might be given some attention. So in other words, we have got the tax structure to consider. I simply refer to that because other people have referred ot it. If you can get the costs down to that extent that is all to the good. But my simple point is that it does not matter about reducing the costs if you do not put pressure on the price.

Mr. HOWE (*Wellington-Huron*): You are from the combines branch. You intimate that the patent pack system creates monopolies; have you examined any of those monopolies?

Mr. HENRY: Not patent monopolies.

Mr. HOWE (*Wellington-Huron*): You say:

—to any program of injecting price competition into the industry that the monopoly at present afforded by the patent system—

Mr. HENRY: Yes; well as I went over that sentence I explained that in fact, the patent does give a monopoly. I am talking in technical language; that is what it does. It gives you, as the patent owner, the right to exclude other people from manufacturing or buying and selling or using the product. That is what the effect of the patent is; it is a monopoly, and as I say there is no particular epithet in that word.

Mr. HOWE (*Wellington-Huron*): It is only a monopoly so long as there is not a compulsory licence given by the commissioners who allow somebody else to make this.

Mr. HENRY: That is right because, sir, you see, the monopoly aspect of the patent protection in the case of drugs produced by chemical process, is impaired to the extent that other people can get a compulsory licence to manufacture that product. Now, this is different, you see, from what happens with the patent

monopoly in connection, shall we say, with a radio set or something like that. You only get a compulsory licence there for an abuse of the patent.

Mr. HOWE (*Wellington-Huron*): We had some discussion the other day in connection with the length of time that it takes to get a compulsory licence, and that a certain drug manufacturer does have a monopoly position for probably two or three years.

Mr. HENRY: I think the time on the issue of compulsory licences was said to be, on the average, about 6 months; I believe that is information which comes from the patent office. But, then there are ranges on either side of that, and it may be that some have taken three years. You may recall, sir, that the Ilsley Commission, in making its recommendations about revising the Patent Act, would preserve the compulsory licencing provision for drugs, but would also make it imperative that some machinery be set up to produce speedy issuing of these licences.

Mr. HOWE (*Wellington-Huron*): As was stated to the Committee before, the Food and Drug people should have a little more people and more facilities to go ahead with these applications.

Mr. HENRY: I think they should be involved in the issue of the licence, so that the licence can be issued to proper, responsible people, and the Food and Drug Directorate should have a hand in that. This is part of the quality and safety control.

Mr. HOWE (*Wellington-Huron*): There was one other point made here today; in your statement you said that drugstores do less than one third of their business in pharmaceuticals. However, this does not indicate that the pharmaceuticals are much more profitable than a lot of the other lines that they carry.

Mr. HENRY: Yes, I think that is correct.

Mr. HOWE (*Wellington-Huron*): Pharmaceuticals create the best profit picture; on toilet paper, or paper napkins or whatever they are selling, they do not make the same profit as they do on pharmaceuticals?

Mr. HENRY: No, this is right.

Mr. HOWE (*Wellington-Huron*): So that I sometimes feel that drugstores carry these products and use them as loss leaders to bring people in to show that they have a dispensary.

Mr. HENRY: This is possible. I must admit that I go into a drugstore to buy Kodachrome every so often on this basis.

Mr. ENNS: I have only one basic question and I hope that will not take too long. We have had discussions and rather interesting views on the whole element of competition. In some ways we are saying this is not really cost reducing, in other ways it is. But in delineating the problem, on page 2, you make the statement that costs of the drugs are higher than they need be, and that this is primarily due to lack of effective price competition. This is repeated again on page 8, where you say that competition on ethical drugs, if it was soundly planned and applied with determination, there is no question in your mind, would bring down the cost of drugs. The discussion up until now has been mainly on the manufacturing level or the retail level. My question is simply,

does this not also apply to the wholesale level? Would competition at the wholesale level not have some bearing on keeping in line, perhaps even bringing down, the cost of drugs?

Mr. HENRY: There is no question about this. All levels of distribution bear their share of responsibility. I will ask Mr. Davidson to correct me on this because he is the economist in our midst. It is my impression that this is not where the problem really lies; that the large wholesaling companies are probably taking a reasonably small margin for their wholesaling activity, and generally speaking are reasonably competitive.

Mr. DAVIDSON: I think that that is true, one of the reasons being that the manufacturers quite often bypass the wholesalers in selling to hospitals and retail outlets, and therefore if the wholesaler is attempting to take too big a spread for the service he performs, the manufacturer can bypass him.

Mr. ENNS: Yes, we have had earlier evidence that a very limited business is really handled by the wholesaler in the pharmaceutical industry. But nonetheless there is a substantial lot going through that channel, the wholesalers. Now, it is also apparent, it seems to me, that there is a near monopolistic situation, in certain areas of Canada, at any rate. Take Manitoba, for example, where National Drug seems to be doing the greater amount of distribution, and where a recently formed wholesale house is not handling the lines, by virtue of the fact that the pharmaceutical manufacturing houses are not willing to deal through a new wholesaler. In other words, it is difficult for a new competitive force to emerge in this field.

Mr. HENRY: As the administrator of the Combines Act, I would want to know why they are not supplying a newcomer.

Mr. ENNS: It is a very interesting question. It seems that it might possibly, even if it is only a few cents, bring down the costs, and yet firms are not willing to deal with a new emerging wholesaler.

Mr. HENRY: Well, without prejudging the issue, of course, this would raise a question under the combines act, a question in part relating to the patent monopoly. And this is something which, if it were brought to my attention, I would feel I would have to give some consideration to.

The CHAIRMAN: Perhaps Mr. Enns could supply you with the complete information so that you could look into it sometime.

Mr. ENNS: I have certain information with me that might be of interest. I am not sure whether it should be on the record of the Committee.

The CHAIRMAN: Perhaps you could see Mr. Henry after this meeting and discuss it with him. Mr. Blakely, do you have any questions?

Mr. BLAKELY: No, I think all my questions have been dealt with.

The CHAIRMAN: Do you have any questions Mr. Laidlaw?

Mr. LAIDLAW: No, Mr. Chairman, I think that if there were any questions Mr. Henry and his colleagues have answered them.

The CHAIRMAN: Are there any other questions from the Committee? If not, we would like to thank Mr. Henry and his colleagues for coming before the Committee this morning, for presenting their brief and answering the questions.

The committee is adjourned until Thursday at 1.00 p.m. when we will again have Dr. Chapman before us. One week from today we will have the brief of the Province of Alberta which takes a great deal of study, I might add.

THURSDAY, February 9, 1967.

The CHAIRMAN: Gentlemen, I think we might proceed. While we are low in numbers the quality is obviously very good. This is, I think, the fourth time Dr. Chapman has been in front of us and we should be able to dispose of him and the Directorate today. As you know, next Tuesday we have a brief which we are counting on taking all day to present from the province of Alberta. That will conclude our hearings. Following this there will be many, many meetings of the committee. Are there any other questions anybody wanted to ask on the appendices or shall we proceed with Dr. Chapman's statement on drug control in Europe?

Mr. MACKASEY: I suggest we go directly to that.

The CHAIRMAN: All right, fine then. The credit for this statement, I think, belongs to you, Mr. Mackasey. Perhaps you could start.

Mr. MACKASEY: Well, in all fairness, Dr. Chapman, I do not intend to spend too much time on it because we only have an hour and I am not too sure what purpose it would serve. We have had a general observation from you on it. You did mention earlier that names had been left out for very valid reasons and these were sources of extreme confidence that you would not want to jeopardize. You also mentioned quite honestly in your remarks, if I recall, there was a certain degree of editing. I am not too sure how much editing has been done when I look at that and I look at the Maclean's review of January 1, 1966. This is taken from Maclean's review of 1966, Dr. Howe, there may be other copies here, I do not know. I think, Mr. Chairman, that my last observation was, in view of Mr. Henry's pointed observations at the last meeting—which unfortunately I could not attend—that someone is suggesting there is added emphasis on the source of supply from Europe. Would you agree with that? Are you familiar with what he said; Dr. Chapman?

Mr. CHAPMAN: Yes, I read his brief, Mr. Chairman. So I am familiar with what he has suggested: it would certainly require greater attention to imports from foreign countries if the proposals which he has made actually increased the flow of drug imports from abroad. I would anticipate that this would be the effect, I am not sure, of the extent of the effect.

Mr. MACKASEY: In the Maclean's and again I do not want to know who the inspector was, it is not important, it says that the FDD and I will quote directly here:

> The raw material from abroad is often processed and packaged by Canadian distributers lacking adequate knowhow on quality control.

I go on a little further.

The CHAIRMAN: Could you identify the portion, Dr. Chapman has the article in front of him.

Mr. MACKASEY: Well, it is in the middle column just above a picture of some unknown gentleman, Mr. Nesbitt, I think, who is a Member of Parliament. It begins:

> One example: An FDD inspector found a kitchen table manufacturer putting out a drug which lost its potency within two days compared with the six-month's shelf life of the same drug produced by a reputable company. He just did not know how to stabilize it, the Inspector explained. All too often these small operators simply don't know what they are doing.

Is there any particular reference in this report, in your observations, that alludes to this experience?

Mr. CHAPMAN: No sir, as far as I am aware it was not in the orginal draft either. Was this Mr. Mackasey's question. You see this article has been put together by Mr. Dreskin, the section in the centre column, as a matter of fact there is a statement which reads as follows:

> Three FDD researchers have just returned from Europe where they studied how these drugs are produced for export. It is a part of the FDD pilot study for their new checking system—officially termed Drug notification.

Well I must say there was much more than that. We wanted to know as much as we could about the production of drugs in Europe. But that is the section that really applies to this document which you have in front of you, Some Observations of Drug Control in Europe. I do not know where the next portion, belongs or what was its source.

Mr. MACKASEY: Well, they are direct quotations if you note the way they are written here. It is not just a paraphrase, it is a direct quotation from an FDD inspector.

Mr. CHAPMAN: I do not know the inspector, Mr. Mackasey.

Mr. MACKASEY: Then whoever wrote the article was very callous and Mr. Dreskin was probably worrying a lot of people who read this. I can just imagine a lot of people at ten o'clock at night putting down Maclean's and then having to go to the table or medicine cabinet to take whatever pill they are supposed to take and look at it rather apprehensively.

Mr. CHAPMAN: Well, I might say sir, with regard to the first paragraph at the top of the third column, where it states:

> "Italy and Poland were recently removed from the U.K.'s list of suppliers in antibiotics".

We still import pharmaceutical material from both countries. In Italy the laws call for manufacturers to assay their own products, but FDD inspectors often find the test equipment dust-covered and obviously unused.

Now that apparently was attributed to Dr. Louis Greenberg who is the man that is referred to as two or three globe-trotting men who inspect the premises of foreign firms in countries ranging from France to Japan.

Mr. HOWE (*Hamilton South*): Excuse me a moment. Can you identify him further?

Mr. CHAPMAN: Dr. Louis Greenberg?

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

Mr. CHAPMAN: Dr. Louis Greenberg is an officer of the Laboratory of hygiene, the Department of National Health and Welfare in charge of biologics control.

Mr. HOWE (*Hamilton South*): He is not associated with your department?

Mr. CHAPMAN: He is a member of our department but not of the Food and Drug Directorate.

Mr. MACKASEY: He is a member of the Department of National Health and Welfare.

Mr. CHAPMAN: That is correct.

Mr. MACKASEY: But he is not a member of the Food and Drug Directorate. Naturally he makes this reports known to you?

Mr. CHAPMAN: He makes his reports to me.

Mr. MACKASEY: He makes his reports to you. But you mentioned the other day, the last time you were here, that his function is not primarily the concept we have here of the Food and Drug Directorate. He is interested in the source of supply of drugs on certain schedules?

Mr. CHAPMAN: Yes, certainly, but this is included in our area of responsibility.

Mr. MACKASEY: Yes, but it does not take in all your area of responsibility of drugs coming in from Europe.

Mr. CHAPMAN: No, that is quite correct.

Mr. MACKASEY: I think we went over this area last time, you and I, in the committee.

Mr. CHAPMAN: Mr. Chairman, I had not finished my point. Mr. Greenberg said he had made no such statement but that this quotation was made previously and he says this is a quote from a quote.

Mr. MACKASEY: A quote from one of his original quotes?

Mr. CHAPMAN: Well from one of somebody's quotes, and a statement which he never made.

Mr. MACKASEY: Well, in other words this article is false? Probably if we had Mr. Dreskin here he would have to admit this, would he not? He could not very well say who the FDD inspector was and yet he had the audacity to put this in public print.

Mr. HOWE (*Hamilton South*): Mr. Chairman, for clarification can this article be identified. I do not even know what article we are speaking of.

The CHAIRMAN: The article appeared in Maclean's magazine the first of January, 1966, and is entitled *Background* and it talks about the drug industry.

Mr. MACKASEY: I will read all the title. It says "Background on the substandard drugs that are on the market and the government's plan to close down the shady manufacturers." It goes on to point out adequately the plans that Dr. Chapman had, which we all agree with, the exact terminology which replaces registration and drug notification. I think it does a good job and it is adequate. But then it goes on, Dr. Howe, to treat or to comment on the findings of three

inspectors of the Food and Drug Directorate on a trip through Europe examining some of the sources of supply. Of course, the direct quotation which upsets me refers to a kitchen table manufacturer putting out a drug and so on.

The CHAIRMAN: Can we clarify that again; I think Mr. Allmark actually answered it but he answered it with his head rather than with a word that would be spoken. I think the purpose was there was no reference in the report to anyone who manufactured drugs on a kitchen table. Is that correct, Mr. Allmark?

Mr. HOWE (*Hamilton South*): The article makes a lot of that thing, is that the idea?

Mr. MACKASEY: Well it says a lot.

Mr. HOWE (*Hamilton South*): I want to get a concept.

The CHAIRMAN: The point is there are not two or three Food and Drug Directorate inspectors in Europe, there is only Dr. Greenburg and he never made the statement attributed to him.

Mr. CHAPMAN: Dr. Greenberg and his assistant—and that might be why there were two or three referred to. Actually there are two inspectors as far as I am aware. Dr. Greenberg says he does not make the statement that was attributed to him. It is not attributed directly.

Mr. MACKASEY: I am to blame for the confusion. Perhaps I should go back to the regular way of proceeding. Did three members of the Food and Drug Directorate tour Europe at any time in the last 18 months or two years or so?

Mr. CHAPMAN: Yes sir, they did.

Mr. MACKASEY: Apart from Dr. Greenberg?

Mr. CHAPMAN: Yes, they did.

Mr. MACKASEY: They are the three I am referring to, not Dr. Greenberg. This article is referring to these three people and not Dr. Greenberg? It says, let me read this to you:

> Three FDD researchers have just returned from Europe where they studied how these drugs are produced for export. It is a part of the FDD pilot study for the new checking system officially termed drug notification.

Mr. CHAPMAN: Yes sir. That paragraph refers to this report but it is the only portion of this article, as far as I can see, that does refer to the visit of those three people.

Mr. MACKASEY: Fine, I am just trying to clarify it now. Just a little further in the article, it then goes on to quote this so-called example of their findings, by an FDD inspector. If you read the article you automatically presume that it is one of the three researchers.

Mr. HOWE (*Hamilton South*): He does not name the inspectors.

Mr. MACKASEY: I would not want them named, it would embarrass them.

Mr. HOWE (*Hamilton South*): No, but does the article name them or not?

Mr. MACKASEY: No. But it quotes directly from them.

The CHAIRMAN: I would not be afraid to name them, they have already been named in previous testimony. Two of them, I think, are in the room.

Mr. MACKASEY: I have the highest respect for them, but when such an incident appears in public and does not appear in the observations: I am asking Dr. Chapman to what degree it has been edited. We have been hearing a lot of things about ministers editing reports lately and I want to know to what degree this has been edited.

Mr. CHAPMAN: Mr. Mackasey the reference that Mr. Dreskin makes to an FDD inspector from the kitchen table manufacturer putting out a drug and so on was never in this report and it was not reported from Europe by three oficers of the directorate that visited Europe. These were Mr. M. G. Allmark, Assistant Director General of Drugs: Dr. L. Levi, Chief, Pharmaceutical Chemistry Division and Mr. R. Ferrier of our Bureau of Operations.

Mr. MACKASEY: I accept that Mr. Chapman. It is quite possible the inspector was someone outside the researchers, someone else. Do we have FDD inspectors as opposed to FDD researchers because the three people are referred to as researchers. A little further on, it refers to an inspector.

The CHAIRMAN: This is getting a little repetitious.

Mr. MACKASEY: Oh no, it is not. It is an important point to me.

Mr. HOWE (*Hamilton South*): Let me clarify one point. Dr. Chapman gave three names, are you naming names, or are the names in this article? I am still confused as to the contents and validity of this article. You gave these names.

Mr. CHAPMAN: Mr. Howe, there are no names in the article.

Mr. HOWE (*Hamilton South*): That is what I wanted to know.

Mr. MACKASEY: Mr. Chapman, you say three researchers?

Mr. CHAPMAN: Yes.

Mr. MACKASEY: The three people who went over there under the category of researchers, who would be considered here as the three researchers who went over on a particular trip.

Mr. CHAPMAN: Well, I believe those three men I have named are the three men that Mr. Dreskin refers to as three FDD researchers—

Mr. MACKASEY: And, when you tell me that they did not make this report I accept it without any reservation, I agree with you. You tell me this was never in their original report and I accept it. I have no argument. I want to come down to another item. Are there occasions then when you do send inspectors over there on a particular mission to visit a particular plant?

Mr. CHAPMAN: In the past to carry out actual inspection, the only one I can recall would be Dr. Greenberg.

Mr. MACKASEY: He does not go for the FDD with regard to the subject matter of this committee.

Mr. CHAPMAN: But, frequently we ask Dr. Greenberg to make visits to other plants that are supplying drugs other than biologics.

Mr. MACKASEY: I think you mentioned he had done this on 75 instances?

Mr. CHAPMAN: No, sir, the 75 instances are those for which licences have been issued to supply the biologics to the Canadian market, schedule C and D drugs. In addition to this we have asked Dr. Greenberg to visit labs that are shipping drugs to Canada, not biologics, other drugs.

Mr. MACKASEY: So, he may have visited more than 75 plants.

Mr. CHAPMAN: Oh, definitely.

Mr. MACKASEY: Could he be the FDD inspector that found this thing?

Mr. CHAPMAN: That found the kitchen table manufacturer?

Mr. MACKASEY: Yes.

Mr. CHAPMAN: Not to my knowledge.

Mr. MACKASEY: Is there anybody else from health and welfare or the FDD other than the three researchers and Dr. Greenberg who may have visited Europe in any official capacity.

Mr. CHAPMAN: Let me ask my colleagues if they are aware of any such official during the past five years.

The CHAIRMAN: Dr. Greenberg and his assistant, so there are two people.

Mr. MACKASEY: Now we have five people to whom this could be attributed and certainly it is not one of the three researchers as Dr. Chapman said. So it is either Dr. Greenberg and his assistant—

Mr. CHAPMAN: Not necessarily, Mr. Mackasey.

Mr. MACKASEY: Then it is a figment of the writer's imagination. It has to be somebody.

Mr. CHAPMAN: I have the feeling that he may have contacted an FDD inspector in Canada and even the reference here is to Canadian production. Well, it is Canadian production so it could have been any of our 162 inspectors.

Mr. MACKASEY: So this kitchen table manufacturer could very well be some firm in Canada, not necessarily in Europe.

Mr. CHAPMAN: You will notice the sentence above also says the FDD, the raw material from abroad is often processed and packaged by Canadian distributors lacking adequate know-how and quality control. Then one example follows. I would anticipate that this is what has happened and Mr. Dreskin has been talking to one of the 162 inspectors we have on our staff and he may have made some such statement.

Mr. MACKASEY: So it is ambiguous. In other words this kitchen table operator may actually have existed in Canada and you people found him.

Mr. CHAPMAN: Yes, that is possible.

Mr. MACKASEY: You sought him out and so on. It goes on to say he did not know how to stabilize the drug.

Mr. CHAPMAN: Yes.

Mr. MACKASEY: Now you brought to the attention of the committee the reference to Italy and Poland, which was recently moved from the U.K. list as supplier of antibiotics. It goes on to say "we still import material from both these countries". Do we still import pharmaceuticals or antibiotics from Italy or Poland?

Mr. M. G. ALLMARK (*Assistant Director-General, Drugs, Food and Drug Directorate*): There are some licenced companies in Italy who market antibiotics in Canada.

Mr. MACKASEY: We do or we could, in other words, there is nothing to prevent us.

Mr. ALLMARK: There is nothing to prevent us.

Mr. MACKASEY: Mr. Allmark, just for our information, are they still banned in the U.K. or do you know?

Mr. ALLMARK: I could not say that they are. I do not know.

Mr. MACKASEY: Do you not have this exchange of information between food and drug directorates around the world?

Mr. ALLMARK: We have some but there is a lot of information we do not have.

Mr. MACKASEY: Is there any reason you should not have any from the U.K.?

Mr. ALLMARK: We could obtain the information if we asked for it but I do not think they would give it to us voluntarily.

Mr. MACKASEY: Well, have you ever asked for this? This article probably came to your attention long before this. You have read this article, were you concerned about it?

Mr. ALLMARK: I would not say I was too concerned about it because we knew that some of the facts in it were not true.

Mr. MACKASEY: You were not concerned to the point that you verified whether or not the U.K. list of suppliers prohibited Italy and Poland from supplying antibiotics to the U.K.?

Mr. ALLMARK: I do not quite know how to answer that. Let me put it another way. If a Polish firm was licensed to sell antibiotics in Canada we would have inspected that firm and found it to be satisfactory and the antibiotics would come into Canada. Now I do not believe there is a firm in Poland that is licensed to sell antibiotics in Canada. There are firms in Italy that are licensed, as you know.

Mr. MACKASEY: Well let us go back to Italy for a moment. Obviously, if this article is accurate—and I have no way of knowing—you say there are so many inaccuracies, that it could be inaccurate, it does state that the U.K. prohibits importation into the United Kingdom of antibiotics from Italy. Now, when you read this you did not find out from the U.K. whether it was a fact or not?

Mr. ALLMARK: No, we did not.

Mr. MACKASEY: Do you not think you should have or was it not important?

Mr. ALLMARK: Well, I do not think it was too important because, as I previously said, if a manufacturer in Italy wanted to sell antibiotics in Canada they would have to pay through our licence procedure. They could not sell on the Canadian market until they obtained a Canadian licence. This would mean an inspection of the premises.

Mr. MACKASEY: So, the inspection would be done by whom?

Mr. ALLMARK: Well, as Dr. Chapman has just said, Dr. Greenberg would inspect the premises of the firm in Italy.

Mr. MACKASEY: Dr. Greenberg would fulfil this function for you regardless of what type of drug this firm intended to sell to Canada, whether it was non schedule or not?

Mr. ALLMARK: No.

Mr. CHAPMAN: It is only those drugs on schedules C and D that require a licence.

Mr. MACKASEY: Are antibiotics on this?

Mr. ALLMARK: Parenteral antibiotics are on this. That includes injectable antibiotics.

Mr. MACKASEY: What about oral antibiotics?

Mr. ALLMARK: No, oral antibiotics are not on the list.

Mr. MACKASEY: Well you can sell oral antibiotics to Canada from Italy without having your premises inspected by Dr. Greenberg?

Mr. ALLMARK: That is true.

Mr. MACKASEY: But you cannot do that to England.

Mr. CHAPMAN: Mr. Chairman, could I just point out that this was a situation that developed. We were aware of the fact there were some shipments that had come in from Italy and the officials of the Ministry of Health in England were not satisfied, for one reason or another, with their quality. I do not think this is a permanent prohibition, not to my knowledge.

Mr. MACKASEY: I am a little confused now, Dr. Chapman. You say you were aware of England's concern?

Mr. CHAPMAN: We were through reports in the press.

Mr. MACKASEY: Only through reports in the press? Is this our only medium of communication?

Mr. CHAPMAN: No sir. If we feel that this is sufficiently important we would cable or even telephone. We have done this or if it is not that important we write.

Mr. MACKASEY: In other words, you did not feel this was sufficiently important?

Mr. CHAPMAN: No sir, we did not.

Mr. HOWE (*Hamilton South*): Mr. Mackasey himself pointed out that our time is short today and I wanted to ask a few questions but nothing too lengthy.

Dr. Chapman, you feel that the imported raw key chemicals from Europe are as pure and efficacious as any that are manufactured in Canada or the United States, for that matter?

Mr. CHAPMAN: You are referring, Dr. Howe, to bulk drugs?

Mr. HOWE (*Hamilton South*): I am referring to bulk drugs in this particular question, yes.

Mr. CHAPMAN: Could I ask Dr. Levi to report on the results of an investigation which has been carried out in his Division on bulk drugs which were obtained from Canadian manufacturers. Many of these would be imported bulk drugs.

Dr. L. LEVI (*Chief, Pharmaceutical Chemistry Division, Food and Drug Directorate*): Yes, we have paid particular attention to the examination of bulk drugs and one of the reasons we concentrated on such an analysis was the fact that we had been in Europe and we wanted to find out the degree of purity and quality of the bulk drugs that are being imported into Canada. We have examined well over 100 different samples representing products of different types and from different manufacturers across Canada.

I am quite happy to say that these products did meet the standards of the official compendia. We did find impurities in most of these products in trace amounts. Now, this brings up the important problem of how pure should a bulk drug be. I think our techniques and technical know-how of analysis have progressed to a point where we can find trace amounts of impurities if we look long enough and if we apply the sophisticated techniques we have available. In order to make an absolutely pure drug might involve a great deal of work on the part of the manufacturer. One has to use one's judgment and really the key problem is what is the ultimate health hazard of the impurities that you find.

Mr. HOWE (*Hamilton South*): Are these trace impurities any more in the European imports than in the home manufactured chemicals?

Mr. LEVI: Well, for one thing we import by far the largest portion of our bulk drugs from abroad and relatively few drugs are actually manufactured in Canada. There are only a couple of primary bulk drug manufacturers in this country. I would, perhaps, go as far as to say we really do not know 100 per cent what the answer to this question should be. We would have to do much more work than we have done. But work we have done up to now would indicate that the bulk drugs we have examined both native as well as drugs imported from abroad do meet the official compendia. But, if we say official compendia, we should realize and this is what the industry should realize, that these compendia specify what should be considered as minimum standards. What we try to accomplish is to create the feeling or awareness that this is not always enough. One should do somewhat more than that actually required by the official compendia because there can be impurities present which behave, in the ultimate analysis, very much like the analysis of the bulk drug itself. Unless you apply some discriminatory techniques, some refined techniques, to detect these impurities, you may have a drug that is not as effective as it is claimed to be. A great deal of knowledge is supposed to be applied. But, to answer your question correctly, we have not found any bulk drug that really would violate existing specifications.

Mr. HOWE (*Hamilton South*): But, in many instances your source of chemical for both the brand name companies and the—I am going to have to use that word again—generic companies are the same? In other words they do not necessarily manufacture their own bulk chemicals here in Canada or in the United States but in both instances they are imported from Europe and used to make the same dosage forms but at different prices, shall we say?

Mr. LEVI: Yes, this is quite true, as Mr. Allmark says, many companies operating in Canada receive their supply from the parent company in the United States.

Mr. HOWE (*Hamilton South*): Yes, I am sorry, I should have clarified my question by saying from Europe to either the parent company in the United States or to a so-called generic firm here in Canada that is receiving raw key chemicals from the same source and manufacturing the same ultimate pharmaceutical in different priced forms from the generic firms and the brand name firms. Maybe I have not worded my question very well but possibly you see the intent of the question is to state that the source of the actual chemical is the same for different priced drugs?

Mr. CHAPMAN: May I speak to that? This may not necessarily be true. They may very well both be imported from Europe but they may be from different sources so you cannot say they are from the same source. They are both imported bulk drugs but that is as far as you can.

Mr. HOWE (*Hamilton South*): But in many instances they could be actually from the same source?

Mr. CHAPMAN: They could be. We do not have that specific information.

Mr. MACKASEY: For a point of clarification, Dr. Howe brought up the question of copiers who obtain permission through compulsory licence to produce from the same raw material. Dr. Chapman, on page 7 it says—and this is only for clarification of the answer you have just given Dr. Howe—"need restrict the control of bulk drugs". You emphasize that they come in from different countries, even though they may be raw materials, theoretically they are the same. They come in from different countries and they have been produced by different methods.

Mr. CHAPMAN: On page 7 of the report?

Mr. MACKASEY: Yes sir.

Mr. CHAPMAN: At what paragraph?

Mr. MACKASEY: The third paragraph toward the bottom, the last four lines. Maybe you could read it out for the committee. I have violated Dr. Howe's time and I appreciate his patience.

Mr. CHAPMAN: Starting with "continued vigilance"?

Mr. MACKASEY: Well, I think "massive quantities" is good enough for me. I am sorry, it is on page 6.

Mr. CHAPMAN: Yes, it reads:

> Massive quantities of bulk drugs made in different countries and often produced by different methods of synthesis are coming into our

country and it is essential that they be thoroughly tested for identity and purity.

Mr. MACKASEY: Yes.

Mr. CHAPMAN: This is correct and this is the reason we have this project under way in order to determine the quality of those bulk drugs that are coming into Canada.

Mr. MACKASEY: But they are not necessarily done by the same—The point I am trying to get at is these raw materials are from different countries and since they are produced by different methods there could be a difference?

Mr. CHAPMAN: Yes sir.

Mr. MACKASEY: In other words, coming back to the point Dr. Hilliard made the other day, there is a difference in them.

Mr. CHAPMAN: I beg your pardon?

Mr. MACKASEY: Your paragraph in here strengthens Dr. Hilliard's contention, made before the committee last week, that there is a difference. This is another point I will go into when it is my turn to question again.

Mr. ALLMARK: May I try to clarify that? What you are trying to put across here, Mr. Mackasey, is the fact that the same drug may come from various sources and it may be made by a different process. We are just a little bit afraid that the specifications which have been established for that drug would not identify the impurities that might possibly be in it.

Mr. MACKASEY: Is this not the basis of the Hilliard report?

Mr. ALLMARK: Yes.

Mr. HOWE (*Hamilton South*): By the same token, these raw chemicals can be bought by any company in this country?

Mr. ALLMARK: Yes.

Mr. HOWE (*Hamilton South*): I mean you are not intimating by this that these less purified drugs are possibly purchased by the generic firms or the copying type firms. These can be purchased by anybody. As you say, many of these chemicals are actually manufactured in Europe or in the United States for importation into Canada by any of the companies. So there is no inter-relation or any comparison of these trace impurities being bought more highly by any one firm more than another.

Mr. ALLMARK: We are not trying to infer any specific company or companies are involved here at all. We are just pointing out the problem.

Mr. HOWE (*Hamilton South*): May I ask a question along the same line, then. What about your finished dosage form tablets or capsules that are imported from Europe? I have the same questions about them, as to their efficacy and their purity in the finished form compared to those that are manufactured here.

Mr. CHAPMAN: These, of course, would show up in the results we have already tabled with regard to the quality of the drugs which are sold under brand name and those which are sold under generic name, and, some of which were imported.

Mr. HOWE (*Hamilton South*): This is for emphasis, Dr. Chapman, I was aware of this but it was a follow-up question to my original question about chemicals and then in the dosage form.

I would ask you one other question; I am not 100 per cent acquainted with the system myself, but what do you think of the British system of drug approval for sale and the determination of price, or do you have any ideas on that yourself?

Mr. CHAPMAN: That is a very broad question and of course there is no agency that corresponds to the Food and Drug Directorate in the United Kingdom. As far as new drugs are concerned they do have a voluntary procedure and I think Mr. Allmark is in the best position to describe briefly the procedure that is employed, if you are interested.

Mr. ALLMARK: Very briefly, Mr. Howe, the Dunlop committee which reviews all new drugs in England is, I think, very similar in its type of operation to our own. In other words, all new drugs are submitted to the Dunlop committee and they go through the same type of examination as do all new drugs in this country. Over there it is on a purely voluntary basis, whereas here, we have regulations to cover our particlar operation.

Mr. HOWE (*Hamilton South*): Does price play some role in this too?

Mr. ALLMARK: No, as far as the Dunlop committee is concerned, they are not concerned with price at all.

Mr. HOWE (*Hamilton South*): Is there another body then?

Mr. ALLMARK: There is another body over there, I think, concerned with price.

Mr. HOWE (*Hamilton South*): Do you know anything about it?

Mr. ALLMARK: I am afraid I know nothing about it.

Mr. MACLEAN (*Queens*): I have just a few questions to ask along an entirely different line of approach. As the committee is dealing with the costs and prices of drugs I suppose it is fair to consider all the costs involved in the availability of drugs to Canadians. Against the background of some recent evidence we have heard, could you make any comment as to how much of the effort of the Food and Drug Directorate is directed towards the inspection and analysis and so forth of imported drugs and, on the other hand, drugs that are partially or completely manufactured in Canada. Is there any ratio between the difficulty of policing, if you want to use that term, imported drugs and drugs of domestic manufacture? Putting it in other terms, if all our drugs were imported, would your job be easier or more difficult?

Mr. CHAPMAN: If I may answer the first part of the question first, the only comparison that I would be able to make is from the total number of drugs in about 20 categories that we examined. I note that we examined 885 domestic dosage forms and 88 imported dosage forms. These are in final dosage form and therefore they do not include the bulk drugs to which Dr. Levi referred. So it would be in the ratio of about, well, ten to one, on the finished dosage form. Now, if the imports were increased certainly this would increase the load on the Food and Drug Directorate.

Mr. MacLEAN (*Queens*): You also, of course, have to put forth a lot of effort with regard to drugs that are imported in the bulk form, whether they are manufactured in Canada or imported for further processing in Canada.

Mr. CHAPMAN: Yes, if these are imported as drugs then they come under our jurisdiction and we do devote a certain amount of time to them as Dr. Levi has indicated.

Mr. MacLEAN (*Queens*): A slight diversion here, is it possible for a Canadian drug manufacturer to import chemicals that were not processed with the intention that they may be made into drugs; even if their purity and so forth is not up to drug standards in the country they come from and could they use this type of material for processing into drugs in Canada without you knowing about it?

Mr. CHAPMAN: This is a problem that has given us some concern. If these come in as a chemical and are not directed to a drug firm, under these circumstances, I think we would have difficulty in assuming that they were drugs. We would have difficulty treating them as drugs and therefore bringing them under our jurisdiction. However, if a chemical is imported into this country and imported by a firm that manufactures drugs then I think it would be reasonable to assume that it is going to be used for the manufacture of drugs and would come within our jurisdiction. Under these circumstances, of course, we could take any action that is necessary.

Mr. MacLEAN (*Queens*): My question is not quite that technical. I assumed all of that but have you ever had a case come up where some legitimate chemical company imports into the country perfectly legally some chemical compound for general use that they never considered to be a drug; and then some drug company comes to them and says: "We will have a half a ton of that sort of thing," without saying why they want it. Then, the drug company would use it in the processing of drugs? Is this possible or if someone attempted it, where would it be caught, only in the finished product? Is that right?

Mr. CHAPMAN: This would be the likely place where it would be caught. Of course, it is the responsibility of the firm that did the purchasing to ensure that the raw materials are satisfactory. So the firm itself would be in violation if they did not check their raw materials and find it to be of satisfactory quality. If we, as under Dr. Levi's survey, had gone into the plant and picked up that bulk drug and found that it was of poor quality and should not be used in drugs, then, of course, we could take action against the bulk chemical.

Mr. MacLEAN (*Queens*): But, you have had no cases such as this?

Mr. CHAPMAN: I cannot recall any. Dr. Levi, do you recall any instances where this has happened?

Mr. LEVI: If I understand this question correctly, what you wish to find out is whether a manufacturer can purchase chemicals, let us say sulphuric acid or acetyl chloride and proceed to make a bulk drug or even some commercial chemical—

Mr. MacLEAN (*Queens*): Perhaps even something simpler still, welding oxygen and panning it off as medical oxygen for example.

Mr. LEVI: Well, all bulk drug manufacture is based on the reaction of chemicals and therefore this is the usual approach. What is important is that the final product, the synthetic material is purified so that all the excess reagents and so forth, by-products and intermediates are removed. But as far as I can see there is nothing to stop the manufacturer from purchasing crude chemicals before the synthesis of bulk drugs. What he has to do, if he is a conscientious manufacturer, is to ensure that the final product has been purified through crystallization or distillation or what-not so it meets the set of specifications.

Mr. MACLEAN (*Queens*): Would you not agree that your task is much simpler when you can do an analysis on the bulk chemical from which the drug is manufactured, where the impurities would be more obvious, than if that impure chemical were used and processed through and you had the dosage form to work on?

Mr. LEVI: This is absolutely correct.

Mr. MACLEAN (*Queens*): Now, my other question is with respect to your forecast of the establishment of the Food and Drug Directorate, 1964 to 1975. As a matter of information could you give—if this has not already been done—an estimate of the cost of the Directorate to the taxpayers at the moment, and what it will be at present costs in 1975? Perhaps, if you are in a position to do so, you might even go on to compare this with the amount of revenue from the sales tax on drugs. I do not know whether you are in a position to do that. The committee has the information, perhaps.

The CHAIRMAN: When it was 11 per cent, roughly $20 million and it would be increased appropriately with an increase in tax.

Mr. CHAPMAN: The budget, for the present year, is $6.7 million, that is for 1966-67. Now, the increase would be in proportion to the increase in staff plus the increasing cost of salaries and services. I am sorry, but that is about as close an estimate as I could give you. The $6.7 million would correspond to our present staff of 820.

Mr. HOWE (*Hamilton South*): Is that the staff payment or is that your entire expense?

Mr. CHAPMAN: I beg your pardon?

Mr. HOWE (*Hamilton South*): Is that the staff payment or is it your entire budget?

Mr. CHAPMAN: No, sir. It is our entire budget including salaries, $6.7 million.

The CHAIRMAN: And your projected staff for 1975?

Mr. CHAPMAN: Yes, which has been extended to 1977 is 1,733. It is just a little over twice our present staff.

The CHAIRMAN: So you would anticipate that your budget would have to increase by about twice as much?

Mr. CHAPMAN: Well, I would anticipate that by 1977 it would be more than twice by quite a bit.

Mr. MacLEAN (*Queens*): Even at present costs it would be a little more than twice?

Mr. CHAPMAN: Yes, that is correct.

Mr. HOWE (*Hamilton South*): Did you or did you not project that from 800 and some odd to 1200 and some odd, or did I not hear you correctly?

Mr. CHAPMAN: Seventeen hundred.

Mr. HOWE (*Hamilton South*): Oh, I am sorry, I did not hear you correctly.

Mr. MacLEAN (*Queens*): In other words, even with this projected increase in staff, at present day costs anyway, the sales tax on drugs at $20 million is more than covering the cost of the entire budget of the Food and Drug Directorate?

Mr. CHAPMAN: Yes sir.

Mr. MacLEAN (*Queens*): I do not want to imply that I am critical of this expenditure. I just wanted a comparison of it in terms of the costs of drugs to the consumer. I think that completes my questioning.

Mr. FORRESTALL: I have a supplementary question about the relationship between your costs and your projected figures for 1975. If my memory serves me correctly the natural escalation in the return from the sales tax would seem to be a fairly compatible figure with what Mr. MacLean was after. In the foreseeable future your Directorate is a self-liquidating process of this one tax. Would that be a reasonable conclusion to draw that for the foreseeable future the sales tax will take care of not only your existing needs but your projected establishment?

Mr. CHAPMAN: Mr. Forrestall, since I am only familiar with one-half of that equation it is very difficult for me to draw any valid conclusions. I am not familiar with the manner in which the sales tax is increasing.

Mr. FORRESTALL: Well I am not saying an increased sales tax, I did not mean to imply that. I mean just the natural increase in the sale of drugs as our population goes up and more drugs are being bought, we are going to be collecting more money. That was all I meant, just the natural growth of the industry in terms of even a fixed or constant sales tax.

Mr. CHAPMAN: Your statement sounds reasonable.

Mr. FORRESTALL: I am curious. We are looking into this. If you cut off the sales tax and take 10 or 11 per cent of the cost of drugs you are not doing the Canadian taxpayers any good because they will have to dig up the $6 million or $18 million of your projected budget. I suspect you are a little conservative and it is very possible it will almost triple. You say almost double but I say triple and that is almost $18 million, literally $20.2 or $20.3 million. I am curious about the two sides of it. There is not much point taking 5 cents out his left pocket and putting it in his right pocket. That does not give him anything. If the Food and Drug Directorate, under your projected plans, can be taken care of with this one item in your own mind then I am content to leave it there because it is self-liquidating.

The CHAIRMAN: I would just point out the difference being that the federal sales tax on drugs would be paid only by the people who use drugs, in other

words sick people. If the Food and Drug Directorate got its money from general taxation then it is liable to be shared by all the taxpayers in Canada. This was pointed out the last day we met in another aspect.

Mr. FORRESTALL: Yes, I have taken that into account.

Mr. MACLEAN (*Queens*): I would like to point out that everyone gets sick sooner or later and needs drugs.

The CHAIRMAN: Not everybody. Were you finished Mr. Forrestall?

Mr. FORRESTALL: Yes, I was.

The CHAIRMAN: I wonder if the Chairman could ask a question here, coming back to Dr. Levi. I am going to ask, going back to the examination of bulk chemicals that he has been testing from various areas, if any of the impurities he found were a significant health hazard to Canadians. Take for example, cobalt, about which we are now hearing medical evidence suggesting that this is, perhaps, injurious to health.

Mr. LEVI: This program has only been under way for about a year and you must realize that the isolation of trace amounts from these materials is a job in itself. In order to do toxicological testing you need quite a fair sample. We have, so far, only convinced ourselves that we do find impurities in trace contamination. But I could not give you any precise accounting of the toxicological effect. This is really something that is very, very important. I think the industry should be more conscious of this fact.

Mr. CHAPMAN: Mr. Chairman, I might just add that I stated previously we had no evidence that these impurities represent a hazard to health. However, as Dr. Levi has just pointed out, we intend to identify the unknown impurities and if warranted, we will determine their toxicity.

The CHAIRMAN: Thank you. Mr. Laidlaw.

Mr. LAIDLAW: Mr. Chairman, I wonder if I could ask Dr. Chapman to elaborate on a few comments he made the last time he was here with respect to the attitude of the Food and Drug Directorate with the Commissioner of Patents in connection with compulsory licencing. I believe at the moment, Dr. Chapman, your department is working very closely with the Commissioner of Patents on compulsory licencing. I wonder if you could elaborate on just what is going on between you and the Commissioner of Patents in this respect.

Mr. CHAPMAN: Yes, Mr. Chairman, I would be very pleased to do so. There has been an exchange of correspondence between myself and Mr. J. W. T. Michel, Commissioner of Patents. It has been agreed that close collaboration between the Office of the Commissioner of Patents and the Food and Drug Directorate should be maintained on matters relating to the issuance of compulsory licences for the manufacture of drugs. This objective could be achieved if the Commissioner of Patents would supply my office with the names of individuals who have applied for a compulsory licence for the production of a chemical to be used as a drug at the time that a notice of such application is published in the Canada *Gazette*. This notification would permit the directorate to carry out the necessary investigation to ensure the competence of an applicant to manufacture a particular drug and the adequacy of manufacturing facilities and controls as required by the Food and Drug Directorate.

Mr. LAIDLAW: As I understand it now, Dr. Chapman, this is an informal arrangement between the two offices?

Mr. CHAPMAN: Yes sir, this is correct.

Mr. LAIDLAW: In your view, if the committee were to make the recommendation that compulsory licences were to be continued, is it desirable that this informal arrangement should be made statutory; in other words written into Section 41(3) of the Patent Act?

Mr. CHAPMAN: In my opinion, yes, this would be desirable.

Mr. LAIDLAW: Therefore, one would not have to depend on the whim of any particular Commissioner of Patents at any particular time?

Mr. CHAPMAN: That is correct.

Mr. LAIDLAW: I have one other question along the same lines, Dr. Chapman. The Ilsley Commission in its report was quite concerned about delays following applications for compulsory licences. These delays were occasioned by patentees who, naturally, were reluctant to see compulsory applications granted and the time varies, I understand from the Commissioner of Patents, from about six months to two and a half years. The Ilsley Commission went on to say if delays of this nature were to be continued perhaps licences should be issued as a right, which means, automatically. The question I would like to ask you is if the Food and Drug Directorate as well as the Commissioner of Patents, by statutory enactment, had to clear every application for compulsory licence, do you think there would be any delay engendered by the activities of your department?

Mr. CHAPMAN: In most instances I would not anticipate this would result in any delay. It would be my understanding that this would be going on concurrently with whatever investigations the Commissioner of Patents is carrying out. The present arrangement is that the Commissioner of Patents will notify us at the time that a notice of such application is published in the Canada *Gazette*. Then, we would immediately carry out whatever inspections, analytical work or other investigations that are required.

Mr. LAIDLAW: You could see no reasons for any undue delay at all?

Mr. CHAPMAN: No sir, I would not think so.

Mr. LAIDLAW: Thank you, Dr. Chapman. That is all Mr. Chairman.

Mr. HOWE (*Wellington-Huron*): I was rather interested in page 5 of this report in connection with 6,873 radio and television commercials being scrutinized. Are these submitted to you as tapes or do you have people watching the television and listening to radio incessantly to find out whether the advertisements are correct, misleading or what?

Mr. CHAPMAN: Well, in the case of radio and television commercials, these are under the direct control of the Board of Broadcast Governors. The Board of Broadcast Governors use the Food and Drug as advisors, and unless a radio or television commercial has been cleared by the Food and Drug Directorate the Board of Broadcast Governors, under the Broadcasting Act, will not allow it to be used on any of the radio or television stations. Now I might, with those preliminary remarks, ask Mr. Hollett just exactly how these radio and television commercials are scrutinized.

Mr. A. HOLLETT (*Director, Bureau of Operations, Food and Drug Directorate*): Mr. Chairman, the radio and television commercials which a manufacturer proposes to use are submitted for review and these are sent to us. Any recommendation will come from the Food and Drug Directorate concerning changes that will need to be made in order to comply with the Food and Drugs Act and regulations, or, perhaps there will be a rejection entirely. We act, in this capacity, as advisors, of course, to the BBG. If the commercial or continuity, as we call it, is rejected, then permission is not granted for the advertising agency or manufacturer to use the commercial. There has to be pre-clearance. This is in a written form, although, on occasion we get the tapes in order to hear the sound and you will appreciate that this gives a better appreciation of the message that is being put across if the sound is heard rather than the mere reading of the words. We do not review them on television. That is, we do not have a television set set-up in the offices of our inspectors to review the continuity. But I think this is desirable and we will have to get to that in the future.

Mr. MACKASEY: One of those colour TVs we heard about in question period.

Mr. HOWE (*Wellington-Huron*): I was just thinking about coloured radio. Do you not think some of the pictures are misleading in connection with the advertising that comes over TV, the depth of pain and suffering that some people have?

Mr. HOLLETT: We realize that this can have an impact upon the viewer and that perhaps a proper assessment or a correct assessment cannot be made unless we view the commercial on TV.

Mr. HOWE (*Wellington-Huron*): In other words, all television advertising and radio advertising has to be cleared by you before it can be put on the radio or TV?

Mr. HOLLETT: That is right.

Mr. HOWE (*Wellington-Huron*): What percentage are turned down?

Mr. HOLLETT: The percentage that are rejected outright? It is a very small percentage. Dr. Chapman may have the figures there. I would say, perhaps,—

Mr. CHAPMAN: Of radio and television commercials, 6,873 were scrutinized. Of these 4,823 were acceptable; 2,050 were not acceptable.

Mr. HOWE (*Wellington-Huron*): In other words, about one-third were not acceptable.

Mr. CHAPMAN: This does not mean that they did not appear after some modification. I think, Mr. Hollett said those which were rejected outright would be a small proportion. But there were 2,050 out of that total that required some modification.

Mr. HOWE (*Wellington-Huron*): And, did they have to appear before you? Did you have to clear the modifications as well as a final submission?

Mr. CHAPMAN: Yes, we do.

Mr. HOWE (*Wellington-Huron*): Now, in connection with the next item, 18,820 advertisements were reviewed. Do they all have to be cleared by the Food and Drug Directorate?

Mr. CHAPMAN: No sir. There is no preclearance for newspaper and magazine advertising.

Mr. HOWE (*Wellington-Huron*): Do you take any action for misleading information?

Mr. CHAPMAN: Yes we do.

Mr. HOWE (*Wellington-Huron*): How many actions were necessitated in that 18,820 advertisements?

Mr. CHAPMAN: One hundred and twenty-three were found to be not acceptable and some action was taken with regard to those.

Mr. HOWE (*Wellington-Huron*): Did you take court action or through the Combines of the Justice Department for misleading advertising or what action are you allowed to take in this regard?

Mr. CHAPMAN: Well, we can exercise the full authority and the penalties of the Food and Drugs Act which states that no person shall advertize a drug in a manner that is misleading or deceptive.

Mr. HOWE (*Wellington-Huron*): Thank you, Mr. Chairman.

Mr. MACLEAN (*Queens*): I have one supplementary to the questioning of Mr. Laidlaw. In connection with licences for the manufacture of drugs, would it be possible or practical, when an application is made for a licence, for the applicant to demonstrate his ability not only by the inspection of his plant and all this sort of thing but by production of a pilot quantity of his proposed manufacture so that it would be available, in advance of being put on the market, for analysis and perhaps clinical testing as well, in cases where clinical analysis might not be sufficient, and where clinical testing would at least be desirable.

Mr. CHAPMAN: We feel that we should have a sample of the drug in order to make a proper assessment. However, under the Food and Drugs Act our legal counsel has indicated that we cannot make such a requirement as a condition of sale. However, I might say that since these arrangements have been worked out with the Commissioner of Patents, any time that we have asked a manufacturer who has applied for a compulsory licence for a sample of a drug, it has been supplied to us. But, if that person refused to provide us with such samples then we would have to be waiting outside his premises when he produced the first lot in order to check it out.

Mr. MACLEAN (*Queens*): So it is rather academic at the moment but would you think it would be desirable for the law to be amended so this would not be a requirement?

Mr. CHAPMAN: This, certainly, would close a loophole.

Mr. MACLEAN (*Queens*): Mr. Chairman, thank you very much.

Mr. HOWE (*Hamilton South*): Have you the staff and or the money to be able to carry out this type of thing as a general rule, as it stands at the moment?

Mr. CHAPMAN: Do you mean, Dr. Howe, in connection with the issuance of compulsory licences?

Mr. HOWE (*Hamilton South*): No, I am sorry, with regard to doing clinical testing.

Mr. CHAPMAN: No sir, we do not have either the capacity nor the facilities to do this.

Mr. MACKASEY: Mr. Chairman, if you have two choices open then, one not to leave these drugs on the market and the other to take a chance because your staff is inadequate; I will leave it up to the public as to which is the best. I am more interested in coming back to the key paragraph in the Hilliard Report as I see it, and I can only refer to it as K.5 because that is the number on this thing. If I recall the main purpose of this meeting was your opinion of the Hilliard Report. It states:

> It is not sufficient any more to perform a simple test on a finished product...Minor changes in process may lead to quite different contaminants in finished products and these contaminants may be toxic and may even be missed by routine chemical analysis.

Do you agree with this?

Mr. CHAPMAN: I agree that this is a possibility. This, of course, is the reason we have set up the tests to check on the raw material. I would like to add to add to that statement however, that cases where a very thorough chemical examination has been carried out and then toxic effects have appeared in the finished product, have been very few and far between. But, it is possible.

Mr. MACKASEY: Of course, knowing your reputation for perfection, very few are too many.

Mr. CHAPMAN: Yes, I agree.

Mr. MACKASEY: I tie this in, again, with the report on page 6 that I mentioned earlier that states:

> Massive quantities of bulk drugs made in different countries and often produced by different methods of synthesis are coming into our country—

Is this not precisely what the Hilliard Report is saying? You admit in your report—I do not like using the word "admit"—you point out quite logically that drugs coming in from different countries are manufactured by different methods. The Hilliard Report ties in to say that:

> Minor changes in process may perhaps lead to quite different contaminants in finished products and these contaminants may be toxic and may even be missed by routine chemical analysis.

You would not define you analysis now as routine chemical analysis, in the Food and Drug Directorate?

Mr. CHAPMAN: The techniques that Dr. Levi has referred to would not be routine chemical analysis. They would be more sophisticated than that.

Mr. MACKASEY: There are a thousand and one questions I would have liked to ask because your answers, objective as I know they would be, would lead to the conclusion I get of all these hearings, Mr. Chairman. I realize the bell is ringing and I am going to have to leave these questions out. But, you did discuss with Mr. Laidlaw, one of the recommendations of the Hilliard Report. In other words, you voluntarily have entered into some kind of informal arrangement

with the Patent Office. Now, we have suggested in this committee, a triumvirate. In other words, you are two-thirds of the way. We were suggesting an economist be added to your board. What do you think of this suggestion?

Mr. CHAPMAN: Well, I presume the economist would be on this committee to give consideration to the economic aspects.

Mr. MACKASEY: He would give consideration to the establishment of realistic royalties. In view of your experience in the research done and so on by the innovator and the copier.

Mr. CHAPMAN: This certainly falls outside the jurisdiction of the Food and Drug Directorate but I would see no objection to it.

Mr. MACKASEY: Since you accept, and I am glad you do, one of the recommendations of the Hilliard Report, do you accept them all?

Mr. CHAPMAN: We are in agreement with the intent of all the recommendations of the Hilliard Report.

Mr. MACKASEY: I am glad to hear this. It brings me to their suggestions or recommendations concerning new drugs. Are you in agreement with their concept of what a new drug is or should be?

Mr. CHAPMAN: This is recommendation no. 5, I believe.

Mr. MACKASEY: You skirt it, in your report, because of legal problems, I think. You do mention it in your own report, recommendation no. 5.

Mr. CHAPMAN: Yes. Recommendation no. 5 reads:

> That the definition of a new drug be amended to include a drug not currently in new drug status if it is to be manufactured or produced by a method or process that is substantially different from the method or process currently being used in Canada; or if with prolonged use, new or more serious or more frequent side effects, develop.

Mr. MACKASEY: Do you agree with this?

Mr. CHAPMAN: I cannot say yes or no, Mr. Mackasey. I will have to offer an explanation.

Mr. MACKASEY: An explanation as to why you cannot say yes or no?

Mr. CHAPMAN: Yes sir.

Mr. MACKASEY: All right.

Mr. CHAPMAN: We consider that the first portion of this recommendation may already be covered under the present definition of a new drug. However, to remove any doubt the definition will be amended in such a manner as to do so and the proposed wording has been discussed with the Department of Justice. We propose to make this change when we make the recommendations which are incorporated in the Boyd report. Now, with regard to the second portion—

Mr. MACKASEY: Would you repeat the second portion so I know we are talking about the same thing.

Mr. CHAPMAN: Yes, the second portion reads:

> —or if with prolonged use, new or more serious side effects, develop.

Mr. MACKASEY: "Or more frequent side effects develop."

Mr. CHAPMAN: Yes, I am sorry I paraphrased this.

Mr. MACKASEY: Well I will get it accurate because it is important:

—or if with prolonged use, new or more serious or more frequent side effects, develop.

Mr. CHAPMAN: We placed this question before the Department of Justice and we have gone back to them a second time and asked them to reconsider their initial decision. The Department of Justice 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".

Mr. MACKASEY: Why did you go back and ask them to reconsider this?

Mr. CHAPMAN: This was because the Pharmaceutical Manufacturers Association approached our Minister with regard to this matter. We met with the legal representatives of the Pharmaceutical Manufacturers Association of Canada and at this meeting we agreed to present the question to the Department of Justice again and the assistant deputy minister of justice, Mr. Thorson, gave us this ruling.

Mr. MACKASEY: Is this the same Mr. Thorson who was here as a witness?

Mr. CHAPMAN: No.

Mr. MACKASEY: No. You used the word "reconsider", and I put the wrong connotation on the word "reconsider" because to reconsider means a change of verdict to me. Whereas, your explanation simply meant that you asked for a review of the decision.

Mr. CHAPMAN: That would be more correct, thank you very much.

Mr. MACKASEY: I think it is important.

Mr. CHAPMAN: Yes, "review" would be better.

Mr. MACKASEY: But, it still does not give me any inkling as to whether the Food and Drug Directorate agrees with the Hilliard Report, provided the Department of Justice agreed that such a move was legal, if necessary.

Mr. CHAPMAN: We agree that the Food and Drug Directorate should be aware, "if with prolonged use, new or more serious or more frequent side effects, develop" in the use of a drug. We are now considering regulations that will require a drug manufacturer to provide us with this information on any drug, whether it is in "new drug" status or an old drug.

Mr. MACKASEY: Before I conclude in this respect, Mr. Chairman, I would just like to offer my appreciation to Mr. Howe for remaining here. I feel very conscious that the bell has finished ringing—

The CHAIRMAN: And the Chairman.

Mr. MACKASEY: And the Chairman, particularly Mr. Howe, and I appreciate it. In other words, Dr. Chapman,—correct me if I am wrong—you do imply therefore that an old drug—I hate the terminology and I think we should in our recommendations, Mr. Chairman, come up with a new definition—after eight,

nine or ten years on the market, which could conceivably be manufactured at that time by the innovator and one or two or more copiers, if it should develop some unexpected side effect, like Thalidomide eventually did, that as far as you are concerned, everybody, innovator and copiers, will have to reconsider their product as a new drug?

Mr. CHAPMAN: Yes sir, if we considered it was serious enough to put it back into a new drug status, we could do that or we could use any other authority we have under the act to control this.

Mr. MACKASEY: But the Department of Justice does not agree with that. Regardless of how serious the side effect is they cannot find any means at the present where an old drug could be considered a new drug?

Mr. CHAPMAN: No sir, possibly I had better read the statement again. "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". However, we do have authority under Section 24 of the Act to make regulations respecting the conditions of sale of a drug. We have discussed this with the Department of Justice and we believe, and they believe, that we have the authority under that section of the act to make a requirement, not relating to the definition of a new drug, but requiring a manufacturer to report to us any previously unknown serious adverse reactions that develop.

Mr. MACKASEY: Do you not think it would be desirable for the sake of safety that this be done with all drugs anyway?

Mr. CHAPMAN: Yes sir, I do.

Mr. MACKASEY: So this is incidental. In other words, at the present moment there is nothing in the Food and Drug regulations that would permit the Food and Drug Directorate to reclassify an old drug as a new drug in case of these side effects we are talking about?

Mr. CHAPMAN: That is correct.

Mr. MACKASEY: Do you think it desirable that you should have this authority?

Mr. CHAPMAN: Yes, I do.

Mr. MACKASEY: Instead of finding alternate ways?

Mr. CHAIRMAN: I beg your pardon, could you clarify that?

Mr. MACKASEY: I would rather not repeat it because it is incidental, and it is unfair to you. In other words, because it is not there someone has expressed the legal opinion that perhaps you can get the same results with some other regulation in a more indirect method.

Mr. CHAPMAN: Possibly it might be the most direct method. We would not be involved then with a definition of a new drug. We would simply require that the manufacturer must keep such records and must report these to us.

Mr. MACKASEY: To be fair, not only to the press and myself and Mr. Howe, would you briefly repeat for us the regulations that new drugs must respect at the present moment that all drugs do not have to respect at the present?

The CHAIRMAN: I think we should shorthly terminate this, Mr. Mackasey?

Mr. MACKASEY: You may think so, Mr. Chairman, and I will accept your ruling, but I do not think so. I think it is vital to the whole 40-odd meetings we have had.

The CHAIRMAN: I would like to say this is a field we have already covered.

Mr. MACKASEY: Then let us say I am a little more stupid than most people, Mr. Chairman, because I need refreshing and I do not know a better man to do it than Dr. Chapman.

Mr. CHAPMAN: Under Section C.08.007 of the Food and Drug Regulations there is a requirement that:

> Where a manufacturer has received a notice of compliance in respect of a new drug submission or supplement thereto, he shall establish and maintain records including adequately organized and indexed files containing full information respecting (h) any unexpected side effects, injury, toxicity or sensivity reaction associated with the clinical uses, studies, investigations and tests respecting that new drug.

Now then in the following section it says that: A manufacturer shall furnish to the Director as soon as possible and in any event within 15 working days of the receipt by him, reports in duplicate of all records respecting the information contemplated by paragraphs (g), (h), (i) of Section C.08.007.

Subparagraph (h) is the one I just quoted. Now, that is required for a drug that is in new drug status.

Mr. MACKASEY: Of course, when a new drug becomes an old drug right now it is a matter of judgment from your department?

Mr. CHAPMAN: That is correct.

Mr. MACKASEY: Usually it is at this time that copiers apply for a compulsory licence, when a drug has reached the old drug status?

Mr. CHAPMAN: Yes sir, I would say that was correct.

Mr. MACKASEY: But, if after both the innovator and the copier or copiers have had the old drug on the market, three, four or five years, and unexpected side effects develop, you would certainly go along with the Hilliard recommendation that the drug be re-classified as a new drug?

Mr. CHAPMAN: I would go along with the Hilliard recommendation that appropriate action should be taken, depending on the circumstances of the situation. I think this was the intent of the Hilliard recommendation.

Mr. MACKASEY: Thank you, Mr. Chairman.

The CHAIRMAN: This meeting is adjourned.

APPENDIX "A"

THE COST OF PHARMACEUTICALS AND MEDICINES IN CANADA, 1961—1965

Research and Statistics Directorate,
Department of National Health and Welfare,
Ottawa, Canada.

January 1967

25609—6½

FOREWORD

In July 1962 the Royal Commission on Health Services requested the Research and Statistics Division of the Department of National Health and Welfare to prepare a report on the provision, distribution, and cost of drugs in Canada. The report was submitted to the Commission in January 1963 and was published by the Commission in July 1965.[1]

Because most of the statistics in that publication applied to 1960 and prior years, and because of the current interest of the Special Committee of the House of Commons on Drug Costs and Prices, the Research and Statistics Directorate has prepared this memorandum updating as far as possible some of the most significant of the statistics in the original volume.

Time and staff limitations have prevented a complete revision of the study. In general, the statistics herein parallel those in the chapters "Present methods of production and distribution of drugs" and "Expenditure on drugs in Canada" of the earlier study, although certain changes in concepts and of tabulation methods in the sources have prevented the production of exactly comparable data in a few cases, and have permitted fuller treatment in others.

This memorandum was prepared by Mr. Arthur F. Smith in the Health Resources and Expenditure Section of the Health Research Division, under the direction of Mr. William A. Mennie, Principal Research Officer (Health).

John E. Osborne,
Research and Statistics Directorate.

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[1] Department of National Health and Welfare, "Provision, Distribution, and Cost of Drugs in Canada", Royal Commission on Health Services, Ottawa, 1965 (Queen's Printer, Catalogue No. Z1-1961/3-1/7).

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I. *The Medicinal and Pharmaceutical Manufacturing Industry*

Highlights

In the period from 1960 to 1963, the drug industry in Canada experienced the following significant changes:

1. The number of establishments was reduced by 25 to 173.
2. The remaining establishments expanded, so that the total number of employees rose from 8,000 to 10,400.
3. Output per employee decreased in dollar value.
4. Total output increased from $165 to $194 million.
5. The very largest firms, those producing over $5 million each, increased in number from 9 to 13.
6. Proprietary medicines account for only 13 per cent of total output, as compared with 15 per cent in 1960 and 20 per cent in 1953.

Other interesting highlights of the industry in 1963 may also be noted:

1. Almost 8 out of 9 firms were located in Ontario or Quebec.
2. Only 1 out of 50 employees worked in firms outside Ontario and Quebec.
3. 10 per cent of the firms produced 60 per cent of the industry's output.
4. Payroll accounted for just over 20 per cent of revenues.
5. Materials and supplies accounted for less than 25 per cent of revenues, as compared with more than 50 per cent in manufacturing generally.
6. "Other" expenses, including advertising, accounted for more than 40 per cent of revenues, as compared with 16 per cent in manufacturing generally.

Size and location

Table 1 sets out some primary statistics concerning the drug manufacturing industry[1] in 1963. The 173 establishments shipped goods with a selling value of $194 million and had 10,400 employees. (In 1960 there had been 198 establishments, $165 million worth of shipments, and 8,000 employees.) The average output per establishment thus rose from $950,000 in 1960 to $1,100,000 in 1963, while average output per employee was falling from $20,600 in 1960 to $18,600 in 1963.

Only 20 establishements were located outside Ontario and Quebec in 1963, and there had been 21 in 1960. Furthermore, the plants outside those two provinces were generally smaller, accounting for only one-fiftieth of the employees of the industry as a whole. Their output, however, did increase sharply from 1.4 per cent of the industry-wide total in 1960 to 1.9 per cent in 1963.

Concentration

Tables 2 and 3 set out selling value of factory shipments and the number of establishments, classifying each by a range of sales volume. From them one can observe that nearly one-third of the plants during 1963 produced less than $50,000 of goods each, and that the establishments producing $5 million or more each—nine in 1960 and 13 in 1963—accounted for 41 per cent of the total output in 1960 and for 49 per cent in 1963.

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[1] The definition of the industry used includes those establishments chiefly engaged in the production of pharmaceuticals and medicinal preparations. Their output includes some veterinary medicines, insecticides, disinfectants, flavouring extracts, and toilet preparations, as well as pharmaceutical and medicinal products in the ordinary sense.

TABLE 1

ESTABLISHMENTS, EMPLOYEES, AND FACTORY SHIPMENTS[a] OF MANUFACTURERS[b] OF PHARMACEUTICALS AND MEDICINES, BY PROVINCE, 1963

	Number of Establishments	Number of Employees	Selling Value[c] of Factory Shipments
			$
Nova Scotia	1	(d)	(d)
New Brunswick	2	(d)	(d)
Quebec	74	4,963	89,664,000
Ontario	79	5,243	101,349,000
Manitoba	5	(d)	(d)
Alberta	2	(d)	(d)
British Columbia	10	80	789,000
Canada	173	10,418	193,718,000

[a] Including patent medicines, veterinary medicines, disinfectants, insecticides, flavouring extracts, and toilet preparations.

[b] Manufacturers chiefly engaged in the production of pharmaceuticals and medicinal preparations.

[c] Excluding sales tax or excise duties.

[d] Confidential to meet secrecy requirements of the Statistics Act.

SOURCE: Dominion Bureau of Statistics, "Manufacturers of Pharmaceuticals and Medicines, 1963".

TABLE 2

SELLING VALUE[a] OF FACTORY SHIPMENTS[b] AND CUMULATIVE PERCENTAGES, BY RANGE OF SELLING VALUE OF FACTORY SHIPMENTS, MANUFACTURERS[c] OF PHARMACEUTICALS AND MEDICINES, 1960 AND 1963

Range of Selling Value of Factory Shipments	1960		1963	
	Selling Value of Factory Shipments	Cumulative Percentages	Selling Value of Factory Shipments	Cumulative Percentages
$	$'000	%	$'000	%
Under $10,000	141	.1	126	.1
10,000– 24,999	371	.3	186	.2
25,000– 49,999	717	.7	646	.5
50,000– 99,999	1,080	1.4	989	1.0
100,000– 199,999	3,374	3.4	1,855	2.0
200,000– 499,999	10,565	9.9	7,727	6.0
500,000– 999,999	10,879	16.5	14,677	13.5
1,000,000–4,999,999	70,546	59.2	71,948	50.7
5,000,000 and over	67,224	100.0	95,563	100.0
Total	164,897	—	193,718	—

[a] Excluding sales tax or excise duties.

[b] Including patent medicines, veterinary medicines, disinfectants, insecticides, flavouring extracts, and toilet preparations.

[c] Manufacturers chiefly engaged in the production of pharmaceuticals and medicinal preparations.

SOURCE: Dominion Bureau of Statistics, "Manufacturers of Pharmaceuticals and Medicines", 1960 and 1963.

TABLE 3

NUMBER OF ESTABLISHMENTS ENGAGED IN MANUFACTURING PHARMACEUTICALS AND MEDICINES AND CUMULATIVE PERCENTAGE, BY RANGE OF SELLING VALUE OF FACTORY SHIPMENTS, 1960 AND 1963

Range of Selling Value of Factory Shipments	1960		1963	
	Number of Establishments	Cumulative Percentage	Number of Establishments	Cumulative Percentage
$				
Under $10,000	29	14.6	27	15.6
10,000– 24,999	22	25.7	11	22.0
25,000– 49,999	21	36.3	18	32.4
50,000– 99,999	15	43.9	15	41.0
100,000– 199,999	23	55.5	12	48.0
200,000– 499,999	32	71.7	27	63.6
500,000– 999,999	16	79.8	20	75.1
1,000,000–4,999,999	31	95.5	30	92.5
5,000,000 and over	9	100.0	13	100.0
Total	198	—	173	—

SOURCE: Dominion Bureau of Statistics, "Manufacturers of Pharmaceuticals and Medicines", 1960 and 1963.

The output of the pharmaceutical and medicinal manufacturing industry in Canada is concentrated to a marked degree in the largest establishments of the industry, and between 1961 and 1964 that degree of concentration was virtually unchanged. With the establishments ranked in order of their factory shipments, the 50 per cent of the establishments with the largest amounts of such shipments accounted for upwards of 97 per cent of the overall total of shipments, as shown in Table 4, and the top 10 per cent of the establishments produced 60 per cent of the industry's total. On the other hand, if the outputs of the smallest establishments, beginning with the smallest of all, be cumulated with respect to their shipments it is necessary to cumulate the output of 40 per cent of the firms before one per cent of the industry's total output is accounted for.

Between 1961 and 1964 such shift as there was, was in the direction of slight reductions in the proportions of total output accounted for by the largest and the smallest establishments (the largest five per cent of establishments produced 39 per cent of the output in 1961 and 38 per cent in 1964, and the smallest one-third of the establishments produced 64/100 of one per cent in 1961 and 50/100 of one per cent in 1964).

Financial operations

The financial operations of the pharmaceutical manufacturing industry may conveniently be examined over time and in comparison with manufacturing industries as a whole by converting all available absolute amounts to percentages of the related total-income figures. Percentages so derived are shown in Table 5 for the period 1960-63.

The table reveals that sales accounted for all but 1 per cent of total revenue over the period studied, both in pharmaceutical manufacturing and in manufacturing generally.

On the expense side, the payroll (here interpreted to include salaries, wages, and cash withdrawals by working owners and partners) took just over one-fifth of the revenue, the precise percentages being slightly higher in pharmaceutical manufacturing (at 23) than in manufacturing as a whole (at 22 or 21).[1]

Materials and supplies took less than 25¢ of the revenue dollar in pharmaceutical manufacturing as contrasted with more than 50¢ in manufacturing generally. In both cases, despite the disparity in proportions spent, the proportionate supply expense rose moderately in 1961 and 1962 and eased off slightly in 1963.

One small but significant component of operating costs, fuel and electricity, took proportionately about four times as much of the revenue dollar—2¢ against ½¢—in the whole of manufacturing as in pharmaceutical manufacturing considered separately, over the four-year period 1960-63.

[1] Comparable data for payrolls of manufacturing companies are not available for years before 1963 (in the case of pharmaceutical manufacturing) or before 1962 (in the case of manufacturing in general).

TABLE 4

CONCENTRATION IN THE PHARMACEUTICAL AND MEDICINAL MANUFACTURING INDUSTRY, CANADA, 1961 AND 1964

Cumulative percentage of largest establishments	Percentage of factory shipments	
	1961	1964
5	39	38
10	61	60
15	—	75
16	74	—
21	83	83
26	88	88
31	91	92
36	94	95
41	95	96
46	—	97
47	97	—

Cumulative percentage of smallest establishments	Percentage of factory shipments	
	1961	1964
7	0.02	0.01
12	0.06	—
13	—	0.04
17	0.12	—
18	—	0.09
22	0.23	—
23	—	0.18
28	0.40	0.32
33	0.64	0.50
38	0.98	0.75
43	1.50	1.16
48	2.24	—
49	—	1.77

SOURCE: Special tabulation by Industry Division, Dominion Bureau of Statistics.

TABLE 5

FINANCIAL OPERATIONS OF ALL MANUFACTURING INDUSTRIES AND OF THE PHARMACEUTICAL MANUFACTURING INDUSTRY, EXPRESSED AS PERCENTAGES OF TOTAL INCOMES, CANADA, 1960–1963

	All Manufacturing Industry				Pharmaceutical Manufacturing			
	1960	1961	1962	1963	1960	1961	1962	1963
	%	%	%	%	%	%	%	%
REVENUES								
1. Sales	99.0	99.1	99.0	99.0	98.8	99.2	99.0	99.3
2. Other income	1.0	0.9	1.0	1.0	1.2	0.8	1.0	0.7
3. Total Income	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
EXPENSES								
4. Cost of sales[a]	72.7	73.2	73.0	73.2	42.9	48.1	48.7	45.9
5. Salaries, Wages and Withdrawals	—[b]	22.6	22.1	21.2	—[b]	—[b]	23.2	22.6
6. Materials and supplies	50.0	51.7	52.3	51.7	20.1	21.7	24.5	23.3
7. Fuel and electricity	2.0	2.0	1.9	1.8	0.4	0.4	0.5	0.5
8. Residual[a]	—[b]	−3.2	−3.3	−1.6	—[b]	—[b]	0.5	−0.6
9. Rents paid	0.5	0.5	0.5	0.5	0.4	0.6	0.6	0.7
10. Interest paid	0.9	0.9	0.8	0.8	0.4	0.2	0.2	0.3
11. Capital Cost Allowance	3.5	3.5	3.5	3.6	2.0	2.1	1.8	1.8
12. Other expense	16.6	16.2	16.2	15.8	44.0	40.5	39.8	40.6
13. Total expense	94.2	94.3	94.0	93.9	89.7	91.5	91.1	89.3
Current year profit	5.8	5.7	6.0	6.1	10.3	8.5	8.8	10.7

[a]Item 4 is the sum of items 5 to 8. Items 5 to 7 were obtained from the D.B.S. sources listed below and item 4 from the Department of National Revenue sources. Item 8 is a balancing item representing the net sum of (i) costs of sales not included in 5 to 7 and (ii) discrepancy between the two groups of sources.

[b]Figures not available.

SOURCES: Department of National Revenue, "Taxation Statistics", 1962, 1963, 1964, and 1965 (data are for years two years before date on covers of publications); Dominion Bureau of Statistics, "Manufacturers of Pharmaceuticals and Medicines", 1960, 1961, 1962, and 1963; "Advance Statement, Summary Statistics of Manufacturing Industries, 1963"; "Summary Statistics of Manufacturing Industries, 1961".

It is the expense category "Other" that the most striking statistical difference occurs between the pharmaceutical manufacturing industry and manufacturing generally. This item, which includes advertising,[1] took upwards of 40¢ of the pharmaceutical manufacturing revenue dollar but only 16¢ or 17¢ of the general manufacturing revenue dollar.

Composition of output

The composition of the output of the pharmaceutical manufacturing industry changed notably over the 1953-1963 decade, as is shown in Table 6. The shift can be described as away from the production of nostrums and toward the production of more potent drugs. Proprietary medicines—primarily those drugs advertised to the public and sold "over-the-counter" to the public without a physician's prescription—accounted for $18.6 millions or 20 per cent of the $93.6 millions total output in 1953 and, although they amounted to $24.5 millions a decade later, their proportion of the $193.7 millions total had shrunk to 13 per cent. Human pharmaceuticals—which correspond roughly to the drugs that are advertised only to the medical and pharmaceutical professions, and include all the drugs that cannot be purchased at retail without a physician's prescription —made up $66.3 millions or 71 per cent of the 1953 shipments and $148.4 millions or 77 per cent of the total for 1963.

[1] The definition used in the statistics reads, "All expenses not otherwise provided for are included in this category, for example, advertising, administrative, and selling expenses"; Department of National Revenue 1965 Taxation Statistics Part Two, p. 22.

TABLE 6

FACTORY SHIPMENTS OF THE PHARMACEUTICAL MANUFACTURING INDUSTRY CLASSIFIED BY COMMODITY GROUPINGS, CANADA, 1953, 1957, 1960, AND 1963

	1953		1957		1960		1963	
	$'000	Per Cent of Total	$'000	Per Cent ot Total	$'000	Per Cent of Total	$'000	Per Cent of Total
Total value of factory shipments	93,557		140,092		164,897		193,718	
Proprietary medicines	18,561	19.8	22,326	15.9	24,443	14.8	24,542	12.7
Human pharmaceuticals	66,304	70.9	99,428	71.0	124,095	75.3	148,363	76.6
Veterinary medicines	1,525	1,6	2,531	1.8	3,783	2.3	6,390	3.3
Insecticides, disinfectants and the like	7,167	7.7	15,807	11.3	12,576	7.6	16,436	8.5
Adjustments[1]	—	—	—	—	—	—	−2,013	−1.0

[1] Represents amount received in payment for work done an materials and products owned by others, less adjustment for value of sales taxes, excise duties and outward transportation charges which could not be deducted from individual commodity groupings.

SOURCE: Dominion Bureau of Statistics, "Manufacturers of Pharmaceuticals and Medicines", 1953, 1957, 1960, 1963.

Selling expenses

Table 7 brings together data from two surveys of selling expenses of pharmaceutical manufacturers made in 1960 and 1964. The surveys were made by the Canadian Pharmaceutical Manufacturers Association.[1] Because not all firms in the industry participated, and because the 40 participating companies in the 1960 survey were not necessarily the same as the 41 in the 1964, the dollar amounts in the table have little intrinsic significance. The percentages, however, are of particular interest, since selling expenses loom so large in the pharmaceutical manufacturing industry. According to the surveys, selling expense took 29.2 per cent of the companies' revenue from sales of human pharmaceuticals in 1960 and 30.6 per cent in 1964. The expense of face-to-face selling to physicians, the largest tabulated item in both years, took 9¢ of the dollar in 1960 and 11.3¢ in 1964, while similar selling to non-physicians was contracting from 4.9¢ to 4.3¢. Samples and exhibits were unchanged. Journal advertising rose slightly and its rise was offset by a slight contraction in direct mail advertising.

[1]Now named the Pharmaceutical Manufacturers Association of Canada.

TABLE 7

SELLING EXPENSES OF COMPANIES SURVEYED FOR THE CANADIAN PHARMACEUTICAL MANUFACTURERS ASSOCIATION,

EXPRESSED AS AN AMOUNT AND AS A PERCENTAGE OF THEIR SALES OF HUMAN PHARMACEUTICALS, 1960 AND 1964[a]

Item	1960		1964	
	Amount	Per Cent	Amount	Per Cent
Field selling expense, selling to physicians	9,738,880	9.0	12,176,598	11.3
Field selling expense, selling to non-physicians	5,278,120	4.9	4,668,035	4.3
Medical exhibits and space rentals for them	206,000	0.2	229,357	0.2
Advertising in medical and pharmaceutical journals	2,030,000	1.9	2,331,527	2.2
Advertising by direct mail	3,048,000	2.8	2,739.423	2.5
Promotional samples	3,953,000	3.7	3,939,446	3.7
Other selling expenses[b]	7,274,000	6.7	6,893,175	6.4
Total selling expenses	$31,528,000	29.2	$32,977,561	30.6

[a]Forty companies, selling $107,994,000 of human pharmaceuticals, were included in 1960; forty-one companies, selling $107,792,082, were included in 1964.

[b]Includes (for 1960) donations, price lists, institutional advertising, displays for drug stores, "etc." and (for 1964) "administration of Marketing, Selling and Advertising Function (Management and staff services, home office salaries and other expenses of the Marketing Department, including marketing research)" and expenses for advertising other than in medical or pharmaceutical journals or by direct mail.

SOURCES: (1960 data) Answers to specific questions received from the Royal Commission on Health Services and provided by Canadian Pharmaceutical Manufacturers Association April 30, 1962; (1964 data) Submission to the House of Commons Special Committee on Drug Costs and Prices by the Pharmaceutical Manufacturers Association of Canada at Ottawa, Ontario, June 1966, page E5.

II. *Imports and exports of medicinal and pharmaceutical preparations*

The self-sufficiency of Canada with respect to medicinal and pharmaceutical preparations[1] tended to increase over the 1953-1964 period, as shown in Table 8, but the increase was by no means uninterrupted. As a percentage of the combined total value of Canadian factory shipments and imports to Canada, the import figure averaged 12.8 in 1953-55 and had fallen to 9.9 in 1962-64. This reduction was coincident with a near-doubling of the value of imports, from $12.5 millions in 1953 to $23.2 millions in 1964, and a more-than-doubling of factory shipments of medicinal and pharmaceutical products, from $87.1 millions in 1953 to $203.6 in 1964[2].

An indication of the new flow of goods into or out of Canada can be obtained by relating imports to exports and subtracting the lesser from the greater. This is done in Table 9 and in the Figure, wherein the data have been reduced to per capita amounts for convenience and to offset the effect of the growing size of the Canadian population. Over the entire 1953-64 period, the Canadian drug trade has been in negative balance, which is to say, imports have exceeded exports. It was only towards the end of the period, however, that exports became half as large as imports. For the single year 1958 this had also been true, but in that year both imports and exports rose, the latter more rapidly. The year 1962 was the first in which an increase in exports had coincided with a fall in imports, and over the period 1962-64 the export total stayed close to half the import total.

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[1] Some of this production would occur as the secondary output of establishments primarily engaged in manufacturing other products; accordingly, production data in this section do not agree with figures for the "medicinal and pharmaceutical manufacturing industry", discussed in the preceding section. For example, a meat-packing establishment might produce hormones and, although meat would be the major product of the establishment, these hormones would nonetheless be a medicinal preparation and therefore would be included in the present context, although they would be excluded from the previous section because they were manufactured in another industry. On the other hand, a drug-manufacturing establishment might produce lemon flavouring for use in cooking; such an operation would be included in the data in the previous section (because manufacturing drugs would be the principal object of the establishment), but would be excluded from the data in this section (because lemon flavouring is not a drug).

[2] Figures used for imports in the report for the Royal Commission were obtained from Dominion Bureau of Statistics sources and, it now transpires, included weed killers, dips, sprays, fumigants, insecticides, pesticides, and disinfectants. Figures for these products have been excluded from the totals shown in the present report.

TABLE 8

VALUE OF FACTORY SHIPMENTS,[a] IMPORTS,[b] EXPORTS, AND NET IMPORTS OF MEDICINAL AND PHARMACEUTICAL PREPARATIONS, AMOUNT AND PERCENTAGE, CANADA, 1953–1964

Year	Value of Factory Shipments		Imports		Total, Factory Shipments and Imports		Exports		Net Imports
	Amount	Per Cent of Total	Amount	Per Cent of Total	Amount	Per Cent of Total	Amount	Per Cent of Factory Shipments	
	$'000		$'000		$'000		$'000		$'000
1953	87,098	87.4	12,515	12.6	99,613	100.0	5,659	6.5	6,856
1954	90,799	86.2	14,557	13.8	105,356	100.0	5,476	6.0	9,081
1955	100,878	88.0	13,774	12.0	114,652	100.0	4,248	4.2	9,526
1956	100,002	88.2	14,650	11.8	124,652	100.0	5,349	4.9	9,301
1957	126,297	88.8	15,913	11.2	142,210	100.0	6,835	5.4	9,078
1958	139,621	89.2	16,901	10.8	156,522	100.0	9,560	6.8	7,341
1959	153,334	89.5	18,149	10.5	172,483	100.0	6,758	4.4	11,391
1960	159,390	90.6	16,598	9.4	175,988	100.0	5,726	3.6	10,872
1961	165,551	88.9	20,750	11.1	186,301	100.0	6,911	4.2	13,839
1962	176,562	90.1	19,490	9.9	196,052	100.0	10,274	5.8	9,216
1963	192,520	90.5	20,261	9.5	212,781	100.0	10,498	5.5	9,763
1964	203,588	89.8	23,168	10.2	226,756	100.0	11,110	5.5	12,058

[a]Total Canadian shipments including some medicinals made in other industries; see footnote 1, page 11.

[b]See footnote 2, page 11.

SOURCES: Dominion Bureau of Statistics, "Manufacturers of Pharmaceuticals and Medicines", 1953 to 1964, Ottawa, and unpublished information from the External Trade Division, Dominion Bureau of Statistics.

TABLE 9

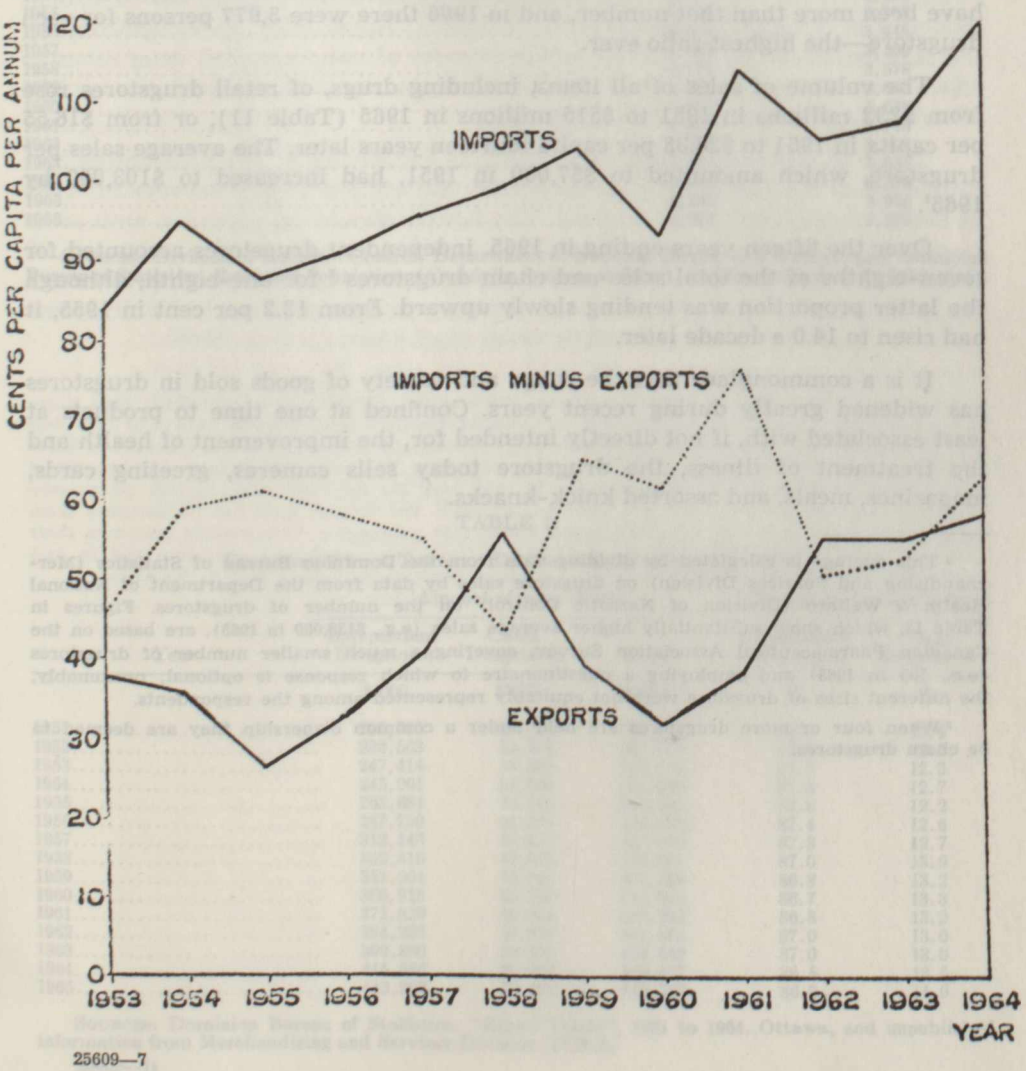
IMPORTS, EXPORTS, AND NET IMPORTS OF MEDICINAL AND PHARMACEUTICAL PREPARATIONS, PER CAPITA, CANADA, 1953–1964

	Imports	Exports	Net Imports
	$	$	$
1953	0.84	0.38	0.46
1954	0.95	0.36	0.59
1955	0.88	0.27	0.61
1956	0.91	0.33	0.58
1957	0.96	0.41	0.55
1958	0.99	0.56	0.43
1959	1.04	0.39	0.65
1960	0.93	0.32	0.61
1961	1.14	0.38	0.76
1962	1.05	0.55	0.50
1963	1.07	0.55	0.52
1964	1.20	0.58	0.63

SOURCES: Table 8 and Dominion Bureau of Statistics, *Estimated Population of Canada by Province at June 1, 1966* (contains data for 1933–1966).

FIGURE

IMPORTS, EXPORTS, AND NET IMPORTS OF MEDICINAL AND PHARMACEUTICAL PREPARATIONS, PER CAPITA, CANADA, 1953-1964



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III. *Retail drugstores*

Over the decade-and-a-half between 1951 and 1966 the number of retail drugstores in Canada rose by 23 per cent from 4,098 to 5,021, as shown in Table 10. The increase was not regular, with large rises in 1953 and 1963 and reductions in five other years (notably in 1964 and 1965); the 1966 total was below the all-time record of 5,171 stores, set in 1963.

During the same fifteen years the population increased by 42 per cent, or at a faster rate than did the number of drugstores. Thus, whereas there were on the average less than 3,600 persons for each pharmacy until 1958, since then there have been more than that number, and in 1966 there were 3,977 persons for each drugstore—the highest ratio ever.

The volume of sales of all items, including drugs, of retail drugstores rose from $232 millions in 1951 to $515 millions in 1965 (Table 11), or from $16.55 per capita in 1951 to $26.33 per capita fourteen years later. The average sales per drugstore, which amounted to $57,000 in 1951, had increased to $103,000 by 1965[1].

Over the fifteen years ending in 1965, independent drugstores accounted for seven-eighths of the total sales and chain drugstores [2] for one-eighth, although the latter proportion was tending slowly upward. From 12.2 per cent in 1955, it had risen to 14.0 a decade later.

It is a commonplace that the range and variety of goods sold in drugstores has widened greatly during recent years. Confined at one time to products at least associated with, if not directly intended for, the improvement of health and the treatment of illness, the drugstore today sells cameras, greeting cards, magazines, meals, and assorted knick-knacks.

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[1] This average is calculated by dividing data from the Dominion Bureau of Statistics (Merchandising and Services Division) on drugstore sales by data from the Department of National Health & Welfare (Division of Narcotic Control) on the number of drugstores. Figures in Table 13, which show substantially higher average sales (e.g., $138,000 in 1965), are based on the Canadian Pharmaceutical Association Survey, covering a much smaller number of drugstores (e.g., 595 in 1965) and employing a questionnaire to which response is optional; presumably, the different sizes of drugstore were not equitably represented among the respondents.

[2] When four or more drugstores are held under a common ownership they are deemed to be chain drugstores.

TABLE 10

NUMBER AND POPULATION PER RETAIL DRUGSTORE IN CANADA, 1951–1966

Year	Number of Retail Drugstores	Population per Retail Drugstore
1951	4,098	3,418
1952	4,094	3,532
1953	4,465	3,325
1954	4,457	3,430
1955	4,638	3,385
1956	4,663	3,449
1957	4,733	3,509
1958	4,773	3,578
1959	4,801	3,642
1960	4,915	3,636
1961	4,877	3,740
1962	4,877	3,808
1963	5,171	3,654
1964	5,017	3,834
1965	4,948	3,955
1966	5,021	3,977

SOURCES: Division of Narcotic Control, Department of National Health and Welfare, and Dominion Bureau of Statistics, *Estimated Population of Canada by Province at June 1, 1966* (contains data for 1933–1966).

TABLE 11

ESTIMATED RETAIL TRADE OF DRUGSTORES, CANADA, 1951–1965

Year	Amount of sales ($'000)			Percentage of total sales	
	Independent Drugstores	Chain Drugstores	Total	Independent Drugstores	Chain Drugstores
	$'000	$'000	$'000	%	%
1951	200,795	31,019	231,816	86.6	13.4
1952	233,563	33,504	267,067	87.5	12.5
1953	247,414	34,805	282,219	87.7	12.3
1954	245,901	35,908	281,810	87.3	12.7
1955	263,681	36,660	300,341	87.8	12.2
1956	287,730	41,299	329,028	87.4	12.6
1957	312,143	45,437	357,579	87.3	12.7
1958	332,819	49,912	382,731	87.0	13.0
1959	351,004	53,264	404,268	86.8	13.2
1960	360,918	55,130	416,048	86.7	13.3
1961	371,820	56,464	428,284	86.8	13.2
1962	384,328	57,336	441,664	87.0	13.0
1963	399,880	59,769	459,649	87.0	13.0
1964	415,586	65,042	480,627	86.5	13.5
1965	443,269	72,128	515,397	86.0	14.0

SOURCES: Dominion Bureau of Statistics, "Retail Trade", 1951 to 1964, Ottawa, and unpublished information from Merchandising and Services Division, D.B.S.

At the same time as the drugstores have been thus diversifying their trade, grocery stores, variety stores, and department stores have been competing with them in selling drugs. The so-called health and beauty aids" counters of supermarkets display dozens of products that until lately would be found only in drugstores.

Throughout the entire period, the drugstores have had a monopoly, as against other retail stores, of the sale of drugs sold under a prescription issued by a medical practitioner. Such sales have constituted an increasing percentage of the total sales of the stores, rising from 17 per cent in 1953 to 29 per cent in 1965 (Table 12). This increase is the more remarkable in the face of the coincident tendency of drugstore-inventory diversification. Apparently the competition by the supermarkets has drawn off sufficient sales of nonprescribed drug items to offset the reduction in the prescribed-drug proportion that diversification might otherwise have been expected to produce.

Table 13 sets out the financial operating experience of the pharmacies that responded to the Canadian Pharmaceutical Association annual surveys for 1961 to 1965, as published in its Journal. The figures should be regarded with some caution,[1] but they do indicate a steadily increasing average level of sales—up 30 per cent between 1961 and 1965, with year-to-year increases of 5, 4, 13, and 6 per cent, and an almost constant level of net operating profit until 1964 (between 4.5 and 4.8), followed by a sharp increase (to 5.6 per cent) in 1965.

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[1] The data represent a voluntary response, not stratified by size or by province; thus stores of various sizes may be overrepresented or underrepresented (see footnote (1), page 15); thus also, in 1965 only 1.1 per cent of the pharmacies in Quebec were included, 10.6 per cent of those in Ontario, and 27.4 per cent of those in Saskatchewan. The same pharmacies did not report from year to year; of the 476 that reported in 1964, only 297 reported again in 1965 (they were joined by another 298 that had not reported in 1964). The figures may not be accurate from an accounting point of view; the 1965 report states that among the "pharmacists who own their buildings . . . many do not impute sufficient rent to their pharmacy operation and in fact some fail to impute any" (Canadian Pharmaceutical Journal, September 1966, p. XXVIII).

TABLE 12

PROPORTION OF TOTAL SALES OF REPORTING PHARMACIES ACCOUNTED FOR BY SALES ON PRESCRIPTION, 1953-1965[a]

	%
1953	17.3
1954	18.5
1955	19.8
1956	21.8
1957	23.6
1958	23.6
1959	26.3
1960	26.3
1961	26.3
1962	25.9
1963	27.8
1964	28.6
1965	28.9

[a] Provincial yearly percentages, adapted from the provincial percentages in the C.P.A. Surveys, were multiplied by total yearly sales in each province, as reported by D.B.S.; the sum of the products was divided by total sales in Canada, also as reported by D.B.S.; the quotient, expressed as a percentage, appears above. Figures differ from the national percentages in the C.P.A. Survey, which were used without adjustment in the corresponding table of the report to the Royal Commission on Health Services. See also footnote 1, page 15 of the present memo.

SOURCES: Adapted from The Canadian Pharmaceutical Association, Annual Surveys by Professor H. J. Fuller, Number 10 to 24; Dominion Bureau of Statistics, "Retail Trade", 1951 to 1964, Ottawa; and unpublished information from Merchandising and Servicing Division, D.B.S.

TABLE 13

FINANCIAL OPERATING RESULTS OF REPORTING PHARMACIES IN CANADA, 1961–1965

	1961	1962	1963	1964	1965
No. of Pharmacies Reporting	619	511	600	476	595
Sales	$106,312—100.0%	$111,684—100.0%	$116,290—100.0%	$131,039—100.0%	$138,471—100.0%
Cost of Goods Sold	70,379— 66.2	74,046— 66.3	76,751— 66.0	86,224— 65.8	90,560— 65.4
Gross Margin	35,993— 33.8	37,638— 33.7	39,539— 34.0	44,815— 34.2	47,911— 34.6
EXPENSES					
Proprietor's or Manager's Salary	8,930— 8.4	9,381— 8.4	9,652— 8.3	10,614— 8.1	10,801— 7.8
Employees' Wages	10,950— 10.3	11,392— 10.2	11,978— 10.3	13,890— 10.6	14,678— 10.6
Rent	2,764— 2.6	2,792— 2.5	3,140— 2.7	3,800— 2.9	3,739— 2.7
Advertising	1,170— 1.1	1,229— 1.1	1,279— 1.1	1,573— 1.2	1,662— 1.2
Delivery	851— 0.8	894— 0.8	930— 0.8	1,048— 0.8	1,108— 0.8
Other Expenses	6,272— 5.9	6,924— 6.2	7,094— 6.1	7,600— 5.8	8,169— 5.9
Total Expenses	30,937— 29.1	32,612— 29.2	34,073— 29.3	38,525— 29.4	40,157— 29.0
Net Operating Profit	4,996— 4.7	5,026— 4.5	5,466— 4.7	6,290— 4.8	7,754— 5.6
Other Income	480	633	660	863	807
Proprietor's Salary	8,930	9,381	9,652	10,614	10,801
Total Income	14,406	15,040	15,778	17,767	19,362

SOURCE: "Canadian Pharmaceutical Association Journal", September, 1962–1966.

IV. *Expenditures on drugs*

The estimated amount spent in Canada for drugs for human consumption rose from about $190 million in 1953 to $405 million in 1964, a 117 per cent increase, as shown in Table 14. In per capita terms the increase was from $12.64 in 1953 to $21.13 in 1964; see Table 15. A percentage distribution of each year's expenditures appears in Table 16. It should be noted that these figures are constructed from data taken from a wide variety of sources and contain very considerable estimative assumptions, so that too much reliance should not be placed on their precision.

Sales by retail drugstores of drugs on prescription rose steadily from about $50 million in 1953 to nearly $140 million in 1964. By 1965[1] they had reached triple their amount twelve years earlier. In per capita terms the increase was from $3.29 in 1953 to $7.15 in 1964 and $7.62 in 1965. As a percentage of total drug expenditures, prescription sales rose from 26 in 1953 to 34 in 1964.

Other retail sales of drugs, primarily made up of sales by retail drugstores and other retail stores of non-prescribed (the so-called "over-the-counter") drugs, but also including all drugs dispensed directly by physicians, have also increased without major interruption, rising from $125 million in 1953 to $225 million in 1964. It is notable that whereas in 1953 this figure was 2.6 times as high as the sales of prescribed drugs by drugstores, by 1957 it was less than double, and by 1964 it was only 63 per cent higher than the prescribed-drug sales by drugstores. Over-the-counter and physician-dispensed drugs amounted to $8.39 per capita, or 66 per cent of total drug expenditures, in 1953. In 1964 their per capita consumption had risen to $11.63 but their percentage of the total had fallen to 55.

Expenditures by hospitals for drugs have increased particularly rapidly. From $14 million in 1953 they rose to $45 million eleven years later, or from 96 cents to $2.35 per capita. The 96 cents spent in 1953 amounted to 7.6 per cent of the national total drug bill, whereas the $2.35 in 1964 represented 11.1 per cent of the total.

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[1] Actual estimate $149.1 millions; data for 1965 do not appear in Tables 14 to 17 because the data for some other components of total drug expenditures in 1965 are not yet available.

TABLE 14

ESTIMATED[a] DRUG EXPENDITURES, CANADA, 1953–1964

Year	Retail Sales			Expenditures by hospitals					
	Prescribed[b]	Otherwise[c]	Total	Active Treatment[d]	Tuberculosis	Mental[e]	Federal[e,f]	Total	Total
	$'000	$'000	$'000	$'000	$'000	$'000	$'000	$'000	$'000
1953	48,800	124,500	173,300	11,700[d]	500	1,200	900	14,300	187,600
1954	52,100	131,400	183,500	13,300[d]	500	1,300	1,100	16,200	199,700
1955	59,500	143,900	203,400	14,600[d]	600	1,400	1,100	17,700	221,100
1956	71,800	147,700	219,500	16,500[d]	600	1,600	1,000	19,700	239,200
1957	84,500	163,500	248,000	19,000[d]	600	1,700	1,200	22,500	270,500
1958	90,300	174,200	264,500	21,700[d]	500	1,900	1,400	25,500	290,000
1959	106,500	191,000	297,500	24,300[d]	500	2,100	1,600	28,500	326,000
1960	109,600	190,400	300,000	26,700[d]	600	2,200	1,700	31,200	331,200
1961	112,800	196,900	309,700	30,700	500	2,500	1,700	35,400	345,100
1962	114,600	205,500	320,100	32,200	800	2,900	1,700	37,600	357,700
1963	128,000	214,300	342,300	35,600	700	3,500	1,800	41,600	383,900
1964	137,600	223,700	361,300	39,100	600	3,400	2,100	45,200	406,500

[a]It should be noted that these figures are constructed from data taken from a wide variety of sources and contain very considerable estimative assumptions, so that too much reliance should not be placed on their precision.

[b]Sold in retail drugstores only.

[c]Comprises all sales of drugs other than by prescription or to hospitals, whether sold in drugstores or elsewhere. and also all drugs dispensed and sold by physicians, whether on prescription or otherwise; based on an analysis of production, inventories, international trade, duties and taxes, markups, and utilization; excludes provincial retail sales tax.

[d]Comprise public and private acute, chronic, and convalescent hospitals.

[e]Estimated at 57 per cent of total for drugs and for medical, surgical, and sterile supplies.

[f]Basic data adjusted from fiscal-year to calendar-year basis; comprise federal active treatment, tuberculosis, and mental hospitals.

SOURCES: Canadian Pharmaceutical Association, *Canadian Pharmaceutical Journal*, May 15, 1954, August 1, 1955 and 1956, August 15, 1957, and September, 1958–1966; Dominion Bureau of Statistics, *Retail Trade*, 1953–1964; *The Medicinal and Pharmaceutical Preparations Industry*, 1953–1959; *Manufacturers of Pharmaceuticals and Medicines*, 1960–1964; *The Feeds Industry*, 1953–1964; Trade of Canada, Volume III, 1953–1960; *Hospital Statistics* 1953–1964; *Tuberculosis Statistics*, 1953, *Tuberculosis Statistics Financial Supplement*, 1954–1964; *Mental Health Statistics Financial Supplement*, 1953–1964; Department of Finance, *Public Accounts*, 1952–1953 to 1964–1965; and unpublished information from Dominion Bureau of Statistics.

TABLE 15

ESTIMATES[a] PER CAPITA DRUG EXPENDITURES, CANADA, 1953–1964

Year	Retail sales			Expenditures by hospitals					Total
	Prescribed	Otherwise	Total	Active Treatment	Tuberculosis	Mental	Federal	Total	
	$	$	$	$	$	$	$	$	$
1953	3.29	8.39	11.67	.79	.03	.08	.06	.96	12.64
1954	3.41	8.60	12.00	.87	.03	.09	.07	1.06	13.06
1955	3.79	9.17	12.96	.93	.04	.09	.07	1.13	14.08
1956	4.46	9.18	13.65	1.03	.04	.10	.06	1.23	14.87
1957	5.09	9.84	14.93	1.14	.04	.10	.07	1.35	16.29
1958	5.29	10.20	15.49	1.27	.03	.11	.08	1.49	16.98
1959	6.09	10.92	17.02	1.39	.03	.12	.09	1.63	18.65
1960	6.13	10.65	16.79	1.49	.03	.12	.10	1.75	18.53
1961	6.18	10.80	16.98	1.68	.03	.14	.09	1.94	18.92
1962	6.17	11.07	17.24	1.73	.04	.16	.09	2.02	19.26
1963	6.77	11.34	18.11	1.88	.04	.19	.10	2.20	20.32
1964	7.15	11.63	18.78	2.03	.03	.18	.11	2.35	21.13

[a]It should be noted that these figures are constructed from data taken from a wide variety of sources and contain very considerable estimative assumptions, so that too much reliance should not be placed on their precision.

SOURCES: Table 14, and Dominion Bureau of Statistics, *Estimated Population of Canada by Province at June 1, 1966* (contains data for 1933–1966).

TABLE 16

ESTIMATED[a] PERCENTAGE DISTRIBUTION OF DRUG EXPENDITURES, CANADA, 1953–1964

Year	Retail sales			Expenditures by hospitals					Total
	Prescribed	Otherwise	Total	Active Treatment	Tuberculosis	Mental	Federal	Total	
	$	$	$	$	$	$	$	$	$
1953	26.0	66.4	92.4	6.2	0.3	0.6	0.5	7.6	100.0
1954	26.1	65.8	91.9	6.7	0.2	0.6	0.6	8.1	100.0
1955	26.9	65.1	92.0	6.6	0.3	0.6	0.5	8.0	100.0
1956	30.0	61.7	91.8	6.9	0.2	0.7	0.4	8.2	100.0
1957	31.2	60.4	91.7	7.0	0.2	0.6	0.4	8.3	100.0
1958	31.1	60.1	91.2	7.5	0.2	0.7	0.5	8.8	100.0
1959	32.7	58.6	91.3	7.5	0.2	0.6	0.5	8.7	100.0
1960	33.1	57.5	90.6	8.1	0.2	0.7	0.5	9.4	100.0
1961	32.7	57.1	89.7	8.9	0.1	0.7	0.5	10.3	100.0
1962	32.0	57.5	89.5	9.0	0.2	0.8	0.5	10.5	100.0
1963	33.3	55.8	89.2	9.3	0.2	0.9	0.5	10.8	100.0
1964	33.8	55.0	88.9	9.6	0.1	0.8	0.5	11.1	100.0

[a]It should be noted that these figures are constructed from data taken from a wide variety of sources and contain very considerable estimative assumptions, so that too much reliance should not be placed on their precision.

SOURCE: Table 14.

Table 17 relates the data for Table 14 to the Gross National Product. Until 1959, except in 1956[1], drugs were accounting for an increasingly large share of the G.N.P.; the proportion rose from 767 thousandths of one per cent in 1953 to 934 in 1959. Thereafter, the G.N.P. expanded faster in most years than drug costs, and by 1964 the drug share was down to 858 thousandths of one per cent. Similar patterns of early increase and later decrease are notable in the "Retail Sales—Prescribed" and "Retail Sales—Otherwise" components, but in active treatment hospitals the expansion in the rate of drug expense continued throughout the period to exceed or at least to match the growth of the G.N.P.

With regard to statistics on drug expenditures in recent years, it is perhaps necessary to emphasize here that which is well known, namely, that the drugs in use today are in many cases new ones that were not available only a few years ago. Accordingly, there is no real reason to suppose that there should be any direct relationship between what was spent on drugs in a recent year compared to what was spent in a more distant year.

To sum up the drug-expenditure situation between 1953 and 1964:

— sales of prescribed drugs tripled;

— sales of over-the-counter drugs rose by 80 per cent;

— hospital expenditures for drugs more than tripled; and

— all expenditures for drugs more than doubled.

Drugs are an essential part of health care. The $400 million spent on drugs in Canada in 1964 compare with $1,400 million for hospital care, $500 million for physicians' services, between $100 and $200 million for dental care, and perhaps another $100 or $200 million for other health care—an overall total of $2.6 billion, with drugs constituting approximately 15 per cent.

Furthermore, it must not be forgotten that drugs enter into the treatment of almost every illness, whatever its nature or severity, and whatever other forms of treatment may also be utilized. Often, for many minor ailments, the only treatment is a drug purchased over the counter. In some cases, remedies prepared in the home from other goods are used as drugs, and no statistics can measure their amount.

It is beyond the scope of this report to make proposals, or to comment upon the many proposals that have been advanced, for dealing with the problem of making drugs available to those who need them. Perhaps the information herein will assist those who must make such judgments.

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[1] In 1956 drug expenses rose by 8% but the G.N.P. increased by 13%.

TABLE 17

ESTIMATED[a] DRUG EXPENDITURES EXPRESSED AS THOUSANDTHS OF ONE PER CENT OF THE GROSS NATIONAL PRODUCT,[b] CANADA, 1953–1964

Year	Retail sales			Expenditures by hospitals					Total
	Prescribed	Otherwise	Total	Active Treatment	Tuberculosis	Mental	Federal	Total	
	$	$	$	$	$	$	$	$	$
1953	199	509	708	48	2	5	4	58	767
1954	209	528	738	53	2	5	4	65	803
1955	219	530	750	54	2	5	4	65	815
1956	235	483	718	54	2	5	3	64	782
1957	265	512	777	60	2	5	4	71	848
1958	275	530	804	66	2	6	4	68	882
1959	305	547	852	70	1	6	5	82	934
1960	302	525	827	74	2	6	5	86	913
1961	301	525	826	82	1	7	5	94	921
1962	282	506	789	79	2	7	4	93	882
1963	295	494	788	82	2	8	4	96	884
1964	290	472	762	82	1	7	4	95	858

[a]It should be noted that these figures are constructed from data taken from a wide variety of sources and contain very considerable estimative assumptions, so that too much reliance should not be placed on their precision.

[b]Based on the Gross National Product at market prices, as published by the Dominion Bureau of Statistics, according to the most-recently-revised figures for each year. Figures used (millions of dollars): 1953, 24,473; 1954, 24,871; 1955, 27,132; 1956, 30,585; 1957, 31,909; 1958, 32,894; 1959, 34,915; 1960, 36,287; 1961, 37,471; 1962, 40,575; 1963, 43,424; 1964, 47,403.

[c]Items may not add to total, because of rounding.

SOURCES: Table 14, and Dominion Bureau of Statistics, National Accounts Income and Expenditure, 1953–1964.

APPENDIX "B"

Ottawa,
January 27, 1967.

Dr. H. C. Harley, M.P.,
Chairman,
Special Committee of the House of Commons
on Drug Costs and Prices,
House of Commons,
Ottawa, Canada.

Dear Dr. Harley:

At my request, my Deputy, Dr. J .W. Willard, and other senior officials in the Welfare Branch of this Department met in Ottawa on October 12, 1966 with the representatives of the National Pensioners and Senior Citizens Federation whose President is Mr. Nathan W. Medd, 928 Spadina Crescent East, Saskatoon, Saskatchewan.

The purpose of the meeting was to discuss a brief which had been submitted to the Prime Minister, to myself and to all members of Parliament for consideration. The brief contained 18 resolutions which were passed at the Federation's annual convention held in Saskatoon on September 30 and October 1, 1966.

It might be of interest to you to know that the National Pensioners and Senior Citizens Federation has been in existence for about 20 years and comprises 8 provincial branches representing approximately 150,000 members.

It was felt that two of the resolutions contained in the brief would be of interest to the Special Committee of the House of Commons on Drug Costs and Prices and Dr. Willard informed the delegation that I would likely bring them to your attention for whatever action you might consider appropriate. The resolutions are worded as follows:

1. "WHEREAS the price of drugs and medical prescriptions are generally far too high for pensioners and others of low income, and appears to lay mind exorbitant; BE IT RESOLVED that we ask for an impartial government inquiry as to whether such prices are justified or necessary and, if found to be so, whether some system would be devised whereby they cou'd be made available free when necessary to those of the low income group."
2. "WHEREAS the high price of hearing aids makes it impossible for pensioners to purchase one, BE IT RESOLVED that we ask for a government inquiry as to whether such prices are justified or necessary."

I thank you for any consideration that you might give to these resolutions.

Yours sincerely,
Allan J. MacEachen.

APPENDIX "E"

Ottawa,
January 27, 1957.

Dr. H. C. Harley, M.P.,
Chairman,
Special Committee of the House of Commons
on Drug Costs and Prices,
House of Commons,
Ottawa, Canada.

Dear Dr. Harley:

At my request, my Deputy, Dr. J.W. Willard, and other senior officials in the Welfare Branch of this Department met in Ottawa on October 15, 1956 with the representatives of the National Pensioners and Senior Citizens Federation whose President is Mr. Nathan W. Medd, 228 Spadina Crescent East, Saskatoon, Saskatchewan.

The purpose of the meeting was to discuss a brief which had been submitted to the Prime Minister, to myself and to all members of Parliament for consideration. The brief contained 18 resolutions which were passed at the Federation's annual convention held in Saskatoon on September 30 and October 1, 1956.

It might be of interest to you to know that the National Pensioners and Senior Citizens Federation has been in existence for about 20 years and comprises 8 provincial branches representing approximately 150,000 members.

It was felt that two of the resolutions contained in the brief would be of interest to the Special Committee of the House of Commons on Drug Costs and Prices and Dr. Willard informed the delegation that I would likely bring them to your attention for whatever action you might consider appropriate. The resolutions are worded as follows:

1. "WHEREAS the price of drugs and medical prescriptions are generally too high for pensioners and others of low income, and appears to be, most expedient: BE IT RESOLVED that we ask for an impartial government inquiry as to whether such price is justified or necessary and, if found to be so, whether some system would be devised whereby they could be made available free when necessary to those of the low income group."

2. "WHEREAS the high price of hearing aids makes it impossible for pensioners to purchase one, BE IT RESOLVED that we ask for a government inquiry as to whether such prices are justified or necessary."

I thank you for any consideration that you might give to these resolutions.

Yours sincerely,

Allan J. MacEachen.

HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966-67

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

MINUTES OF PROCEEDINGS AND EVIDENCE

No. 33

TUESDAY, FEBRUARY 14, 1967

WITNESSES:

On behalf of the Government of the Province of Alberta: Mr. J. J. Frawley, Q.C., of Ottawa, Special Counsel; The Hon. J. Donovan Ross, M.D., Minister of Health; Dr. P. B. Rose, M.D., Deputy Minister of Health; Dr. Henry B. Steele, Ph.D., Houston, Texas, Associate Professor of Economics, University of Houston.

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

25611—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

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

and

Mr. Brand,	Mr. Howe (*Wellington-Huron*),	Mr. O'Keefe,
Mr. Clancy,	Mr. Hymmen,	Mr. Orlikow,
Mr. Côté (*Dorchester*),	Mr. Isabelle,	Mrs. Rideout,
Mr. Enns,	Mr. Johnston,	Mr. Roxburgh,
Mr. Forrestall,	Mr. MacDonald (*Prince*),	Mr. Rynard,
Mr. Goyer,	Mr. Mackasey,	Mr. Tardif,
Mr. Howe (*Hamilton South*),	Mr. MacLean (*Queens*),	Mr. Whelan,
		Mr. Yanakis—24.

(Quorum 10)

Gabrielle Savard,
Clerk of the Committee.

MINUTES OF PROCEEDINGS

TUESDAY, February 14, 1967.
(47)

The Special Committee on Drug Costs and Prices met this day at 9.45 a.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout, and Messrs. Harley, Howe (*Hamilton South*), Isabelle, Johnston, Mackasey, O'Keefe, Tardif.

In attendance: *On behalf of the Government of the Province of Alberta*: Mr. J. J. Frawley, Q.C., of Ottawa, Special Counsel; The hon. J. Donovan Ross, M.D., Minister of Health, Dr. P. B. Rose, M.D., Deputy Minister of Health, Dr. Henry B. Steele, Ph.D., Associate Professor of Economics, University of Houston, Houston, Texas.

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

Agreed,—That certain corrections to the printed record of Mr. Jules R. Gilbert's evidence before the Committee on December 13, 1966, being Issue No. 26 of the Committee's proceedings, be made at his request.

The Chairman tabled the following:

1. An article entitled "*Doctor's Choice: The Physician and His Sources of Information About Drugs*", by Raymond A. Bauer and Lawrence H. Wortzel, from the Journal of Marketing Research, Vol. III (February 1966), 40-47:

2. Two articles reprinted from the Canadian Medical Association Journal, entitled "*A Comparative Study of Some Brands of Tolbutamide Available in Canada*"

(a) Part I. *Clinical Aspects*, by Dr. J. B. R. McKendry, M.D., M.Sc., F.A.C.P., F.R.C.P. (C), and others; (92), 1106-1109, May 22, 1965);

(b) Part II. *Pharmaceutical Aspects*, by Dr. F. C. Lu, M.D., and others; (92, 1166-1169, May 29, 1965);

3. A paper entitled "*Physicians and Continuing Education—An Educational Trust—How Well Are We Fulfilling It?*" presented at the 59th Annual Meeting of The College of Physicians and Surgeons of Saskatchewan and The Canadian Medical Association, Saskatchewan Division, on October 20, 1966, by Dr. Donald H. Williams, M.D., of the Faculty of Medicine of The University of British Columbia;

4. A copy of Bill S-260 in the Senate of the United States, January 12 1967, introduced by Mr. Hart, "to strengthen the antitrust laws by prohibiting the sale by licensed practitioners of drugs, or devices, prescribed by such practitioners and knowing receipt of rebates, refunds, discounts, or

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commissions in connection with the supplying to patients of such products, with certain exceptions, and for other purposes";

5. Report on Survey of Dispensing Costs prepared on behalf of The Pharmaceutical Association of the Province of British Columbia, by Walter W. Fee, F.P.I.A., R.I.A., Management Accountant and Consultant, of Vancouver, October 1965.

The following documents were ordered printed as appendices to this day's proceedings:

(a) Letter dated February 13, 1967, from Mr. W. J. Blakely, C.A., Accountant for the Committee, enclosing six tables of statistics prepared for the Pharmaceutical Manufacturing Industry in Canada. (*See Appendix "A"*)

(b) Letter dated February 4, 1967, from Mr. Leslie L. Dan, B.Sc. Phm., Chairman of Canadian Drug Manufacturers, and additional description on the sales tax on pharmaceuticals. (*See Appendix "B"*)

(c) Letter dated January 31, 1967, from Mr. Douglas A. Denholm, B.S.P., Registrar of the Pharmaceutical Association of the Province of British Columbia, with reference to the brief presented by Mr. S. S. Bass to the Committee on November 17, 1966, and evidence given by him (Issue No. 19); (*See Appendix "C"*)

(d) Letter from Mr. C. A. Rogers, Vice-President and Managing Director, Parke, Davis & Company, Ltd. supplying additional information at the request of a member of the Committee; (*See Appendix "D"*)

(e) Table showing comparative prices of certain drugs in London, Paris, Berne, Rome, Bonn, Boston, Chicago, Los Angeles, and in Canada (*See Appendix "E"*)

The Chairman read a letter from Dr. Wm. W. Wigle, President of the Pharmaceutical Manufacturers Association of Canada.

Agreed,—That the request of the PMAC for another hearing be referred to the steering committee.

The Committee proceeded to the consideration of the submission of the Government of the Province of Alberta.

The Chairman introduced Mr. Frawley who introduced the other members of the delegation.

Agreed,—That the above submission be printed as an appendix to this day's proceedings; (*See Appendix "F"*)

Dr. Ross read an opening statement and was examined thereon.

Mr. Frawley made short remarks and tabled the following for the information of the Committee:

(i) An article from The American Journal of Economics and Sociology (Vol. 25 January 1966, No. 1), entitled "*The Fortunes of Economic Reform Legislation: The Case of the Drug Amendments Act of 1962*", by Henry Steele.

(ii) An article reprinted from The Journal of Law & Economics Vol. V, October 1962, entitled *"Monopoly and Competition in the Ethical Drugs Market"*, by Henry Steele.

(iii) An article entitled *"Patent Restrictions and Price Competition in the Ethical Drugs Industry"*, by Henry Steele.

Dr. Steele read a prepared statement and was examined thereon by the Members, by the Accountant and by the Legal Counsel of the Committee.

Dr. Ross was further questioned.

At 12:30 p.m. the Committee adjourned to 3:30 p.m. this day.

AFTERNOON SITTING
(48)

The Committee reconvened at 3:45 p.m., the Chairman, Mr. Harry C. Harley, presiding.

Members present: Messrs. Brand, Goyer, Harley, Howe (*Wellington-Huron*), Hymmen, Isabelle, Johnston, MacDonald (*Prince*), Mackasey, O'Keefe, Rynard (11).

In attendance: Same as at the morning sitting, with the exception of the Honourable Dr. Ross and Dr. Rose.

The Committee resumed consideration of the submission of the Government of the Province of Alberta.

Dr. Steele was further examined by the Members, by the Legal Counsel and by the Accountant.

At 5:45 p.m., the Committee adjourned to 8 o'clock p.m. this evening.

EVENING SITTING
(49)

The Special Committee on Drug Costs and Prices reconvened at 8:20 p.m., the Chairman, Mr. Harry C. Harley, presiding.

Members present: Messrs. Brand, Harley, Johnston, MacDonald (*Prince*), Mackasey, O'Keefe.

In attendance: Same as at the afternoon sitting, with the exception of Mr. Blakely.

The Committee resumed the questioning of Dr. Steele on the Submission of the Government of the Province of Alberta.

The questioning concluded, on behalf of the Committee the Chairman expressed appreciation to the Government of Alberta for having presented a submission, and thanked the representatives of the Province for having supplied additional information to the Members.

At 10:00 o'clock p.m. the Committee adjourned to the call of the Chair.

Gabrielle Savard,
Clerk of the Committee.

EVIDENCE

(Recorded by Electronic Apparatus)

TUESDAY, February 14, 1967.

The CHAIRMAN: Gentlemen, as we open the meeting this morning there are some administrative chores I would like to carry out first before we call on our witnesses today.

First of all in Issue No. 26, Mr. Gilbert who was appearing before the Committee that day has written us a list of corrections. We have gone over them, and they are not changes in testimony, they are merely corrections of some words that have been mistaken. As Mr. Gilbert apparently wants to distribute copies of this issue we are suggesting that the Printing Bureau actually print this as a slip in that will go in the next issue printed. This will not be done at the expense of the taxpayer.

Mr. MACKASEY: Are you satisfied that it does not change the testimony here?

The CHAIRMAN: They are mostly corrections of names and spelling errors, and I do not think there is any change of meaning in any of the changes that are listed. Is it agreed.

Some hon. MEMBERS: Agreed.

Mr. HOWE (*Hamilton South*): As you realize that the proceedings come out many weeks after the meeting has taken place. I have seen some very obvious errors in things that I have said, errors in spelling and so on. In this case, are the proceedings reprinted or not?

The CHAIRMAN: The only way of catching a mistake is to read the transcript before it is printed.

Mr. HOWE (*Hamilton South*): How does one find out when the transcript is available? I have never been notified of this and there have been many errors.

The CHAIRMAN: We normally do not notify the members, but we do notify the people who appear before us, and tell them when they may see the transcript, but members are on their own I suppose. Have some of the printed copies had errors in your testimony?

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

The CHAIRMAN: If there are any glaring ones, I am sure we could do it the same way by putting an insert in the next issue. Do you want to do it that way?

Mr. HOWE (*Hamilton South*): When I get time, Mr. Chairman, I will go through all the evidence and try to find the errors.

The CHAIRMAN: There are some articles and reprints that I think I should like to table with the Clerk and if any member of the Committee wishes to study these, they are available at the Clerk's office. One is called "The Doctor's Choice"; "The Physician and His Sources of Information About Drugs"; "A

Comparative Study of Some Brands of Tolbutamide Available in Canada"; "Physicians and Continuing Education—An Educational Trust—How Well Are We Fulfilling It?" I think this is the article that you referred to, Dr. Howe. It is on paying for continuing doctor education.

Mr. HOWE (*Hamilton South*): Is that being printed?

The CHAIRMAN: No; I am putting this in the hands of the Clerk and if anyone wishes to study it, it is there.

Bill No. S-260 which Mr. Mackasey asked for, a bill of the Senate of the United States which would prohibit practitioners from participating in drug-stores and so on.

Mr. HOWE (*Hamilton South*): What is the name of the Senator who is responsible for that?

The CHAIRMAN: Senator Hart.

There is a report on the survey of dispensing costs prepared on behalf of the Pharmaceutical Association of the province of British Columbia and there is some other material that I would like to have included as part of today's record: first of all, a letter from the Committee's accountant, Mr. Blakely. As you remember, I asked Mr. Blakely to prepare certain tables concerning tax statistics and this sort of thing. Mr. Blakely, who is here, has just written me a letter and I quote:

> As requested, I have prepared six tables of statistics for the Pharmaceutical Manufacturing Industry in Canada showing comparisons to the corresponding statistics for all the Canadian manufacturers, three copies of each table are enclosed.

I would like to have that made part of today's record. Is that agreed?

Mr. MACKASEY: Is there any way we can get this information. There are some very revealing statistics in this book?

The CHAIRMAN: I have three copies here and if you wish a copy, we could probably have it reproduced within the next 15 minutes.

Mr. MACKASEY: If we could have it photostated, it might strengthen the arguments in this brief and it might not.

The CHAIRMAN: This was in answer to many questions that have been brought up, and Mr. Orlikow's motion asking that we consider whether the pharmaceutical industry is making more profit than other manufacturing industries.

Mr. O'KEEFE: Mr. Chairman, in connection with those corrections, how is this not done at public expense?

The CHAIRMAN: I understand Mr. Gilbert is going to pay for the insert, and it will become part of the record.

Mr. O'KEEFE: You are satisfied with that?

The CHAIRMAN: Yes. It will become part of the record.

Mr. MACKASEY: Mr. Chairman, just for clarification on the insert which will be sent out; obviously Mr. Gilbert is going to send out, at his own expense—and that is his privilege—copies of the proceedings when he was here.

The CHAIRMAN: That is right, at his own expense.

Mr. MACKASEY: In addition, he has come across certain errors in spelling, grammar and reference that he would like to rectify and attach to the brief. Will we print these changes, at his expense?

The CHAIRMAN: We will print them in the next issue that comes out.

Mr. MACKASEY: How will we make certain that the explanation or the changes that go out with the brief are the ones which are printed by the government. In all fairness to Mr. Gilbert, and in all fairness to you, Mr. Chairman, we cannot give him blanket approval to make whatever changes he thinks should be made in the testimony. This is the point I am getting at.

The CHAIRMAN: Normally the witnesses who appear before the Committee have free access to the transcript and do make grammatical changes. In this case it was not possible for Mr. Gilbert to do so.

Mr. HOWE (*Hamilton South*): Then why should it be at his expense?

The CHAIRMAN: I should have said that the copies, and so on, which he gets, will be at his expense. Actually the little insert itself, I am sure, will be printed just as part of the normal record.

Mr. MACKASEY: I think Dr. Howe has made a very good point. If there are errors, I think we should look after the printing free of charge. At the same time, there are one or two changes here that I would like to check out before I give my approval. I am sure everything is just the way it should be, but I would like—

Mr. HOWE (*Hamilton South*): Mr. Chairman, I hope this is in line with the same thing. Eventually this Committee will be making recommendations which will involve a meeting or many meetings—

The CHAIRMAN: Many meetings.

Mr. HOWE (*Hamilton South*): Conceded. Will we have all these printed proceedings in front of us before we make these recommendations. In all fairness, we should have.

The CHAIRMAN: I would think so. I do not think we are running that far behind now.

The CLERK OF THE COMMITTEE: Everything is typed; it is the editing that is late.

The CHAIRMAN: How many issues behind are we?

The CLERK OF THE COMMITTEE: Two or three.

The CHAIRMAN: We are only two or three issues behind.

Mr. HOWE (*Hamilton South*): Certainly, I would hate to be one to make recommendations without the inclusion—

The CHAIRMAN: I am sure by the time our Committee report is ready, the reports will all be finished.

Mr. HOWE (*Hamilton South*): This is only fair. As I say, this is presumably our last series of meetings, considering today's brief and this, in my opinion, should not be left out of our considerations.

The CHAIRMAN: I am sure we will be able to arrange that.

Mr. MACKASEY: Mr. Chairman, after having seen the corrections referred to, I am quite satisfied the changes are in order.

The CHAIRMAN: Does anyone else want to study these changes?

Mr. HOWE (*Hamilton South*): We have confidence in Mr. Mackasey's perusal, in this regard.

Mr. MACKASEY: Thank you, Dr. Howe, for your confidence, I hope it is not misplaced.

Mr. HOWE (*Hamilton South*): I just said "in this regard" Mr. Mackasey.

The CHAIRMAN: I hope you remain as nice to one another the rest of the meeting.

The other material I have that I would like to become part of today's record is a letter from the Pharmaceutical Association of the province of British Columbia, commenting on the testimony of Mr. Bass. It is a five page letter that I think should become part of the record.

There is also a letter from Parke, Davis & Company Ltd., concerning f.o.b. prices of five products that Dr. Howe had inquired about, discusses f.o.b. products Canada and f.o.b. products elsewhere. That also should become part of today's record. Is that agreed?

Some hon MEMBERS: Agreed.

Mr. MACKASEY: Mr. Chairman, is there a possibility of obtaining the five page letter, which again may have some bearing on this very full brief which is in front of us. There are references in the Brief to Mr. Bass' evidence, if I recall correctly.

The CHAIRMAN: There is only one reference that I can recall offhand, and the letter has a great deal to do with the training of pharmacists, but if you wish we can have it copied.

Mr. MACKASEY: I would like it, because the brief has a lot to say—and refreshingly so—about the druggsits in general, as part of the over-all problem.

The CHAIRMAN: We can arrange to have that done.

There is also a letter from Mr. Dan, the Canadian Drug Manufacturers. It is a small two page discussion on federal sales tax. As you can appreciate, I am trying to get all these things in on the last official day.

I also have in my possession drug prices of 12 products, the same 12 products we have discussed before. These are retail prices of drug products and the 12 listed are: Chloromycetin, Achormycin, Gantrisin, Pentids, Decadron, Librium, Equanil, Enovid, Butzaloidin, Mobenol, 222's and Premarin. These are comparative prices in London, England; Paris, France; Berne, Switzerland; Rome, Italy; Bonn, Germany; Boston, Chicago and Los Angeles in the United States.

Mr. HOWE (*Hamilton South*): Mr. Chairman, these are actual prices, these are not Dr. Briant's adapted prices?

The CHAIRMAN: These are actual prices of drugs bought in those localities.

Mr. MACKASEY: Mr. Chairman, who prepared that?

The CHAIRMAN: The list of drugs was prepared by the Chairman.

Mr. MACKASEY: I am not questioning the fact, because I think it is valuable evidence, but who did this research; is this done by the Committee, or by a group?

The CHAIRMAN: No; it was done by a source in whom we can have confidence. The only problem is that in some of these countries, I understand, they have a law against disclosing what prices might be in any particular country. It brings up the point, if we do disclose the source, whether we put someone in a very embarrassing situation.

Mr. MACKASEY: In all fairness,—I have not seen the prices—is is obviously going to put someone in an embarrassing position, either the generic firms or the brand names, and since we are putting someone—

The CHAIRMAN: These were all brand name products. They were not generic names.

Mr. MACKASEY: This is not my point. The testimony in the particular set of figures is obviously very relevant. I would like very much to know the source.

The CHAIRMAN: I do not see how I can disclose it.

Mr. HOWE *(Hamilton South)*: Mr. Chairman, I will accept your faith in the source without having to divulge it. The material should be added to our voluminous records. I cannot see where it does any harm to anyone, and I do not know the figures, and I do not see why this cannot be incorporated in our records.

The CHAIRMAN: I have not checked the figures myself.

Mr. MACKASEY: If you tell me that it comes from the Food and Drug Directorate, then I am quite happy to accept the figures without question. That is all you have to say, because obviously that is where you got the information.

The CHAIRMAN: I will say that it is from a government department.

Mr. MACKASEY: Fine, that is all I want to know. I thought it was from a private source—

The CHAIRMAN: It is not a private source; it is from a government source.

Mr. O'KEEFE: I do not think, Mr. Chairman, that we are overly worried about embarrassing anyone. Apparently they embarrass themselves.

The CHAIRMAN: The only other piece of correspondence that I have is from the Pharmaceutical Manufacturers Association of Canada and it states:

> During the recent appearances of various government groups before your Committee, testimony was given that is in direct conflict with evidence presented by our Association in our appearances in June and November. In addition, certain critical new issues have been raised which we would very much like to have an opportunity to comment on.
>
> In the interests of fairness, we respectfully request the opportunity to appear once more to offer further testimony on these matters. I appreciate that the hearings have been protracted and that you are under some pressure of time to conclude them. Our appearance, however, could be

very brief, possibly one hour on Thursday, February 16th. Because of the time element involved, I am sending you this by courier, and would very much appreciate your consideration.

It is signed, Dr. Wigle, President, PMAC. Are there any comments?

Mr. HOWE (*Hamilton South*): Yes. This would be an endless procedure as to who is going to be last. We have accepted their brief and we have accepted their testimony and I think it should be up to us to decide between the two which is right. I cannot see that we can keep on having people back to contradict other people's evidence and never end this Committee.

Mr. MACKASEY: Mr. Chairman, I think Dr. Howe has a very valid point in that the Committee meeetings could go on forever. I agree with Dr. Howe. After three years of hearings I have been looking forward to sleeping in one morning of the week and not have to be here at 9.30. I am just wondering what has agitated the PMAC to such an extent. Frankly, Mr. Chairman, my curiosity has been aroused. I certainly agree that we should not be prolonging things, but at the same time, in view of the fact that most of the testimony has been directed, and properly so, against the PMAC, it is quite conceivable that they have something that will make our judgment a little easier to render. If Dr. Wigle promises that his appearance will be limited to only one of our meetings, then I have no objection to spend another hour. I have said that at every meeting, I do not mind spending all night if we are learning something.

Mr. HOWE (*Hamilton South*): We are never going to be able to finish questioning any witness inside of an hour.

Mr. MACKASEY: Mr. Chairman, last week we met here at 1.10 p.m., and we started at 1.25 and within an hour—2.20 p.m.—after the witnesses had had their opportunity to speak, just Mr. Howe and myself were left here. So if we are going to get into the question of not being able to do anything in an hour we would have to abolish the testimony of about 90 per cent of our hearings.

The CHAIRMAN: We certainly have no objection to receiving further testimony from the PMAC. I will make two suggestions and one of the two suggestions will probably be preferable. First of all, that we receive a written submission frm them. If the Committee members would rather hear them, then perhaps we could do with what we did with the Food and Drug Directorate and have their appearance from 1.00 p.m. to 2.30 p.m. and this would give them an hour and a half. It would certainly meet their request for an hour.

Mr. HOWE (*Hamilton South*): Mr. Chairman, in all fairness, this is going to open up the whole thing again. It is not going to be limited to the points that the PMAC group alone want to bring up. Now, that is not fair to us. It is going to open up both sides of the issue again on many lengthy briefs and testimony that we have had. I cannot see the limitation of this in defence of one point. I cannot see where it can be limited to that. I think your idea of a submission in writing is a good one and then we can decide whether we should or should not see them.

The CHAIRMAN: Is there any other feeling on that or does the Committee wish the Chairman to discuss this with the steering committee?

Mrs. RIDEOUT: I would suggest that perhaps the steering committee should decide instead of wasting time in the Committee right now.

Some hon. MEMBERS: Agreed.

The CHAIRMAN: Now, we will get down to today's witnesses. We apologize to them for taking a little time to get the paper work straightened away. As this is potentially our last meeting these things had to be part of today's record.

I will introduce a gentleman who is well known to the members of the Committee because I think he sat in the audience most of the days that we have met—Mr. Frawley, who is the special counsel to the executive council of Alberta who, in turn, will introduce the other witnesses.

Mr. J. J. FRAWLEY, Q.C. (*Special Counsel in Ottawa for Government of Alberta*): Mr. Chairman, Mrs. Rideout and gentlemen, thank you very much. All I want to do at the moment is tell you who is here. We have with us today the Hon. Dr. J. Donovan Ross, the Minister of Health in the Province of Alberta; his deputy minister, Dr. P. B. Rose is with him, and Dr. Henry Steele, Associate Professor of Economics at the University of Houston, in Houston, Texas. Dr. Ross would like to lead off with a short preliminary statement. I would ask Dr. Ross to please do that now.

Hon. J. DONOVAN ROSS, M.D. (*Minister of Public Health, Province of Alberta*): Mr. Chairman, Mrs. Rideout and gentlemen. My presence here this morning along with my Deputy Minister, Dr. P. B. Rose, is to indicate to you and through you to the people of Canada the concern we feel as a provincial government, and the importance we place upon the subject of your enquiry.

Alberta's Special Counsel in Ottawa, Mr. J. J. Frawley, Q.C., and myself, on behalf of our Government have on the occasions of the Restrictive Trade Practices Commission and Royal Commission on Health Services for Canada submitted briefs in regard to drug prices, and we are appreciative of the opportunity afforded us to appear before your Committee today.

In order that our submission might perhaps prove to be helpful in your deliberations and findings, and eventual recommendations to the Government of Canada, we searched around on this continent to find some person whose knowledge and educational background might enable our presentation to be a useful and unbiased source of information, and in the submission being made by Professor Henry Steele of the University of Houston in Texas, on behalf of my government, I believe you will find such a document.

The interest of the Alberta Government in the field of drugs has been one of long standing and has been a result of the inordinately high retail price of drugs, which in many cases are of a life-saving or life-sustaining nature and which must be continued in use for months or years and which results in a financial burden that many citizens find themselves unable to cope with. As a result, they perhaps naturally turn to their government seeking assistance.

Shortly after insulin became commercially available, the Alberta government provided it to their citizens with limited financial resources, on the prescription of their doctor, and since the advent of oral hypoglycemic agents, these as well have been provided. During the past ten years the Department of Health in Alberta has developed a number of special drug programs. One provides penicillin, sulfonamides and in some cases wide spectrum antibiotics to any Alberta resident up to the age of 18 years, who was considered by a medical advisory committee to have rheumatic fever, in order to lessen the incidence of

recurrent attacks. Another program provides Lofenalac (a dietary supplement) for children suffering from the metabolic disturbance of phenylketonuria, up to six years of age, in order that the mental retardation, that will almost certainly occur if the patient does not receive treatment, may be prevented. Any Alberta child suffering from cystic fibrosis is entitled to receive from the Department of Health supplies of various types of wide spectrum antibiotics and pancreatic enzyme material as prescribed by their doctor.

These programs of supplying drugs required for long periods of time, to maintain health and in some cases life itself, were instituted because it became apparent that the cost to the individual citizen through normal retail channels of supply was of such a magnitude that an adequate or medically desirable program often could only be obtained by depleting savings, going into debt, denying other members of the family, or doing without an adequate program of prescribed drugs.

The fifty to sixty thousand dollars a year we spend as a Government to obtain and distribute these drugs would in our estimation cost the individual citizens at least five times what we are spending to provide them.

We also provide a wide range of tranquillizers to mentally ill patients who have been discharged from our own provincial hospitals and who require a continued medication on the prescription of the doctor.

The total number of people benefitting from our special drug programs may not be a very significant percentage of our total population—only some 2,800 out of 1½ million—but for those individual citizens who require these drugs to maintain their health over many years, the financial impact is a very real and serious one.

With the increasing likelihood of a health care insurance program becoming an accomplished fact across our nation, in which a drug benefit program may well be included, if not initially at least in the future, it is my firm conviction that the problem you are applying yourselves to now takes on an even greater urgency.

Most of us are well aware of the too often indifferent attitude taken by the public in regard to the costs involved in "so-called free", state or society supported programs, which may well be the form of our own national medicare.

If drug benefits do become available under a national health care program, as we have done in our own Alberta Health Plan, then the costs involved through the normal retail pharmacy outlets could well become a sum of considerable magnitude unless the prices from the pharmaceutical manufacturing industry are very drastically changed from what they are today. The public, whom we in government represent, should not be lulled into a false sense of security in regard to the costs involved in their health care by the suggestion that a national medicare program will take care of the problem.

It is because of our concern as a government representing the people of Alberta that we are here today before your Committee to provide information and suggest certain measures that we believe would prove of great benefit not only to our own citizens but to the people of Canada as a whole.

I wish to thank you, Mr. Chairman, and members of the Committee, for this opportunity of being present today to bring to you the benefit of a study made by Professor Steele on behalf of the provincial government of Alberta. We believe

that this presentation can be beneficial to you and we hope that the end results of your deliberations will prove of benefit to the people of our country. Thank you.

The CHAIRMAN: Thank you very much, Dr. Ross.

Mr. MACKASEY: Mr. Chairman, I have one or two questions with respect to this statement. May I ask them now? Dr. Ross, it is only one of curiosity because I think your province should be congratulated on its desire to help people in the cost of drugs. I am intrigued by the word "Lofenalac". Is this a generic or brand name. Is this the right spelling. I have never come across it.

Dr. ROSS: Yes, it is a brand name. I believe it is the correct spelling—l-o-f-e-n-a-l-a-c. Mead Johnson put it out. It is a powder with—

Mr. MACKASEY: It is a by-product of Pablum.

Dr. ROSS: Yes.

Mr. MACKASEY: Thank you.

Mr. HOWE (*Hamilton South*): Would you say that the need for tranquillizers has decreased since the worry of acquiring the money to buy them has been eliminated?

Dr. ROSS: Mr. Chairman, Dr. Howe, I would not think that there has been any decrease in the number of tranquillizers provided because of the fact that they are being provided free.

Mr. FRAWLEY: As the Committee is aware, the province of Alberta made representations respecting the price of prescription drugs first to the Restrictive Trade Practices Commission and then to the Hall Royal Commission on Health Services. When this Committee was turning its attention to costs and prices of drugs I asked the Minister of Health for instructions and I was instructed to prepare a case for presentation to this Committee.

I ran across some articles written by Dr. Henry Steele and I was impressed with the knowledge of the economics of the drug industry which those articles disclosed. I might stop here and indicate that I took the trouble to provide myself with only five or six copies of these three articles and, as far as they will go, I will be very glad to make them available to the Committee. One appeared in *The Journal of Law and Economics* published by the University of Chicago. The article is called "Monopoly and Competition in the Ethical Drugs Market." The other one is entitled "The Fortunes of Economic Reform Legislation: The Case of the Drug Amendments Act of 1962" and it appeared in *The American Journal of Economics and Sociology.*" The third one is called "Patent restrictions and Price Competition in the Ethical Drugs Industry" and appeared in the *Journal of Industrial Economics,* published in England. As I have said the members of the Committee are welcome to have these articles to peruse and keep if they are interested.

I felt that an economist so well informed concerning the industry in the United States would be able to do the sort of study of the Canadian industry, in both its domestic and international aspects, that is required. I had in mind, of course, the fact that just recently the last of our major Canadian firms had passed into United States ownership, and I, therefore, was not at all alarmed that I was proposing to have an American economist do this study for us. I proposed

this work to Dr. Steele, and he accepted the assignment. The result is the submission which we have filed with the Commission. Dr. Steele is here from Houston to present the submission. He has made a summary of his submission, and I now will give place to Dr. Steele.

The CHAIRMAN: Before Dr. Steele speaks, is it agreed that we print his statement and today's brief as part of today's record?

Some hon. MEMBERS: Agreed.

Mr. MACKASEY: Mr. Chairman, on a point of procedural information, there was a question that I would have liked to address to the Province of Alberta, and I do not know whether to do it through Mr. Steele or direct it to Dr. Ross.

The CHAIRMAN: Had the question any relevance to the brief?

Mr. MACKASEY: Well, in a way it could. In the back of the brief, I think in Appendix E, I may get my Appendix wrong as there are so many of them, there appears:: "An Act to amend the Alberta Pharmaceutical Association Act". Dr. Ross indicated he would like to answer that.

Dr. ROSS: I think probably I might be able to answer that rather than Professor Steele, since I am responsible for the act.

Mr. MACKASEY: Yes, I know, and I was quite intrigued by that. Essentially, Dr. Ross, as I understand it, it permits the druggists—I use the word druggist instead of pharmacist, if I may—to substitute generically for brand name prescriptions unless specifically ordered otherwise by the doctor. And I believe, at the time, you expressed the hope and desire that this would bring down the cost of prescriptions. What has been your experience?

Dr. ROSS: Quite frankly, Mr. Chairman, I have been disappointed in the fact that doctors have not made use of this opportunity of permitting druggists to perhaps have fewer numbers of brands of the same drug on their shelves as they have to have when they fill the prescription of a number of doctors for any one of perhaps 10 to 12 similar drugs under different names. There have been some doctors who have made use of the change in the act, and some druggists who have done so as well. I think, I would have to say on the whole, though, the expected desired result of our change in legislation did not accomplish what we had hoped it would.

Mr. MACKASEY: Because the doctors have refused to go along with the spirit of the act.

Dr. ROSS: Well, you said it, I did not. I would have to say this, though, the doctors are the ones that write the prescriptions and that they are the ones that say "no substitution" on the thing, and they are responsible for not making use of this beneficial part of the act.

Mr. MACKASEY: Dr. Ross, are you a medical doctor?

Dr. ROSS: Yes, I am. I had been a practitioner for 20 years before—

Mr. MACKASEY: Do you feel that in the final analysis, in view of your experience with this act, that it lies within the ambit of the doctor, to prescribe whatever he feels is in the best interest of his patient?

Dr. ROSS: I would say that this is his responsibility.

Mr. MACKASEY: His duty?

Dr. ROSS: Yes, it is his duty to consider all aspects of his patients' health, their physical, mental and financial—

Mr. MACKASEY: Would you feel then this is the reason why so many doctors have insisted—they are exercising their privilege or their right as a doctor to prescribe what they think is in the best interest of the patient.

Dr. ROSS: I would say in many cases they think in terms of two or three names of a drug that has been brought to their attention by the advertising put out by pharmaceutical companies, and they remember a name and write it down.

Mr. MACKASEY: Could it also be because of past experiences with a specific drug that has resulted in a—

Dr. ROSS: I would not think so.

Mr. MACKASEY: In other words, you feel that if a doctor last week prescribed a drug, brand or generically, that had happy results, then he would not be inclined the next time a similar case came along, to prescribe the same drug?

Dr. ROSS: I have never felt that a doctor is closely aware really of the effects of drugs on his patients, as perhaps you are suggesting, doctor.

Mr. MACKASEY: Well, I am only a layman, doctor. Are you telling me that a doctor does not follow up to see what effect a drug has on his patient?

Dr. ROSS: No, if you are suggesting that he is aware of any small adverse effects or small beneficial effects; I think the general effect he is aware of, or should be.

Mr. MACKASEY: In other words, if the drug that he prescribed is not doing the job, naturally he would want to try something else.

Dr. ROSS: This is correct.

Mr. MACKASEY: One last question sir, then Dr. Howe can get his supplementary in unimpeded. Do you know—I know, but I am wondering if you do—the average cost per prescription in Alberta as compared to other provinces, at the present moment?

Dr. ROSS: I am aware that about 90 per cent of the druggists in Alberta are using their cost, plus a prescription fee, so that the average price of prescriptions in Alberta is somewhere between $3 to $5.

Mr. MACKASEY: Do you have any first hand knowledge of how this compares to provinces where such an act does not exist?

Dr. ROSS: I have no knowledge, no, sir.

Mr. MACKASEY: Well, if I recall the evidence of the Pharmaceutical Association, it is a little higher in Alberta than in most provinces. Thank you, doctor.

Mr. HOWE (*Hamilton South*): What I wanted to ask, Mr. Chairman, was, do you think that the doctor is subject to any external forces that cause him to prescribe certain drugs over certain others by name? In other words, do you think that he is persuaded by the drug companies' advertising, and this is what really determines what specific drug he will write a prescription for?

Dr. Ross: I think, doctor, that the ease of recalling any drug for certain illnesses is something that is useful to a doctor, and if a drug company comes up with a simple catchy name, he remembers that more easily than he does some of the other names. I think that the advertising of drug companies does have a certain effect.

Mr. Howe (*Hamilton South*): So it does not necessarily have any bearing on the efficacy or anything to do with that drug, nor the price. It is, as you say, the catchy trade name that the doctor remembers?

Mr. Mackasey: This is why you have got Lofenalac in your own paper rather than the generic name.

Dr. Ross: We have Lofenalac in there because there are only two companies who make it, and Mead Johnson gave us the best price, sir.

Mr. Mackasey: I should hope so.

Mr. Howe (*Hamilton South*): From the sound of it you are as guilty as some of the doctors that write their prescriptions.

Dr. Ross: Well, this is a clear—

Mr. Mackasey: You do not get my point, Dr. Howe.

Mr. O'Keefe: Mr. Chairman, may I say that I would be frightened if I thought that my doctor was prescribing for my children on the basis of a catchy trade name. Would the detailmen have any effect on the doctor's choice of drugs for prescription? We have heard quite a lot about the detailmen.

Dr. Ross: I think he could. There is the kind of doctor who believes that the detailman is doing his job. You have let him into your office and you take time to sit down and have him tell you about his product which he is bringing to your attention.

Mr. Howe (*Hamilton South*): Would you say the detailman is a prejudiced man?

Dr. Ross: He is trying to sell the product of his particular company, so I suppose he would have a certain bias towards the products of his own company.

Mr. O'Keefe: But surely, doctor, the detailman is not prescribing for patients, rather than a doctor.

Dr. Ross: No; the doctor is doing the prescribing, but I think that the knowledge regarding drugs the detailman puts before a doctor, does play a part in what the doctor prescribes for his patient. When he comes up against a case that requiries a particular drug, he recalls what this particular detailman said to him, as I say, a catchy trade name; he remembers it, and says "Oh, I will try this."

Mr. O'Keefe: I am very interested to what degree the detailman affects the doctor.

Dr. Ross: This is hard to say. I think it depends on the doctor himself and how he is affected by this. If he is an "easy sell" doctor, well, I think that perhaps he is more affected by it than some who are "hard sell" doctors.

Mr. O'Keefe: In your experience doctor, are there many "easy sell" doctors?

Dr. Ross: I only looked after my own business as a doctor practising medicine, I did not really try to determine what my colleagues were doing, Mr. Chairman.

Mr. Howe (*Hamilton South*): Would you say that these detailmen have the ability to insidiously disparage, and I quote "generic drugs" in their type of conversation with doctors when they are in the office. I said "insidiously" purposely.

Dr. Ross: Perhaps my memory, because of age and distance, from having been in practice—I have been out of practice for some 10 years—makes it difficult for me to really recall the detailman's pitch to me, as a doctor.

Mr. Howe (*Hamilton South*): Where would this disparagement come from if it did not come from the detailman?

Dr. Ross: Yes, I would think that the disparagement of other companies' drugs, would have to come from the detailmen. I do not think that the drug companies would take the chance of putting it down in black and white in print—

Mr. Mackasey: You said "other companies' drugs", but not necessarily other generic companies. In other words, someone pushing Stelazine might have something derogatory to say about a substitute. I share your concern, Dr. Ross, about detailmen. I think our recommendation should include some type of schooling or academic level for detailmen, and take them out of a classification of salesmen into professional advisers. I think this is an area that we must do something about. But since Mr. Steele has a lot to say about detailmen in his brief, perhaps we could pursue it then, Mr. Chairman.

The Chairman: I was going to say, I think the questioning at the moment is really putting the Minister of Health on the stand as a doctor. He is not really here in that capacity; he is here as a representative of the government of Alberta.

Dr. Ross: I am here really as a politician, like all of us are, at least all of us around here. However, I can never get away from the fact that I am a doctor first and foremost, and I am concerned as a doctor. And one of these years I may have to be back practising as a doctor.

The Chairman: I was going to say, one of the reasons why the Chairman has let the questioning go on, is that I happen to know that Dr. Ross has to return to Alberta this afternoon, so that anybody had any questions for him, he should ask them. Dr. Steele, is going to be here, I think, later on.

Mrs. Rideout: Could I ask a supplementary, please, Mr. Chairman? I met Dr. Ross before, and I know that he is a family man aside from being a politician, and he has children. I remember seeing a picture of a very beautiful young baby when you were here last. Would you not be a little alarmed if you thought that some doctor was prescribing for your children a drug because it had a catchy name?

Dr. Ross: No, no. Because I would still have faith in the doctor I would choose to look after my family; although he might use a catchy name to recall a drug, this could be useful for an illness of my child. I am not saying that he just remembers a name, having heard it; he retains in his memory that particular

drug for that particular use. However, like most doctor's families, I use the doctor's book.

The CHAIRMAN: I should perhaps point out and I think this is often true for instance, where a generic name is unpronounceable, a very simple one may be called Tolbutamide, most people would find it much easier to think of Mobenol or Orinase, than use the generic name, Tolbutamide.

Mr. O'KEEFE: Does the customer find it is easier to pay for that?

Dr. ROSS: It is the same price, exactly.

Mr. ISABELLE: I have a question for the Minister of Public Health, Alberta. He said that he was very much disappointed at the amendment—

Dr. ROSS: The lack of utilization of the amendment.

Mr. ISABELLE: Yes, the Alberta Pharmaceutical Association Act, you were very disappointed in the fact that doctors did not seem to prescribe by the generic name, and did not let the pharmacist fill the prescription, as it were—In other words, they were prescribing the brand name. They probably phoned the druggist not to use the generic name. According to the law, if the doctors would let the pharmacist do whatever they please, they could have used a generic name instead of a brand name in their prescription. We were told here, that it was not the doctors, but it was rather the pharmacist who did not want to take the onus of using a generic name drug when filling their prescription. Is that correct?

Dr. ROSS: Partly, both ways, that the doctor sometimes puts down "no substitution" and the pharmacist did not want to take the responsibility of changing what the doctor put down in his prescription to another drug, alhough it was the same drug under either a different trade name brand, or the generic name.

Dr. HENRY B. STEELE Ph.D. (*Associate Professor of Economics, University of Houston. On behalf of the Government of the Province of Alberta*): I would like to begin by correcting an error which Mr. Blakely pointed out to me about half an hour ago. It is an arithmetic error on page 5 or Appendix A; it is on page 129 of the entire brief. This is an arithmetic error on line 6 of page 129 which reads: "5/6 of $1.32, or $.933." It should read: "5/6 of $1.32, or $1.10" instead of $.933. This means that the other computations in the paragraph are incorrect. The only other correction I would wish to make, is that at the very last line of the paragraph, the 2.8 per cent should read 3.28 per cent. Then, also in Appendix A, on page A-1 or page 125 of the brief in the third paragraph, beginning:

Let the retailer's markup be assumed initially—

In line 4 of that paragraph, I make the statement: "it is obvious that P-2C". It should read: "it is obvious that P=2C". And, one last correction on page 139, that is, Appendix B, page B-5, the last but one line of the first full paragraph on this page, the figure of 4.17 per cent should be changed to read 41.7 per cent.

I will begin my statement by making the obvious remark, which is that I wish to apologize for the length of the brief, and for compounding the offence by having to summarize it in a relatively lengthy statement.

When asked by the government of the province of Alberta to prepare this submission, I learned by recourse to the orders of reference of this Committee

that it was resolved "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." The presentation of a comprehensive program to reduce drug prices necessarily requires a lengthy document. Furthermore, very few of the briefs presented before this Committee have dealt directly and consecutively with the economies of the drug industry—that is, with drug costs and prices as such. In fact, the Consumers' Association of Canada is the only group which proposed an integrated program of economic reforms aimed at the reduction of drug prices. Under these circumstances, I felt that the submission of the government of the province of Alberta could best be devoted to a detailed analysis of the economic factors affecting drug supply and demand, and hence drug prices, and to the development of a group of recommendations designed to permit a reduction of drug prices.

By how much can the price of drugs be reduced? It is interesting that the orders of reference for this Committee take it for granted that drug prices are too high, since they simply contemplate the recommendation of an effective program to reduce the price of drugs. To determine whether drug prices are too high, and hence can and should be reduced, it would be desirable to compare present drug prices with the prices which would be charged by drug firms in an efficiently competitive drug industry. Under efficient competition, prices would be just sufficient to cover costs of production and distribution, plus a rate or return on investment which is no higher than is necessary to elicit the required capital investment.

But how can one estimate the prices which would be charged by an efficiently competitive drug industry? For the most part, only indirectly. The production costs for individual drugs produced by the major firms should cast more light on the matter than any other set of data—if only these could be obtained. Since the Committee did not obtain and publish data on drug production costs of the major firms, one has only the choice of using the best available substitute data, or of speculating in an economic vacuum.

The former alternative seems preferable. Consequently, cost-price comparisons have been made, wherever possible, by comparing recent Canadian drug prices with two types to cost data. First, recent drug prices can be compared with current drug production costs, to the extent that statements have been made by witnesses appearing before this Committee which identified certain costs or at least permitted some approximation of their magnitudes. Unfortunately, there are only a very few such instances. Second, recent Canadian drug prices may be compared with Canadian drug costs as reported in the "Green Book," which is the only publicly available source of any Canadian drug cost data. Since these cost figures date from around 1960, however, it is likely that some loss of comparability is associated with their use, although the degree of such loss cannot be determined. Moreover, the data in the "Green Book" refer frequently not to actual factory costs, but to prices paid for the imported bulk chemicals. Since many of these chemicals were imported from United States parents of Canadian subsidiaries, one may consider the reported Canadian import and production costs in conjunction with the computed costs of the same drugs as calculated for the United States producers by the Kefauver Subcommittee Staff, in those few instances where such data is available for the same drugs at about the same period in time.

A comparison of prices and estimated costs for all the drugs for which any basis for making comparisons exists, indicates that the ratio of production costs to prices ranges very roughly from about five per cent to about twenty-five per cent of the price received by the manufacturer on sales to wholesalers. There is some clustering of the observations in the ten to fifteen per cent range. This is an unusually low ratio of production cost to price received.

The Pharmaceutical Manufacturers Association of Canada has presented evidence on the breakdown of the manufacturer's sales dollar, which shows that about 30 per cent went to manufacturing costs. This does not refer to any individual product, but to the average for all products included in the PMAC survey. Since this ratio is about twice the average cost estimated for the group of single drugs considered just above, one wonders about the discrepancy. It is possible that the drugs in the former group had a ratio well below the average of all prescription drugs, but it is also possible that the PMAC calculations average in the experience of all sorts of products sold by drug firms, and do not segregate packaged prescription pharmaceuticals for human use from bulk drug sales, veterinary products, feed supplements, and other lower profit margin items with which the Committee is not as directly concerned. Also, combining margins on non-patented drugs, with those on patented drugs, probably obscures the higher margins on the latter.

A breakdown between human pharmaceuticals and other products is available for the computation of the cost of goods sold, however, and the ratio of cost of goods sold to sales is about 33 per cent, for 1964. This is strikingly low in relation to the ratio of 73.7 per cent for the average of all Canadian manufacturing firms as shown by the 1962 Dunn and Bradstreet of Canada survey introduced into the record of the Committee. For all manufacturing firms, the equivalent markup of total price over cost of goods sold is approximately 36 per cent (that is the gross margin of 26.3 per cent divided by the cost of goods sold of 73.7 per cent), while the markup for drugs is 203 per cent. If we assume that manufacturing firms in Canada are on the whole workably competitive, their average markup of 36 per cent might be applied to the 33 cents in the drug sales dollar which is accounted for by the cost of goods sold. The resulting markup would add about 11.9 cents to the cost of goods of 33 cents bringing the price up to about 45 cents. Hence, very roughly speaking, the ability of the drug industry to raise itself above the necessity for price competition has enabled them to charge $1.00 for selling at wholesale a product the average cost of goods sold. Even if we raise the figure to 50 cents, the price of drugs in Canada is still market pressures as the average manufacturing firm in Canada, they would have to be content with charging only 44.9 cents for 33 cents worth of cost of goods sold. Even if we raise the figures to 50 cents, the price of drugs in Canada is still indicated as being twice as high as it might be in the presence of more adequate competition.

What factors are responsible for permitting a gross margin of 67 per cent in drugs while all manufacturing companies have to be content with only 26.3 per cent? Here is where elementary economic analysis is useful in illuminating the relationship between supply, demand, and prices. Because of the great urgency of the need for medication, demand is almost completely insensitive to prices charged. There is no economic reason why low prices should be charged just because production costs are low, when a price which is for example ten or

twenty times as great as production costs will not significantly reduce the amount purchased. Broadly speaking, prices are determined almost entirely by the urgency of demand, and ordinarily have extremely little to do with the costs of production. Hence there is no real reason to lower prices if costs should decline, and conversely there is not much room for increasing prices if costs should rise, since prices have presumably been set initially at the profit maximizing level relative to demand.

Drug industry economics are such that only perhaps about 30 cents out of every sales dollar of cash flow has to be devoted to factory costs of production. What governs the disposition of the remaining seventy cents? Firms apparently find it necessary to dissipate about 30 cents of each sales dollar in sales promotion efforts, which arguably are largely mutually offsetting as among firms, the emphasis being on persuading the prescribing physician rather than on simply informing him. About seven cents is spent on research and development, largely applied research and product development. In drugs, as in other chemicals industries, research is rationally viewed as a means of implementing a profitable marketing operation, hence the share of the research budget devoted to truly fundamental research is understandably small.

Between 4 and 15 cents in the sales dollar goes to distributing the warehousing costs, and to actual outlays for manufacturing administration. The ambiguity arises here because it was never made explicit to the Committee how much, if any, of the eleven cents in the sales dollar which was designated as costs of manufacturing administration was accounted for by management fees assessed against Canadian subsidiaries by foreign parents. This leaves between 18 and 29 cents in the sales dollar for profits before taxes, royalties, and management fees. This sum represents the pre-tax residual receipts of the drug firm after allowing for actual expenditures. While intra-company management fees and royalties may indirectly relate to certain actual costs of administration and research, the arrangements by which these fees are determined do not reflect the discipline of an arms-length market transaction. And royalties paid are generally not in any way systematically related to past or future research costs, but instead partake more of the nature of a levy on the expected profits to the licensee from the exploitation of the patent license. In other words, intra-company management fees and royalties represent imputations of portions of the surplus of revenues over actual costs, and it makes a lot of difference to the buyer whether the profits of the Canadian subsidiary are imputed away or competed away.

Hence the sales dollar breaks down roughly into 30 cents for manufacturing plus a maximum of 15 cents for distribution and manufacturing overhead. The remaining 55 cents is the subject of discretionary disposition to a greater degree. About 7 cents is devoted to the quasi-marketing functions of development and research, about 30 cents is spent in sales promotion, and a minimum of 18 cents remains for profits before taxes, royalties paid to others, and intra-company imputations regarding royalties and management fees.

This is the quantitative breakdown of the sales dollar as presented to this Committee by PMAC, but it differs considerably from the qualitative impression created by drug firm spokesmen both in their appearances before this Committee and in their public relations activities generally, where the height of drug prices is attributed to the magnitude of the research budget and the costs of quality

control. Since research and development combined amount to only about 7 cents in the sales dollar, and since quality control costs—to the extent that it is meaningful to isolate them—add only one or two more cents, it is apparent that drug prices are being explained or defended in terms of factors accounting for less than ten per cent of the total price.

Since the basic cause of high drug prices in Canada is the lack of price competition, both among major drug manufacturing firms and among retail druggists, it is appropriate to ask what reforms are necessary to institute price competition at all levels of the industry and thus lower drug prices. Each of the recommendations made in this submission will be stated and briefly discussed.

A. Recommendations pertaining to patent and trade mark reform.

Drug buyers in Canada are fortunate in that drug product patents may not be obtained independently of process patents, and that such patents are subject to compulsory licensing under normal circumstances. In contrast, drug patent protection is absolute in the United States. Why, then, have Canadian drug prices often reached higher levels than are charged in the United States? There are four respects in which the present state of Canadian patent law contributes to high drug prices. First, relatively few applications have been made for compulsory licenses, and none of the firms which have been granted licenses have been truly major factors in the industry. Second, applications for licenses to import patented drugs have been refused. Third, since the products of firms selling under compulsory licenses are usually marketed under generic names, or under little-advertised brand names, the burden of securing a market in competition with the highly promoted brands of major firms, taken in conjunction with the habit of brand name prescribing and the atmosphere of disparagement of generic name products created by brand name sellers, puts even the successful applicant for a compulsory license in at best an inferior position in the market. He may undercut his rivals by selling at prices only a tenth as high as theirs, and yet not be able to gain even a tenth of the market. Such an outcome would be unthinkable in any sort of truly competitive market, and must be attributed to sales promotion and prescribing practices, which are supported by patent protection in general in spite of occasional compulsory licenses. Fourth, if a firm produces or imports a drug which is covered by a Canadian process patent, the burden of proof is on the producer or importer to show that the drug was produced by a non-infringing process, and the costs and hazards of litigation may easily deter such production or importation.

To further reduce existing patent-related barriers to new competition in the drug industry, the following recommendations are made:

1. Compulsory licenses to import patented drugs should be granted, subject to the payment of reasonable royalties. These licenses should provide for the importation of semi-finished and finished dosage forms as well as bulk drugs.

2. Section 41(2) of the Patent Act should be amended to put the burden of proof of infringement of drug process patents on the plaintiff.

3. Every effort should be made to further expedite the process of acting upon compulsory license applications. If reasonable expedition cannot be achieved, such licenses should be issued as of right.

Two further recommendations relate to patents and trade marks.

4. Section 19 of the Patent Act should be amended to allow provincial governments and their agencies as well as the Government of Canada to use any patented drug, subject to the payment of reasonable compensation.

This recommendation of the Hall Commission is highly appropriate since it would further safeguard the Canadian drug buyer against restriction of supply and high prices.

5. The Trade Marks Act should be amended to allow in general the importation of trade-marked drugs which have been produced by a company related to the company possessing the Canadian trade mark.

I think in the interest of time I will omit the explanatory paragraph which follows, as it merely contains arguments already presented to the Committee several times.

(The above paragraph reads thus:)

The securing of this reform would make it possible for independent Canadian wholesalers to buy drugs from wholesalers in, for example, the United States, and sell the drugs in Canada at a lower price than that charged by the Canadian subsidiary of the United States manufacturer, provided that the difference in prices between the two countries is greater than the import duty payable. At present the owner of a Canadian trade mark is permitted to monopolize the importation and distribution of any product bearing this mark, whether or not any production of the product is carried on in Canada. If the proposed amendment were adopted, the only direct retaliation would consist in having the Canadian subsidiary take out a new trade mark for its drug, but it would hesitate to do so to the extent that sales promotion efforts in both the Canadian and United States markets had made the trade-marked name itself a valuable business asset, the changing of which would occasion a capital loss.

B. Recommendations Pertaining to Tariffs and Anti-Dumping Laws.

Three recommendations are made which relate to import duties on drugs.

6. The schedule of tariffs on drugs should be reviewed by the Tariff Board, with a view toward:

(a) Limiting the liability of drugs to tariff duties to those drugs of a class or kind actually made in Canada, and

(b) reducing applicable rates to the minimum level consistent with the provision of the desired degree of protection of domestic producers.

Tariffs are intentionally designed to protect domestically situated producers by imposing an import tax burden on foreign goods. Except perhaps in the very long run, tariffs tend directly to increase domestic prices by encouraging higher cost domestic producers at the expense of lower cost imports. Hence the complete elimination of drug tariffs would be the most expedient tariff measure for maximizing the potential decrease in Canadian drug prices. But if it is desired to retain protection for domestically situated producers, the customs laws should be such as to give protection only to those drugs which are actually being produced in the country at any given time. This could be done by limiting tariff protection to drugs of a class or kind actually being made in Canada, but care should be taken to avoid defining "class" too broadly. Rather than regarding all antibiotics as belonging to a certain class and hence applying tariffs to all antibiotics if even

a single antibiotic is produced in Canada, it would be preferable, if feasible, to maintain an exhaustive current enumeration of all drugs which are sufficiently close therapeutic substitutes for drugs made in Canada, and to exempt from tariffs any drugs not on the list. This would not prevent the establishment of new domestic drug plants since tariffs would become applicable to imports of any drugs of a class or kind produced by domestic plants as soon as Canadian production were to be established.

7. Liability to anti-dumping duty should be limited to drugs of a kind actually made in Canada, where "kind" is defined in terms of the active ingredient.

Again in the interest of time I will omit the explanatory paragraph which contains familiar material.

(The explanatory paragraph follows:)

The existence of the anti-dumping duty tends to motivate foreign parents of Canadian subsidiaries to impute a larger share of total profits to the parent by setting prices tothe subsidiary at levels high enough to avoid all possibility of being subject to the anti-dumping duty. While abolition of the anti-dumping duty would eliminate this particular parent-subsidiary complication, this would expose domestic producers to the threat of dumping. A preferable expedient would appear to be the limitation of anti-dumping duties to drugs of a kind actually made in Canada. At present, while most of the pharmaceutical drugs used in the preparation of dosage forms in Canada are not themselves made in Canada, most pharmaceutical preparations containing these pharmaceutical drugs are considered to be of a class of kind for dumping duty purposes. Hence although the active ingredients in a drug are not manufactured in Canada, dosage forms containing these drugs may be subjected to anti-dumping duty which protect sellers of dosage forms but do not afford protection to domestic manufacturers since the drug is not being domestically produced. Drug prices may therefore be increased by the amount of anti-dumping duty paid, or by the increase in invoice prices necessary to eliminate the danger of anti-dumping duties, not only for drugs made in Canada, but also for all other drugs of a general class made in Canada. Limiting the application of anti-dumping duties to drugs of a kind made in Canada would therefore eliminate the possible price-increasing effects of measures taken to minimize the likelihood of liability for payment of anti-dumping duties for all drugs of the same class sold in Canada.

8. The valuation for customs purposes of imported drugs should be based on production cost plus a maximum allowance for gross profit (or on invoice cost, if higher) in situations where it is not possible independently to ascertain fair market value.

The reduction in the scope of anti-dumping duties would eliminate many of the instances in which valuation problems for imported drugs arise. The goal of valuation of those imported drugs still subject to dumping duties at levels which are not so high as to motivate foreign parents of Canadian subsidiaries to take too large a portion of the combined profits of parent and subsidiary in the foreign country, would be most expeditiously arrived at by setting this value equal to production cost plus an allowance for gross profit. To simplify administration, a reasonable maximum allowance for gross profit should be stipulated, as is now done for some items of import, such as the 5 per cent

allowance for imported car parts of a class or kind not made in Canada. If after appropriate study a maximum rate of for example ten per cent were to be adopted for drugs, the motivation to charge high prices to Canadian subsidiaries to avoid antidumping duties would be removed. If a drug cost $1.00 to produce, invoice costs need be no more than $1.10 to avoid all liability to dumping duty.

9. The federal sales tax on drugs should be removed.

Since demand for drugs is almost completely insensitive to price levels, the imposition of an eleven per cent sales tax at the manufacturer's level will be pyramided upwards through distribution channels and the increase in price to the consumer will range up to a maximum of eleven per cent, depending upon the pricing policy of the retail druggist. (See Appendix A to this Submission for detailed calculations.) But it does not follow that the removal of the sales tax, in itself, would result in corresponding price reductions. Only in a highly competitive market can one safely make the assumption that reductions in taxes or cost levels generally will be passed forward to the consumer in full in the form of lower prices. Sales tax abolition must be only one part of a comprehensive reform program to introduce genuine price competition into the drug industry.

10. The Food and Drug Directorate should be provided with sufficient authority, funds, and staff to enable it to carry out an inspection program adequate to prevent the manufacturing of substandard drugs and establish confidence in all drugs sold in Canada.

It is of extreme importance that public inspection of drugs be made adequate enough to establish confidence in the quality of all drugs on the market, for only under these circumstances can domestic and imported generic drugs compete with brand name drugs on a price basis. Dr. R. A. Chapman, Director-General of the Food and Drugs Directorate, has recently stated before this Committee that even under present inspection levels, there does not seem to be any significant difference between the quality of generic and brand name drugs sold in Canada, whether the drugs were domestically produced or imported. Although this Committee would seem to be concerned predominantly with issues of drug economics, it is fair to say that on many occasions its concern for drug safety has prevented a sufficiently sharp focus on the economic issues.

Drug firm spokesmen argue that maintaining acceptable quality standards is not compatible with price competition. This argument can be made to seem plausible because of natural anxiety over drug safety. What drug firm spokesmen apparently do not realize is that any argument against price competition is an argument for price control. If competition cannot function satisfactorily regulation of some sort must be substituted.

It has been said that one cannot divorce questions of safety from questions of cost. The obvious way to proceed is simply to compute the full cost of—

Mr. MACKASEY: Mr. Chairman, my copy does not follow on from the bottom of 10, what page are you on now.

The CHAIRMAN: He added in several lines that are not written, and he is now proceeding with the bottom of page 10.

Mr. STEELE: I continue. The obvious way to proceed is simply to compute the full cost of insuring safety, taking into account both the public cost and the

increase in private costs to be passed on to consumers. Against these costs one should weigh the twofold benefits of the elimination of both inferior brand name and generic drugs, and the pressures for price reduction which will develop when generic drugs are seen to be of equivalent quality with brand name drugs, but of much lower price. There is no doubt in my mind that the cost savings alone from lower drug prices would repay many times the added expense of expanded inspection. For example, from available information it appears that in the United States in 1958 an adequate inspection program would have paid for itself even if the resulting price reductions for brand name drugs had been as little as one-quarter of one per cent. Similar data for Canada are not at my disposal, but I doubt if the order of magnitude of required cost reductions is greatly dissimilar between the two countries.

11. Unnecessary barriers to the marketing of new drugs by additional firms should be eliminated. Where a new drug has been cleared for marketing on the basis of adequate data compiled by an original applicant, the same drug should by approved for marketing by any firm capable of producing the identical drug. Similarly, unnecessarily onerous burdens in the way of supplying drug information which merely duplicates existing known information should not be imposed.

The emphasis in this recommendation is upon avoiding truly unnecessary barriers and burdens, which unnecessarily prolong the monopoly power period of the patent holder. I am in favor of saafety, but I am also a believer in economy and am opposed to requirements which involve wasteful duplication of effort in busy-work which accomplishes nothing which has not already been done.

12. The publication of a governmentally sponsored newsletter evaluating drugs, similar to the *Prescriber's Journal* in Great Britain should be considered, particularly if widespread subscription by Canadian physicians to presently or prospectively published independent newsletters of this type fails to develop.

If vigorous price competition is injected into the drug market the ability of major firms to finance sales promotion will decline greatly. To the extent that this eliminates merely persuasive sales appeals and reduces excessive competition for the attention of the physician, the results will be salutary. It is moreover desirable that independent publications develop to supplement the informative releases of individual firms, and to completely supplant the purely persuasive promotional materials. It is to be hoped that physicians would voluntarily subscribe to independent newsletters. But the experience of the *Medical Letter* in the United States is not encouraging—only about 15 per cent of physicians have subscribed. If similar apathy is betrayed by Canadian physicians, the publication and distribution of such a newsletter at public expense may be necessary, as in the United Kingdom.

13. Every reasonable effort should be made to inject more price competition into drug retailing. Serious consideration should be given to the liberalizing of the requirements for operating drugstores and dispensing prescriptions, so that the development of lower priced outlets for drugs such as discount pharmacies and mail order drug houses can be encouraged.

Too little attention has been devoted to the role of the retail druggist in the over-all level of drug prices. The conclusion reached in the "Green Book" is that price competition among retail druggists is distinguished by its almost complete absence. If and when price competition among drug manufacturers is brought

about, the full benefits of lower prices at the manufacturers' level and of the hopefully more widespread practice of generic prescribing, will not be realized unless drug retailing also becomes more competitive. Since this situation prevails even after resale price maintenance has been outlawed, the problem appears to be a deep-seated one. Its solution must await the adoption of the maximum practical liberalization of the traditional restrictions limiting entry into drug retailing. This liberalization should be such as to constitute recognition that the traditional pharmacist's distinctive functions are being altered away from professional competence in compounding and toward skills in merchandising. This more than anything else would probably bring about new entry into the market by those who are not traditionally opposed to price competition. In many lines of trade, sellers were inefficient and distribution methods stagnant until competition developed from sources such as supermarkets and mail order houses. Drug "supermarkets" or discount houses are by their nature better suited to large urban centers, but the encouragement of mail order pharmacy, where feasible, would do much to spur competition in more thinly settled areas where druggists may have local monopolies.

14. If the above reforms do not succeed in reducing drug prices to competitive levels in a reasonable period of time, drug patents in Canada should be completely abolished.

In its Report, the Restrictive Trade Practices Commission recommended the abolition of drug patents. The Hall Commission was more sensitive to the possible adverse effects upon Canada of retaliation by nations committed to drug patents, and recommended retention of drug patent privileges, modified only by the provision for compulsory licenses to import, during a trial period during which the effect of various reforms on price levels would be observed. This recommendation appears to be very appropriate.

The CHAIRMAN: Thank you very much, Dr. Steele. Ladies and gentlemen, the meeting is open for questioning, but because the brief is very lengthy and many members are going to have many qeustions, the Chairman is going to impose a ten minute limit on questions and answers for each person; you will have another turn next time around. I would ask, therefore, if you ask a very lengthy question and get a very lengthy answer which uses up all your time, that you wait until the next time around. Once your ten minutes is up I will bang the gavel and ask you to come quickly to a conclusion.

Mr. HOWE (*Hamilton South*): Thank you, Mr. Chairman. I will not waste time with preambles, except to congratulate Dr. Steele on the tremendous colossus that he has put in front of us for us to attempt to read and absorb, which will be next to impossible, but I cannot help but agree with it. As a matter of fact, it has been my feeling since reading it, that if we could tear the cover off it and put on a new cover saying recommendations of this Committee to the government, I would be quite satisfied; that is a personal opinion.

Dr. Steele, I am going to ask you, if you do not mind, to try to make your answers brief so that I can get more questions in. Unfortunately, I will not be here this afternoon and I would like to get in all my questions in ten minutes. Would you say that the whole fault now lies in the system whereby a power group known as the PMAC—I presume the "P" and "C" mean private club —exerts a pressure on the doctors, through, shall we say, a brain washing

mechanism and they have plenty of money to do this. Consequently the doctors cannot, shall we say, conceive of the role that the cheaper drugs can play because they are so bogged down with gimmicks and trick names, and because much money is spent to advertise to these doctors so that they can only see this one particular group as the drug manufacturers that count. Then, associated with this as I pointed out to Dr. Ross before, is the disparaging tone—an undertone —in the detailing of the so-called generic firms, the copiers, the cheaper drug manufacturers or, shall I say, the non-PMAC group?

Mr. STEELE: I am glad you asked me to keep my answers brief. I might want to make some minor qualifications, but the brief answer here is, yes. I concentrate on the economic implications, but I think the factors which you enumerated are the determining ones.

Mr. HOWE (*Hamilton South*): So this is a system which is wrong. In other words, what we really have to do is to start in with an educating system and then a re-education so that this thing will be seen on the proper basis, as it should be, as evidenced by Dr. Chapman who showed that the so-called cheaper drugs on the average were just as efficient or efficacious as the brand name PMAC group drugs.

Mr. STEELE: One qualification I would like to make is that I do not think it is true—I certainly would not single out the PMAC for the entire blame for a drug marketing situation which is prevalent on the entire North American continent and other places in the world. The industry is an international industry and the tactics which are adopted by manufacturers to maximize profits vary with the institutional circumstances in the different countries. It happens that in Canada and the United States the manufacturers find it profitable to adopt these tactics.

Mr. HOWE (*Hamilton South*): Could I put them in the proportion that they claim themselves to be, 85 cer cent?

Mr. STEELE: There has been argument about what the 85 per cent stands for. I would say that as far as all sales are concerned, the dollar volume of sales prescription drugs, my estimate would be 85 to 90 per cent.

Mr. HOWE (*Hamilton South*): You do say in your brief, for point of emphasis, that the price of drugs, the ultimate sale price of drugs, has no bearing whatsoever on the manufacturer's cost.

Mr. STEELE: That is substantially true. We could make elaborations, fine points and economic theory, but from drug to drug there is substantially no relationship.

Mr. HOWE (*Hamilton South*): You refer to the Medical Letter which I subscribed to at one time and lost faith in, not for any particular reason but I did wonder if there was any pressure on this Medical Letter, or do you think this is a sincere assessment of the drugs without any pressures brought to bear?

Mr. STEELE: To the best of my knowledge, yes, but I am not the best informed person on this.

Mr. HOWE (*Hamilton South*): I am quoting in part from your brief. You say that "many so-called breakthrough drugs are merely minor adaptations of an already developed drug, proving really that research by drug firms reflects only an endeavour to make a competitive product or an adaptation that will sell for

this reason, because it is an adaptation, and compete only as far as advertising is concerned". In the light of that statement from your brief, how many actual new discoveries have been made by private drug companies in the United States and Canada, say, in the past ten years?

Mr. STEELE: I am not able to assess the quality of various discoveries of different drugs. I would say that in antibiotics, for example, no basic major new drug has been developed since the late 1950's. This is not my opinion alone; if you read the speeches made by security analysts you will see they talk about the problem which the drug industry has in developing basic new thereapeutic breakthroughs. The increasing cost or the diminshing returns through research have their effect on new drugs. I could not give a number.

Mr. HOWE (*Hamilton South*): Well, all antibiotics have been an out-branching of the original discovery of penicillin as far as the theory and practice of antibiosis is concerned.

Mr. STEELE: Yes.

Mr. HOWE (*Hamilton South*): I am sorry this is a little disorganized, but there was a state of disorganization when I tried to write these questions down. Do you feel that the doctor is in a vulnerable position re advertising because, as you state on page 67 of your brief:

—he is not in a position to evaluate the quality of the drugs he prescribes.

Mr. STEELE: Yes, I think this is true. It would take a frantic devotion on the part of the doctor to undergo the expense of having the drugs tested privately which he uses. It would be impossible I think for him to test all of the drugs which he might be interested in using.

Mr. HOWE (*Hamilton South*): Therefore, he is going to naturally prescribe something which he is more bombarded with, as far as advertising is concerned, and this has been proven many times in this Committee to be tremendous. As I understand it, in the United States there is approximately $5,000 per doctor per year spent on, shall we say, the pushing of the PMAC group drugs. This involves your detailman and on. The pressure is tremendous on the doctor when it comes to this amount of individual pressure.

Mr. STEELE: Without any knowledge of the way in which a doctor reacts personally to this type of sales promotion appeal, I would take it merely as axiomatic that if it did not pay off the companies would soon cease to promote drugs at this great expense.

Mr. HOWE (*Hamilton South*): Assuming that most doctors are human beings, they are subject to the pressures as any other human beings from bombastic advertising, are they not?

Mr. STEELE: I sympathize with anybody in their place.

Mr. HOWE (*Hamilton South*): I want to ask another question which is based on your brief, too. I have asked this question before. Do you think there is any direct relationship between a low or reasonable price and the existing high price in the quality or efficacy of any drug?

Mr. STEELE: I think it is easy to create doubts about the quality of low-priced drugs, particularly if the drugs are selling at 5, 10, or 15 per cent of the

price of the brand name drugs. From my knowledge of the technology of drug production, which is admittedly limited, and the knowledge of the inspection procedures employed, which I admit is more extensive for the United States than Canada, it strikes me that there is almost no substance in these claims, and that, if they have a point and some statistics are used to prove this point, the point is greatly overstated.

Mr. HOWE (*Hamilton South*): With respect to the education process that we discussed in relation to my first question, what do you think of the acquiring of a Canadian formulary as a solution that could conceivably get around this problem?

Mr. STEELE: I am surprised there has apparently been none since about 1949. Is that correct?

Mr. HOWE (*Hamilton South*): Well, there is a sort of unused formulary, but I really meant, putting one into use. In other words, what I mean is, let us say there are 20 forms of brand name penicillins and they all passed Food and Drug administration or, let us say, 14 of them passed, they would simply be listed as penicillin and the doctor would only write a prescription for penicillin, being assured that the Food and Drug administration had made sure that all 14 of these had passed all the tests and were equal in quality and efficiency, and the druggist would simply dispense penicillin, any one of the 14, and he would need to have only one brand on his shelf which would reduce his costs and reduce the need of the drug companies to advertise to the doctors, and have the drug companies tender to the drugstores as a means of lowering the price to the drugstores. We know full well that tendered prices to the government are much lower than the prices that the public pays for drugs.

Mr. STEELE: As far as a Canadian formulary is concerned, I would consider this an ideal arrangement, if one could be devised with sufficient expedition and kept reasonably up to date. Especially is this true if you are starting a new formulary, and you have a number of other formularies in existence which are also being used as semi-official compendia. There may be a lot of time wasted in just deciding what features to incorporate from the other compendia, but ideally if you could devise such a formulary and keep it up to date I think this would go a long way towards solving the information problems which doctors face.

Mr. HOWE (*Hamilton South*): It should not take any longer to produce this formulary than it should to educate the doctors.

Mr. STEELE: Probably not.

Mr. O'KEEFE: Mr. Chairman, Dr. Steele, this is a very impressive brief and I think the Province of Alberta should be congratulated on its initiative in importing Dr. Steele. Luckily, I always agree with imports particularly in the area of experts, but in this case I am not an extreme nationalist. On page 4, Dr. Steele, of your condensed version, you discuss demand, and you state:

> —demand is almost completely insensitive to prices charged. There is no economic reason why low prices should be charged just because production costs are low, when a price which is for example ten or twenty times as great as production costs will not significantly reduce the amount purchased.

What I am interested in, Dr. Steele, is, whose demand? Normally, demand is caused by the consumer, the buyer. Surely, in this case, particularly in the important area of prescription drugs, the demand is made by the doctor and not by the consumer.

Mr. STEELE: Yes, that is true. I tried to cover that in my section on demand in the major brief. In that section I tried to develop the notion that the demand, as far as the consumer is concerned, is insensitive to price. The effective demand for a drug or a group of substitute drugs depends really upon the extent to which the doctor can be induced or persuaded or is naturally inclined to prescribe the drug. The doctors demand is very price inelastic. As I suggested, perhaps a typical doctor may either have little knowledge of prices or he may feel that the higher the price of the drug he prescribes, the more prestige he will be accorded. I think these two factors work together. The doctor allocates the ability of the patient to present prescriptions for particular brands to druggists and the druggist has a certain amount of discretion over setting the price which the consumer finally pays. The demand on the part of the druggists is a derived demand because if the druggist can charge a high price for prescriptions in terms of the final consumers' demand, the manufacturer can charge the druggist a high price at the wholesale level, at the druggist's purchase level.

Mr. O'KEEFE: On page 6, of your condensed brief, you talk of the habit of brand name prescribing, and the atmosphere of disparagement of generic name products created by brand name sellers. Have you any specific examples in mind you can give up of this?

Mr. STEELE: Yes, I gave two or three examples I believe in the brief. Dr. Solomon Garb who was conducting a class at a New York university in the United States tried, as I think over 80 per cent of the medical schools do, to convince students that it was rational to prescribe in terms of using generic names, but he allowed, or perhaps invited a detailman to have a seminar with the students and he pointed out that after one session with the detailman over half or about half the students were convinced by the detailman's suggestions that it was really unsafe to prescribe by generic names. Dr. Howe has given another example which I have also quoted, and Dr. Frederick Myers of the University of California Medical School also testified to this effect.

Mr. O'KEEFE: Would you abolish the detailman?

Mr. STEELE: I would not abolish him. I would not pass a law saying that there should be no detailmen in the drug industry; rather, I would stimulate competition and let the price level which is competitively determined, regulate the amount of sales promotion in the industry.

Mr. O'KEEFE: On page 19, Dr. Steele, there is an explanation of the inspection program you suggest. We have been told over and over again in this Committee that it is impossible to have a complete inspection program. Of course, I do not accept the word "impossible" and I should like your comments on this.

Mr. STEELE: Well, the information which was given me—first, I believe that Mr. Henry said, on the basis of study made by his group, he thought that the cost of ensuring adequate inspection of all imported drugs would run around $4 million. This would not include presumably any additional domestic inspection of

the products of domestic producers. I have no idea whether the total figure would be in the vicinity of $4 million, $5 million or $10 million; but I do think that even if it cost in the range of $50 million, or upward of that, the reduction in the average price of drugs brought about by the competition which would result, once the confidence of the doctor could be established in all products sold on the Canadian market, would result in a cost reduction to the consumers of this magnitude.

Mr. O'KEEFE: And the safety of the drug, which is just as important, probably more important. I am just confirming you, doctor.

Mr. STEELE: Yes.

Mr. O'KEEFE: I have one final question. You suggested that super markets and discount drugstores would have an effect on the prices of drugs. We have discount drugstores or so-called discount drugstores in Ottawa, and I have never met a person who suggested to me that the price of the prescription drugs at least is lower at these discount drugstores than in other stores.

Mr. STEELE: Well, the economics of the retail drug industry—the retail druggists are very different from those of the manufacturer and they deserve a study all by themselves. If the discount druggist has to obtain quarters in a higher rent section of town, this is going to put him at a very great disadvantage at the outset. Actually, what you need is large volume, and you need the freedom to compete in price. If you have a large volume and no constraints of any sort on the price you can charge, I think some reduction in the prices which are charged by druggists would be allowed. Of course, the lowering of prices would have something to do with the increase in volume. I know from my own experience in Texas, for example—Texas is one of the three states in the United States which has never had a fair trade law—the prices for drugs in particular have always been lower than in any of the other states. Even so, there is a big difference between the prices which are charged by the corner drugstores, the individual unit pharmacies and those charged by the discount drugstores. For example, I can buy brand name drugs at prices from one third to 40 per cent off, let us say, at the discount drugstores from registered pharmacists of the same brands you would buy at the old line drugstore, let us say. I think the secret here is simply in the larger volume done and the greater buying powers they have, coupled with the freedom from the restraint of the so-called free trade laws which do not exist in Texas.

Mr. O'KEEFE: Dr. Steele, do you know of a code on a prescription that shows so that a druggist, if the prescription is brought from one drugstore to another, will know exactly what the other drugstore, the first one, had charged the consumer?

Mr. STEELE: Yes, I have heard of that.

Mr. O'KEEFE: Do you think that is fair?

Mr. STEELE: No, not at all.

Mr. O'KEEFE: Do you know of any prices where prices are kept artificially by agreement with druggists? I will give you a case here in point that I had in Ottawa. During the Christmas period I was buying some presents and I went to a drugstore to buy some perfume. It is not a prescription drug, I admit, but I asked

for a discount—I was buying several bottles—and I was told quite frankly by the salesman that it is necessary before they can get this particular item to sign an agreement not to sell at a lower price than the price that was charged me. Have you any comment to make on that, Dr. Steele?

Mr. STEELE: Where did you try to buy this perfume?

Mr. O'KEEFE: In Ottawa.

Mr. STEELE: I do not know. I suppose Mr. Henry is the appropriate person to whom you should direct this question.

Mrs. RIDEOUT: Do you not know what perfume?

Mr. MACKASEY: It is a question of smell.

Mr. HOWE (*Hamilton South*): May I ask for whom it was bought?

Mr. O'KEEFE: It was for my wife, Dr. Howe.

Mrs. RIDEOUT: Several bottles.

Mr. O'KEEFE: Thank you, Mr. Chairman. I did not get an answer.

Mr. HOWE (*Hamilton South*): Mr. Chairman, I think by way of correction, maybe there is a slight error in this code marking of prescriptions. A number goes on every prescription that goes to a patient, but this is only for identification in his own file. This is not a code number that identifies the drug that is being—

Mr. O'KEEFE: No, no; identifies the price is the point I was making, if you took that prescription to another drugstore in another city.

Mr. HOWE (*Hamilton South*): You still would not have any idea what it is without contacting the druggist by whom it was originally dispensed. This is not a code number; it is only so that that druggist can find the prescription in the series of numbers in his own files. The number does not identify the drug. I thought that should be straight.

Mr. O'KEEFE: I did not—

The CHAIRMAN: No, it is not straight, Dr. Howe, because you are both talking about two different numbers. You are talking about a prescription number and Mr. O'Keefe is making reference to a habit that does occur where a price is actually coded into the prescription, and this has been admitted by I think the pharmacists who were here before, that this used to occur. I should also say that Mr. Henry is in the room.

Mr. STEELE: May I ask a clarifying question of Mr. O'Keefe to make sure I understood his question?

The CHAIRMAN: Yes.

Mr. STEELE: I think the coding you are referring to is—for example, I know a few systems which involve misspelling the word "pharmacist". Let us say, they spell it p h a r m o c i s t—it has ten letters in it, and "p" stands for wanting to go from one to zero. This is the kind of coding you are talking about.

Mr. O'KEEFE: I think it is deceptive.

Mr. MACKASEY: I have a better one, that you may pass on to your clients and make profit. This does the same thing. There are ten letters there and no two are alike. Perhaps it is easier to remember when you are in the retail business.

Dr. Steele, anything I may say about your brief now will be superfluous. All kinds of praise has been accorded to it which I heartily endorse. I have gone through it six times and I intend to go through it six more. I do not want to use up my time in the preamble. On page 6, section 3, you say:

Although very little research is done in Canada—

I could not agree with you more heartily, Dr. Steele. If you have read the proceedings since the beginning I think I have emphasized that point constantly that the amount of research done in Canada by the pharmaceutical industry is a shame, particularly in view of the fact that Canadians are supporting, or are supposed to be supporting, research of that pharmaceutical industry every time we swallow an aspirin. I hope that the pharmaceutical industry, when these hearings are over get hep, as we say, and realize their duties to this country. Now, you have a very comprehensive section on research which I have spent a little time on. You have expressed I think strong beliefs in the differentiation between basic research and applied research. Am I right in that?

Mr. STEELE: Yes.

Mr. MACKASEY: You feel there is a distinction. You give economic reasons why private companies, private industry, would normally tend to concentrate on applied research rather than on basic research.

Mr. STEELE: I did give reasons. Are you asking me to state the reasons?

Mr. MACKASEY: Well, yes.

Mr. STEELE: One of the reasons I gave, I think I gave eight reasons in all, why ordinarily private firms in the drug industry or any other industry would tend to devote relatively fewer funds to fundamental research than the social value of the activity might justify and they all boil down to the fact that, well, a private firm spends all the money and perhaps reaps none of the benefits or very few of the benefits.

Mr. MACKASEY: I think you have pointed out the economics of the reasons why but is it not a fact also that if the pharmaceutical industry ignores basic research entirely for any lengthy period of time applied research itself will produce no fruits to the industry.

Mr. STEELE: Yes, that is true. I think I made that precise statement.

Mr. MACKASEY: I know you did. Is it not already reflected in the number of drugs that is coming on the market today as opposed to ten years ago?

Mr. STEELE: Ye, I believe that to be the case.

Mr. MACKASEY: Do you know the number of drugs that has come on the market this year as opposed to ten years ago?

Mr. STEELE: Well, it is hard to say. It depends on how you classify the drugs, taking the United States classification, whether these are new drugs applications which have been o.k.'d for marketing and in total, whether they are mixtures of old drugs or different dosage forms of old drugs or actually new chemical

compounds. I would say that the number in recent years has dropped, the last category has dropped to about one third of what it was perhaps around 1955 or 1956.

Mr. MACKASEY: Well, you are more familiar I am sure than I am, as an expert on this industry, with De Haen's tabulation which I got from the Library for the information of the Committee, it shows that in 1966, 82 new products on the market which may be, as you say, molecular manipulations in some instances, as opposed to 403 in 1955. Do you not think that as applied research dries up or at least the results, the pharmaceutical industry will then have to go back to basic research?

Mr. STEELE: Somebody will have to do the basic research and I am not sure since applied research and sales promotion under present market circumstances seem to be so lucrative that the companies will return to fundamental research in time.

Mr. MACKASEY: You say, "so lucrative", but at the same time you make a strong case in your brief for the fact that applied research will eventually no longer be lucrative, or the fruits of applied research, unless someone does the basic research.

Mr. STEELE: Well it depends upon how long it takes. The industry is marked by strong rivalry. I have said it is not price competition but I have said there is an awful lot of rivalry in it, and the rivalry increases cost so a firm which has a certain amount of money to budget to basic research, applied research, sales promotion, cannot very well all of a sudden just stop and start reducing the amount of sales promotion and increasing the amount of basic research as long as its rivals are not doing the same thing.

Mr. MACKASEY: But you are fully convinced that there is a fundamental difference between basic research and applied research?

Mr. STEELE: Yes, I am, although as I said if it comes to a matter of drawing a fine line between which project is basic and which is applied I do not think anyone can do that.

Mr. MACKASEY: But your brief does it. You make a very strong case in your brief as I have read it, and as I say, I have read that section and I am quite willing to quote it back to you if you want me to, that the pharmaceutical industry are concentrating in applied research as opposed to basic research. And, of course, you have logical economic reasons why.

Mr. STEELE: Yes, I do not want to repudiate the validity of the basic distinction between basic and applied research or to contradict anything that I have said in the brief about that. I do not think though that you have a distribution of research projects, let us say, a kind of bi-modal distribution; in other words, you have a thousand projects which are definitely fundamental research and a thousand which are definitely applied. I think that there is a line you have to draw somewhere between those which are chiefly oriented towards the acquisition of entirely new knowledge, new ways of looking at things, and those which are devoted to developing new products from existing knowledge.

Mr. MACKASEY: The reason, Dr. Steele, that I have asked you this is that the other day in discussing penicillin I immediately realized my knowledge was very sketchy and Dr. Howe and other learned doctors corrected me about my lack of

knowledge of penicillin. Typically, I went to the library to find out and there I came across a reference to Professor Chain. Are you familiar with Professor Chain?

Mr. STEELE: Chain?

Mr. MACKASEY: Yes. You know he won the Nobel Peace prize for his work on penicillin. I also got his comments on applied and basic research and I would like to read them to you; to me, the uninitiated, they seem to contradict your brief and I would just like to get your comments. He starts out to say:

> I must confess that the continuing discussion on the relative merits of pure versus applied science gets a little tiresome as it centres around fictitious pseudo problems to which there is no substance. No one except very ignorant people—

And I do not class you that way, Dr. Steele; these are his remarks.

> —believes that a sharp line of distinction can be drawn between pure and applied research, and that the former is limited to academic, the latter to industrial laboratories.

Which is the point you have made.

> What about penicillin?
>
> Can any discovery be more "applied"...He puts that in quotation marks. In nature? Yet it originated in an academic laboratory and I can assure you this audience, that we had no objection when we realized that it could be put to a practical use in medicine.
>
> What about the discoveries of histamines...? Their theoretical importance is immense yet they originated in an industrial laboratory. In fact, the only way in which I have been able to classify research is into the categories of useful and useless.

Mr. STEELE: I thought perhaps you were going to read me a different excerpt from Dr. Chain. Well, I agree with the beginning of that excerpt. As far as the classification between useful and useless is concerned I rather agree with Professor George Wright. In some sense—

Mr. MACKASEY: Is Professor Wright of Empire Laboratories?

Mr. STEELE: Yes.

Mr. MACKASEY: I see.

Mr. STEELE: In some sense little research is completely useless because at least it shows you what areas are blind alleys and should not be followed again; but I think there is a considerable difference between doing research in an area in which you are completely free to choose your own area of interest and of emphasis and doing research, let us say, in applied research and deciding upon the best dosage form for antibiotics. Admittedly, you may discover new fundamental knowledge of the operation of micro-organisms just from this sort of applied research. I think it is a question of the probability; that you have a much greater universe of possibility of expanding the horizons of knowledge if you are working with no commercial constraint. It is just a question that the universe is possibly much greater there. It is smaller when your object is defined very closely.

Mr. MACKASEY: Well, Dr. Steele, in other words, it is a matter of opinion between economists and scientists as to what is one type of research and what is another. For instance, Dr. Wright of Empire Laboratories has one opinion and Dr. Chain, the Nobel Peace prize winner, has another. It is a matter of whose school of thought you would endorse.

Mr. STEELE: It is a matter of economics too, because I think Dr. Chain's experience in research is probably different from that of Dr. Wright's.

Mr. MACKASEY: I am not arguing with either one of them. My main purpose on the Committee, other than to concern myself with the cost of drugs is to try and persuade, peacefully, if possible, the drug industry to spend some money on research in this country. Whether it is applied research or basic research is not really too important.

On page 21—again I am talking about research,—you have two statements there which seem to contradict each other. In one you say that the Canadian drug firms, and I agree with you, do little research in Canada. I will read it:

> The major drawback perhaps, of the fact that Canadian drug firms do little research in Canada is not that the quality of available drugs suffers, but that Canada loses many of its highly trained research workers because of the lack of opportunities for domestic employment.

And I agree with this. If there are no availabilities in Canada, positions for research, then we are going to lose our trained employees and we have statistics to prove that we are losing some of them to the state of Texas. You are a welcome exchange visitor. Then you go on to say:

> In order to rectify the situation, it may be desirable not so much to attempt to increase the amount of basic research done by private firms, as to take steps to reduce the ability of these firms to drain off very scarce human resources for employment in less productive capacities than they might be assuming.

To me, this is contradictory. On the one hand, you say they are not doing enough and for this reason we are losing trained scientists. On the other hand, you are saying that perhaps we should prevent them from doing any at all.

Mr. STEELE: No, I am saying that in my view, which you regard as a difference of opinion, fundamental research is more appropriately financed by taxpayers, by society as a whole. So that if the drug industry as currently set up tends either to do little research in Canada and hence, offers little employment opportunities for biochemists and pharmacologists, and so on, in Canada or else, offers so many research opportunities south of your border that they all go down there, then you are losing these research workers and also they are doing what I would regard as potentially less productive work in applied research lines. The best thing to do if you want to keep them in Canada is to devise some sort of program whereby more of them can be employed more productively at the public sector.

Mr. MACKASEY: Would we not achieve this laudable desire by forcing or persuading or inducing the pharmaceutical firms to do some of the research which they do south of the border and do it in this country. Would this not also help?

Mr. STEELE: It depends on the way it is being financed and the total quantity of the research done, and also the character of the research. Certainly, you can keep them employed in Canada if you provide sufficient inducements to the pharmaceutical producers to assure they do the research and these inducements may be direct subsidies, tax subsidies, increased patent improvement, and so on. But the question is could they be employed more efficiently in Canada by working with philanthropic foundations or public sector research.

Mr. MACKASEY: We have no legal way of forcing them into an environment that they may not necessarily want. One last question, because the Chairman has his hammer out, on the bottom of page 20, you have a footnote which compliments a drug company with one hand and I find this a tendency throughout the book, and you then qualify it always with the word "may". Do you not think that if there is one firm amongst all the big companies that has had the initiative to sponsor, as it mentions here, a truly fundamental research lab in Switzerland, we should not cast aspersions on it by stating that it is probably paid for by the purchasers of medication?

Mr. STEELE: I would agree with that except for the last sentence. I would say that this is one major criticism of drug industry research generally. This company I think has a greater claim to our admiration because at least it does fundamental research but all research which is done by all companies is financed out of the payments of the sick and afflicted.

Mr. MACKASEY: I understand, incidentally, that this firm is Cyanamid.

Mr. STEELE: This is correct.

Mr. MACKASEY: Many of the people over there are graduates or members of our own Canadian National Research Council, whom I have discussed the problem with and they tell me that there is absolutely no limitations on what they can do, or any limitations of the facilities or equipment at their disposal.

Mr. STEELE: These are Canadians who have been on employment in Switzerland?

Mr. MACKASEY: In this particular plant and were trained in our National Research Council and who of course, will some day come back. Of course, there are people from Switzerland who were trained here and have gone home. Thank you, Mr. Chairman.

Mr. HOWE (*Hamilton South*): Mr. Chairman, may I at this point ask one very brief question, realizing it is out of order, no supplementaries, and a very short question.

THE CHAIRMAN: Because you are not going to be here?

Mr. HOWE (*Hamilton South*): Because I am not going to be here. It is not related to anything that has taken place but does Dr. Steele have any figures showing the per cent of prescriptions written by doctors that are actually dispensed?

Mr. STEELE: That are actually dispensed? You mean written generically?

Mr. HOWE (*Hamilton South*): No. I mean what per cent of prescriptions written by doctors are actually dispensed?

Mr. STEELE: No, I do not have that. I wish I did.

The CHAIRMAN: You mean people who get prescriptions but never fill them?

Mr. HOWE (*Hamilton South*): That is right.

Mr. JOHNSTON: I would also like to congratulate you on the length of the brief and congratulate Mr. Frawley on finding you. I think it took some perception on his part to bring you here as well.

I notice on page 10 of your summarization that you recommend that federal sales tax on drugs should be removed. I think again most members of the Committee would agree with you and it is my understanding that the government awaits this Committee's report to take action in this regard. Then you say at the end that "sales tax abolition must be only one part of a comprehensive reform program to introduce genuine price competition into the drug industry". I do not know how familiar you are with the workings of our parliamentary system but we are faced at the present time with a very extensive load of legislation, none of which has anything to do with intoducing comprehensive reform to bring about price competition. It means that there is going to be a very considerable delay before this parliament could accomplish what is set out here. Your brief deals with whole varieties of things, with the Patents Act, trade mark legislation; all this sort of thing would have to be dealt with. How strongly do you feel about this? Would you feel that the removal of the sales tax should be delayed until the other can be accomplished? This I gather is your meaning here.

Mr. STEELE: Well, the only reason for delaying the passage of the sales tax abolition would be the possibility that there might be more harm than good. For example, if prices of prescription drugs do fall by about 10 per cent and people are satisfied with this and say, "well, that is all the reform we need." I think it might do more harm than good at the present time.

Mr. JOHNSTON: Well, then, in a way you are not trusting the vigilance of this Committee to then carry on and insist on introducing the others. It would seem to me that if this were possible, and you have sort of suggested it in your answer, to drop the price by 10 per cent this would be a very worth-while immediate step knowing that it might take another two years before we could establish this comprehensive reform program that you discussed.

Mr. STEELE: It is not so much that I do not trust the vigilance of the Committee as that I think this might be looked upon by consumers as a substantial victory, and that they would be less aware of the problem and less prone to push for reforms when finally suggested for competition reforms.

Mr. ISABELLE: Dr. Steele, I must commend you on your brief and I am sure that with this presentation you have everything that you need to become a good Canadian citizen.

On page 12 of your brief you said:

> Too little attention has been devoted to the role of the retail druggist in the overall level of drug prices.

Could you comment more on this because I think there is something wrong along the line between the manufacturers and the pharmacists, whether you think the trouble is with the manufacturers or somewhere else along the line.

Nobody mentioned anything about the pharmacists or dispensing. Could you comment on this?

The CHAIRMAN: Your reference is in relation to the short statement.

Mr. ISABELLE: Yes, to the short statement.

Mr. STEELE: Yes, I would say that there are really three levels. The production, the distribution and the retailing level and that at the production level and the retailing level there are forces in the market which tend to put the consumer at a disadvantage. As far as the wholesaler level is concerned, I do not think these same forces exist. I think the wholesaler is sort of caught in the middle. In fact the Canadian Wholesale Druggists Association recently submitted in its brief that because wholesalers in eastern Canada were faced with the competition of co-operative wholesalers who offered rebates that the wholesalers who were not co-operatives also had to reduce some of their discounts in order to compete with the co-operatives. The drug producers had retaliated and were taking this into account and had reduced the margin which the wholesaler enjoyed, so that instead of having the wholesaler pass on some of this surplus to the retailer, this was taken by the manufacturer.

I would say that the problem of not lack of competition so much as inefficient competition at the retail druggist level has been given too little attention and this is because the retail druggist ordinarily divides his time between his pharmacy, his dispensary, let us say, and many other lines of goods. I think on the average about one third of the sales of drugstores are made in the pharmacy line. I think that the pharmacist may be either selling a lot of low profit margin items in order to increase his total income to the acceptable level, because the profit margins on the pharmaceutical items are really higher than the competive level. This means that you have too many people entering into the drugstore field. Let us say, if you had one third as many pharmacies they could all specialize entirely in drug retailing and make the same profits at lower profit margins and allow a more efficient system of distribtion. I think the problem here is really, in metropolitan areas at least, excessive numbers and an excessively broad range of products distributed.

Mr. ISABELLE: On page 11 of your short brief you said:

> Unnecessary barriers to the marketing of new drugs by additional firms should be eliminated.

Do you mean that you would eliminate what we are calling new drugs compared to an old drug. Would you lift those barriers?

Mr. STEELE: No, I would not abolish the distinction between new drugs and old drugs. In my next paragraph I say: "The emphasis is on removing truly unnecessary barriers." What I am against is measures which I do not think, or at least some of which may not be absolutely essential for ensuring safety, but which do function to prolong even if only be a few month the very lucrative period of early market penetration by the patent monopolist.

Mr. MACKASEY: Could you give us an example of this—excuse me, Dr. Isabelle—particular step the Food and Drug Directorate takes that is not designed to ensure safety.

Mr. STEELE: I would say the difference between the procedure followed by the Food and Drug Administration in the United States and the Food and Drug

Directorate in Canada. In the United States, as I understand it, and I am open to correction here, if the first applicant, who may be the inventor, or he may just be the American licensee of the foreign patent, submits to the F.D.A. in the U.S. a sufficient volume of experimental and chemical testing, which allowed the F.D.A. to pass on this drug as being safe and today also efficacious, that other producers, who can produce the identical drug, will not be subjected to the same let us say information supplying hurdle by the F.D.A. I think in Canada this may be an additional hurdle and the holder of a compulsory license may be held off the market for a period of many months because of duplicating in effect experimental and critical evidence on a drug, the actions of which are identical.

Mr. MACKASEY: Well, our Food and Drug Directorate does accept the clinical research evidence that is submitted to the Americans. We do have that reciprocal arrangement. We do accept them.

Mr. STEELE: I think though that Dr. Chapman said that he did not, and this may not contradict you at all, accept as evidence of passing an indirect hurdle the mere fact that the drug had been cleared for marketing by a foreign agency.

Mr. MACKASEY: No, I did not say that either. I will pursue this later.

Mr. ISABELLE: Dr. Steele, through your knowledge and experience, do you believe that there is a price fixing policy between pharmaceutical companies in Canada.

Mr. STEELE: In Canada, I would say that the basic support to high level of prices, the basic support to the non-competitive level of prices, which prevails among major brand name manufacturers in the world at large, is related to the patent situation in the major producing countries—in the United States, in Switzerland, in Germany. I very much doubt whether in the United States the companies ever get together in a smoke-filled room and say, "let us fix the price of this new drug." But, I think that the availability of the patent privilege creates an atmosphere of community of interest, particularly in questions of cross-licensing agreements, and the companies tacitly adopt a sort of policy such, that they set the price for a new drug in the range of profit maximizing level and they do not reduce the price because one of the major brand name companies decides that he wants to increase his share of the market, let us say, by cutting the price 25 percent. The danger of retaliation is too great. This is true not only in drugs but in other markets where you have only a few large producers. As far as outright collusion is concerned, I am sure that the antitrust laws in the United States rightly restrict the scope for this.

The CHAIRMAN: Did you hear the last part of Dr. Steele's remarks.

Mr. ISABELLE: No.

Mr. STEELE: Let us see. What I was saying was in any industry where you have a few relatively large firms, each firm is conscious of the possible reactions of other firms, to decisions it makes on prices and on output. This is also true in the automobile industry, for example. It is true in any industry which the economists call oligopoly, where you have only a few large firms.

Now, this means that firms may never have to collude overtly. They may never have to get together and fix prices because they know that this is dangerous in countries that have antitrust laws, and it might also be, and it is

often, unnecessary if the industry structure is such as to compel a community of interest for defensive purposes in pricing and production policies.

Mrs. RIDEOUT: Dr. Steele, on page 4 of your summary I find it interesting that you say about thirty cents of each sales dollar are spent in sales promotion efforts. Then, on reading your brief I find you say that the physician because of his interest in training should be able to decide for himself the value of the drugs that are available to him to prescribe, and that the physician should rely on completely unbiased sources of information. Of course, I am concerned with the cost of drugs and any way in which this Committee can recommend a reduction in the price of drugs to the consumer. You do say that there should be a medical letter which is is in existence in the United States and which was recommended by the Hall Commission Report. You go on to say that no matter how it is financed it will result in savings, and I would be interested in knowing just how you have reached this conclusion because you also say that in the United States about only 15 percent of physicians bother to subscribe for this news letter. I just cannot understand how this could effect a lowering in the cost and a savings in the price of drugs.

Mr. STEELE: I think there are two basic facts here. One is that the PMAC evidence shows that about 30 per cent of the sales dollar is spent on various types of sales promotion. The other fact is only 15 per cent of American physicians, roughly, have subscribed to the medical letter. I also think it is a fact, of course, that physicians are very well trained, very intelligent and very busy, and very prosperous.

Mrs. RIDEOUT: Are you suggesting—you say it in your brief—that drug firms are subsidizing physicians at the expense of the consumer.

Mr. STEELE: Yes; I say this because the drug firms are spending in total this amount in supplying the physician with what I think is at lest largely redundant information. I would say, at a guess, in an effectively competitive drug industry maybe about one tenth of what is now done in the way of sales promotion would be profitable.

Mrs. RIDEOUT: How can we under a free enterprise system that we have in Canada in a very competitive business as the drug business is today, keep the price of drugs down if the drug companies, in order to do so, are going to have to lower the cost of their sales promotion; in other words, sort of minimize their sale promotion? Do you think this can be done?

Mr. STEELE: I do not think the direction of causation flows from lower sales promotion costs to lower prices; rather, the other way around. If we induce price competition in the market the companies will be forced to lower many of the items in their budget and I think that the sales promotion items will be one of the most flexible for downward pressure.

Mrs. RIDEOUT: In the case of drugs, which is such a delicate product, do you envisage it might lower the standards of drugs? I am looking to you for advice because you are an economist and obviously have had wide experience.

Mr. STEELE: Well, as an economist, I cannot give you a complete answer to that question, but my impression primarily as an economist and for reading what I have read, Dr. Chapman's testimony, the reports published by the Food and Drug Administration in the United States, at present even under present admit-

tedly imperfect regulations governing safety and quality, the quality of products is not a major problem. Dr. Chapman said that in seven years, they have only got five batches of drugs which tested posed a significant hazard to health. I think if we expand the public inspection of drug manufacturing plants and products in conjunction with programs to bring about more price competition, we can eliminate it this way. As we are set up right now, the private drug companies are ensuring the safety of brand name products and in return for this, they charge you high prices. This is a kind of system of private taxation, I believe, and this could be carried out more economically by public inspection financed by public taxation.

Mrs. RIDEOUT: Well, then, you would probably agree with me that the consumer is in the position of having to rely on the physician and the pharmacist and sort of using their good judgment on what they decide to prescribe and what they have to pay for the drugs. The consumer really is the one who is sort of in the dark in so far as the drug that is being prescribed is concerned whether it is a brand name or a generic? They really have no choice. They take what the doctor prescribes.

Mr. STEELE: The consumer is certainly in the dark, but I think that the physician, if he relies only on the sales promotion material which he receives from the company, is not too much better off. I think that the physician relies not only on the brand name, which is advertised to him, but also on the presence of public inspection.

Mrs. RIDEOUT: Thank you very much.

Mr. BLAKELY: Dr. Steele, on page 3 of your brief, you mentioned the relationship of rish to an appropriate rate of profit as a very complex matter. The drug manufacturing companies state that they believe their returns of profit to be consistent with the risks involved and capital employed. Are the risks in the pharmaceutical industry high?

Mr. STEELE: I think that in the "Green Book" and in the report of the Restrictive Trades Practices Commission, some evidence was indicated where it was shown that the risk of variability in earnings, the danger of having a loss year, is greater in the pharmaceutical industry in the years covered by the survey than in other Canadian industries generally. I think the report properly made note of this observation. However, I think that the risks in the industry are not really inherent. I think that the high prices and high risks, are largely as I said, both symptoms of the same disease. The fact that the large gap between production costs and prices results in a great deal of sales promotion and a great deal of applied research and development, and the fact that a new drug which is developed in one particular month may be superseded a few months later by a molecular rival, is definitely a risk increasing circumstance, but you cannot say very well that the industry is a high risk industry and just leave it alone. If you leave it alone, its risks and profirs will remain high; whereas if you induce more competition, certain types of risks will decline along with the wide gross profit margin.

Mr. BLAKELY: Do you think that the risks that are present in pharmaceutical manufacturing industry are higher than, say in manufacturing in general?

Mr. STEELE: I am going again on the Canadian data, and relating risks of a loss year and the size of the loss, and I think as far as this data are concerned, comparing drugs with other industries in industry, the evidence does tend to indicate a higher risk for the industry in so far as this particular dimension of risk is concerned. This is just comparing drugs as such with all other industries. You can pick other industries, I think, which have equally high or even greater likelihood of individual loss years.

Mr. BLAKELY: The statistic to which you are making reference I would understand is the one that the rate of negative return on capital invested by the loss companies in the pharmaceutical industry generally tends to be higher than that in all manufacturing in general; is that correct?

Mr. STEELE: That is right.

Mr. BLAKELY: Would you think that there should be some consideration given to the proportion of the total industry that is affected by profits, for example, the assets of the loss companies as a proporation of the total assets of the industry; is this a valid comparison?

Mr. STEELE: I think it is valid. I think, as I said in the brief the nature of risks faced may not be understood, and the way in which you measure risks is subject to much debate. I think basically, the risk which is associated with a given investment, or let us say a given year, in lack of a term, has to do with the dispersion of possible profits versus possible losses; the probability distribution of possible profits versus possible losses, would result in a given investment project or from the fortunes of a given firm, say, during a given fiscal year. Now this is in part a subjective measurement, and for this reason I think it is almost impossible to measure the type of risks which are faced directly. The measure which you mention is a good measure of risk.

Mr. BLAKELY: Would you think it is proper to conclude that if an industry has particularly high risks, then, the portion of the total industry that will incur losses will be a fairly significant proportion and by way of comparision should be expected to be higher than all manufacturing in general?

Mr. STEELE: Well, take two industries, one of which is very safe and one of which is regarded by the public at large as being risky, say oil well drilling versus public utilities. To take an extreme case like this, it does not make too much difference what sort of measure is used to distinguish between the risky industry and the less risky industry, but in terms of asking whether or not drugs are relatively risky because of the rate of return on investment, whether it is positive or negative, what percentage of assets in the industry are subject in any given period to a negative rate of return, this is a relatively good measure, but not infallible.

Mr. BLAKELY: Is the rate of return in Canada consistent with the risks involved?

Mr. STEELE: I think the rate of return in Canada is higher than the rate of return in manufacturing industries in Canada in general, and I think probably the risks which are involved are higher; the risk of product obsolescence, and so on, regardless of where the product was originally developed. But I would not base a public policy decision upon the workability of competition in terms of

risks versus profit rates, but in view of the existing structure of the industry, I would say that if I were making a public policy recommendation what I would do would be to introduce more competition, and at the same time reduce profit rates and measured risk.

Mr. BLAKELY: The PMAC made a calculation which they referred to as the rate of return on resources employed. The Restrictive Trade Practices Commission, as you know, had the calculation, rate of return on capital invested. Would you care to indicate which of the two is the better, or is a better indication of the profitability of the industry?

Mr. STEELE: Well, I have done relatively little in my brief in terms of measuring the rate of return on investment because I do not think the data which are available in Canada enable you to define investment very well. I would like to know what the rate of return on investment in facilities used for the production of packaged pharmaceutical products is. I would be more interested in this, say, than the rate of return as shown by the consolidated balance sheets of the international company or of the Canadian subsidiary itself. As far as economic meaning is concerned, I think that the most important measure of the rate of return is the rate of return on invested capital, on the actual value of capital resources which are embodied in the production facilities of the industry.

Mr. BLAKELY: On page 6 you make reference to the method of allocating research costs, I believe it is, "the extent to which the methods chosen are appropriate is another question." Now, from the information presented to this Committee, I would understand that generally the method followed is to allocate research costs to the Canadian subsidiaries on the basis of sales. Do you have an opinion on whether this is an appropriate method?

Mr. STEELE: Well, to some extent I understand the problems which the drug firms have, in that the profitablility of their investment depends not only upon the actual monetary value of resources invested in productive facilities, but also on let us say, theoretically the capitalized value of the know how, and the monopoly power which they have. I do not think they could go about capitalizing this monopoly know how—well it is the capital value of the patent monopoly as such on their balance sheet. I think that it is plausible, as an exercise in accounting to allocate a certain percentage of sales in foreign to research costs undertaken elsewhere. You can argue one way and you can argue the other. The question is not so much whether or not this is done, but how large a proportion of total sales revenue is allocated in this manner. What relationship does it bear to the actual sunk investment in research in other countries. What relationship does it bear to the relative tax treatment of such transactions in different countries, tariff treatment, and for that matter, the pressure which might be at a point in time put on drug prices and profits by investigating committees like this.

Mr. BLAKELY: Do you think that it is proper that there by any charge to Canadian subsidiaries for research costs incurred by the parent organization?

Mr. STEELE: Well, I said you could defend a method like this, and I think a person whose training is primarily in the field of accounting is going to be interested in trying to estimate what total costs went into the research, both successful and unsuccessful, which eventually produced a given drug, and it is an academic exercise perhaps to allocate these costs against the subsequent cash

flow resulting from the production of the marketable product. Now, I am sympathetic to this position because there are financial realities and financial records have to be kept, but in an economic sense, I think, what the companies probably do, is to take a part of their cash flow—it varies from company to company, but it is not very great—invest it in research as a kind of gamble, and a certain amount of gambling pays off. Here is where the risks are involved. Then they market the products, obtain the best prices they can in various countries. I know in the U.S., if they get a U.S. patent, they can make, during the period of patent protection, a large cash flow. In other countries, it depends on the share of the market. In Canada, if they cannot get the same kind of cash flow, it is a question of does the additional cost of setting up a marketing organization in Canada justify the smaller volume of additional revenues from having the drug licensed, so economically I would say there is no real necessity for this.

Mr. LAIDLAW: Mr. Chairman, I would like to direct an odd question or two at Dr. Steele. As you are aware, Dr. Steele, the PMAC group stated, and repeated emphatically, that they considered drug prices to be fair and reasonable, and in support of their statement, Professor Briant of McGill University came here and put forward an argument with respect to the price structure in Canada as opposed to other countries. You have referred to this thing in your brief, and in the appendix at page 138. Now, if the argument put forward by Professor Briant has any merit, and this argument was refuted by Professor English, and economist who was here for the Consumers Association, if Professor Briant is laying a bogey in respect to this method of determining whether the price in Canada is not really as high as is indicated, I would like to see that bogey laid to rest. Have you any comment with respect to this method of interpretation used by Professor Briant?

Mr. STEELE: Well, I think in Appendix B I have gone into this in some length. Basically, it is a way, I think, of relating the relatively high productivity of Canadian labour and a relatively high standard of living of Canadins to the relatively higher prices which Canadians pay for drugs. It so happens that the ratios as computed show what they show. They show that prices in Canada in terms of the labour hours input to purchase a given drug, are lower than in certain other countries, but I think the comparison economically is really meaningless. As I said at the beginning of my Appendix B, the only sort of interest which this kind of comparison would have would be in answering the specific question which is set up to answer. Just how long does it take the workingman in various countries to buy drugs in terms of drug purchasing power; and this question, as I say, is of limited academic interest. It shows what the workingman's real standard of living is in terms of his command of the ability to buy drugs and his income over the years. To start again, the command of his income over drugs in terms of drug prices in various countries. But the data given by Dr. Briant do not answer this question, because they deal with the price to the druggist rather than to the final consumer. I think this distorts the comparison very greatly because the ratio of the druggist's mark-up to the final consumer price appears to be greater in Canada than in any other of the countries mentioned. Beyond this though, the question of relative costs of drugs in different countries is a question not just of the workingman's ability to work so many minutes and buy a capsule or two, it is a question of the cost of producing, selling and shipping drugs in a given market; and to measure this, you have to take into

account other factors of cost than just labour. You have to take directly into account the costs of production and distribution and the actual profit margins earned in different countries.

Mr. LAIDLAW: You would feel that you would prefer to back up Dr. English's submission rather than Professor Briant's.

Mr. STEELE: Yes, definitely.

Mr. LAIDLAW: I would like to pass, Mr. Chairman, to another question. I noticed, Dr. Steele, that you did not include in your recommendations one of the recommendations of the Hall Commission, which was to the effect that promotional expenses should be confined to 15 per cent of the manufacturers dollar. In other words, there would be no tax credit for any expenses incurred beyond that figure. Is there any particular reason that this was omitted from your recommendations, or are you opposed to this particular recommendation, or do you feel that open competition, as you have suggested, would automatically take care of that?

Mr. STEELE: Well, I think the Hall Commission's recommendation would probably have some impact on drug company profits with probably little, if any, impact on prices. I think we ought to let competition determine the level of sales promotion and other outlays, and if competition is really brisk, the level will probably fall below 15 per cent, and this would be reflected not only in lower tax revenues, but also in lower drug prices.

Mr. LAIDLAW: In other words the Hall Commission recommendation might well reduce the cost in so far as the manufacturer is concerned, but this would not necessarily be passed on, do I understand this point?

Mr. STEELE: Well, I would say this, it depends on the response of the manufacturers to a 15 per cent limitation or a flat limitation like this. They may decide, if they all decide to keep on advertising at the same rate as in the past, simply to sacrifice some of their previously after tax profits to taxes; if they decide to cut expenditures 15 per cent, then the result is that these expenditures fall, taxes paid stay the same, prices stay the same. The fact that they spend 1 per cent or 2 per cent of 20 per cent of the dollar on sales promotion expenses has little to do with the demand on the part of the individual consumer for the drug, and this is what really determines the price level.

Mr. LAIDLAW: Thank you, Dr. Steele; my third question follows along the lines that were raised earlier by Mr. Mackasey dealing with research. As you are aware, there are government incentives in existence now with respect to research in Canadian industry. In view of your statement that the drug manufacturers are primarily only interested in applied research or product development, I am wondering whether or not, if research was further encouraged in the Canadian drug industry by tax incentives, this money might be in fact wasted because the companies might use the available funds for working around patents held by their competitors and so on, which would result in increased costs, increased promotional activity and as a result increased prices. Have you any comments on that?

Mr. STEELE: I would agree that in my view it is probably more worth while in terms of long run gains in the entire society to spend money on fundamental

research than on applied research. If research incentives result chiefly in inducing more applied research by the Canadian drug industry, it is a question of the cost to the taxpayers of these subsidies, these inducements, and the resulting value of the discoveries. Now, as you say, this might increase the—it depends upon the nature of the subsidy—this might increase the cash flow, it might result in the development of more duplicate products which would be promoted in such a way as to perhaps raise promotion costs. I would not agree with your final statement that raising promotional costs would necessarily raise prices since, as I said before, I think the prices are determined chiefly by demand, and this is largely independent of Canadian prices.

Mr. MACKASEY: You said prices were largely dictated by demand? Before you said demand had no effect on prices because of the inner elasticity of this type of market.

Mr. STEELE: No. I wish to correct that, if I made that statement. My statement was that prices were determined almost entirely by demand.

Mr. LAIDLAW: Excuse me, Mr. Mackasey.

Mr. MACKASEY: Go ahead.

Mr. LAIDLAW: If the government chose to increase tax incentives, in so far as the drug industry was concerned, concerning research, it might be advisable to confine these tax incentives to certain types of research, if this is practical, I do not know.

Mr. STEELE: I think this would be advisable; even here, all you could do would be to control the direct result of the spending, not the indirect result.

Mr. LAIDLAW: I have only one final question, Mr. Chairman, which I would like to put; it is really not in the brief and I would like perhaps Dr. Ross also to participate in this answer. I have a little book in front of me entitled "Medicine and Politics" written by the Rt. Hon. J. Enoch Powell, who was the Minister of Health in the United Kingdom, I believe, between the years 1960 and 1963. In this booklet, at page 65, he discusses a voluntary price regulation scheme which was set up in the United Kingdom in which the government personnel of that department presumably and members of the drug industry worked together in determining the prices for drugs covering only medicare or the health services aspect of hospitals, and so on. This, I have been told, has been working very well as a voluntary scheme. In view of the approach now in Canada both federally and provincially, to medicare and other health services, do you feel that a similar type of voluntary arrangement is possible in this country, or do you think it would work; do you think that drug purchases by pharmacists should be handled by tender and not under any voluntary scheme; have you any comments to make about this?

Mr. STEELE: I believe that as far as Canada is concerned the bargaining power of the Canadian authorities relative to the international drug companies is smaller definitely than it would be in the case of Britain, and I think this is what counts. In Great Britain the bargaining power with regard to many drugs is not very great. I would not place very much reliance on a program of voluntary restraint. In the same context I find it as I say hard to take seriously the value of a program of voluntary restraint taken by itself. The difficulties in the case of

Canada would be that if we were going to induce the companies, let us say by admonition, by negotiation, to voluntarily restrain their prices, you have got to have some data to base an appropriate price level upon. If the important data are the property of foreign parent companies, it is going to be hard to get your hands on this data. This is what the British government has found. Let us say the promotion of a program of voluntary price restraint may very well have an adverse effect on the vigilance of public opinion.

Mr. LAIDLAW: Dr. Ross, have you any comments to make on that approach?

Mr. ROSS: All I would say in regard to the question that you raised as to the purchasing by governments of supplies of drugs is that I would favour, and I think it is usual government policy to have closed tender purchase of practically all of the supplies that are purchased by government. My own personal opinion is that is provides the competitive advantage to the government from the various suppliers that may be capable of supplying the items that they are wanting to purchase since the companies, often times for prestige, are prepared to make competitive bids that are really quite substantial, and in this way the public being served by such a program does benefit. In our experience certainly, and in the various drug programs we have entered into our putting out to tender for supplies has resulted in a very substantial savings to the public at large who eventually use these drugs. We use this method certainly in our purchasing for our provincial hospitals although we often times may specify a particular drug; some of the doctors may specify a particular drug they wish. In this case we are dependent then upon the company that is manufacturing that to provide us with a price that is what we would hope to be a realistic one.

Mr. LAIDLAW: Thank you, Dr. Ross; that is all, Mr. Chairman.

The CHAIRMAN: Gentlemen, I think we should probably recess—

Mr. MACKASEY: At one o'clock.

The CHAIRMAN: No, at 12:30. Well, the gentlemen have been here since 9:30.

Mr. MACKASEY: So have I, Mr. Chairman, and the other gentlemen as well. This is a very comprehensive brief and we would insult Dr. Steele by not putting in all the available time.

The CHAIRMAN: We will be starting again this afternoon.

Mr. MACKASEY: I have been here since 9:30 and I have been restricted properly to precisely ten minutes in three hours. Now if you feel that this is an appropriate, fine; you are the Chairman.

The CHAIRMAN: Well, it is just that most of the other Committee members seem to feel that they have other engagements.

Mr. MACKASEY: The Committee members have a responsibility to this Committee, particularly the fact that this is the final day and particularly in view of the fact that we have got a very complete brief. It could be considered controversial, but it certainly is complete. Anyway, you are the Chairman, I have no—

The CHAIRMAN: Well, what have the other members of the Committee to say?

Mr. JOHNSTON: Well, personally, I question the wisdom of making Committee hearings into ordeals of time and endurance, and this I think is one of the reasons why the attendance falls, as it does. If the witnesses are agreeable to stay, I do not mind holding out for another half hour, but I do feel that starting at 9:30 and going through to one o'clock is simply too much, at a stretch, of an ordinary committee sitting.

The CHAIRMAN: I would remind Committee members present that we are sitting again at 3:30 or if the question period is not over, whenever it is completed.

Mr. MACKASEY: We will be sitting from approximately four to what time, Mr. Chairman?

The CHAIRMAN: Five thirty or six o'clock. I understand that Dr. Ross will not be here but Dr. Steele can be.

Mr. ROSS: We are booked to go out this afternoon. This can be changed if the Committee wishes to have us here.

Mr. MACKASEY: Dr. Ross, you explained this morning you have other commitments and I appreciate it, but firstly, to hand this committee a 210-page brief and expect us to accept it as gospel truth, without questioning by at least certain members who feel that they should question it, and any questions I have are for information to clear up many of the arguments that I have heard from PMAC and which seem to be adequately refuted here. It just seems to me to be a mockery of the whole committee process. I agree with Mr. Johnston that three and a half hours is a long time, but I must emphasize that, as one committee member, I have been properly restricted as everybody else has to ten minutes. So I evaluate the Committee not at three and a half hours, but at ten minutes as far as I am concerned.

The CHAIRMAN: Well, Mr. Mackasey, other people's questions are important, too.

Mr. MACKASEY: They are, and I have listened to them with great interest too, but I have heard many of them before.

Mr. ROSS: Mr. Chairman, as far as the Alberta group is concerned, Professor Steele will be here just as long as the Committee wishes to have him. Dr. Rose and I are prepared to stay over until tomorrow and get the plane back tomorrow if it is the wish of the members of the Committee for us to do so. I realise that my contribution to this brief cannot be very much because certainly Professor Steele has prepared a brief, not that we consider it entirely gospel truth, but it is the submission that we are making as a government of one of the provinces of Canada to assist the Committee here in an inquiry that we consider is a most important one. I think in view of the potential developments in the health field in our nation, this total inquiry that you are undertaking ranks among one of the most important inquiries that the various committees will be undertaking this session and for many other sessions. We are at the wish of the Committee if you would like us to stay over. I am sure we can change our plane reservations until tomorrow.

The CHAIRMAN: I think really that the Committee as evidenced by the questioning this morning, are interested in spending a great deal of time with Dr.

Steele primarily, and as Chairman, I would certainly like to commend the province of Alberta for the tremendous undertaking they have had here. Unless there are questions, that Mr. Mackasey or Mr. Johnston might have of Dr. Ross, perhaps we could start this afternoon with Mr. Mackasey on the understanding that Dr. Steele will be here if—

Mr. MACKASEY: Mr. Chairman, there are 200 pages, and I have an average of two questions per page. Now, you just tell me as Chairman, how I am going to ask my questions?

The CHAIRMAN: The meeting is also set for eight o'clock this evening. We are hoping we will get a considerable amount of work done. We will start the meeting again at 3:30, or if the question period is still on, after orders of the day. We will start with Mr. Mackasey.

AFTERNOON SITTING

The CHAIRMAN: Gentlemen, I see we have a quorum, so I would like to continue the hearings of this morning. We will hold to the same rules, ten minutes for each set of questions and we will start with Mr. Mackasey.

Mr. MACKASEY: Dr. Steele, your brief refers to just about every brief that has been filed before the committee; PMAC, consumers' report, and so on, but there is absolutely no reference in your brief that I have been able to find—perhaps it does exist—to the Hilliard Report. Is there any particular reason why you have not discovered the Hilliard report?

Mr. STEELE: No, there is no particular reason. I thought the impact of the Hilliard report recommendations on economics were reasonably neutral.

Mr. MACKASEY: Well, is that the only observation you have on the Hilliard report?

Mr. STEELE: That is by way of explanation of why I did not refer to it. I think their recommendations are reasonable, except there is the question at the back of my mind whether or not if the Hilliard Report recommendations could not be implemented so as to cause additional delay in putting on the market the products produced by compulsory licensees.

Mr. MACKASEY: Excuse me. I am just checking my notes so I can come back to it. I am rather intrigued at the additional delay, you mention this I think in your brief, and I understand why you have not touched on the Hilliard Report since your brief obviously is meant to treat strictly with the economics. Am I right in the presumption?

Mr. STEELE: That is right.

Mr. MACKASEY: Although you do make quite a few references in it to ways and means of increasing the safety of drugs. What are the additional delays that the Hilliard Report would implement that you would take objection to?

Mr. STEELE: As I say, it is not so much the wording of the Hilliard Report, and it is not even the spirit of it, but it is the overriding concern with drug safety and quality which very properly is expressed in the report. I think this might

very well lead to, let us say, providing really redundant requirements for additional clinical and experimental testing and provision of information, brochures and this sort of thing, not only delaying the time required for the compulsory licensee to put his product on the market, but also increasing certain of his costs.

Mr. MACKASEY: Dr. Steele, I say this with the greatest respect, cost and safety are included among the mandates of this Committee. The Hilliard Committee was composed of doctors and scientists who naturally were concerned with safety. You are, logically, concerned with cost, but we cannot entirely divorce the two things. If, in the opinion of the Hilliard committee, some of these additional delays are prescribed in what they consider to be the best interests of Canadians in so far as safety is concerned, do you not think that this overrides even your concern for the cost of drugs?

Mr. STEELE: Well, I certainly agree that drug safety is of overriding importance, and, as I say, nobody wants to be exposed to the hazards of drugs, whether they are cheap or expensive.

Mr. MACKASEY: I agree with you; you can be exposed to bad drugs. The cost is necessarily any criteria as to whether a drug is safe or unsafe. I am fully convinced of this after listening to Dr. Chapman. I do not disagree with you on this. We have a meeting of minds. Nevertheless, I am rather surprised that you place so little emphasis on the Hilliard Report when you have placed an awful lot of time and effort on just about every other report. Many of the other reports were not necessarily directed entirely to costs, if I recall.

Mr. STEELE: No, it is really a question, I think, of the context of the discussion of drug costs, and prices, and drug safety. I believe that this Committee previously considered drug safety at great length.

Mr. MACKASEY: Having read some of your articles that were distributed this morning, and having read your brief quite excessively, I realise that the bulk of your findings are based on the Kefauver hearings supplemented by what you have found of value from our hearings, but I have always had great faith in our Food and Drug Directorate, which has been above suspicion, which, I must say, is unlike some regulatory bodies in other countries. I cannot imagine our Food and Drug Directorate holding up a new drug for any other reason than that they are interested in the safety of the Canadian people.

Mr. STEELE: Well, my position on safety is that clearly it is worth spending as much money on the part of the Food and Drug Directorate to ensure safety as it costs, and if it is going to cost more money, more money ought to be appropriated. As I said, I think that if it is possible to create a doubt in the mind of any physician in the country that Food and Drug Directorate inspection is not adequate, then the physician is going to be, to that extent, the more reluctant to prescribe generic named drugs; so no matter what it costs, if it costs $10 million I would prefer to see the Food and Drug Directorate inspection powers made adequate.

Mr. MACKASEY: In other words, we both agree that an attack on generic drugs as being unsafe is really an attack on the Food and Drug Directorate which has the responsibility to see that all drugs made available to the Canadian people are safe.

Mr. STEELE: Yes, I would agree.

Mr. MACKASEY: We both agree, but I am more concerned with your implication—and I will refer to the specific page in a minute if I can recall it—that drugs do not get to the market quite as fast as they should. I am a little puzzled, because I was under the impression that it was the Food and Drug Directorate responsibility to take all the time in the world until they are fully convinced that the drug to be introduced to the public is, in their estimation, completely safe. This is the part that concerns me. This is really the basis of the Hilliard Report.

Mr. STEELE: If I understand you, you are saying that as far as the original applicant is concerned, you think that the Food and Drug Directorate would, under no circumstances, rush through the approval of a new drug?

Mr. MACKASEY: Well, the reason I come to this conclusion is that many of the innovators—if we are going to fall into their terminology, or you call them monopolists, I think, but we all know who we are talking about—have complained at times that the Food and Drug Directorate are slow in clearing their applications. Their pleas, at least to me, fall on deaf ears because I am more concerned with the Food and Drug Directorate carrying out its functions properly, and that is to make certain that the drugs that eventually get on the market are safe. Yet, I have read in your brief, and I am going to try to get the page, that you are critical of the time that it takes a new drug to get to the market. Am I right in this appraisal or am I wrong?

Mr. STEELE: No, this would be a misinterpretation. If the text justifies this, I would like to change it. My feeling is that as far as the original applicant is concerned, the processing of the application should be done at a pace appropriate to the importance of the task. Once the material has been gone over very thoroughly, then I think anybody who can produce an identical drug should be able to achieve expedition in the processing of his application.

Mr. MACKASEY: Now, you are talking about people who have obtained permission to reproduce a drug through compulsory licence in this country.

Mr. STEELE: That is right.

Mr. MACKASEY: You feel that there is undue delay in obtaining this permission?

Mr. STEELE: Frankly, I feel there might be, and I feel by dwelling on the possible dangers of, let us say, compulsory licensees going out and producing drugs in back alleys and things like this, that this will tend to create an atmosphere of suspicion and, if a delay is only an additional month or two, this certainly prolongs the period of primary high prices in the market.

Mr. MACKASEY: Well, I can understand your point of view that the sooner someone with a compulsory licence starts to compete with a monopolist, the tendency will be to drive the price down. Now, I do not share your viewpoint, because you used the word might. I am just wondering if you have any evidence of the fact that the Food and Drug Directorate does impede a successful compulsory licensee from getting his product to the market.

Mr. STEELE: No, I have no evidence. It is only that I want to minimize the possibility of such delay.

Mr. MACKASEY: How do you want to minimize it; in what way, what fashion?

Mr. STEELE: Well, to minimize the possibility of delay, I would lay down a number of administrative steps which should be made routine. I think the Hilliard report recommendation that there be more co-operation between the Food and Drug Directorate and the Commissioner of Patents is very appropriate. This might expedite matters.

Mr. MACKASEY: Have you any other suggestions because this one has already been carried out. I understood from Dr. Chapman last week that this had already gone into effect, if on an informal basis; that co-operation as a result of the Hilliard report is already in effect. Have you any other positive suggestion?

Mr. STEELE: No; I am more sensitive to the dangers of overstressing the hazards of the product of the compulsory licensee.

Mr. MACKASEY: I am a bit confused, overstressing the hazards by whom?

Mr. STEELE: Someone could take the Hilliard Report, for example, and say that on the basis of this study, which was done by a number of very competent and very dedicated men, completely above the battle as far as the drug industry infighting is concerned, perhaps we ought to set aside a period of up to one year during which the extensive clinical and experimental testing of compulsory licensees' products is to be carried out.

Mr. MACKASEY: You are afraid that someone may make this suggestion?

Mr. STEELE: I was afraid of that.

Mr. MACKASEY: Why are you afraid of that? Why would this suggestion be advanced by people of the calibre of the professors that were on the Hilliard Committees; what would be the purpose of recommending a year's moratorium as you might want to call it, of the actual production?

Mr. STEELE: I do not think the people who are responsible for the Hilliard Committee Report would made such a recommendation. But I think recommendations could be advanced on the basis of that report, at least it is easier for recommendations to be justified on the basis of reports such as that.

Mr. MACKASEY: In other words, the report does give some indication that this is valid and perhaps necessary?

Mr. STEELE: Well, I am hypersensitive to this issue of safety. I think this is a sort of red herring which is continually raised, that the generic drug maker really does not know what he is doing and he is trying to foist off poisonous products on the public.

Mr. MACKASEY: You do not have to convince me because I agree fully with you that there is no evidence that this is so. I share your sensitivity about the red herring of safety, but not everybody—and I think you will agree with me—will agree that safety is necessarily a red herring; that the Food and Drug Directorate is concerned with safety. The purpose of the Hillard Committee was to ensure safety under certain conditions. If it implies that this type of action should be considered by the Food and Drug Directorate, do you not think such a suggestion is proper; even at the cost of providing competition, no monopoly?

Mr. STEELE: Well, what about the adequacy of present inspection? From what Dr. Chapman said, with only five drugs in seven years constituting a hazard to health, I think the present inspection is adequate. Is it not an argument that we do not need the sort of inspection we have right now?

Mr. MACKASEY: Well, you have brought up a valid point except that you probably have not read all the briefs; Dr. Chapman has the very pleasant habit of bringing six or seven supplementary briefs along with him as most witnesses do. He did express, I think, in a report concerning importations from Europe, a concern about the fact that the end result of certain bulk drugs coming in are obviously manufactured by different processes, and that the Hilliard Report has expressed some grave concern that this different method of processing can result in bad effects.

Mr. STEELE: Yes; this is one of the points that bothers me specifically. I got preliminary copies of several of the transcripts of Dr. Chapman's questioning, and in particular I think there is a danger that—suppose the manufacturing processes are exactly the same, except one of the dimensions of quality control is somewhat different—

Mr. MACKASEY: Well, I see the hammer half raised, so I will ask my last question and that might close the Hilliard Report. I may not ever get another chance to come back to it. You mention the desirability of complete co-operation between Dr. Chapman and the Department of Justice in the question of compulsory licencing, but I think there is a third recommendation, or another phase of it which you would appreciate as an economist. Could you approve or express your comments on a board of three, the Department of Justice to seek out the validity of the compulsory licensee or the application, Food and Drug to make certain that the licensee meets the safety standards and an economist, preferably one with your knowledge, to establish a realistic royalty, when and if a compulsory licence be granted?

Mr. STEELE: I think it would take a political scientist to answer that question, whether it is better to have, the tribunal of one, two, three or four; in theory it is fine, if it does not too seriously retard the process of reaching decisions.

Mr. MACKASEY: Well, Judge Thorson who was here representing a very competent firm, I will not call it a generic firm, but a good firm, expressed the opinion that the royalty being paid out at the present moment under compulsory licences was a pittance. He also expressed the opinion that they should be upgraded if proof could be made that research was done in Canada. Would you agree with this?

Mr. STEELE: The question here is what sort of reward a royalty should represent. Now, I am not clear in my own mind as to the desirability of the patent incentive in inducing more productive new invention, but this is a broader issue. The narrow issue is, should the royalty be a reward for the research carried out to allow the firm making the invention to recoup its research costs, however reasonably defined? Or should it be a device which would prevent the compulsory licensee, give him a sort of cost penalty, so that he could not compete too stringently with the original patent holder? If the compulsory licences contain royalties which were related to the recovery of reasonable

research costs, I would have less objection than if it is a question of—as in the United Kingdom—preventing the patentee from having a cost structure similar to or lower than the original.

Mr. MACKASEY: But you quote a Dr. Wright in your brief, so obviously you have read his testimony, and I think in the same testimony, he admitted that in a particular instance where he had obtained compulsory licence, the margin of profit which he, the innovator, is able to realise, is greater than that of the monopolist. So what penalty are you really talking about?

Mr. STEELE: Well, clearly the royalty which in this case I presume the original patent holder would have described as a pittance, was not sizeable relative to production costs.

Mr. MACKASEY: I must correct you; it was not described as a pittance by the patent holder; it was described as a pittance by the legal adviser of the licensee.

Mr. STEELE: Yes, you are right. I am sorry, I have read Judge Thorson's remarks. I was trying to speak for the patent holder and I should not have done that.

Mr. MACKASEY: You are not supposed to be speaking for anybody here; you are speaking for your brief, as I understand it.

Mr. STEELE: Yes; this is a big question and it relates to the expediency of the patents and it has a way of bringing about new research, invention innovation. I think the fact that the cost structure of the firm which is in the position of having to consent to a compulsory license really should not be controlling here. I think it is the fact that competition should be introduced and—

Mr. MACKASEY: As soon as possible.

Mr. STEELE: As soon as possible.

Mr. MACKASEY: Thank you, Mr. Chairman.

Mr. O'KEEFE: Mr. Chairman, can I ask how much is a pittance?

The CHAIRMAN: How much is a pittance? Fifteen per cent, I think, of the bulk price of the drug was the figure that we had quoted?

Mr. MACKASEY: Fifteen per cent of the material.

The CHAIRMAN: Of the price of the bulk drug.

Mr. RYNARD: Mr. Chairman, if I am asking a question that has already been dealt with will you stop me. I was unable to be here this morning. On page 8 Dr. Steele says: "limiting the liabilities of drugs to tariff duties to those drugs of a class or kind actually made in Canada". I would like to ask Dr. Steele if he would eliminate these tariffs? Is that your point?

Mr. STEELE: Which recommendation is this?

Mr. RYNARD: This is on page 8, No 6, at the top.

The CHAIRMAN: Of the brief or the summary?

Mr. RYNARD: The brief, the small brief.

Mr. STEELE: What is your question?

Mr. RYNARD: Well, I just want to know, are you for eliminating all the tariff on drugs that are being imported?

Mr. STEELE: No; I am not making that recommendation.

Mr. RYNARD: What is the point you are trying to make there? I am very unclear about some of these recommendations that you are making, in reading them over quickly.

Mr. STEELE: Well, there are two points here with regard to recommendation No. 6 on page 8 of the statement. First, 6a, I want to eliminate tariff protection for those drugs which are not currently being made in Canada; those drugs of a class or kind which are not being made at all in Canada. Second, I want to reduce the applicable rates for drugs of a class or kind actually made in Canada, to, as I say, the minimum level consistent with maintaining necesary protection for our domestically situated firms.

Mr. RYNARD: I still do not get the point. If you are importing a drug into Canada, if it is made in Canada, then you still want the tariff to stay there. You say "limiting the liabilities of drugs to tariff duties to those drugs of a class or kind actually made in Canada". To me, that is a contradiction. Maybe I am dense on that?

Mr. STEELE: Well, maybe the wording here is inappropriate. All I am saying is that if a drug is currently being made in Canada, retain some of the tariff protection but a minimum degree. If it is not currently being made, then eliminate the tariff.

Mr. RYNARD: Then you change that "A"?

Mr. STEELE: Change what?

Mr. RYNARD: Well you changed it at page 8, at A it says you would limit the liability of drugs to tariff duties to those drugs of a class or kind acually being made in Canada. In other words, if the drug is made in Canada, you want to retain protection?

Mr. STEELE: Yes.

Mr. RYNARD: That is all right. Now, it is says, "(b) reducing the applicable rates to the minimal level consistent with the provision of the desired degree of protection of domestic producers". How would you arrive at that?

Mr. STEELE: Well, I think this is essentially a political decision.

Mr. RYNARD: An economic one.

Mr. STEELE: No, economically, you would eliminate tariffs entirely, I think, if your only consideration was minimizing the cost of drugs to consumers in Canada.

Mr. RYNARD: In other words, what you are saying is then, from the economic standpoint, you would eliminate tariffs entirely, and you would not even protect the firm that was manufacturing in Canada; this is in effect what you mean.

Mr. STEELE: Yes, that is true. If they can produce more efficiently, let them produce.

Mr. RYNARD: Then politics keep the tariff up?

Mr. STEELE: Yes, that is why I say politically.

Mr. RYNARD: I guess we will have to talk to the government. Well, I want to deal a little bit further with this summary. You feel that research should be taken out of the hands of the drug firms and put into the hands of the public sector, and the universities to do this research?

Mr. STEELE: Well, I would like to have some up to date figures on the percentage of medical research which is done at the private level and at the public level in Canada today. The most recent figures I have seen are those from the Hall Commission Report, I think, for 1955-56, in which they indicated that about 17 per cent of all medical research in Canada was done by private pharmaceutical firms, and the percentage may well have increased somewhat since then, I do not know. At present it seems to me that most of the research is being done at the public level or through non-profit, perhaps philanthropic foundations.

Mr. RYNARD: You are advocating that this 17 per cent even be done away with, from the standpoint of economics?

Mr. STEELE: Yes, it might be desirable to have that reduced still further.

Mr. RYNARD: Would you tell me why?

Mr. STEELE: Well, in the early part of my brief I try to outline reasons why I believe that the existence of a highly profitable pharmaceutical industry tends to bias drug research in a nation away from fundamental research and towards applied research. What is important is not so much draining off 17 cents of each research dollar as being able to pay the very highest prices for the best individuals and the draining off, let us say, more than 17 per cent, of our top talent to applied research.

Mr. RYNARD: Do you not think you would take away some of the incentive and some of the competitive spirit once you put everything in the public sector? Do you not think that this is a spur to keep the drug firms growing and working to produce something new that they are going to make some money out of of?

Mr. STEELE: It depends on the conditions under which the research workers employed by the drug firms operate. There have been arguments especially from British drug firms, I think these arguments relate to a period now 5 or 6 or more years in the past, that for carrying out the kind of applied research which during that period of time at least, drug firms were engaging in, you really did not need Ph.D's; you did not need highly trained people; that perhaps the positions were overqualified if you required even university graduates to engage in this particular sort of research activity. It was team work; it was a routine sort of thing, and the British companies at least felt they could get along pretty well by training their people, provided they were intelligent enough to begin with.

Mr. RYNARD: Well, I think probably, Mr. Chairman, what goes on in Canada is quite a lot different from what goes on in Great Britain. Great Britain is an old country, and we are in our infancy in the establishment of drug manufacturing. Take Ayerst, McKenna and Harrison. I believe they do most of their research work right here in Canada. I know some of the work they are doing has been of inestimable help in the field of agriculture and what concerns me is that you would change this and put research in the public sector, which is absolutely

contrary to what we are doing in industry. We give incentive to industry to establish in certain areas, but you are taking an altogether different attitude so far as the drug business is concerned. I cannot see this, and I would like you to explain why you take this attitude?

Mr. STEELE: Well, I have tried to explain in the first section of the brief—it is in the section on basic and applied research of chapter two—that on the whole, the ultimate productivity of basic research is greater than that of applied research. Now, they have to go together in some sort of combination, and figures which were devised for the United States industry as a whole, showed that out of the total research development budget, about one per cent of it went to true fundamental research, and about three per cent went to the higher reaches of applied research. Well, this is about a 3 to 1 ratio, but only 4 cents out of the total research and development dollar in the United States. I think that the successes of the drug industry in the immediate post-war period, say the entire post-war decade, were due primarily to basic research breakthroughs, and that since that time, the industry has been expending less effort on fundamental research, exploiting more and more intensively the breakthroughs made in basic research now a generation or so ago.

I would certainly have no objection to private firms employing highly qualified research workers, and just letting them do basic, fundamental research. Some companies do this, or indicate that they do, but I think this is the exception. However, I think that the business managers or the managers of the firm who allocate the firm's sales dollar among the various categories of expenditure tend, for perfectly valid and perfectly rational reasons, to relatively stint the basic research side of research programs because they may very well spend hundreds of thousands or millions of dollars in developing some totally new breakthrough, and then be able to exploit the advantages only over a period of 20 or 30 years and obtain only a small portion of the total benefits from their breakthrough. Therefore, I would think it would be ridiculous on business grounds alone for a firm, let us say, to devote 50 cents of the sales dollar to basic research. In the long run it may prove of great benefit to society, but it would probably benefit their rivals as a whole much more that it would benefit them.

Mr. RYNARD: Well, basically, regardless of whether it is done in the public sector or private sector, it is going to cost the people money, and the government is either going to pay for it in the public sector or private industry is going to pay for it out of what they get from the products they sell. What in effect you are saying here, and I may be wrong in saying this, Dr. Steele, but I am very concerned about this, that to cut the costs, you would cut out all advertising by these drug firms? Now, let us carry that to the logical conclusion. Then you cut off all advertising in your daily papers, for all the firms that are doing business across Canada. What happens to your daily papers? How long is it before your daily papers have to be supported and owned and controlled by the government?

Mr. STEELE: No; I think this misinterprets the direction of cost reduction versus price reduction in my brief. My analysis is this, unless a lot more price competition is introduced into the industry, you can cut costs and not have any effect on the prices. Prices are governed by demand, not by cost, so if you get the drug industry to cut its sales promotion and expenses from 30 to 15 cents, this need not have any effect at all on prices.

Mr. RYNARD: Well, if you introduce price competition, then a lot of your firms are going to go down, and this is what we see to day in many industries. They get bigger and bigger, and finally you have got three or four controlling the whole thing, so where is your competition gone?

Mr. STEELE: Well; we are a long way from that right now. The danger of this exists in industries where economies of large scale production are important, and I do not think this is the case in drugs; in automobiles, certainly. If you have competition, as I think I said in my brief, it is competition to establish a monopoly. The most succesful competitor in an industry where you have economies of large scale production will eventually become a dominant firm, but in drugs, this is not the situation. You can produce drugs, enough drugs to supply the entire national market, on the basis of relatively small investment, and your costs per unit of production do not really decline significantly as the rate of production increases.

Mr. RYNARD: In other words, you say you agree with the car situation where there are the big three or the big four, but how about your drugs? Would you bring them down to the big three or big four and then the doctors have very little choice?

Mr. STEELE: No; I think that in drugs, if price competition were to prevail, short price competition, I agree with part of your statement, a lot of firms would go under. These would be the higher cost producers, as happens in competitive industry, textiles, and otherwise. I think that it would be much more difficult for the most efficient firms in the industry to become very large on the basis of economies of large scale production alone since they do not exist in drugs.

Mr. RYNARD: Well, then, Dr. Steele, they could get together and three or four of them could set their prices and their profit? This is what you are saying right there; this what I was bringing up a little earlier—and you said you did not think it was relevant—while we were discussing this very point.

Mr. STEELE: Well, I would question whether you ever get to the point where there are only three or four large drug firms. I would say that the economies of scale are such that you could support 25 or 30 firms, none of which would be dominant in size, and this large group does not make a very stable basis for collusion in price setting.

Mr. MACKASEY: I have a supplementary question here. I believe in your brief you emphasized a statement of the Restrictive Trade Practices Commission, that there was no evidence of such collusion in Canada in the pharmaceutical industry; am I right?

Mr. STEELE: Yes, I did.

Mr. MACKASEY: Yes, that there is none, or yes that there is.

Mr. STEELE: Yes; there is none.

Mr. MACKASEY: Thank you.

Mr. RYNARD: But, Mr. Chairman, this does not mean that there could not be. We know of very many organizations and business firms today where we feel that perhaps there is some collusion on prices so that they do not go down. This could happen in the drug business when you allow free competition. I am concerned about your attitude towards the drug firms. If your suggestions

were carried into business, why pretty soon you would have everything publicly owned, even the newspapers and everything else. This may be a long step in that direction.

Mr. O'KEEFE: Dr. Steele, I believe a few minutes ago in answer to a question by Dr. Rynard, you advocated the abolition of tariffs on drugs and I have a feeling Dr. Rynard agreed. As an economist, Dr. Steele, would you say that if you extended this policy, in view of the fact that most goods manufactured in Canada could be more cheaply manufactured elsewhere, would you not at one fell swoop abolish all our manufacturers?

Mr. STEELE: Well, in my brief I did not recommend the abolition of tariffs, I recommended—

Mr. O'KEEFE: I thought you did in answer to Dr. Rynard.

Mr. STEELE: I said that on the basis of obtaining the maximum possible price reduction for drugs, you could probably do this most rapidly by abolishing tariffs entirely, and it was a political decision whether or not you wished to protect production to some extent while enjoying lower prices to some extent.

Mr. MACKASEY: I think what Mr. O'Keefe is referring to, because I pricked my ears up, is that you suggested as an economist it was logical to obtain your goods, whatever they be, wherever they can be produced most economically.

Mr. STEELE: Yes, this is abstracting—

Mr. MACKASEY: This is the free-trade policy which is controversial in Canada at the moment.

Mr. STEELE: Yes; this, as I say, is abstracting the economic sector entirely from the other sectors of the economy, political and social.

Mr. O'KEEFE: You also advocated, Doctor, I believe, mail order houses for drugs. Now, if this were done in my own province of Newfoundland, and most of the people bought their drugs through mail order houses, who would get up at two in the morning in a small village in an emergency to fill a prescription for a sick child?

Mr. STEELE: My comment on that would be that if this service was necessary, the person who required the service would be likely to have to pay the full cost of the performance of this particular service. Now, I do not think mail order pharmacy will reduce, or do away entirely with the local pharmacist, because clearly there are a lot of drugs which are needed very rapidly and very quickly. Certainly, the pharmacist in a local area would have to reduce his prices to be competitive with the mail order service or else he would lose this part of his business. However, I think, taking into account the additional cost of the mail order service, that this threat would be sufficient to bring about price reduction in areas where druggist previously had local monopolies without actually depriving them of too much of the business.

Mr. O'KEEFE: But you do have some reservations on the mail order service? Surely that cannot be a very satisfactory one all over Canada?

Mr. STEELE: I think, let us say, somebody who uses oral anti-diabetic drugs all the time can keep the pipeline open. Let us say, he can refill his prescription safely in advance of the probable delivery date.

Mr. O'KEEFE: You would use that as a threat to the local pharmacist to keep his prices down; is that the basis of your presentation on this point?

Mr. STEELE: To the extent that low cost production, let us say, is always a threat to higher cost sellers.

Mr. O'KEEFE: Thank you, Doctor.

Mr. HOWE (*Wellington-Huron*): Dr. Steele, I was interested in the reply you gave to Mr. O'Keefe in connection with the fact that there might be monopolies developing in certain areas. Do you think this can exist in very many places in Canada today with travel and transportation facilities so available in most areas. It might develop in some remote area, in the north of Newfoundland, but this would not have any drastic effect on the reduction in the cost of drugs, would it?

Mr. STEELE: I was just reading the Hall Commission Report, I think they said that there were some 674 communities that were supplied only by a single drugstore. After all, you have to take into account often the relative urgency of filling a prescription; you may not wish to drive too far, from one drugstore site to another, just to get a lower price; it might not justify itself economically.

Mr. HOWE (*Wellington-Huron*): Yes. You probably have never lived in one of these small areas but if it is found out that the druggist is overcharging in one particular instance he will not be too popular in that community in doing business. This will have an effect on him, too. I do not agree with this that there are that many places where monopolistic situations develop in regard to druggists in the smaller communities.

Mr. STEELE: Well, I would suggest this though, that if he is truly a monopolist, then the good will of the buyers does not matter too much. If there are no alternative sources of supply, you can resent paying high prices, but what can you do.

Mr. HOWE (*Wellington-Huron*): Yes; but we were told by Dr. Chapman the other day that only two thirds of the business done in the drugstore is done through the dispensary and through the pharmaceuticals, the remainder is the chocolates and all the other types of things that he has in his store, so that he still depends on the public for a great deal of his business, and if the word gets around that he is charging more than he should, he will not stay in business too long.

Mr. STEELE: Well, it depends; if there are no alternatives available his customers do not know what a reasonable cost price standard is.

Mr. HOWE (*Wellington-Huron*): Well, after all, because of the newspaper media, transportation facilities today and the advertising, I do not think that this would really be the situation.

Mr. STEELE: That would be the situation if there is no alternative source of supply. On the other hand, even in a large urban centre there may be less price competition than would be justified because of the nature of the prescription market. He may very well find that prices charged in these 674 isolated pharmacies—just for illustration purposes—do not differ too much from the prices charged in pharmacies as a whole. But if you institute a mail-order service and lower your average cost, increase your volume, I think that a substantial difference would develop.

Mr. HOWE (*Wellington-Huron*): Do you not think that a mail order service for special types of drugs—as Mr. O'Keefe said—would not work out because so many of these special drugs are required in a hurry. You would not have time to go through a mail order office and get a return.

Mr. STEELE: Yes.

Mr. HOWE (*Wellington-Huron*): I am rather interested in the statement that you make on page 10 in connection with the freedom of entry of drugs. You say, "The freedom of entry in drugs is greatly lessened by the existence of a patent privilege, a trade mark device, and the necessity for newcomers to match the enormous advertising outlays of existing rivals". Does the quality of the drug that is coming in not have something to do with it as well. We hear the story of the better mousetrap; somebody has discovered something that is outstanding. The advertising would not enter into so much in that case, would it? He has discovered a drug that can cure certain diseases, say cancer, for instance. Do you think he would have to do a lot of advertising? He would just have to tell a few people and prove that he was right and it would be sold immediately, would it not?

Mr. STEELE: I certainly agree that if a drug were developed which would cure cancer, the word would get around very rapidly.

Mr. HOWE (*Wellington-Huron*): In other words, the amount of advertising he has to do depends on the product that the newcomer is bringing into the market?

Mr. STEELE: Yes, I would say so.

Mr. HOWE (*Wellington-Huron*): In the next paragraph, you intimate that there are big, bad boys in the drug business; they are big operators; the little fellows are afraid of incurring their displeasure, and so they have to maintain the same price irrespective of whether they can sell it for less; is that what you mean there?

Mr. STEELE: Well, paragraph four, which you are quoting from, does not refer solely to the drug industry. This is just a list of requirements of a workable competitive market where price competition would prevail. Now, let us see, I say, "none of the sellers should be so large that he overshadows the magnitude of his competitors and poses a potential threat should they incur his displeasure. In general, this is true, particularly in industries where price competition is a danger, and if somebody cuts prices in the local market, let us say, his rivals undercut him and show him the error of his ways. This does not happen in drugs.

Mr. HOWE (*Wellington-Huron*): Has it been tried?

Mr. STEELE: Has it been tried?

Mr. HOWE (*Wellington-Huron*): Do you know of any instances where some small operator was forced out of business because he felt he could sell that drug at less than the big operator and still stay in business? Do you know instances where he has been forced out of business by the big operator?

Mr. STEELE: I know one instance in which a wholesaler began to engage in price competition on certain products sold by one of his suppliers, and the supplier did discipline the wholesaler; he did not force him out of business, but he did definitely subject him to punitive price competition. But this is the only

instance I know, and I would say the nature of the drug industry is such that this sort of punitive price competition does not in fact develop. The sanctions which the large competitors might impose are of a different nature.

Mr. HOWE (*Wellington-Huron*): But there is a law in Canada, in the combines legislation, that says that nobody can undersell, or sell a product at a price that is going to be detrimental to somebody else in the same type of business; is this not so?

Mr. STEELE: But the difficulty is in establishing that they—

Mr. HOWE (*Wellington-Huron*): In other words, the big operator is not allowed to do this, to move in around the small man and put him out of business by a tremendous number of loss leaders, for instance.

Mr. STEELE: Well,

Mr. HOWE (*Wellington-Huron*): The small man can appeal to the combines branch and lay a charge under this law in Canada.

Mr. STEELE: But it depends upon the likelihood of getting a conviction. Were the prices charged really lower than the cost of the price cutter, and what was the intent of the price cutting strategy? It can be done, but I think it is difficult.

Mr. HOWE (*Wellinton-Huron*): At the bottom of Page 8 you make the statement that "unfortunately the competition referred to is the cost raising type rather than the price reducing type". This is not usual in competition, is it?

Mr. STEELE: No, that is why I distinguish between competition as price competition and the sort of rivalry which develops when there are a small number of relatively large firms.

Mr. HOWE (*Wellington-Huron*): There are cut-rate drugstores, are there not?

Mr. STEELE: Yes; I understand that in the larger metropolitan centres there are; in Vancouver and in Winnipeg I have heard that there are.

Mr. HOWE (*Wellington-Huron*): What has happened in those centres? Do the other drugstores try to meet the competition, or do they have more attractive quarters, or something like that, stores that bring people in, or how do they meet this type of competition?

Mr. STEELE: Well, I suppose, as in most markets, there are price conscious buyers and there are quality conscious buyers; some buyers I would say are much more price conscious than others. These buyers will learn the identity of the lowest price seller, if they can, if they are not prevented by institutional barriers. I would think the discount houses, the discount drugstores attract a large portion of the price conscious buyers, and the other stores either have to reduce their prices correspondingly, or else be satisfied with supplying a smaller part of the market, the less price responsive buyers, quality responsive buyers, are just, let us say, buyers not interest in comparing alternatives.

Mr. HOWE (*Wellington-Huron*): You intimate at the bottom on Page 9 that there are certain doctors that have a great interest in their patients and try to prescribe the lower price drugs, but due to the pressure of high pressure advertising, their trust in those lower price drugs is shaken to a certain extent.

How would you overcome this practice? You intimated that there should not be nearly as much advertising?

Mr. STEELE: This is not carried out by advertising in journals or direct mail advertising I think this is the sort of message which can be most effectively conveyed by the detailman. I would think the best way to combat this would be to make public inspection perfectly adequate and make it known to the public, the doctors, the patients, the pharmacists, that the inspection program is such that the likelihood of any drug sold in Canada being subnormal in quality is almost completely negligible.

Mr. HOWE (*Wellington-Huron*): How would the doctor find out the value and the quality and the purpose of the drugs, if it was not for the journal advertising and the detailman that comes around and tells him about the new drug, how would they find out about them?

Mr. STEELE: Well, I think it is a question of actually facilitating the flow of informative communications by eliminating a lot of the persuasive communications. In other words, the doctors have complained before many committees that they are swamped with junk mail, and Mr. Lawrence Wilson testified to this Committee that one of the worst things about the redundant mass of this mail was that valuable and informative communications would simply be overlooked in the vast mass of paper on the doctor's desk.

Mr. MACKASEY: Mr. Howe, could I ask a further supplementary question? Would you repeat for me what Mr. Wilson said?

Mr. STEELE: Just a moment, please.

Mr. MACKASEY: I know it is in your brief, well, I can tell you want what he said. What you have not said is that this valuable information that gets buried comes from the drug companies.

Mr. STEELE: Oh, yes, it does.

Mr. MACKASEY: You did not say that and I wish you would and then we could understand that there is no bias in your answer.

Mr. STEELE: Oh, yes, I would like to make that clear. This was information from a drug company, informative information, presented very objectively.

Mr. MACKASEY: But it comes the same way as the junk?

Mr. STEELE: Yes.

Mr. MACKASEY: And then it is up to the doctor to decide which is junk and which is informative?

Mr. STEELE: Yes.

Mr. HOWE (*Wellington-Huron*): I think you will agree that the doctors are not the only ones who get a lot of junk across their desks. Am I through, Mr. Chairman. I was rather interested in the statement that Dr. Walter Modell of Cornell University Medical School commented that some 40 odd new diseases have been identified as being brought about by the untoward effect of drug therapy. Your reference is on page 13. Were these diseases brought on by lack of knowledge of the doctors who prescribed them or knowledge of the drugs?

Mr. STEELE: I do not recall precisely the trend of Dr. Modell's testimony, but I think pretty clearly he was inclined to attribute this to insufficient information given out on the proper use of the drug.

It was improper use which could not be safeguarded by reasonable labelling precautions, brochures and so on, but a lot of it he thought was really brought about by the pressure to market products rapidly with insufficient experimental and clinical testing of drugs.

Mr. HOWE: (*Wellington-Huron*): In other words, the drugs are put on the market without proper research and checking by the departments involved?

Mr. STEELE: I believe this was at least part of the burden of Dr. Modell's testimony.

The CHAIRMAN: This was not in Canada; this was an American—

Mr. STEELE: Yes.

Mr. HOWE (*Wellington-Huron*): This does not make much difference because an awful lot of the drugs that are made and used in the United States are brought into Canada and used here under the same recipe, so to speak; it is the same formula that is used. That is very interesting. Of those 40 odd new diseases, were any of them fatal diseases, or disease that would take on epidemic characteritics, or were they just diseases of the individual?

Mr. STEELE: Fatalities did occur. Certainly, the physicians present could clarify this matter.

The CHAIRMAN: I should point out that Dr. Steele is not a medical doctor. Probably some of the medical doctors could answer the question. I think that in some of the testimony that we had from Dr. Wightman before he pointed out that somewhere between 5 to 10 per cent of hospital admissions now are from the result of treatments by various drugs and this is not necessarily poor treatment; it is just that a drug prescribed had an adverse reaction, one that you were not expecting and these reactions, of course, can be fatal.

Mr. RYNARD: Mr. Chairman, I would like to add to this as a supplementary comment. This is very true of penicillin, and yet it is a very valuable drug. I think that is a statement, that should be either deleted or put in its proper perspective. As the Chairman has indicated, those are side effects; but those drugs are very valuable drugs and are probably life-saving, and I do not think that is a proper statement.

Mr. STEELE: You do not question its accuracy, though?

Mr. RYNARD: Yes, I do question its accuracy when it is put in that perspective, because you would have to bring in penicillin and say that this has caused new diseases; but penicillin is a very valuable drug. The reaction to it, I think I saw somewhere, and some of my medical friends will tell me, is that fatalities occur in the proportion of about one every other day. Is that correct? This has got to be put in its proper perspective and that does not put it in its perspective. They are not new diseases; they are side effects.

Mr. STEELE: What are they called, iatrogenic diseases?

Mr. RYNARD: Well, they are side effects from the reactions to the drug.

Mr. STEELE: I think it is very interesting in that, I think that it is underemphasized in literature on the net benefit of drugs, of drug therapy. You usually hear about the number of diseases which have been substantially wiped out by wonder drugs. You do not hear about the sometimes lethal incidents of side effects.

Mr. RYNARD: Yes, but any drug has dangers, even aspirin, and yet you can go down to the corner drugstore and buy it. This is why I think it introduces a wrong impression in this brief.

Mr. STEELE: My only point was that the gross benefit from wonder drugs is not the same as the net benefit. Many, many lives are saved but some are lost.

Mr. MACKASEY: You are thinking of an economist's view of safety. You are talking about gross and net; how could you ever measure gross benefits against net benefits?

Mr. STEELE: Well, it is worth attempting. Certainly in the United States, the drug manufacturers' commissioned a very extensive study, I think by Arthur D. Little & Company, to show how many man hours of productive time had been gained.

Mr. MACKASEY: Would you like to evaluate my experience when my son was saved at the age of nine by sulfa and my wife had just spent six weeks in hospital from a side effect of penicillin? This is serious to me. How would you evaluate that as an over-all effect from wonder drugs? Am I supposed to be mad at wonder drugs because my wife spent six weeks in hospital and not be thankful that my son is alive today?

Mr. STEELE: No.

Mr. MACKASEY: Thank you.

The CHAIRMAN: I think Dr. Steele's point is that the statement, as it stands, is accurate enough. He has just quoted it in that way and it possibly can be misinterpreted but it can also be substantiated, I am sure.

Mr. RYNARD: I would like to see the list of those 40 new diseases.

Mr. HOWE (*Wellington-Huron*): Mr. Chairman, I have one more question in connection with this. I do not say it is very prevalent but it happened several times and there are these new diseases. Do you think more research is necessary before drugs are put on the market to ensure that these things do not happen.

Mr. STEELE: I certainly do.

Mr. HOWE (*Wellington-Huron*): In other words more money should be spent on research?

Mr. STEELE: No. I think that the product should be more carefully screened. I think that the intense profit expectations, whether or not these expectations are realized, are the chief motive in stimulating a flood of new products, many of which are imitative, and that if the purely commercial incentive for developing these sorts of products was reduced, we would have fewer such potentially dangerous, also potentially beneficial, products released; we would have longer clinical testing. You might increase the average cost of testing each drug fully evaluated, but I think the total amount spent on drug evaluation would probably decline.

Mr. HOWE (*Wellington-Huron*): You speak of more research and more screening; more of anything has a dollar sign on it, has it not?

Mr. STEELE: It all has a dollar sign, but, you used to be investigating 500 drugs a year and because of the premium placed on speed in developing the drug, the amount spent in evaluating each drug was, let us say, $100,000; later you may be investigating only 100 drugs a year and yet be spending $1 million or more in investigating each drug; spending more years, let us say, on the average drug being evaluated.

Mr. HOWE (*Wellington-Huron*): Thank you Mr. Chairman.

The CHAIRMAN: Mr. Laidlaw?

Mr. A. W. LAIDLAW (*Legal Counsel for the Committee*): I shall try, Mr. Chairman to widen the discussion to bring in several points that I do not believe have been discussed up to this time and they may, or may not have some bearing on the cost of drugs, and if adopted may, or may not reduce the cost of drugs and I would like Dr. Steele's opinion on these.

In the first instance, Dr. Steele, do you think it would assist matters to have the prescription on drugs placed on the label, required by law to be on the label, so that the drug consumer can shop around for his particular drug, knowing exactly what the doctor has prescribed? Now, I am told by some physicians that certain persons are apt to get upset if they know precisely the drug that has been given to them and this might have a bad effect on a patient. I do not know about these things, but from an economic point of view, do you think it would assist matters if the drug was actually marked on the label of each prescription?

Mr. STEELE: Well, certainly from the economic point of view this would facilitate the process of the consumer going out and making comparisons, especially cost comparisons for the same drug, among different pharmacies. Economically I think it would be a good idea.

Mr. LAIDLAW: And there might be an increase in the so-called shopping around for any particular drug?

Mr. STEELE: Yes.

Mr. LAIDLAW: The next question I would like to ask you is, as you are aware, the manufacturers in their literature to pharmacists and so on, have a suggested list price for the drugs. I believe there is a tendency now to omit the suggested list price but would it also help matters, economically speaking, if all suggested list prices of drugs were abolished; so that the pharmacist, although he would know how much he paid for it, he might for example not have paid quite as much as another pharmacist may have paid in a different part of the country. Would this increase any particular competition?

Mr. STEELE: I think the trend would be in that direction; very definitely if you print price catalogues, price books, and give suggested list prices, even though the prices are indicated very carefully as being only suggested prices, this cannot help but influence the thinking of the retail druggist and in the absence of this information I am sure there would be a greater tendency towards price diversity.

Mr. LAIDLAW: The reason I bring this up, I believe there is a tendency now for the manufacturers to package their final doses in smaller bottles and suitable

sizes so that the pharmacist merely hands the bottle across the counter. He does not have to break a larger bottle and extract a certain number of pills and put them in a small box, and therefore, this question may become quite acute in the future. Can you still hold to the opinion that the suggested price is probably wrong in so far as competition is concerned?

Mr. STEELE: Yes; from experience in many industries I think this is a valid observation, that if you give sellers some indication of a suggested list price there is naturally more—well, to many sellers this is the only real guide they have in setting a price. If everybody has the same price list in his possession, other things being equal, they are more likely to charge uniform prices.

Mr. LAIDLAW: One final question on a different subject, Mr. Chairman: Dr. Steele, you recommended this morning, a compulsory licensing system for imports. Now, presumably, if this happened, a number of these imports would be made from related companies, for example, the Canadian company. Would you expect in these circumstances that the parent corporation, which would be the parent of the Canadian subsidiary as well as the parent of the related company, for one moment would allow such a thing? In other words, would the importer who is desirous of importing, who has a compulsory licence to import, be allowed to import?

Mr. STEELE: I think that the holders of compulsory licences to import in the first instance will have to obtain their supplies by and large from countries where patent protection is less absolute and to the extent that most Canadian companies are subsidiaries of American companies, I am sure that small firms given compulsory licence to import will not be able to, let us say, import from the U.S.; but I think that, since many of these drugs can be obtained at much lower prices abroad, if physicians accept these drugs and begin prescribing them by generic name, in order to maintain their share of the market in Canada the domestic companies, no matter whose subsidiaries they are, are going to have to cut prices and compete on price terms regardless of the fact that they do not sell to these compulsory licensees.

Mr. LAIDLAW: So the threat is at least there by this compulsory licensing system to import?

Mr. STEELE: Yes.

Mr. LAIDLAW: Thank you, Mr. Chairman.

Mr. W. J. BLAKELY (*Accountant for the Committee*): Following up on one of the questions of Mr. Laidlaw, which was in reference to the elimination of suggested list prices, consider the possibility of printing on the label, in addition to the generic name and the manufacturer's name, a suggested list price; would this facilitate the process of shopping around?

Mr. STEELE: I considered that in my brief. I considered it just for the sake of completeness but I am inclined to reject it. In the first place, this might help if the suggested list price were placed on advertisements. If it is placed on the label of the bottle, I think this reduces the chance that the retailer will actually cut prices if everybody's bottles have the same price tag on them. In terms of advertising, this might serve a more useful function if physicians receive advertisements and find that x's brand costs $10 while y's brand costs $5; this will make an impact and the only objection I would have to this is that the suggested

retail price may be set at a level which is understood to be the price—the level—but of course if the suggested price is adhered to, then there may be cause for proceedings under the Combines Act; so this is an additional difficulty. In general, I would not think this was desirable either in advertisements or especially on the bottle label.

Mr. BLAKELY: On page 31, you mentioned that there may be excess capacity and that excess capacity has economic costs. Do you believe there is excess capacity in the drug manufacturing industry in Canada?

Mr. STEELE: I think it is very likely. It depends on how you define manufacturing. I think in terms of facilities to manufacture the bulk active ingredient, the costs of excess capacity are greater than if you are looking at facilities to, let us say, just tablet or capsule and bottle the active ingredient in various dosage forms. I would think that since relatively little manufacturing of the basic ingredients is carried out in Canada, perhpas excess capacity of the first type is smaller than the second type. However, I would think in the United States and in the drug industry generally the problem of excess capacity is probably significant. When prices are maintained at high levels, and when many companies are producing different brand name versions of the same drug there is bound to be more capacity in existence which could potentially be used to produce the drug than the market can absorb. After all, advertising in the drug industry tends to switch the share of the market around from one firm to another rather than increase the natural size of the market. For these reasons I think the more firms that get into the market the more excess capacity there is likely to be.

Mr. BLAKELY: On page 59 of your brief, you mention the term "excessive profit margin". I read the sentence carefully and I do not believe in that particular sentence you are saying there is excessive profit margins. My question is, do you believe there are excessive profit margins being earned?

Mr. STEELE: Which sentence is this?

Mr. BLAKELY: The very last sentence on page 59, and I quote:

> To the extent that it is the profitability of selling drugs at inflated prices which justified and motivates marketing outlays, reforms would be needed to institute genuine price competition which would eliminate excessive profit margins and thus eliminate both the ability and the desire to engage in sales promotion rivalry.

Mr. STEELE: Yes, I think the way I have stated the sentence, does imply that there is an attractive spread between the price of the product and the actual cost of producing the product, and that the gap is filled in by marketing outlays. To the extent that it is possible for brand A to compete with brand B, then, let us say, a 67 per cent profit margin is certainly more than adequtae to induce new entry into the industry. You may get no more than competitive profit margins in a monopolistic industry because of excessive entry and the reduction in the profit margin because of, let us say, mutually offsetting sales promotion activities.

Mr. BLAKELY: Are you in a position to state an opinion on whether or not there are excessive profits being earned in Canada?

Mr. STEELE: Well, the comparison I made in my opening statement between the gross margin on drugs and the gross margin on manufacturing industry in

general in Canada, I think the disparity here, 36 per cent constructive mark-up versus 203 per cent constructive mark-up, is wide enough to indicate that drugs really have economic characteristics that are different from the rest of the manufacturing industries in Canada.

Mr. BLAKELY: On page 3 of the statement which you read this morning, in the middle of the page, you state:

> If we assume that manufacturing firms in Canada are on the whole workably competitive,—

My question is, is this a reasonable assumption?

Mr. STEELE: I think perhpas it is a generous assumption. By a workable competition on economist ordinarily means the market in which at any point in time there is a tendency for excessive profit margins to be reduced to reasonable levels. Now, this tendency may never be realized, but at least there are forces which, in the absence of barriers to entry and so on, tend to create new competition to existing entrenched positions. I think—actually, I am of the opinion, that although most industries are not sharply price competitive, they are workably competitive in the sense that cost reductions will eventually be passed on to the consumer, at least in part in price reductions, and that there is not an excessive waste of resources in the selling activities generally.

Mr. BLAKELY: You, therefore, feel that it is reasonable to apply the average mark-up to the figures for the pharmaceutical industry, which I think is what you are doing in this particular computation.

Mr. STEELE: I think because of the difference in the two figures, the comparison is significant. I would like to use better data. This is just an indirect comparison.

Mr. BLAKELY: Thank you, Mr. Chairman.

Mr. BRAND: Mr. Chairman, I apologize for not being here sooner. I am not aware of all the questions that have been asked so perhaps some of mine will be repetitive, but I am sure you will—

The CHAIRMAN: You will not take very long to do your best.

Mr. BRAND: Well, perhaps this has been asked, but perhaps it will be safe, in view of the headlines I just read coming out of the airplane, to ask, Dr. Steele, how he proposes and how long it will take to reduce the cost of drugs by 50 per cent. This was all in the headlines; this is what we got out of your testimony this morning.

Mr. STEELE: Well, as far as proposals are concerned, these 14 proposals which are embodied in chapter 5 of the brief constitute the program—

Mr. BRAND: The ones that are so similar to the ones in the Hall Commission Report.

Mr. STEELE: This is true. They are very similar; one or two differ.

Mr. BRAND: Which ones are different?

An hon. MEMBER: After all, they are all pretty well the same.

Mr. STEELE: Greater emphasis I think on promoting competition at the retail level, and especially with regard to easing requirements for entry into retail pharmacy?

Mr. BRAND: Yes. I would be prepared to agree with that. Do you recommend that druggists be allowed to advertise drugs, and say, "I can sell my aureomycin cheaper than you can"—that sort of thing?

Mr. STEELE: Well, this may come as a shock, but I do not see any great harm in this.

Mr. BRAND: Quite frankly, I do not see any harm in it either, when you get right down to it, so it is not a shock to me. How long do you think it will take to reduce the cost by 50 per cent. That is a pretty broad statement, let us face it.

The CHAIRMAN: I do not remember in the statement 50 per cent being used.

Mr. BRAND: Well, it is in every headline in every newspaper this afternoon. That is why I asked it.

An hon. MEMBER: Somebody got that—

The CHAIRMAN: It was not in the testimony.

Mr. MACKASEY: The newspapermen probably read the brief, I presume; it is in the brief.

An hon. MEMBER: It is on page 103, Mr. Chairman.

The CHAIRMAN: I was thinking in relation to the testimony, in that the actual figure was not used at all. I am sorry, Dr. Steele.

Mr. BRAND: Yes, I see; Chapter 3, item 2A on page 103.

Mr. STEELE: Yes. I say on page 103 that it is by no means impossible that a price decline of 50 per cent might result. The speed with which this price decline would develop would depend upon the ability of certain reforms, primarily licenses to import, in introducing new competition from the outside, and the rate at which these new drugs, mostly generic name drugs, were accepted for prescription purposes by physicians.

Mr. BRAND: This would depend on one of your other recommendations about the Food and Drug Directorate. Is that right?

Mr. STEELE: It would depend on several others, but this would be one of the most important.

Mr. BRAND: Yes; about the quality of the drug concerned. I do not have it with me, but I recall in some of the briefs presented to us that there was the cost of actual production, or the total cost of goods using pharmaceutical was pretty high. If you reduced everything by 50 per cent that would leave a pretty small margin.

Mr. STEELE: No. My thinking is this, that practically every component except manufacturing costs can be cut substantially. I think manufacturing costs can be cut because of excess capacity; I think the sales promotion budget can be cut very greatly, perhaps a 90 per cent reduction; and that even the research and development budget could be reduced to some extent.

Mr. BRAND: I take it from your brief that you do not think research is too important in Canada. Is that a fair assumption?

Mr. STEELE: The amount of research done within the borders of Canada quantitatively I do not think is too important.

Mr. BRAND: Would your remarks apply equally in the United States?

Mr. STEELE: Qualitatively they might; quantitatively the amount is much greater. My point here is just that—

Mr. MACKASEY: Percentagewise, in sales or just dollar volume?

Mr. STEELE: Just dollar volume is all I am thinking of.

Mr. MACKASEY: How would they compare percentagewise?

Mr. STEELE: Percentagewise, practically the same.

Mr. MACKASEY: Well, I—

Mr. STEELE: Well, excuse me, as reported by the PMAC and as reported in the Kefauver hearings, practically the same.

Mr. BRAND: Well, you are suggesting, I would take it from your brief, that most of the basic research, and I think you quote from the PMAC brief to bolster your argument, should be done in universities?

Mr. STEELE: Yes, I think basic research is a sort of activity where the agency incurring the cost is likely to recoup only a very small portion of the benefits, and it just does not make sense for business firms too to spend too much on basic research unless they want to do this for philanthropic reasons.

Mr. BRAND: What do you mean by basic research?

Mr. STEELE: By basic or fundamental research, I mean research which is really aimed at expanding the frontiers of knowledge. It is not aimed at any specific commercial application.

Mr. BRAND: You mean, like space research.

Mr. STEELE: Space research—like some types of it, yes; most types, perhaps.

Mr. BRAND: Well, I would think so. I do not think there will be much commercial revenue out of all the money that is spent there. I was thinking of the brief of 1964, the Restrictive Trade Practices Commission on the cost of drugs, in which there is a list of the drugs that have been discovered by pharmaceutical manufacturing companies. I am thinking of aureomycin and things of this nature. Presumably this would be prety basic research, or would you not consider that basic? In other words, a large number of these antibiotics have been discovered by the pharmaceutical houses, and not by universities.

Mr. STEELE: Well, of course, this is a matter of controversy. I think—

Mr. BRAND: That was a matter of history.

Mr. STEELE: —as far as antibiotics are concerned, the real breakthrough of course was made with the discovery—

Mr. BRAND: You are talking about penicillin, but I am talking about the antibiotics more recently.

Mr. STEELE: Yes, I would say that this is more in the category of applied research than basic research.

Mr. BRAND: You do not think we should spend money on this, or very much money.

Mr. STEELE: Well, we should not spend as much as we are spending. I think, let us see, this was discovered around 1947 or 1948; at that time the field was more fertile. The basic discovery had been made and the application of applied research techniques had not progressed to the point of diminishing returns, so in the late 40's I think it was quite appropriate to exploit this field. Today, I do not think the returns are anywhere near as rewarding. New basic research has not been accomplished which would point the way for additional and truly productive lines of applied research.

Mr. BRAND: You confuse me a little bit here. You are talking about returns. Are you talking about economic returns, not just the beneficial results of the new antibiotics?

Mr. STEELE: I am talking about both economic returns and, let us say, the over-all social value of the research—in dollar terms, of course, the economic returns.

Mr. BRAND: In effect, what you are saing is that no longer should they bother about developing any new antibiotics because it just does not make sense, economically or socially. Is that correct? Surely, that cannot be what you mean?

Mr. STEELE: Well, I have seen statements by security analysts which indicate that the performance of the drug industry in the last couple of years has been disappointing from a profit standpoint because of the inability of the industry to come up with really major breakthroughs, new drugs and new antibiotics—

Mr. BRAND: Surely what you are saying is that they are spending a lot of money and not getting any value from it.

Mr. STEELE: Exactly.

Mr. BRAND: Therefore, this would be a legitimate area of concern, yet you say in your brief that you do not think this is a legitimate area of concern.

Mr. STEELE: Perhaps I am not following your statement. What I am saying is that there are diminishing returns here; that the high costs of discovering one more drug reflect lower productivity of applying the same old method which has been applied for years to more and more—

Mr. MACKASEY: May I put a supplementary question here, Dr. Brand? Well, if they are now approaching the period of no return, and they have exhausted the field of applied research, does that not mean that they will eventually have to turn back to basic research for new ideas and new discoveries?

Mr. STEELE: They eventually will, but the question is, when. Perhaps somebody will do the work for them and—

Mr. MACKASEY: Well, by the fact that there are only 60 odd new drugs on the market this year, it has to be pretty soon. In fact, does it not come back to what our economists asked you earlier, that this is a very high risk industry and therefore they must make their profit when—is it not possible, for instance, that

in the next ten years, unless some new startling discovery is made through basic research, these firms are going to be hard pressed to maintain a profit?

Mr. STEELE: Well, as far as the high risk ordinarily is concerned, I think one aspect of it was not given attention, and this is the cyclical stability of earnings. The drug industry has often been called a recession proof or depression proof industry. This is an aspect of risk which is very important in capital goods industries, durable consumer goods industries, but it is not at all in drugs. As far as the risk of product obsolescence is concerned, I think this is very important to the major firms, but I think, as I said before, this is an artificial risk in that, under present market circumstances, it may pay a firm to spend a lot of money developing a minor modification and all the rest of it, market it and then expect another firm to come around in six months or so and wipe out its monopoly. Even so, the six months of protected market monopoly may pay for the program and any associate failure of the program.

Mr. BRAND: But surely what you are saying as well, is that the pharmaceutical houses should get out of these obviously non-profitable compounds, such as some of the chemicals which are used in the treatment of leukemia and things of that nature, from which they make no money really, because it is economically not feasible.

Mr. STEELE: Well, the costs of these products I think are carried by the costs of the—by revenues from the successful products, and I think this is basically a combination of humanitarian motives on the part of the research workers themselves and these humanitarian motives are condoned, let us say, by the business office because it is simply good public relations to carry these lines.

Mr. BRAND: But you do not condone this—

Mr. STEELE: To be consistent—

Mr. BRAND: —speaking as an academic economist.

Mr. STEELE: To be consistent—well, let me put it this way. If price competition came along and made the industry tighten its belt, these drugs would cost more—these low volume higher cost drugs would cost more and the cost would have to be met perhaps in part by taxpayers as well as individual patients.

Mr. BRAND: Well, you are just going to spread the cost; it is going to be the same anyway. You are going to lower the cost of drugs by 50 per cent, as you say it can be done, and at the same time the government may be paying for it or somebody else, but ultimately the taxpayer is going to pay for it anyway. Is that what you are saying.

Mr. STEELE: I do not think so, because the drugs which you point out would have higher costs under a purely competitive market situation precisely because the demand for them is small. If you take a weighted average of drug prices and costs under the new scheme, the higher cost of these small volume demand drugs is not going to have much influence on the total price picture.

Mr. BRAND: But surely you suggest here that they should get out of this type of thing. They should get out of this type of research because it is not realistic—I have forgotten how you phrased it—and leave basic research and that to the universities. You say that, do you not, in your brief?

Mr. STEELE: Yes, I say so. I say that this is really a philanthropic activity which some of the private firms engage in because they are genuinely interested in advancing the borders of knowledge. However, this sort of activity has been advanced in its entirety out of the prices paid by prescription buyers and these people are not in the best position to support this kind of philanthropic activity.

Mr. BRAND: Well, who is?

Mr. STEELE: The people whom the activity benefits; society as a whole, theoretically, the world as a whole.

Mr. BRAND: Well, now, that is getting pretty philosophical. We are talking about Canada right now. What are we going to do in Canada? Who is going to pay for it? There is something basically wrong with producing a drug for leukemia on which, let us say, they are losing money. You apparently do not like philanthropy in this sense because it means that somebody else is paying for it, but not the person who gets it. I personally do not see a darn thing wrong with that. I think it is an excellent idea that they should do this. It is a very essential service. I can give you a list as long as my arm, if you like, which will show you the drugs which are produced by a lot of the pharmaceutical houses which are loss leaders, if you like, but which are vitally essential to the practice of medicine today.

Mr. STEELE: Well, I would repeat—and this is a question of income distribution as well as economic efficiency—that if you have loss leaders, as you say, being sold by drug firms to the sick at prices which are lower than the full cost—this is your position, is it not—these people are being subsidized by a smaller group than the whole society. They are being subsidized by the people who buy the other drugs at a higher price than would be justified under a competitive situation. I think the higher price which is charged the other drug buyers results in a higher average incidence on this group than the average incidence would be on the entire community if you reformed drug marketing, cut prices and simply faced up to the fact that some drugs, a few drugs which are sold in small quantities, would probably have to be subsidized by the people as a whole instead of the drug buyers as a whole.

Mr. BRAND: I am running out of time, so one last comment perhaps. In other words, you are in favour of economic planning?

Mr. STEELE: Economic planning?

Mr. BRAND: Yes, you like to see everything planned so that you can distribute the cost equally to everyone in the country.

Mr. STEELE: No. In my brief I go at great lengths into the question of voluntary health insurance.

Mr. BRAND: Well, I have seen your reference to *Fortune* magazine in your brief, I understand that. That is what puzzles me.

Mr. STEELE: The question here, though, I think, is not one of economic planning, not one of comprehensive economic planning. The question is, how should the real social costs of drug therapy be divided among the population, and I say that those who can pay for it would be most prudently advised to engage in voluntary health insurance programs. As far as those who cannot pay for it are concerned, it is just a question of charity to the indigent.

Mr. BRAND: Do you think governments could do a better job of providing these new drugs than has been done so far by the industry, particularly in the antibiotic field. I think your brief, particularly the appendices, indicates that you spent most of your time on the expense of antibiotics and tranquillizers.

Mr. STEELE: Well, I do not know. I think in the last ten years, let us say, the record of the industry has not been as impressive as it was in the decade before that. I think, personally, and here I am not sure that I am speaking for the province of Alberta, but just stating my own personal opinions, if the rate of the introduction of new drugs was slowed down as a result of having less money spent on research in the drug industry, the net result of this would not necessarily be detrimental to health and to prospects for a living standard, length of life.

Mr. MACKASEY: Mr. Chairman, I have a lot of questions, but I will try to cut down on them, just to tidy up things. On page 73—this is just a comment, Dr. Steele—you talk about costs incurred by distribution. You talk about Canada and you describe it, as I recall it—well, anyway, long, lean and hungry is the way I describe it, but you say:

> It may justify some level of additional costs over, say, comparable costs in the United States—

And here you refer to bilingualism, I think, but no evidence beyond mere assertion has been provided. To Canadians, this is self-evident, the cost of translations is a very valid and a very heavy expense on parliament, for instance. With our two official languages, it is only logical that literature of all descriptions coming into the pharmaceutical industry be in the two official languages of the country. This is perhaps why no evidence has been brought forward—or that you have come across—in your reading of the Committee proceedings. I just want to point out to you that it is self-evident to the Committee—this is just an aside, actually. I draw your attention to page 103, and I apologize for hopping all over, but I am trying to get at what I think is important at different times. Page 103 is, perhaps to me, the philosophy of the whole brief. You talk about the unemployed. In other words, the possibility, which was mentioned in Mr. Henry's brief, and which in many ways is similar to yours—and also a very fine brief—of about 10,000 people in Canada being out of work, theoretically, if we destroy what bit of manufacturing we have now, and reduce Canada to an importing nation; but you do say that they could easily be absorbed in Toronto and Montreal because of the size of the cities, which is a subject of controversy. You say they could find more productive jobs. How do you define more productive jobs?

Mr. STEELE: Well, this is a question of the net benefit to a country of having a foreign owned pharmaceutical industry. The industry is relatively capital intensive—

Mr. MACKASEY: I did not really phrase it properly. In other words, you are saying that any job other than working in the pharmaceutical industry is more productive to the country as a whole. When I was over in Poland this summer there was a lot of talk about putting people in productive jobs. It was a question of telling them where to go and what to do because the state felt this was more productive. Again, I want to be fair to your brief because I do not think this is what you mean here—perhaps you would explain what you do mean.

Mr. STEELE: Right. I think the patent law is telling people, in effect, and the tariff law is telling people, in effect, that they will not be penalized if they go into the drug industry because we are keeping prices relatively higher here than they would be in a free market situation. What I am saying is that if we restore a free market situation, then instead of telling people where to go we will be rescinding the previous instructions which were not consistent with free market activities.

Mr. MACKASEY: You talk here as though they were unemployed. You say that once they become unemployed; you are talking on pages 101 and 102—I cannot read the whole brief—about the possibility perhaps for most of the industry being forced to lay off people in research and manufacturing, such as it is, and these people finding other employment in the Montreal and Toronto areas. You say that they may probably find more productive jobs. What you are saying is that anything else but what they are in now would be more productive to society.

Mr. STEELE: Well, I am tailoring this material through the example which I took, which is one of trying to point out that you cannot have your cake and eat it, too. You cannot try to get benefits from protectionism, and also from comparative advantage at the same time.

Mr. MACKASEY: I am g'ad you made this point because it comes back to the free trade area. In the next section at page 103 of your brief you say:

> Above and beyond this, a practical man might have doubts about the extent to which a foreign-owned capital-intensive industry is an unequivocal asset to a country.

This I must emphasize to you is a vey important point in Canadian politics right now.

Is this not equally true in the petroleum industry that Alberta is so dependent on?

Mr. STEELE: Yes; it is true, I would say. The industry is capital intensive. I do not have figures on foreign ownership; I am not sure that I can give you them—

Mr. MACKASEY: I could give them to you. They are 91 per cent of the petroleum industry—perhaps the same as the pharmaceutical industry.

Mr. STEELE: Yes. The only difference I would see there is that probably the ratio of dividends repatriated by the stockholders in these companies is somewhat lower relative to the total sales from pharmaceuticals.

Mr. MACKASEY: Why?

Mr. STEELE: Well, look at value relative to the price of the product and the composition evaluated as regarding returns to labour and returns to factors employed within the country.

Mr. MACKASEY: Well, do you not emphasize somewhere in your brief—there are statistics that were advanced, I think you mentioned them—that so far many of the major pharmaceutical industries in this country have re-invested their money into Canada. Mind you, there will be a day of reckoning which is what is bothering Walter Gordon and many of us. There will be a day of reckoning, but

up to now the pharmaceutical industry has ploughed its profits back into Canada, have they not?

Mr. STEELE: I think the same is true of petroleum.

Mr. MACKASEY: Exactly, so they are identical. I am just wondering if Alberta would come here on the same philosophical argument and suggest that we do something about the petroleum industry as you are suggesting we do to the drug industry, since they are identical. It is refreshing that an American would come up here and strengthen those of us who are a little worried about our economic future, by suggesting quite openly in a brief that you have grave doubts about the extent to which a foreign owned capital intensive industry is an unequivocal asset to a country.

Mr. STEELE: I would say though that the extent to which the petroleum industry is regulated in Alberta is much more in the interests of the province and of the nation as a whole than the sort of regulation which exists for drugs. For example, there is proration of production. There is a sizeable amount of taxation on the product as severed from the ground.

Mr. MACKASEY: Coming from Texas, as you do, and being a renowned economist have you not had any direct association with the petroleum industry.

Mr. STEELE: Oh, yes, I have done a lot of consulting in both.

Mr. MACKASEY: So that you could state categorically the type of restriction that Alberta has on petroleum?

Mr. STEELE: Yes, limitations on production.

Mr. MACKASEY: Would you explain just a little more about this limitation of production? Does limitation of production keep the price up, or is it that limitation of production because you do not want to glut the market? Why is there a limitation of production?

Mr. STEELE: Why is there a limitation of production? Let us see if I can make some analogy with drugs—

Mr. MACKASEY: With drugs, yes.

Mr. STEELE: —to keep the question relevant.

Mr. MACKASEY: Well, it is relevant to me. It is important.

Mr. STEELE: Let me see, the impact is this that the petroleum industry is competitive because there is easy entry into it. You discover a new field. Land holdings are widely dispersed. You ge a lot of wildcatting—a lot of successes, if the field is large. Producers tend to produce too much, and the result is excess of demand relative to supply and a decline in prices.

Mr. MACKASEY: So you in a sense monopolize or direct the industry, a little like the diamond industry, to limit its production—

Mr. STEELE: Yes.

Mr. MACKASEY: —to keep prices up.

Mr. STEELE: This is true. The conservation laws do limit production in the interests of—

Mr. MACKASEY: Of conservation or maintaining prices?

Mr. STEELE: —conservation, both physical and economic conservation. I would say that this is because the industry, left to itself tends to be overly competitive and wasteful. It is regulated, but in drugs the reverse is true.

Mr. MACKASEY: You say the reverse is true. Now, when I go to a gas station with my old jalopy and I have to pay 45 cents for a gallon of gas, have I really got a choice?

An hon. MEMBER: Forty-seven cents.

Mr. MACKASEY: Forty-five, I said, 25 cents if I was a farmer. Forty-five. That is a debatable point.

Mr. STEELE: I suggest you are a quality-conscious gas buyer.

Mr. MACKASEY: Is there a difference basically? Any more than there is a difference between stelazine and somebody else's product.

Mr. STEELE: I would say a great difference, yes.

Mr. MACKASEY: You say that there is a difference between one brand of gas and another. For instance, I know that in Montreal that Supertest buys their gas from its competitor who has a station down the street. You tell me that there is a difference—

Mr. STEELE: No. I misunderstood your question. I thought you were referring to the probability of price competition at the gasoline marketing level as compared with the retail druggist. No. As far as quality is concerned I doubt whether there is very much difference between them.

Mr. MACKASEY: Now, this price competition; how is it manifested since every station in the province of Quebec at least, is identical?

Mr. STEELE: Is this actually true? I do not know.

Mr. MACKASEY: Yes; this is absolutely true.

Mr. STEELE: I have not studied the gasoline situation.

Mr. MACKASEY: There is the odd generic gasoline station! Unfortunately, people look at it with suspicion, so I simplify it with the generic drug firms, but in general it is true. However—

An hon. MEMBER: This is not true in Ontario.

Mr. MACKASEY: To get up to page 116, if we may, you may have been able to get some information that I have not been able to get. About three quarters of the way down the page, you say:

> It is my understanding that the present level of drug imports has already prompted the assignment of drug inspectors to some Canadian embassies in drug exporting countries, so that foreign factories can be inspected as well as their products.

Would you mind telling me what you base that statement on?

Mr. STEELE: Well, I am afraid that this is based on hearsay evidence.

Mr. MACKASEY: Well, surely, you would not put hearsay evidence in a brief of this importance.

Mr. STEELE: I am afraid I must confess to that.

Mr. MACKASEY: I might ask you what else is hearsay evidence, and I would not want to destroy my illusions of this brief.

Mr. STEELE: Well, many of the statements—I really do not know the definition of hearsay evidence in terms of the rules of evidence. I just said "it is my understanding" and this came out in my many conversations with Mr. Frawley that they were—

Mr. MACKASEY: Perhaps Mr. Frawley could explain that since he is here.

M. J. J. FRAWLEY (*Special Counsel for the Government of Alberta*): I have no knowledge at all. You are speaking about whether or not some of the Canadian embassies have drug inspectors already assigned to them?

Mr. MACKASEY: Yes.

Mr. FRAWLEY: No, I have no knowledge of that but I did hear it somewhere.

Mr. MACKASEY: So you did not get it from Mr. Frawley?

Mr. FRAWLEY: Oh, yes. He may have got the impression, but if you are asking me for the source of my information, all I can tell you in all honesty is that I just heard that some place, that there was developing the assignment of staff to the Canadian embassies in foreign countries so that drug plants could be inspected.

Mr. MACKASEY: Well, I think it is desirable, Mr. Frawley, but I think that when Dr. Chapman was here, just to make your brief that much more authentic, we had been informed that in certain countries of the world there are definitely laws that prevent Canadian inspectors from entering these plants to inspect them.

An hon. MEMBER: In Switzerland.

Mr. MACKASEY: Very definitely, it is one of them.

Mr. STEELE: Yes, I recall that you inquired whether or not there were laws against exporting to Canada in Switzerland.

Mr. MACKASEY: Well, that was a little bit of sarcasm, I am afraid. I do not usually indulge in it. I have little use for it. Nevertheless, this is contrary, of course, to what Dr. Chapman had said and this is why I am interested actually in this section of the brief; because as I understand it we have only one floating inspector and he is interested in drugs that are what we call unscheduled.

The CHAIRMAN: Injectible drugs.

Mr. MACKASEY: I beg your pardon.

The CHAIRMAN: Injectible drugs.

Mr. MACKASEY: Injectible drugs.

The CHAIRMAN: Biological.

Mr. MACKASEY: I think this is awfully important, Dr. Steele, because I am intrigued at the possibility of licensing imports and I do agree with you that we need a very strong Food and Drug Directorate so that we can dispel much of the propaganda and so forth that is used unfortunately in the industry. But I am still a little puzzled, after talking to Ross Chapman for whom I have the highest regard, as to how he is going to police these potential sources of imports. Once

we get into licensing of drug imports, I think you wi'l agree that we are opening the door to imports from Italy, for instance and from Poland and from the world market with very little possibility of checking the source of supply. Do you agree with that?

Mr. STEELE: Well, to the extent that Mr. Henry said that it would cost only about $4 million to inspect the nature of the products as imported, I would say that this could provide at least a partial safeguard at a cost which I do not think is entirely out of the question.

Mr. MACKASEY: You know $4 million in Texas pays for a barbecue, but up in this country it is quite a problem; I agree with you. Mr. Chairman, have you the mallet up just for practice, or am I just—

The CHAIRMAN: No; it is there for a purpose.

Mr. MACKASEY: I would like to—

The CHAIRMAN: A last question and then we will drop it.

Mr. MACKASEY: All right. On page 25 you do refer to drug manipulation. I am glad you brought it up. "It is the well known game" which denotes a little bias which you are entitled to periodically in your brief—"of mo'ecular manipulation". Seriously, has nothing been discovered by drug manipulation?

Mr. STEELE: It is a question of costs versus benefits.

Mr. MACKASEY: That is not what I asked you. I asked you had any new product, any really beneficial product, not just alternatives to a competitor's product, been discovered by drug manipulation? Give the answer, and I will help you out.

Mr. STEELE: The answer, of course, is yes. I am just wondering as to the value of the answer.

Mr. MACKASEY: Well, I can understand your problem because our minds are changing; you are thinking constantly as an economist. You are equating the value of this with the extraordinary waste in doing years perhaps of research through molecular manipulation. To an economist as trained as you are this is inefficiency and, therefore, waste. But what about the person who has benefited by a drug that has been discovered by molecular manipulation? What about this aspect of the whole thing?

Mr. STEELE: Well, of course, you are introducing a criterion there which is very difficult to evaluate in purely economic terms. The question is, would the drugs have been developed in the absence of emphasis on molecular manipulation. I do not know. They have been developed. There has been molecular manipulation. There has been waste. I am not sure that I would speculate on the probability of their development if there were not this incentive.

Mr. MACKASEY: No. What you are saying is that if it were not done this way, they would be found another way. Right? But they were not found another way; they were found this way and they were patented. Obviously, they were not found another way or they could not have been patented. They could have been in this country but not in the U.S.A. This is the point that bothers me when you call it a well known game, and you are not the only one who has brought my attention and the attention of the layman to molecular manipulation. Not being a

chemist, and having flunked chemistry, I did not want to display my ignorance earlier, and I did try to find out what I could about this and exactly what it meant, and I found that there are three and a ha'f pages of products that have been discovered—new products, not just variations of old products, Mr. Frawley,—from what is basically known in the research field as molecular manipulation.

Mr. STEELE: But just counting drugs does not tell the whole story.

Mr. MACKASEY: Of course not. Well, I am not counting drugs; I am talking about drugs that have been beneficial particularly I am told in tuberculosis, in the alleviation of this particular illness.

Mr. STEELE: There is the other side of the coin, though. There is the cost of engaging in this kind of research in that alternative resources of the workers, or the alternative opportunities for work for these men are—

Mr. MACKASEY: You keep coming back to the socialistic philosophy that everybody must be best employed in the state where he can make the greatest return to the state. This type of perfect society does not exist and it is not going to exist no matter what type of suggestions you bring in.

Mr. STEELE: I take exception to you calling this socialistic.

Mr. MACKASEY: I am not saying you are a socialist. I am saying this is my definition of socia'ism.

Mr. STEELE: I would say that socialism is the control of productive factors by the state, the allocation of those productive factors and the distribution of income by the state. This is not—

Mr. MACKASEY: Does the state not consider an individual a productive factor?

Mr. STEELE: Perhaps the reverse. I think that in a competitive economy, the problem is really limiting the ability of individuals to put the state to work for their own private purposes.

Mr. MACKASEY: Well, to wind it up, what you are saying is if they had not been engaged in molecular manipulation, which is a fancy word for applied research, they might have been doing something more productive for the state?

Mr. STEELE: And for themselves, perhaps.

Mr. MACKASEY: And for themselves; I agree.

Mr. STEELE: Yes.

Mr. MACKASEY: And possib'y some of these drugs that were discovered by molecular manipulation may have been discovered, and then again, they may not. Is this a fair analysis?

Mr. STEELE: Yes.

Mr. MACKASEY: Thank you.

The CHAIRMAN: It is now 5.45. Is it the wish of the Committee and witnesses that we sit a little while longer to finish this off or adjourn now until eight o'clock? How much more questioning do Dr. Brand and Mr. Mackasey, and the other gentlemen, have?

Mr. BRAND: Longer than fifteen minutes, I imagine.

The CHAIRMAN: Shall we adjourn until eight o'clock?

Mr. MACKASEY: Are they in committee in the house, Mr. Chairman?

The CHAIRMAN: I have no idea.

Mr. MACKASEY: There is a possibility that there will be a vote in the house tonight?

The CHAIRMAN: There was that possibility this afternoon and I just told the whip where the Committee was meeting.

Mr. MACKASEY: Yes, but it is a committee vote, Mr. Chairman, and it may be a standing vote. Well, anyway if you meet tonight at eight and I am not here, it is because I am in the house.

Mr. FRAWLEY: So far as we are concerned, we can continue on now.

Mr. MACKASEY: Well, it is in the hands of the Chairman and Dr. Brand.

The CHAIRMAN: We will adjourn until 8.00 p.m.

EVENING SITTING

The CHAIRMAN: Gentlemen, we may or may not have a very great length of time left for the Committee and I think Dr. Brand had some questions left. Perhaps he could just carry on with his questioning.

Mr. BRAND: I would like to pursue this 50 percent cut in drugs if I could as delineated on page 103 of your brief and how you would go about it. In view of the fact that your brief is so comprehensive and covers such a lot of territory, it is vitally important to this Committee that we know exactly how you could envisage in the future—and I understand this—reducing the cost of drugs by 50 percent. I had an opportunity over the recess to look through your statement and I notice on page 3 of your statement this morning, the ratio of cost of goods sold to sales is about 33 percent for 1964, and then you go on to discuss on page 4 the drug industry economics and you say that 30 cents out of every sales dollar of cash flow have to be devoted to factory costs of production. Now what I am not too clear about and, I think it is fairly important, is whether you are referring at all to the PMAC breakdown of the manufacturing dollar.

I would like to hear your views on the distribution of drugs and distribution costs and all other parts of the breakdown, including research, which I think we have covered fairly well already, that you feel do not necessarily have to be done, and quality control and everything like this. In other words, the 30 cents that you quote here refers to the actual cost of production, and do not include administration cost, distribution cost, and a lot of other things. Am I correct in so assuming?

Mr. STEELE: There is one point. I am not sure just exactly how much manufacturing overhead, that is manufacturing administration overhead, might

be included in the 30 cents; in fact I am not sure just where the manufacturing administration overhead does turn up in this PMAC figure. This is the PMAC breakdown that I am using.

Mr. BRAND: Yes. That is what I thought.

The CHAIRMAN: Could I sort of paraphrase it. What you are really interested in is if Dr. Steele could give you a breakdown of where the 50 per cent is coming from. In other words, 5 percent of the cost from removal of federal sales tax, so much per cent from this area, and so much per cent, if he can break the 50 per cent down for you.

Mr. BRAND: Yes. I am a little confused with some of your statements here and perhaps that is because I am not an economist. As the Chairman has pointed out this is what I would like to see, just where you think the 50 per cent would come from. You do point out somewhere in this brief, that it would be 11 per cent, I think, by taking off the sales tax. We will make allowance for the fact that it has been increased to 12 per cent by the government, but if I understand you correctly, the 11 per cent, and we will use that figure for the moment, would be on the consumer dollar, that it may escalate up to this point or pyramid, I think is the word you used.

Mr. STEELE: Pyramid, yes.

Mr. BRAND: Up to 11 percent.

Mr. STEELE: Up to a maximum of 11 percent. It depends on the way the prescription is priced by the retailer.

Mr. BRAND: We have had some evidence before us here that seems to vary this actual percentage from, I think, 4 to 22 per cent, by economists, I presume and others. I am beginning to believe the statement that if you put four economists into a room together you will get four opinions.

Mr. STEELE: Well, my Appendix A, I think, covers this very thoroughly, and I would like to try to point out why I think 11 percent is an absolute maximum. It may very well be 3, 4 or 5 percent, but in Appendix A, I analyse the effects of this 11 percent tax—it was 11 percent then—on the price to the patient for prescriptions priced by different methods and I used three different methods; first straight 66⅔ per cent mark-up.

Mr. BRAND: The 11 per cent tax is on the manufacturer's price, and certainly in some instances on the wholesaler's. The dol'ar cost to wholesaler works out to about 10 per cent; is that right?

Mr. STEELE: We will take an example. Suppose that the manufacturer's cost is $1.00 and he adds 11 cents to this. This is then pyramided by the wholesaler and a 20 percent margin is added. Then this is further pyramided by the retailer.

Mr. BRAND: Twenty per cent margin, what do you mean?

Mr. STEELE: Yes, the wholesaler makes a 20 per cent mark-up over his invoice cost from the manufacturer.

Mr. BRAND: Forty per cent, I understand.

Mr. STEELE: No; this is the wholesaler.

The CHAIRMAN: Sixteen and two thirds, I think, is the figure that is commonly quoted here.

Mr. STEELE: This is sixteen and two thirds per cent discount with a 20 per cent mark-up.

Mr. BRAND: You just confused me quite easily as you are doing, but go ahead.

Mr. STEELE: Well, let us take the figures. Take without the tax: take a cost $1.00: the invoice cost to the wholesaler is $1.00. Now he sells this for $1.20, so his spread is twenty cents on the basis of $1.20, that is one-sixth or sixteen and two thirds per cent, but his mark-up is the twenty cents over the dollar, which is a 20 per cent mark-up.

Mr. BRAND: Yes.

Mr. STEELE: In other words the sixteen and two thirds per cent discount is 20 per cent mark-up.

The CHAIRMAN: Looking at it from the other direction.

Mr. BRAND: Yes.

Mr. STEELE: That is right. Let us take an example: the $1.00 invoice cost of the manufacturer pre tax is boosted to the $1.11 by the tax itself. Now, the wholesaler puts a 20 per cent mark-up on this, so this is $1.11, plus 20 per cent of $1.11, which is twenty-two and two-tenths cents. So you get the cost to the retailer up to $1.33 3/10. The retailer doubles his cost of materials. On the basis of the Canadian Pharmaceutical Association surveys, it seems the pricing method which he has used tends to just about double the ingredients cost to the druggist so you get, let us say, $2.64 as the price charged to the final consumer. Now, in the absence of the tax you would get, let us see, $1.00, no sales tax pyramided, a mark-up of 20 per cent added, so the price to the retailer would be $1.20, and double this is $2.40. So, you are comparing $2.40 with $2.64. This is the increase in price brought about by the sales tax under this sort of pricing system.

Mr. BRAND: In actual fact, although it is 11 per cent, presumably, or approximately 11 per cent of the retail cost, it is an actual doubling of the sales tax by the retailer.

Mr. STEELE: A doubling of the amount but the percentage stays constant.

Mr. BRAND: A doubling of the amount but your percentage stays constant, yes.

Mr. STEELE: Yes.

Mr. BRAND: In other words, there is double taxation to the consumer. In effect, he is paying the tax twice. Is that not correct?

The CHAIRMAN: But the government are only collecting it once.

Mr. BRAND: Somebody else is getting the rest of it.

Mr. STEELE: Yes, in Appendix A, I pointed out that the government gets about half of the increase in the price and the wholesaler gets one tenth of the increase, the retailer gets the other four tenths of the increase.

Mr. BRAND: Now, the question arising from that is do you think it is right that anyone except the government should get this money?

Mr. STEELE: I think it is an inefficient tax in that the consumer pays, let us say, $2.00 for every $1.00 that the government collects. A different type of tax

might result in the consumer paying $2.00 for every $2.00 the government collects. The wholesaler and the retailer collect half of the addition in price to the final consumer.

Mr. BRAND: Another point you discussed was quality control. I think it is on page 69 of your brief. You say, "and efforts to justify prices in terms of quality control border on the ludicrous." When Dr. Hilliard was before us a few weeks ago he made a statement something to the effect that we all know that to reduce the price is to reduce control. Do you agree with this?

Mr. STEELE: What was the statement, I did not hear it.

Mr. BRAND: He said that we all know that to reduce a price is to reduce control; he was referring to quality control on drugs. Would you agree with that?

Mr. STEELE: I would disagree with that.

Mr. BRAND: You would disagree with that.

Mr. STEELE: Yes.

Mr. BRAND: On what basis?

Mr. STEELE: At present, the cost of quality control is between, let us say one and a maximum of about 3 per cent of the sales dollar, and if you cut the sales price—I do not think firms can possibly afford to cut down on quality control at any rate—they can much more easily cut X per cent out of sales promotion than they can out of quality control.

Mr. BRAND: This is the point I was getting to originally. Where would you cut your 50 per cent: where would you save the 50 per cent of the manufacturer's dollar in order to cut prices to the consumer?

Mr. STEELE: Well, I could—

Mr. BRAND: We have taken the 3 percent: Let us say, we will take the maximum. Say that they will absorb the quality control, since you do not agree with Dr. Hilliard on this point. You have more faith in some manufacturers than I have, I must say.

Mr. STEELE: This may be.

Mr. BRAND: But when it comes down to what they can afford, I sort of wonder. Where else would you cut down, on the distribution of the drugs, the methods of getting them across the country, the methods of making the physician aware of them, and I am aware that you are in favour of the Medical Letter?

Mr. STEELE: Let us put it this way. Suppose that a license to import is issued to somebody and he brings in the drug and the Food and Drug Directorate inspect it and they say this is good and the drug is a generic drug and the doctors begin to prescribe it on the basis of the assurance by the Food and Drug Directorate. The drug is priced at, say, maybe 40 per cent of the price of the brand name drug. The brand name drug, in order to be able to compete with the generic import, cuts their price down by 50 per cent. How do they do this? Well, in the short run, what they do is cut 50 per cent, I would say, out of this roughly 70 per cent, or 67 per cent gross margin above the cost that it would have sold at. If the sales tax is reduced, let us say, 10 or 11 per cent goes here if the sales tax

is eliminated; I would say that probably about nine tenths of the selling cost would be cut, which would be about 27 per cent; that is 27 cents out of 30 cents. I would say that the other 12 per cent, in the short run, would come out of profits before taxes, so 6 per cent in profit after taxes, 6 per cent in taxes; just picking figures for illustrative purposes.

In the long run it might be different. I think the industry can improve the efficiency of its operation, particularly through reduction of excess capacity. This might mean some cut in the 30 cents of the sales dollar devoted into manufacturing cost.

Mr. BRAND: You do not think that they should have detailmen going around talking to doctors? I know in your brief you make some comments which seem to indicate that doctors are taken in by the propaganda of the detailmen.

Mr. STEELE: As I said, some place else in my brief, I am in the only other market I know where the person who prescribes the product does not have to pay for it himself. We have detailmen in the textbook industry, and we are visited by a lot of textbook salesmen, and comparing the two, I think, in the first place, the power of the professor to prescribe textbooks for students is certainly much less than the power of the physician to prescribe drugs for drug users.

Mr. BRAND: I will challenge that statement, as a former university student just as everybody here. When you get a required list of textbooks that the professor suggests, and it always seems to include the professor's—I do not know quite why—you buy it; you know that as well as I do.

Mr. STEELE: Yes; you can buy second hand textbooks, but second hand drugs—

Mr. O'KEEFE: If you buy the textbooks you might live; if you do not buy the drugs you could die.

Mr. BRAND: This is true. There is also the point, and I think it is a fair one, that even with some of the bad drugs we may have on the market, they are probably easier to digest than some of the textbooks they put out. I do not honestly know if this is a valid comparison when we are dealing with something that is lifesaving in many instances. Do you really think it is a valid comparison?

Mr. STEELE: What, textbooks versus drugs?

Mr. BRAND: Yes.

Mr. STEELE: No, the comparison is not valid, I am just saying that I am not wholly without experience in dealing with salesmen who came around trying to sell you on products which you may require—

Mr. BRAND: Tell me, sir, are you taken in by the salesmen, by their smooth talk—

Mr. STEELE: No.

Mr. BRAND: —and their promise, because you are a prominent individual, that they want to give you a set free, and all this sort of jazz?

Mr. STEELE: They do give away free samples.

Mr. BRAND: Are you taken in by this?

Mr. STEELE: No, you can read a textbook, but the doctor cannot test the drug.

Mr. BRAND: You are suggesting that the doctor does not bother to find out what that drug does before he gives it to the patient. There are several places, I think on pages 52 and 58, if I remember correctly, you seem to suggest that the doctor does not seem to know what he is prescribing.

Mr. STEELE: Unless he tests the drug himself, he does not really know; he takes the word of the detailmen.

Mr. BRAND: Oh, does he? This is the point exactly: Do you think he takes the word of the detailmen alone?

Mr. STEELE: I think the facts speak for themselves.

Mr. BRAND: Are you going to give me those facts; I am going to challenge this as a physician?

Mr. STEELE: The facts are that about half of this 30 cents is spent on detailmen.

Mr. BRAND: That is not a fact, as far as this is concerned. Because the drug company happens to spend this money, you are suggesting two things. First, you are suggesting that the doctor is taken in completely, and prescribes because the detailman tell him to do so. Secondly, that all the material he gives the doctor is useless. Is this what you are suggesting?

Mr. STEELE: No.

Mr. BRAND: What are you suggesting?

Mr. STEELE: What I am saying—

Mr. BRAND: I am sorry if I got the wrong inference but that is the impression I get.

Mr. STEELE: No, you said the 15 cents out of the 30 cents was irrelevant; I would say that it is very relevant.

Mr. BRAND: I never mentioned that term at all.

Mr. STEELE: Relevance?

Mr. BRAND: No, I never mentioned that it was irrelevant at all. All I want to know is what you think, and the manner in which you can reduce the cost of the drug by doing away with detailmen, and promotion, or people or whatever you want to call them, who call on the doctors. I get a distinct impression from your brief, and your reference to the sad number of doctors—15 per cent, I believe—who subscribe to the Medical Letter—and you are making an unwarranted assumption there, by the way, which I will deal with later—and that automatically this is all bad, an effort that could be done away with in order to reduce the cost of drugs. That is correct, is it not?

Mr. STEELE: I am saying it is relatively unproductive. The patients are paying for this, and I do not think it is worth the cost.

Mr. BRAND: You do not think it is worth the cost at all to have this done? Are you familiar with some of the material which is brought to doctors; I am not referring, as you have mentioned in the report, to some of the gimmicks that

were brought by Dr. Howe to this Committee. I am thinking more of some of the very useful types of journals and papers which are brought to doctors to explain exactly what the drug does; papers which are culled from reputable medical journals.

Mr. STEELE: Oh, yes.

Mr. BRAND: Do you think this is a waste of time?

Mr. STEELE: No; I have, in at least three places in my brief, made a distinction between informative material and persuasive material. I think the ratio here may be about 10 to 1. Keep the informative material, yes; but the bulk of the persuasive material tends to obscure the presence of the informative material, as Mr. Lawrence Wilson pointed out in this Committee.

Mr. BRAND: I have never been able to accept completely that the persuasive material was exactly in this ratio; certainly this has not been true in my practice. I am a little curious about where you got these figures.

Mr. STEELE: This is the general impression I obtained from the testimony given by physicians in Canada and before the Kefauver Committee.

Mr. BRAND: The Kefauver Committee?

Mr. STEELE: In the United States.

Mr. BRAND: Well, I will not pursue that much further, except to say that you think we can do away with this pretty effectively, and in its place put something similar to a governmental medical letter;—I have forgotten the term you used—is that correct?

Mr. STEELE: I would hope that the doctors would prescribe voluntarily either to the Medical Letter, or to a publication like this which would develop in response to the need for information, if the detailmen no longer were capable of being financed by the drug companies because of price competition.

Mr. BRAND: Are you familiar with the study done at Harvard—some years ago now, 1960 or 1961—in which a comparison was made of the drug industry in Russia and the drug industry in the United States?

Mr. STEELE: Yes; I started to put in a separate appendix refuting the points made in that study; but the brief is extremely long and I left it out. I think the study comes to unjustified conclusions because it really assumes that there is no difference between the United States and the Soviet Union, except in the way in which the drug industry is regulated.

Mr. BRAND: I am sure if you had put it in as a supplementary to your brief, you would not be quite as blunt as that, surely; not with that paper.

Mr. STEELE: I read it very thoroughly.

Mr. BRAND: And you still come to that conclusion that there is no difference; or would you rather put in the phrase that perhaps the major complaint among doctors in the Soviet Union was that they were not being informed as to what the drugs were. I think that is more valid.

Mr. STEELE: The medical profession differs a great deal in the United States, and in the Soviet Union.

Mr. BRAND: They all treat a type of people; they all treat patients; they are all human beings.

Mr. STEELE: They are all human beings, this is true.

Mr. BRAND: The United States and Russia are putting people in orbit with the same medical background behind them, and I do not really think there is that much difference; perhaps in the method of practice only. You make so many assumptions here that I get the impression—I may be wrong about this, and I am open to correction—that brand name houses are, of course, charging excessively and you could reduce the costs there by 50 per cent. Would this apply to the generic houses as well?

Mr. STEELE: I try, although I do not always succeed, to be consistent in contrasting low price generic drugs with higher price brand name drugs. What I am interested in really is the—

Mr. BRAND: In other words, you have been selective, have you, in picking drugs in your survey?

Mr. STEELE: This is in general terms. I try to avoid the confusion between generic and brand. Some brand name drugs are more expensive than others; some small houses produce brand name drugs. What I am really interested in is the relationship of the cost of the drug to the price charged.

Mr. BRAND: If we take one of the firms that has appeared before us, and that, admittedly, has no medical men on staff to give information to physicians, and to do studies, that has no research facilities whatsoever, and making no attempt to do research—and that is not correct, perhaps one of them is—and has a very limited detail staff, and I take your brief and look at the price charged to the government of Alberta, for example, the Frosst company's colisone, which is one of the steroids—

An hon. MEMBER: What page, doctor?

Mr. BRAND: This is on page 161, under corticosteroids. The list price is $4.20 per 100. Right next to that we have prednisone made by Intra, which is one of the smaller firms here without any of the benefits that the larger houses have, such as medical staff, extensive detailing, and so on, at $4.20 per 100. Prednisone by Empire shows a difference; it is $4 per 100, and Empire, of course, from their evidence here, do not spend a great deal of time in detailing, and do not have a medical man on the staff. I am rather curious. How do you think this comes about, that Frosst which is a member of the larger group of manufactureres—the PMAC—sells this drug for $4.20. As a matter of fact, if you go a little further, Parke Davis, one of the larger houses owned in the United Staes, as Frosst is, too, sells it at $4.20 per 100. I am curious. If you get rid of all this distribution, which does not exist apparently to any great degree, at least at Intra, or at Empire, how are you going to reduce the cost of this particular drug by 50 per cent? It does not make sense, does it?

Mr. STEELE: I do not quite understand the focus of your question.

Mr. BRAND: Well, let us try again.

Mr. STEELE: You are assuming that Parke Davis, and Frosst, because of their practice of relatively intensive detailing, should have a higher price.

Mr. BRAND: No, no; I did not say that at all. I said these are companies who do have a large detailing, who are members of the group who presented the percentage, or the amount of the manufacturing dollar which they devote do distribution, advertising, promotion, or whatever you like. I am comparing them, from your brief, with some who do not have this same amount of money, and claim that it is not necessary, and yet seem be selling this same drug, prednisone, for a price which in one instance is the same, and in another instance is 20 cents less out of $4 per 100. Where is your 50 per cent there?

Mr. STEELE: I would say this backs up my point that prices are really not related to costs; they are related to demand. Prednisone, of course, has been described as a price football. This drug has been given more attention in hearings of this sort than any other drug, because of the great price spread between Schering and other brand name sellers, and a large number of generic name sellers. I do not believe it is typical of the contrast between brand name and generic name drugs. I would say that companies other than Schering have reduced their prices in order to meet the competition of the generic name firms. This is a drug in which firm patent protection was not achieved for a good while. Actually, airtight patent protection, in the sense of new licensees, was never achieved for this particular drug. It does not fit the pattern of, let us say, a drug which is subject to a patent from its very outset and is only available from foreign importers at low prices.

Mr. BRAND: I am afraid you lost me somewhere around the last economic corner, Dr. Steele.

Mr. STEELE: The basic act is that—

Mr. BRAND: You think they have not reduced their prices and have not bothered to continue pushing the drug. As you point out in your brief, if you have a truly competitive situation and they are not going to have the money available to do the advertising, therefore, prices will come down. That is valid, is it not—you did say that?

Mr. STEELE: I think a lot of these firms have lost interest in it. Parke, Davis' Paracort has a very small share of the market.

Mr. BRAND: How about Colisone?

Mr. STEELE: Colisone? I do not know what Frosst's share of the market is.

Mr. BRAND: I did not think you did.

Mr. STEELE: I do not think it is in the record.

Mr. BRAND: Let us find out. I do happen to have with me somewhere the share of the market of various things. It is going to take a little time to go through it for all of those but I can go through it for some of these other drugs.

Mr. STEELE: I did not think such information was available.

Mr. BRAND: I think it is available.

Mr. STEELE: May I ask where I could obtain it.

Mr. BRAND: I think we will make it available to you. We will be very happy to do so.

Mr. STEELE: I will be glad to receive it.

Mr. FRAWLEY: Dr. Brand, has it been filed with the Committee?

Mr. BRAND: No, not as yet. There is a lot of material which is not filed until afterwards, sir.

Mr. FRAWLEY: That is very generous of you to offer it to Dr. Steele.

Mr. BRAND: I think in all fairness, Dr. Steele should have all the facts before he makes a conclusion. Do you not agree with this?

The CHAIRMAN: They do this to confound the Chairman. They bring in evidence which is not before the Committee. Carry on, Dr. Brand.

Mr. BRAND: We are not trying to confound Dr. Steele, because this is a very comprehensive work you have here. I was just a little puzzled by the inconsistencies. I do not think I have Paracort here but I will look it up afterwards. I will find out what I have here. However, I think this can be obtained without too much difficulty. The point I was trying to make here was that you feel this is due to the fact that the other prices are lower. Empire has put it out at $4 per hundred; the others have come down to meet the competition; is that right?

Mr. STEELE: Yes, this is true. I am surprised that Schering has not.

Mr. BRAND: How would you explain that?

Mr. STEELE: I do not know how you would explain that.

Mr. BRAND: If your thesis is valid in that this is wde open for competition and, certainly, when I see the number of companies putting it out, surely it should be competitive to a degree.

Mr. STEELE: My only thought here is that since Schering was the initial major marketer of the drug—

Mr. BRAND: It was Merck Sharp & Dohme, was it not? I may be wrong. Was it Schering?

The CHAIRMAN: It was Schering. I think Schering is selling the same drug now for $22.00?

Mr. BRAND: It is selling for $22.70 per hundred.

The CHAIRMAN: Could we ask you what share of the market they now hold with this price differential?

Mr. BRAND: I think it will be very interesting to find out. I do not have that information but I think I will be able to find out. This is a most important point, is it not?

Why do some of them stay up when apparently they are still selling. I know Meticorten is still selling because I saw some the other day.

Mr. STEELE: I think this indicates the absence of price competition. My only hypothesis is that Schering's initial position in the market, its advertisng and promotion secured for it a preferential position in the physican's estimation.

Mr. BRAND: This fact about prices holds true in a lot of your appendices. I was surprised to find, in fact, I was rather astonished to see, the comparison in prices as we go through them. I will not take the trouble at this time to do it but I presume they would all be explained on the same lines of competition and

things of that nature. Is that correct? Dr. Steele, the only point I am trying to make is whether—since apparently some of the larger companies had not cut down their sales force—and are still selling more cheaply. You feel this would really be the absolute effect if we went into a wide open business of supply and demand with lots of competition. They would not be advertising as much; they would not have as many detailmen and presumably not as many samples, which I would regret very much.

Mr. STEELE: If I may ask; what was the percentage of the market that Frosst's Colisone held?

Mr. BRAND: As I have said, I will give you some of these figures afterwards. I have a long list here and I do not think we should read them all into the record. If you like I can put this all in the record afterwards.

Mr. STEELE: You have suggested that it is a relatively large figure.

Mr. BRAND: I made no such suggestion but what I did say was that I had some of the figures relating to the share of the market of some of the pharmaceutical products. Whether Colisone is in it or not, I will have to go through the list to find out. I do not have the specific ones that I have mentioned to you. Do you follow me?

Mr. STEELE: I do.

Mr. BRAND: That will lead us to one other question. As far as investigating the cost of drugs is concerned, did you—this may have been asked before and I apologize if it has—discuss or just look into prescription drugs or did you look into all drugs.

Mr. STEELE: Just prescription drugs.

Mr. BRAND: Strictly prescription drugs. You did not look at over the counter products such as aspirin which I heard mentioned here earlier today. I believe Dr. Rynard mentioned it.

Mr. STEELE: No, I do not believe this is the purpose of this Committee.

Mr. BRAND: I agree with you but I was just curious to see whether or not you had.

Do you think this medical letter would be sufficient, one produced by government?

Mr. STEELE: No, I did not say it would be sufficient. I just said in conjunction with official compendia.

Mr. BRAND: One prepared by the government again?

Mr. STEELE: Official compendia. Of course, Canada does not have one at present and it uses several. If the compendia could be kept up to date, I think that this would—

Mr. BRAND: I am curious to find out how you would do that? Knowing governments I am curious to find out how you could get it within five years.

Mr. STEELE: I only suggested that it can be kept up to date. That is why we need a periodical newsletter to supplement it.

Mr. BRAND: The reason I am curious about your comment regarding a medical letter is this: Although a medical letter in many ways is a very useful exercise it is not always accurate. You are assuming it is.

Mr. STEELE: I am assuming it is more accurate than proprietary information which detailmen and advertisements carry.

Mr. BRAND: Do you realize that the Food and Drug Directorate—when a new drug is brought on the market—depend to a large degree on the reputation of the company that is bringing that drug to them.

Mr. STEELE: Yes, and I would imagine they are justified in doing so.

Mr. BRAND: If they are justified in doing so, would they not also be justified in the information they give most of their detailmen because it would be from the same sources.

Mr. STEELE: No, that would not follow. They are reporting to a government agency in one case, and there is a great incentive to report precisely and accurately. In the other case, they are advertising and everybody gives the advertiser a certain margin of, let us say, puffing.

Mr. BRAND: You realize, of course, that all the advertising is overseen by the Food and Drug Directorate and approved by them before it can be put in journals. Is that not correct?

The CHAIRMAN: No, this is not correct. This applies only to radio and television; it is not true for journals or newspaper advertising.

Mr. MACKASEY: We rely on the integrity of the doctors to police their own journals.

Mr. BRAND: I did not realize that. I apologize if this is true. I assumed they have. This just goes to show you how much I am under the influence of the Food and Drug Directorate. I believe what they say is law most of the time although I have had my confidence shaken lately.

You do not know of any method by which you are going to get the doctors to read this governmental letter which is sent around.

Mr. STEELE: Only self-interest, shall we say.

Mr. BRAND: I must confess I was a little concerned about your—although I know there are bad apples in every barrel, and I am sure this is true about the economists as well—suggestion that the physician is going to be taken in and I think somewhere in here you have made the suggestion that some of the problems are because of the way the physician prescribes. It was between pages 50 and 70 that you made this statement. I am a little concerned about this. Do you really believe this? On page 62, for example, you state:

> Almost any drug will sell, if promoted intensely enough, at least for a while.

Mr. STEELE: Dr. Brand, a moment ago you said that doctors in the United States and Russia were human beings and I think this applies. I think that intensively utilized sales messages cannot help but have an impact—it is just a saturation. If doctors are human they respond to this. In the United States they

may think the detailman is a nice fellow and in fact in the Restrictive Trade Practices Report one of the doctors, I think a doctor at the University of Saskatchewan, said that the chief value of the detailman was to relay professional gossip, especially in more isolated areas. I think this is one of the features which the detailman in textbook selling has in common with the drug detailman. You have friends and they come in and give you professional gossip about economists in various universities. You say that this is a nice fellow and he must sell a good product. I will prescribe his drug or I will require his textbook in the course.

Mr. BRAND: You state on page 62 that:

—advertising alone can sell physicians on a drug, if intensive enough,—

Mr. STEELE: I believe that to be true.

Mr. BRAND: You do not have a very high opinion of the integrity of most doctors, do you, Dr. Steele?

Mr. STEELE: I do not believe that follows.

Mr. BRAND: I believe it does. Doctors are not necessarily trained to take for granted either what a person such as yourself may say to them as a physician or what the detailman says to them. He may agree with him just to get him out of his office but that does not necessarily mean to say he is going to risk giving a drug to a patient if he does not know what that drug is. This is why: It is because they do not have any confidence in some of the smaller houses that the larger firms are able to sell more drugs here today.

Mr. STEELE: Of course, I have my own theory on that relationship.

Mr. BRAND: I am sure you have. But, nevertheless,—by the way, what is your theory? I am curious.

Mr. STEELE: It is the theory—which I think has been brought up time and again by physicians and medical educators testifying in North American hearings—that the detailman tends to disparage the quality of lower price drugs, primarily generic drugs—

Mr. BRAND: You state that in your brief; I know that. May I say for the benefit of the record that never in my experience have I heard this stated in my office. Maybe it is unusual with me.

The CHAIRMAN: I can say as a practising physician that this has been done.

Mr. BRAND: Very often, Mr. Chairman?

The CHAIRMAN: I do not remember exactly but I remember specific instances.

Mr. BRAND: I certainly have not had this experience. I apparently have been very lucky in the type of gentleman who has called on me.

Do you think that by disparaging this will make them use this more expensive and better drug, because a detailman says so.

Mr. STEELE: I think the doctor is in the position where he really has no objective guide for determining the relative qualities of different drugs. It makes sense to him.

Mr. BRAND: That is absolute, nonsense, and you know it.

Mr. STEELE: I do not know that.

Mr. BRAND: I am sure in the economics profession you have journals and things which you look at. Do you have such things—I do not know?

Mr. STEELE: We have journals.

Mr. BRAND: We do have medical journals and we do have very excellent publications which are brought out each year suggesting the type of drugs that should be used by physicians. A lot of physicians use these but, of course, some of them do not and I admit this freely. But I would say the great majority of them do. They do not depend on somebody coming and saying: "Here we have a cure-all, use it."

Mr. STEELE: My reaction would be this, first from what I have read—reading through about 10,000 pages of hearings,—that, in the United States, at least, it is the advertisements which are financed directly or indirectly by the major drug companies which get the more rapid publication. And, it is the more objective things which appear for obvious reasons, months or even years, after the drug has first gone on the market. Now, the doctors' hope is that although the test drugs have perhaps proved relatively ineffective, that a new drug may be better than the previous drug. To the extent that the doctor hopes that the new drug will be effective, he begins to prescribe it before results of the really objective data come in.

Mr. BRAND: Of course, I think you are making one wrong premise here. Most of the drugs that come into Canada have already been used. You are using United States figures which you cannot compare here at all. The great majority of these drugs that are brought on the Canadian market have already been on the market in the United States for several years before they are brought in here, and there are innumerable studies available to us. So, this may be valid in the United States, but it is not necessarily valid in Canada.

Mr. STEELE: Do not Canadian doctors read United States journals?

Mr. BRAND: Certainly, we do. But when you cannot get the drug here, and it is only sold in the United States, it is awfully difficult to prescribe it.

Mr. STEELE: Well is this the fact that there is a lag of a year or more?

Mr. BRAND: This is a fact. I am sure this can be substantiated from many sources.

Mr. STEELE: Well, let us take the case of Thalidomide. This was available in Canada a long time before it was available in the United States. In fact, it never became available in the United States.

Mr. BRAND: Well, do you have any babies with phocomelia in the United States?

Mr. STEELE: The drug was used experimentally, that is true.

Mr. BRAND: You do have?

Mr. STEELE: There are some, but very few.

Mr. BRAND: I may point out that the drug was brought into the United States for use in nausea and vomiting of pregnancy. It was brought into Canada for use as a sedative, to put people to sleep. Unfortunately, we had some very nasty experiences with it in this country in that it was prescribed for those who incidentally happened to be pregnant at the same time. But it was brought into the two countries for different reasons. So I do not think you can use that necessarily as an example. It is one of those that came in—

Mr. STEELE: I do not see why not. How does the fact that it was used for different purposes in the two countries alter—

Mr. BRAND: It makes a tremendous difference. If you are going to bring in a drug that is for nausea, and vomiting in pregnancy, you are going to give it to pregnant women. Surely you are not going to give it somebody such as yourself, who is hardly pregnant? But, the fact remains, that in this country it was brought in as a sedative, therefore it was given to males, and the problem did not arise, you understand, as they are not prone to gestation, you might say. And I think there is a difference here, quite a considerable difference. I think that is beside the point anyway.

Mr. STEELE: I think the point was that you said that drugs which are used in Canada had been used in the United States first.

Mr. BRAND: I said a great majority, and I think this is quite true, cortisone is a good example. It was used in the United States extensively before it was brought into Canada, and there are many other drugs which fall into exactly the same category. And, so the very reason you pointed out in your brief, that we do not do that much new drug research in Canada. Is that correct? We do not bring out the new drugs here, they are brought out in other countries, the great majority of them.

Mr. STEELE: That is true.

Mr. BRAND: Therefore, we get them second hand, right?

Mr. STEELE: You might say second hand.

Mr. BRAND: And therefore the thing that is a problem here with your Thalidomide is the problem of your examination of the drug by the Food and Drug Directorate or the FDA in the United States, is that not correct? As you pointed out in your recommendations that you must expand the staff to such an extent that you can make sure that the drugs—and I presume you mean this—all the drugs that come into this country, would be safe for human consumption. Is that not right?

Mr. STEELE: I recommend that yes.

Mr. BRAND: I am talking too long, you had better let somebody else speak.

The CHAIRMAN: You would be interested to hear—I know you were not able to be here this morning—there was tabled this morning an article actually from the Journal of Marketing Research, called "Doctor's Choice: The Physician and His Sources of Information About Drugs" and they go into the aspect of the things you have been talking about. I had read it earlier, and one of the first statements that they make says:

> —these findings show that commercial sources of information form a major and predominant part of the physician's means of keeping informed about new drugs.

And they list detailmen as the most common source of information. Mr O'Keefe?

Mr. O'KEEFE: Mr. Chairman, I was going to say that the Clerk of the Committee has this if anybody wishes to see it.

An hon. MEMBER: I would be very interested.

Mr. O'KEEFE: Dr. Steele, I will not delay you very long. Just one general question, you have been very patient. In your obviously thorough investigation of the Canadian Drug Market, do you find a difference between generic and brand name prescription drugs? Did you find a difference?

Mr. STEELE: A difference in quality or price?

Mr. O'KEEFE: In price and in quality.

Mr. STEELE: Yes, in comparing the price book—in comparing the prices charged by generic named sellers for generically designated products, and in looking at the brand named prices, I found very large differences.

Mr. O'KEEFE: Could you give me some example of how great the difference is?

Mr. STEELE: Yes, I think Tetracycline, for example, sold for $18.00 versus about $3.65.

Mr. O'KEEFE: Eighteen dollars versus $3.00?

Mr. STEELE: Three sixty to sixty five.

Mr. O'KEEFE: Have you got another one?

Mr. STEELE: We can look at the figures in these tables in Appendix D. The brand name version versus the generic version, looking at the first page of Appendix D, in column 4. Tetracycline. Here we have the Brand name prices $29.50 per 100. $30.00 per 100. $30.00 per 100. $32.00 per 100. $29.60 per 100 on the next page under Empire Generic. $6.00 per 100 under Gilbert generic. This is the figure I was looking at. Pfizer, $30.00 per 100, and 40 per cent off that would give you $18.00. Gilbert $6.00 per 100, and 40 per cent off that would give you $3.60. Gilbert may actually sell at 50 per cent off so this is $3.00. Now, with Chloroamphenicol, Parke, Davis is $39.40 per 100. Empire $15.70 per 100. We have gone over Prednisone. With regard to Prednisolone—

Mr. O'KEEFE: That is enough doctor, that is plenty. Are you competent to give me an opinion on the quality of those drugs, the comparative quality.

Mr. STEELE: Comparative quality, I think, that—

Mr. O'KEEFE: We heard Dr. Chapman a little while ago say there was very little difference.

Mr. STEELE: Yes.

Mr. O'KEEFE: What is your opinion?

Mr. STEELE: I agree. I think that—as I have stated before today—I think the issue of relative quality of brand named drugs and generic named drugs, or let

us just say high priced brand named drugs and low priced generic named drugs, has been greatly exaggerated. I think you can produce a perfectly good drug for a very small percentage of the price which the brand name seller charges. I think if you have got to cut costs, it makes no sense whatsoever to cut costs for quality control and for testing the identity, potency, purity of the ingredients, if it—

Mr. O'KEEFE: What do you base your opinion on doctor?

Mr. STEELE: I think I have spelled it out here in the brief, but basically it is this. The Food and Drug Directorate does examine products, and—

Mr. O'KEEFE: Very few, is that not so?

Mr. STEELE: Very few. I think it concentrates more heavily on the products produced by generic named firms, both brand named and generic products of generic named firms, the risk is greater. And, I think the brands which—

Mr. O'KEEFE: Excuse me doctor, the risk is greater where?

Mr. STEELE: The risk is greater for a small generic named company being visited by an inspector during a certain period of time. As Dr. Chapman said, they concentrate on those producers whom they think are likely to be cutting corners.

Mr. MACKASEY: Why should he presume that they would cut the corners more than anybody else?

Mr. O'KEEFE: That is the question I am trying to ask.

Mr. MACKASEY: I am sorry.

Mr. STEELE: I believe that it is in the interests of economy that his budget is limited, he said it was too small. He investigates the larger firms less frequently on the basis of his assumption that they are less likely to have infractions.

Mr. MACKASEY: Do you think that is a valid assumption?

Mr. STEELE: I am not sure it is always valid. I am sure that it is the principal policy, as an economist I would certainly say yes. If your funds are limited, and based on past experience you have more confidence in certain producers, brand name or generic name, then investigate them less frequently. But it could be a dangerous policy, if your budget is too low relative to your total needs, you might run astray on either end of the price spectrum.

Mr. O'KEEFE: As a scientist, doctor, are you an analyst as well? I mean, are you qualified to express an opinion like that personally?

Mr. STEELE: As an analyst?

Mr. O'KEEFE: As an economist. Are you also an analyst?

Mr. STEELE: No, I am not a chemist.

Mr. O'KEEFE: Or a chemist?

Mr. STEELE: No.

Mr. O'KEEFE: I am not quite clear on this terminology that the doctors use. What I am trying to get at doctor, is your qualifications to express that opinion personally.

Mr. STEELE: Well, the qualifications I think, are related chiefly to the, let us say, the precautions which a rational business man would take to stay in business. A small firm which might get a fine up to $2,000 let us say, seeing that the FDD imposed one fine of $2,000 on a company, this is going to do a lot more harm to a small company than to a large company. And to this extent, I would think, a rational small firm is going to be quite careful as to the quality of raw materials it uses, and its quality control processes. An infraction will hurt it more than it will hurt a large firm.

Mr. O'KEEFE: I understand that, but that is not quite the question I asked. I was asking about your personal qualifications to advance an opinion.

Mr. STEELE: You mean does my part in the drug industry qualify me to say that my opinion is that there is not as much difference between the qualities of generic named drugs and brand named drugs, as has been suggested. Is that the question?

Mr. O'KEEFE: That is it, thank you doctor.

Mr. MACKASEY: Mr. Chairman, I almost feel guilty asking more questions, because Dr. Steele looks tired, he might need a librium right now or something like that.

Mr. STEELE: Please, chlordiazepoxide.

Mr. MACKASEY: I just want to verify a statement you made today—not to trip you up, but just to verify the statement, because we may not receive the transcript for a little while. I am going on holiday. I think you did state the opinion that control on direct mail was advocated in certain studies of the Hall Commission because of the peculiar type of imperfect competition of the drug industry functions, and it would have no effect on pricing.

Mr. STEELE: Yes, I did state that opinion.

Mr. MACKASEY: Would you like to elaborate just briefly on it, because it has been one of the recommendations that has been considered, and I have always shared your opinion that this would serve no useful purpose, and I would just like you to—

Mr. STEELE: Well, if I do not get mixed up. I would like to take a numerical example. Let us suppose that drug firms are spending 30 cents out of the sales dollar in sales promotion, and a law is passed which cuts it to 15 per cent. Now, let us say that production costs and so on, just for simplicity let us say that all the production costs, research costs, and so on, add up to, say 50 cents in the dollar. Sales promotion 30 cents, profit before taxes, 20 cents. And now the government says you have a 15 per cent limitation on the matter of sales promotion which you can carry out. Well, if a company decide that it is still worth it to keep on carrying out the same amount of sales promotion, then what happens? Well, they can deduct as an expense only, 15 cents on the dollar instead of 30 cents. So, they have to resign themselves to paying taxes on, let us say, 7½ more cents. A greater tax bill of 7½ cents on the dollar. Now, this in itself merely shows that their profit margin is sufficiently large that they can withstand this reduction, but the fact that the amount of sales promotion done has been reduced by law for income tax purposes does not necessarily change the demand schedule of the buyer at all.

Mr. MACKASEY: Fine. Now, the one area today that I do not think we have explored as much as I would have liked—and I am rather persistent in it—and that is the Hilliard Report. You did, I think, express an opinion today that amounted to one of neutrality. It certainly did not mean anything to you as an economist. Am I right?

Mr. STEELE: I did not hear you.

Mr. MACKASEY: Would you like to give me another capsule opinion of what you think of the Hilliard Report?

Mr. STEELE: Yes, I think I can summarize my opinion as one of neutrality. I am in favour of safety and if the Hilliard Report increases the safety of products, naturally I am in favour of the recommendations in the Hilliard Report.

Mr. MACKASEY: This I appreciate and because it is in line with other responsible men like Dr. Chapman who, in his last testimony, was a little more explicit than on his first appearance. I doubt if you saw his last visit to our Committee but I am sure you read the record of his earlier one with a little more—I should not use the word "evasive"—but he realized that the Department of Justice had pointed out the Hilliard Report could not be implemented under our present Food and Drug Regulations.

To come back, doctor, to new drug-old drug status, as an economist could you give me a reason why the copiers in Canada, at least, never apply for compulsory licence while a product is still under the new drug definition, or were you aware of this fact?

Mr. STEELE: Yes, this is what you told me a short while back.

Mr. MACKASEY: I am sorry if this has happened but I will take your word for it. If I am wrong then someone will correct me.

Mr. STEELE: Yes, the copier or the price competitor in the market wants to minimize costs to the extent that his overhead costs would be reduced by failing to have to comply with all of the formal requirements of a new drug application, he is naturally going to wait. I would not say that this is necessarily in all cases in the interest of the drug consumer because this means a longer period of high prices.

Mr. MACKASEY: You see, you have emphasized several times in your testimony and your brief, that everything being equal and the present statement which I have to agree with, that an element of competition should be introduced into the market as soon as possible. Are you aware that under our regulations discretion to classify a drug as an old drug or as a new drug, is left to the discretion of the Food and Drug Directorate? In other words, there is no statutory period of time or anything of this nature.

Mr. STEELE: Yes, I do recall reading that.

Mr. MACKASEY: Would this not, despite all your precautions, rules, regulations or changes be defeated—if I want to use that word—by this source of jurisdiction where this judgment rests within the Food and Drug Directorate? In other words, if the compulsory licencees, at the moment, do not apply for a drug while it is considered a new drug and yet the Food and Drug Directorate because of particular side effects or potential hazards have spent five, six or

seven years before they decide this new drug should be classified as an old drug, would this defeat much of what you have been saying today?

Mr. STEELE: Yes, I cannot argue with that. It might even be a good thing if the drug is hazardous and has high side effects, perhaps, the maintenance of the high price might, to some extent, discourage the use, but not very much, but to this extent it would be a good thing.

Mr. MACKASEY: The Kefauver Hearings which you have referred to quite frequently in your brief and which I read but not with your knowledgeable ability to absorb it. What recommendations that were implemented that come out of the Kefauver Hearings that you would suggest would be of benefit to the Canadian consumer?

Mr. STEELE: Recommendations that were implemented?

Mr. MACKASEY: Yes.

Mr. STEELE: You do not mean the patent recommendations which were thrown out?

Mr. MACKASEY: If they were thrown out they were hardly implemented. Why were they thrown out?

Mr. STEELE: I think for political reasons in part, at least, and part for the case of patent protection is very well established in legislation.

Mr. MACKASEY: Why do they not have compulsory licensing in the United States?

Mr. STEELE: I think it is partly political pressure and partly short sightedness.

Mr. MACKASEY: Since we have it, would you say that the political pressure in this country has not been too oppressive?

Mr. STEELE: I would say it has probably been much less.

Mr. MACKASEY: But you feel there is still some political pressure? You feel that anybody on this Committee or this Committee in general, from reading the testimony are prisoners of the industry?

Mr. STEELE: Oh, no.

The CHAIRMAN: That is hardly a fair question.

Mr. MACKASEY: I have learned from the witness today that he has no fear of unfair questions. He has been very frank and I appreciate it. I think it is important, however, because after three and a half years the press is finally discovering that we exist. This is the first time that television cameras have been trained on this room, to the best of my knowledge. This is, I think, due to your appearance.

Could I just have a couple of minutes of the Committee's time to run down very briefly with you because I think this will be our last opportunity, the recommendations, just for capsule comment. I do not necessarily approve of them all but I do not think we have done this today, Mr. Chairman.

The recommendations are on page 123. The first one is as follows:

> Compulsory licenses to import should be granted, subject to the payment of reasonable royalties.

This certainly is in the field of economy. Am I ahead of you there?

Mr. STEELE: No.

Mr. MACKASEY: Take your time.

Mr. STEELE: Page 123?

Mr. MACKASEY: Yes. How would you as an economist say we could establish what is a reasonable royalty?

Mr. STEELE: It depends; I think it is better—it has to be arbitrary—to try to arrive at some reasonable allocation of past research costs and how this allocation is arrived at, is the major problem.

Mr. MACKASEY: I do not have the Hilliard Report in front of me, doctor, and I apologize for not having it. I would gladly leave it with you but it is in the back of the P.M.A.C. brief. I think they did attempt to approach this problem by suggesting the tribunal. As I mentioned to you earlier today, we are two-thirds of the way. I will come back to this. I cannot quite understand the reluctance today that you had in answering this question as to why the third party—one, the Department of Justice; two, the Food and Drug Directorate and, third, a trained economist—should not be on this tribunal when compulsory licence applications are being considered to establish reasonable rivalry. What is your objection?

Mr. STEELE: As I said, it is not an economic objection it is just my own experience that the fewer people there are in a group the more expeditiously the group's work is accomplished.

Mr. MACKASEY: We could leave the Food and Drug Directorate off and then you would not have to worry about safety. We could leave the Department of Justice off and then we would not have to define the law. We could leave the economist off and you could not establish a reasonable royalty. You recommended reasonable royalties. I have not; you recommended it and knowing your knowledge, I sense you do have some suggestions as to how reasonable royalties can be arrived at.

Mr. STEELE: I was thinking if you put an economist on there the disagreements would be long and the process would be prolonged very greatly.

Mr. MACKASEY: You mean the compulsory licence may be held up while royalties are being decided?

Mr. STEELE: Yes, and other issues.

Mr. MACKASEY: What other issues would the economist be involved in?

Mr. STEELE: As far as the tribunal is concerned, the role of the economist has not been made clear to me.

Mr. MACKASEY: It would be to establish royalties because nothing is black and white in this world but neither is the drug industry. I have realized that after three years, but I am talking about my own country. I do not know anything about the United States and I have never believed in curing a nosebleed by cutting my head off. I am reluctant to destroy an industry no matter how imperfect it is and I have been uncomfortable about the pittance, as Judge Thorson calls it, that has been paid out in the form of royalties. This is why I thought the Hilliard Report was a very objective recommendation and I thought, perhaps, you would have endorsed it a little more vigorously as an economist.

Mr. STEELE: It depends upon what the pittance is added to. In other words, there is a pittance royalty but the price which the company obtains in its other transactions elsewhere in the world may be more than sufficient to allow it to brave a somewhat lower price on the Canadian market.

Mr. MACKASEY: Because it is so international in scope how do we determine whether it would be regained around the world in other markets for the general research development on the drug?

Mr. STEELE: You mean, if you were interested whose evidence would you look at?

Mr. MACKASEY: How would you gather it all? You would need an international body. You would have to go through the United Nations. If every country took the attitude that royalties should be allocated on the value of the susbstance which can be 1½ cents and everybody in the world theoretically did this, do you think the innovator—the monopolist—would be treated fairly?

Mr. STEELE: I am not sure it is a question of looking only at the fairness of treatment between the innovator, the monopolist and the copier or competitor. I think that if everything else in the drug market were justly arranged, you might say there is some discrimination against the innovator in favour of the copier. In fact, I think, this was brought out in the Ilsley Commission Report. They said this is certanly a possible inequity but the benefits which the public at large would gain from compulsory licensing would outweight this inequity.

Mr. MACKASEY: You made this point many times today and I appreciate your concern for the public. I have the same concern, but I also have a sense of fair play to everybody concerned including the companies that manufacture these drugs. I think we have to hit a happy medium somewhere along the line including our responsibility to the generic firms.

Mr. STEELE: I did not finish my comment.

Mr. MACKASEY: I am sorry.

Mr. STEELE: I was saying that there is this question of possible inequity between the innovator and the copier, to use those terms, but then there is also the question of possible inequity existing in the absence of compulsory licensing. In other words, is the public really getting its money's worth out of the prices charged by the innovator? It is not a question, let us say, of taking an initially just situation and introducing a certain type of inequity. It is a question of taking a situation where possibly there is an initial inequity and then remedying it by an offsetting inequity.

Mr. MACKASEY: We will go on to number 2.

> Section 41(2) of the Patent Act should be amended to put the burden of proof of infringement of drug process patents on the plaintiff.

In other words, we are stacking the cards. I am not saying we should not be but we are again on the monopolist here, are we not?

Mr. STEELE: We are stacking them in one way. They used to be stacked or are stacked the other way at present.

Mr. MACKASEY: Yes, but of course the gain of the layman, it seems to me when I own something, the responsibility should be on someone else who is

taking it away from me, but obviously in the drug industry it should be the other way around.

Mr. STEELE: This depends on your basic philosophy with regard to the patent system. Is a patent a privilege or is it more in the nature of a property right?

Mr. MACKASEY: It is a little like a radio station—try and get one if you can.

We will jump to No. 3:

> Every effort should be made to further expedite the process of acting on compulsory license applications. If reasonable expedition cannot be achieved, such licenses should be issued as of right.

I have no evidence in Canada that anybody has blocked compulsory license applications. As I mentioned, it seems that people asking for them are the ones who wait until the drug has reached an old drug definition before they apply.

Mr. STEELE: That is what you told me and I will take your word for it.

The CHAIRMAN: I think that evidence has been shown that up to two and a half years have been taken, after it has been applied for, for it to be granted.

Mr. MACKASEY: After they apply for it but they do not apply for it until it is an old drug.

Now, to go on to No. 4—

Mr. BRAND: Can I bring this out Mr. Laidlaw?

Mr. LAIDLAW: Dr. Brand, about from 5½ months, I believe, to 2½ years over the 14 applications I have seen.

Mr. BRAND: You mean the minimum and the maximum?

Mr. MACKASEY: Am I right in saying that all 14 have been given controlled drug status?

Mr. LAIDLAW: I think you are right.

Mr. MACKASEY: I would not want to mislead our Texas friend here.

> No. 4. Section 19 of the Patent Act should be amended to allow provincial governments and their agencies as well as the government of Canada to use any patented drug, subject to the payment of reasonable compensation.

Would you explain that just a little more fully?

Mr. STEELE: Yes; I believe that, as you just suggested, there may be cases where drugs are patented and prices are set at a high level and yet no competitor comes in to request a compulsory license, particularly, let us say,—well, just under present circumstances. Under these circumstances, if provincial governments and their agencies could step in and fulfil the various requirements, this as I say would further safeguard the Canadian drug buyer against restriction of supply and high prices. It would increase supply and exert a downward pressure on price.

Mr. MACKASEY: Of course, from that province to other provinces. In this country we have eleven governments. If the province of Alberta were to take

advantage of Section 4 to obtain a compulsory license, which is the same thing, or ignore a patent, surely, it would have an effect right across the nation, would it not?

Mr. STEELE: It would have some effect, yes. It would increase the total supply within the nation.

Mr. MACKASEY: Yes.

The CHAIRMAN: Could I ask Mr. Laidlaw a question. Now the law says that the government of Canada may do this. Has the government of Canada ever done this?

Mr. LAIDLAW: In relation to Section 19?

The CHAIRMAN: Yes.

Mr. LAIDLAW: The government of Canada, I believe, has this in the back of its mind and this is the result of the tendering that goes on through federal agencies but at the moment the provincial agencies tender but the law is not geared—Section 19 does not yet include provincial governments or agencies.

The CHAIRMAN: Excuse me Mr. Mackasey.

Mr. MACKASEY: Number 5.

> The Trade Marks Act should be amended to allow the importing of trade-marked drugs which have been produced by a company related to the company possessing the Canadian trade mark.

Which I think is one of the recommendations of the royal commission.

Do you put any credence in the argument that they will change the trade marks from one country to another?

Mr. STEELE: Well, let me see, I am not sure I am clear on your question.

Mr. MACKASEY: Well, there has been a suggestion made that if Section 5 was brought into force the major companies could get around it quite easily by simply changing their trade mark.

Mr. STEELE: Oh, yes. I point out in the last sentence of this paragraph just below it, I believe, that this would occasion some capital loss to the extent that in Canada they had already built up a goodwill for their trade name. It would not be costless; they could certainly do it.

Mr. MACKASEY: I am going to skip tariffs because I do not know anything about them.

Number 7.

> Liability for anti-dumping duty should be limited to drugs of a kind actually made in Canada, where "kind" is defined in terms of the active ingredient.

Would this not be kind of hard on the few companies we do have, such as Ayerst-McKenna.

Mr. STEELE: The ones that actually are producing in the country?

Mr. MACKASEY: Yes, or would this stimulate more production in the country?

Mr. STEELE: I do not think this would hurt Ayerst-McKenna.

Mr. MACKASEY: Do you think it would stimulate more production?

Mr. STEELE: I think it would not be a positive disincentive.

Mr. MACKASEY: Would it be a positive incentive? Would you not start manufacturing something in Canada and therefore circumvent this anti-dumping duty?

Mr. STEELE: Circumvent the anti-dumping duty?

Mr. MACKASEY: Well, I should not say circumventing; enforcing the anti-dumping duty. In other words—you would be limited to drugs of a kind actually made in Canada, so would it not be to the advantage of these big companies to make more drugs in Canada? Otherwise, you are just going to get the over-production from the Americans, are you not? That is what we have had in magazines, and just about everything they produce down there. They run the machines twenty-two minutes more and they have enough production for all of Canada. Right?

Mr. STEELE: Well, I think your relation to the Canadian market—how many hours a day do they ordinarily run the machines?

Mr. MACKASEY: In the States or here?

Mr. STEELE: In the States.

Mr. MACKASEY: Well, if I know Americans, they run them twenty four hours but they are always looking for a market to dump their products. They do this in the magazine industry.

Mr. STEELE: Well, this implies the Canadian market is one-sixtieth of the U.S. market—twenty-two minutes versus twenty four hours.

Mr. MACKASEY: That is about right, I think, in certain fields.

Mr. STEELE: Well, in this brief I have evidence to show that the per capita income of Canada is about 70 or 75 per cent of the United States. The population is about one tenth.

Mr. MACKASEY: One tenth.

Mr. STEELE: I do not think that—

Mr. MACKASEY: Well, this is all due to page 103 of your brief but when the day of reckoning comes we will not be too sure just what our standard of living will be. You know when you people decide to take your dividends and your investments out of here, as you suggested.

Mr. STEELE: Yes I agree.

Mr. MACKASEY: That is when the day of reckoning will come, and I hope it is long after I am gone. No. 8:

> The valuation for customs purposes of imported drugs should be based on production cost plus a maximum allowance for gross profit (or on invoice cost, if higher) in situations where it is not possible independently to ascertain fair market value.

Is that not pretty well what we are doing now?

Mr. STEELE: Yes; I think this recommendation is really a minor recommendation.

Mr. MACKASEY: No. 9 is self-explanatory. So is No. 10. I think we all agree with that recommendation. No. 11:

> Unnecessary barriers to the marketing of new drugs by additional firms should be eliminated. Where a new drug has been cleared for marketing on the basis of adequate data compiled by an original applicant, the same drug should be approved for marketing by any firm capable of producing the identical drug. Similary, unnecessarily onerous burdens in the way of supplying drug information which merely duplicates existing known information should not be imposed.

Again, are we not asking the monopolist to do things that we are asking the innovator not do do here?

If you are going to manufacture anything, even as a copier, do not have some moral responsibility to provide some information on safety and testing. Should you not be part of the family scheme where you let the Food and Drug Directorate know what the side effects that come to your attention are, the inquiries in the middle of the night for doctors, etc; should you not be part of the industry?

Mr. STEELE: Well, I would have to agree that a conscientious firm should do what conscientious people do. But I would not want this sort of statement to be interpreted that the fact that the drug has been on the market, let us say, for 15 years, and one firm has been selling it, and they have distributed in this brochure some information about the drug, it is written up in the official compendia, I would say then that if physicians do not know about this they have been remiss in their self-education and it is not the responsibility of a competitive firm to make up for this omission.

Mr. MACKASEY: Suppose after 15 years, and you and I have discussed this privately, but I would like to get it on the record, a particular drug is now manufactured by one or two people under compulsory license, and suddenly serious side effects are discovered, such as, if taken in conjunction with cheese or beer there will be high blood pressure. Do you not think those who are manufacturing this drug under a compulsory licence should have the same legal and moral responsibilities as the originator, from there on in, if this drug is reclassified as a new drug?

Mr. STEELE: Well, under those circumstances, if after 15 years this occurs, appropriate steps should be taken on the part of all concerned; surely.

Mr. MACKASEY: Including the copier or the competitor, I think, is the expression I must learn to use. This is your terminology, monopolist and competitor.

Now in No. 12, what you are saying is that if you do not give the doctor some journals free of charge they are never going to get around to filling the prescription; they are too busy. No. 13:

> Every reasonable effort should be made to inject more price competition into drug retailing.

This is an area that I think has been sadly neglected in the three years we have been here and you are the first person to put so much emphasis on the

druggist's role, apart from myself. I have said on several occasions that the cost to the consumer is not only the responsibility of the manufacturer but also of the wholesaler to some extent, although you give him a clean bill of health, and the retailer.

> Every reasonable effort should be made to inject more price competition into drug retailing. Serious consideration should be given to the liberalizing of the requirements for operating drugstores and dispensing prescriptions, so that the development of lower priced outlets for drugs such as discount pharmacies and mail order houses can be encouraged.

Well, we do have mail order houses and we do have discount pharmacies, but Canadians do not support them to the same extent they do in the United States.

Mr. STEELE: Well, if they do not support them they cannot generate the volume necessary to cut costs.

Mr. MACKASEY: Precisely. But they are there; it is nothing new. People have tried.

Have there not been problems in the United States about mail order drug houses that I have been reading about?

Mr. STEELE: Oh, yes.

Mr. MACKASEY: What type. Would you mind telling us because they could potentially happen up here?

Mr. STEELE: Yes, this I think is a very, very interesting area, and I wish I had brought documentary evidence on this. In the Kefauver hearings, the first hearings, say, late 1959 through 1960, a woman appeared. She had established a mail order house for retired teachers primarily. She had had difficulty with some of the major companies cutting off her supplies. I think to the credit of the Merck Corporation they offered to extend her credit when it was necessary. Parke-Davis on the other hand cut off her supplies when they found out they were being sold through a mail order and when the president of Parke-Davis was asked by Senator Kefauver why they did this, in effect, he said, well it is just against our principles to supply mail order houses.

Mr. MACKASEY: This is not the type of trouble I was talking about.

I was guest speaker last year at a convention in Montreal of Americal law enforcing officers who were discussing the problems of narcotics, and so forth, and speaker after speaker pinpointed much of the trouble on mail order drug houses. This is the trouble I am talking about.

Mr. STEELE: Oh, yes, narcotics, I think, would be a special case. I would be very careful about, at least, distributing certain types of narcotics through mail order houses.

Mr. MACKASEY: Mind you, we do a scheduling here that I do not think you have in the United States. But this is the type of problem that does exist in the United States, am I right?

Mr. STEELE: Yes, narcotics are a different case entirely.

Mr. MACKASEY: I do not know the status of LSD in this country and I am not sure whether you would be able to buy it from one of these discount houses or by mail order one of these days.

The CHAIRMAN: It is illegal for sale, but not illegal to possess.

Mr. MACKASEY: Well, I will have to put some in my handkerchief one of these days. No. 14:.

> If the above reforms do not succeed in reducing drug prices to competitive levels in a reasonable period of time, drug patents in Canada should be completely abolished.

In other words, did you put it last because of international repercussions?

Mr. STEELE: Yes; this is the major reason why it is put last.

Mr. MACKASEY: Otherwise, you would have put it higher up on the list.

Mr. STEELE: Yes; I would say that the chief value of the patent law for Canada is avoiding international difficulties, because of the low ratio of patents held by Canadian citizens. I think it is very low, at about 8 per cent or so for patents in general, and roughly 3 per cent for the drug patents.

Mr. MACKASEY: I have one last question, Dr. Steele, and that has to do with a statement you made today that intrigued me and I am afraid I lost the exact phraseology. You can correct me, but I thought I heard the very classic statement that industry should purchase wherever the source is most efficient. Am I right or wrong in paraphrasing you?

Mr. STEELE: That industry should purchase wherever the source is most efficient?

Mr. MACKASEY: Well, I think it was Mr. O'Keefe who asked you.

I will phrase it better. In other words, it is inefficient not to take advantage of the source of supply that is the least expensive.

Mr. STEELE: Oh, yes the lowest cost source. Yes; this is a basic principle in economics but again this, *ceteris paribus*, other things being equal.

Mr. MACKASEY: Well, I am glad you have qualified it a little. Do you adhere to this theory? Would you enforce it, if your were, say, in a position to do so?

Mr. STEELE: I would certainly try to. In fact whenever I get a prescription filled I try to buy a generic drug or induce my physician to prescribe.

Mr. MACKASEY: But I am looking at it in a broader sense because of the fact that our economy is now dominated by Americans; If we do something here in the drug industry there is no telling where it will stop. We do not know where it would spread or could spread. I imagine the drug industries are rather concerned about what we do here that could spread to other countries. We do have a controversy going in this country over free trade and I thought today that you advocated free trade.

Mr. STEELE: Yes, I do, you might say. I have a bias in favour of free trade. But I am not dogmatic about it, I realize there are other values and purely economic values.

Mr. MACKASEY: One last question—

The CHAIRMAN: You mean this is the last question.

Mr. MACKASEY: You have made a very telling point all day which is bound to impress everybody and that is the relationship between the selling price and

the cost of the actual ingredient; it is a fantastic percentage. As an expert in the petroleum industry, would you tell me precisely what it costs to produce a gallon of gasoline?

Mr. STEELE: Well, I think the—

Mr. MACKASEY: Raw materials.

Mr. STEELE:—cost varies a great deal. There are some very low cost sources and some very high cost sources of crude oil.

Mr. MACKASEY: This is true of raw materials in the drug industry as well, is it not?

Mr. STEELE: I think nothing like the same extent. You can get crude oil from the Middle East for five cents a barrel and you can produce it in Pennsylvania for $5.

Mr. MACKASEY: Let us take the five cents a barrel because the analogy would fit the raw materials. What would this five cents a barrel end up at in actual cost per gallon of gasoline at the manufactuer's level?

The CHAIRMAN: You mean per barrel to make it equivalent—

Mr. MACKASEY: A gallon. Because we have been talking here in drugs and dosage form.

The CHAIRMAN: But you have to keep the figures the same. If you are going to say it was worth five cents a barrel, then how much did it finally sell for the same barrel.

Mr. MACKASEY: Then I will ask you after how many gallons in a barrel. So we will end up with the same question. Right?

Mr. STEELE: What is the order of your question?

Mr. MACKASEY: I want to know the relationship; because, you see, all day long we have hit logically—and it has almost frightened us—at the $3 prescription containing about twenty cents worth of material. I would like to know the actual cost of a gallon of gasoline which costs me 45 cents.

Mr. STEELE: Well, it depends upon whether you want the average cost or the incremental cost here. Now, it is the incremental cost which determines the price, and in drug manufacturing the incremental cost tends to be pretty constant. It costs you about as much to produce the first thousand capsules—

Mr. MACKASEY: Excuse me. I am not interested in the producing of a capsule. Your brief keeps talking about the value of the raw material.

Mr. STEELE: Oh, no; the factory cost, this is what I am interested in; the factory cost of the tablet or capsule as bottled and labelled. These are the figures I am quoting relative to price.

Mr. MACKASEY: All the way through here, and not raw materials.

Mr. STEELE: Not raw material costs.

Mr. MACKASEY: Well, can you give me the analogy, or is there any comparative figure that you know of, off the top of your head of the petroleum industry?

Mr. STEELE: Well, as I say, this is a question of relating the average cost production to the increment cost—

Mr. MACKASEY: Fine. I am well related. I am just try to find out what it costs—

Mr. STEELE: Well, I have to explain it, but I can just state the results. In other words, you may have an average cost of producing a gallon of gasoline which is ten cents and an incremental cost which is 20 cents.

Mr. MACKASEY: Yes. Well, I will give up because then we get into all the by-products of the product. That is all, Mr. Chairman.

Mr. JOHNSTON: Mr. Mackasey has made a very thorough study of this brief from the province of Alberta. I would suggest he also study the royal commission report on gasoline prices from that other great Social Credit province of British Columbia.

Mr. FRAWLEY: We have one going in the province of Alberta now, Mr. Mackasey, and when they make the report I will send you a copy.

Mr. MACKASEY: For a reactionary province you are very forward in your investigations.

The CHAIRMAN: Gentlemen, I personally would like to ask three questions and I think Dr. Steele could answer "yes" or "no" to all three. For those who are not aware of it, there is a TV program on tonight at 10.30 which is going to solve all the problems of drug prices. None of the experts in this room, I think, actually attended the program.

An hon. MEMBER: What program and what station?

The CHAIRMAN: "Public Eye", CTV, channel 4—

Mr. MACKASEY: Would you mind telling us who is on it?

The CHAIRMAN: It is chaired by Mr. Levesque, Mr. MacEachen is one guest and Dr. Howe of this Committee is another guest, and I think Dr. Wigle. I do not know who else.

The three questions I wanted to ask, if I may, quickly as Chairman, are: When you talk about royalties, and you are talking about increasing the pittance, if you increase the royalties, the chances are your are going to increase the price of the drug; is this correct?

Mr. STEELE: Yes, I think this is true.

The CHAIRMAN: The second question: You said many times that the price of a drug is not related to the cost of the manufacture of the drug?

Mr. STEELE: I am sorry to qualify that first answer but you wanted a "yes" or "no" answer so I said "yes", Now, the person who seeks a compulsory licence is a copier; that is, a competitor, and he is going to price his product initially as low as he thinks he has to in order to attract business from the original firm. I think Mr. Gilbert, for example, cuts his prices about 95 per cent; whereas Empire cuts their prices about 75 per cent below the price—

The CHAIRMAN: In other words, their prices are not related to cost either?

Mr. STEELE: Well, the high price is not related to cost. It is related to demand. The low price is related to the fact that there is a high price producer in the market and that his price is at a certain level. As soon as you have

competition, even though the competition is, say, second class competition, you begin to worry a little bit about the relationship of the price of other sellers. It is not a question of relating price to cost but it is relating price to the price of the rival seller, and what I expect would happen is that the compulsory licencee first sets his price at about 75 per cent of the brand name seller, and if his generic version gains acceptance, then the price of the brand name seller falls, not because the cost of production of the brand name seller has declined but because the licencee is gaining market acceptance and his lower price is resulting in taking part of the market away. So the brand name price comes down 25 per cent. Then the licencee's price comes down another per cent, and so on. This is certainly what was hinted at in the Hoffmann-LaRoche brief.

The CHAIRMAN: In other words, in both cases but for different reasons the price is not related to cost?

Mr. STEELE: Until you get to the level where real competition is really down there and what you are trying to do is to sell at a competitive supply price; that is, cost plus the minimum rate of return, which would allow you to invest in this industry and keep it going out and finding another investment which is relatively more profitable.

The CHAIRMAN: Fine. My last question, and you will probably have to draw on your experience in the United States for this because I do not think this Committee had the figures to enable you to arrive at this. Is it you impression that both the innovator and the copier of the generic and the brand name company, the small and large company, are both making the same percentage profit on the money they have invested?

Mr. STEELE: I am glad you brought this point up. As far as the consumer is concerned, he wants the lowest price. He does not really care what profit the seller is making; that is, if he is a price conscious consumer. It is quite possible that there may be profit conscious consumers, but since they do not know what the seller's profit is and they do know what his price is, if one seller sells at $2 and makes 50 per cent on the investment, another seller sells at $4 and makes 40 per cent on the investment, the average consumer is going to buy from the producer with the lower price if he has the alternative, if the price differential is large. I think that the lower cost producer is simply in a good position, regardless of the reason why his costs are lower, and the competition between lower price sellers and the higher price sellers is going to reduce the profit levels of both companies.

The CHAIRMAN: But as examples, copier and innovator, despite the gross discrepancy in their price, they may for one reason or another be actually making the same amount of money on their invested dollar?

Mr. STEELE: This is certainly possible and I would not be surprised if it does occur.

Mr. MACKASEY: Why would it be possible?

Mr. STEELE: Why would it be possible?

Mr. MACKASEY: What expense does the copier not have that the innovator did have?

Mr. STEELE: Let us put it this way; sales promotion, I think, first and foremost.

Mr. MACKASEY: All right. Did you compare the figures in the two briefs? They were less than 15 per cent. That would hardly be the dominant reason.

Mr. STEELE: The figures in the two briefs?

Mr. MACKASEY: Yes. We have had a brief from the generic firms which placed their marketing costs at 20 cents as compared to 30 cents on the other.

Mr. STEELE: Thirty is greater than 20.

Mr. MACKASEY: Yes, I agree, but it is on 10 per cent difference.

Mr. STEELE: Well, it is 50 per cent more.

Mr. MACKASEY: Yes, O.K. Would you say that is the only reason?

Mr. STEELE: No. The point you are getting at, I take it is—

Mr. MACKASEY: The question I asked you arose out of Dr. Harley's question. My question was why is it that sometimes an innovator, despite a rather sizeable decrease in price over the monopolist, still can end up with a greater profit, and you said because of marketing costs. I do not agree—because I went into this area with them at the time—that in Canada, at least, the marketing between the monopolist and the copier is that great. It is certainly not as great as the difference in their selling price, if they are going to maintain the same problem. There have to be other factors that have not been considered.

Mr. STEELE: Well, it is really a question here of trying to untangle the difference between absolute numbers and percentages. The obvious answer is that this copier is a parasite; he has no research costs.

Mr. MACKASEY: This is one of the answers I wanted.

Mr. STEELE: Yes, but what does research cost, 7 per cent? Ten per cent difference in sales costs more than makes up the difference.

Mr. MACKASEY: And you say the parasite and has no research costs at all, which are still 7 per cent. Go ahead. I am tired.

The CHAIRMAN: If I might correct you though and say that if you are referring to the brief, and I think you are, they did list a cost for research somewhere about 4 per cent. Then you have reduced your 7 per cent to about 3 per cent; not basic research, just research it was called.

Mr. MACKASEY: Research.

The CHAIRMAN: They are not saying what is done under that.

Mr. MACKASEY: They sent someone out to find a broom closet and that is under research, particularly if there is no broom closet.

The CHAIRMAN: Do you have any questions, Mr. Johnston? Everybody has been having a "go" at it but you; no other plugs for astrologists?

Mr. FRAWLEY: I think that is a different committee.

Mr. BRAND: How come this Committee did not hire Dr. Steele instead of the province of Alberta?

Mr. FRAWLEY: We bow.

The CHAIRMAN: Mr. Mackasey?

Mr. MACKASEY: No; I am exhausted.

Mr. LAIDLAW: If I am not responsible for having a general election called, there is just one question I would like to ask; it relates to what you said earlier, Mr. Chairman, about the difference between costs and prices. In one of your recommendations, and it appears at page 110 of your brief, Dr. Steele, you say that it is appropriate to revise certain tariff laws, one being the application of tariffs only to those drugs of a class or kind actually produced in Canada, and a second one being that the application of anti-dumping duties only to those drugs of a kind actually produced in Canada. Now, if this recommendation was put into effect, this would reduce the cost to the drug manufacturers but you have just stated that it really does not matter; it is the price that matters. So is this an essential recommendation from your point of view?

Mr. STEELE: Well, yes. You have to take this as one recommendation among many. The other recommendations would bring in price competition and would make costs relevant to prices. By itself this would have no effect on prices charged. But if sharp price competition is introduced, then this tariff charge does become much more important.

Mr. LAIDLAW: In other words, if price competition could be instituted, then these two recommendations to revise the tariff laws would be in favour of the company. They would have more leeway. They would be saving on their imports of the basic ingredients.

Mr. STEELE: In favour of which companies?

Mr. LAIDLAW: In favour of the Canadian company which was importing basic materials.

Mr. STEELE: Canadian base producers?

Mr. LAIDLAW: That is right.

Mr. STEELE: This is true. These proposals certainly do not suggest that the principal tariff protection be sacrificed.

Mr. LAIDLAW: I think I understand the point. Thank you, Mr. Chairman.

The CHAIRMAN: If there are not other questions we would like to thank Dr. Steele and Mr. Frawley for bringing Dr. Steele before us on behalf of the province of Alberta. It has been a long and gruelling day for Dr. Steele and we appreciate the frankness and thoroughness with which he has dealt with our questions. Thank you very much.

The meeting is adjourned.

APPENDIX "A"

ENGLAND, LEONARD, MACPHERSON & CO.
CHARTERED ACCOUNTANTS

FEBRUARY 13, 1967

Dr. H. C. Harley, M.P.,
Parliament Buildings,
Ottawa.

Re: Special Committee on Drug Costs and Prices

Dear Dr. Harley:

As requested, I have prepared six tables of statistics for the Pharmaceutical Manufacturing Industry in Canada showing comparisons to the corresponding statistics for all Canadian manufacturers.

Yours sincerely,
W. J. Blakely, C.A.,
Accountant for the Committee.

TABLE 1

RATE OF RETURN ON SALES

	Profit Companies		Loss Companies		Profit & 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
1964	12.23	6.35	− 7.13	−3.66	9.52	5.11
Average	11.22	7.15	− 9.22	−4.71	9.55	5.82

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*. 1961–1964 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 & 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
1964	26.27	11.92	−100.00	− 5.08	23.22	9.20
Average	23.49	13.15	− 28.77	− 6.77	20.00	10.30

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*.

1961–1964 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

	Profit Companies		Loss Companies		Profit & Loss Companies	
	Pharmaceuticals	All Manufacturing	Pharmaceuticals	All Manufacturing	Pharmaceuticals	All Manufacturing
	(per cent)	(per cent)	(per cent)	(per cent)	(per cent)	(per cent)
1953	14.56	13.29	− 5.09	−4.05	13.08	11.26
1954	16.75	11.06	− 7.32	−4.40	14.42	8.87
1955	16.55	12.08	−10.78	−4.05	13.75	10.51
1956	19.05	11.61	− 8.75	−3.00	17.00	10.29
1957	19.41	11.50	−11.45	−2.15	16.27	8.82
1958	18.17	10.57	− 4.41	−1.61	14.77	7.89
1959	18.56	11.37	− 2.21	−1.34	16.30	8.77
1960	17.39	9.94	− .83	−2.24	14.65	7.90
1961	14.36	9.66	− 8.11	−1.48	12.77	7.22
1962	16.01	10.06	− 6.69	−2.55	12.31	7.97
1963	16.71	10.16	− 8.84	−1.55	14.16	8.11
1964	18.19	9.72	−11.66	−1.76	14.61	7.73
Average	17.14	10.92	− 7.18	−2.52	14.50	8.78

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

DEFINITIONS: Return—net profit before income taxes and interest expense.
Resources—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 were derived from unpublished data used by the Department of National Revenue in its 1965 publication of *Taxation Statistics.*

DEFINITIONS: Return—net profit before income taxes.

Average return: this refers to the average for each specific classification. for example, 71 companies in the classification, Pharmaceutical Preparations, had a rate of return which was above the average return for this classification. The average return for these 71 companies was 26.7%. Similarly, 107 companies in this same classification had a rate of return which was below the average return for this classification. The average return for these 107 companies was 8.6%.

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
1964	28.35	26.00
Average	27.24	28.24

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*. 1961–1964 calculated from Department of National Revenue, *Taxation Statistics*.

TABLE 6

	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)
1953	7.56	11.76	2.83	8.94
1954	9.31	14.18	6.51	12.53
1955	10.24	9.72	6.72	7.14
1956	7.33	9.03	4.52	7.05
1957	10.19	19.63	8.60	11.52
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
1964	12.03	17.33	14.13	12.38
Average	10.92	16.40	8.42	11.57

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

APPENDIX "B"

CANADIAN DRUG MANUFACTURERS

SCARBOROUGH, ONTARIO
FEBRUARY 4th, 1967

REPRESENTING CANADIAN OWNED DRUG MANUFACTURERS

Dr. Harry C. Harley, M.P.
House of Commons,
Ottawa, Ontario

Dear Dr. Harley:

I am taking the liberty of sending you a brief additional description on the sales tax on pharmaceuticals for your added information.

As you know, our Brief was "submitted" to your committee, but was not "heard", because of the shortage of time. This, of course, is understandable.

I somehow felt that the lack of personal presentation and discussion took away some of the colour from the presentation and left the members without a strong enough impression on this very important matter. It was also my feeling that the views presented so far on this subject have been erroneous and not properly thought out.

Please accept the brief description in the above light.

Your sincerely,
Leslie L. Dan, B.Sc. Phm.,
Chairman,
CANADIAN DRUG MANUFACTURERS

CANADIAN DRUG MANUFACTURERS
PRESS RELEASE

Scarborough, Ontario

SUBJECT: SALES TAX ON PHARMACEUTICALS

Several Associations advocated the removal of sales tax on pharmaceuticals as a way of reducing drug costs. In our opinion, their argument is faulty and full of holes, although the Associations may have had good intentions. Here are the reasons:

(1) *It is unsound from the viewpoint of financing*

Under Medicare, prescriptions are paid by general taxation from the Treasury. When the Treasury refunds 11 million dollars (approximate amount applicable to prescription medicines) the Treasurer will be short 11 million dollars in funds which may be intended for "education". In short, the Treasury has to go back to the taxpayer for 11 million dollars, to fill the gap and obtain the funds by general taxation.

(2) *Political red herring*

The removal of the sales tax has only one value to the public as a "political bait". We feel that the public should not be "fooled" by telling them that money is saved on drugs, when in reality it is not.

To offset the political aspect, we suggest that the public be offered "better health standards" by the creation of a new agency or a non-profit entity, "The Drug Research Institute" (details are described in our Brief).

From the viewpoint of financing, perhaps only 1/2 to 1 million dollars would be spent on this project, thereby retaining 85%-90% of 11 million dollars sales tax.

(3) *It is a cheat to the public*

As pointed out before, the public is not saving a nickel when the sales tax is removed, since it has to plug in the hole in the tax gap.

Besides, the sales tax is remitted through an "intermediary"—the manufacturer, and we are dubious that he will pass on the savings to the public in their "entirety".

If the Government refunds 11 million dollars sales tax to the public, but the public receives only 6-7 million dollars, because the difference "somehow gets lost in the shuffle"—by having been absorbed by the manufacturers—obviously the public has been "cheated". Therefore, we feel that the Special Committee on Drug Costs and Prices should Face the Facts and say the truth squarely, by observing that

> SALES TAX ON PHARMACEUTICALS SHOULD NOT BE REMOVED FOR IT DOES NOT REPRESENT A *TRUE SAVING* TO THE CONSUMER, SINCE UNDER THE PROPOSED MEDICARE THE CONSUMER PAYS FOR THE MEDICINES AND ALSO FOR THE GAP, CAUSED BY THE REMOVAL OF THE SALES TAX.

APPENDIX "C"

PHARMACEUTICAL ASSOCIATION OF THE PROVINCE OF BRITISH COLUMBIA

410-207 WEST HASTINGS STREET, VANCOUVER 3, B.C.
JANUARY 31st, 1967

Dr. H. C. Harley, M. P.,
Chairman,
Special Committee on
Drug Costs and Prices,
Parliament Buildings,
Ottawa, Ontario.

Dear Dr. Harley:

During our perusal of the Brief presented to you on November 17th, 1966 by Mr. S. S. Bass and the Evidence recorded in the Committee's Minutes (No. 19) we have noted a number of statements which we feel may be misleading to the Committee.

The following notes are submitted in order to assist the Committee in evaluating some of these statements. There are many matters upon which Mr. Bass has stated controversial opinions and we have not dealt with them, confining ourselves to the more obvious inaccuracies and conflicting statements.

Knowledge and Training required by pharmacists
(Brief, pp. 6 and 7; Evidence, pp. 1289 and 1298)

Bass equates the occupational role of the pharmacist with the dispensing function alone, in contrast to the Royal Commission on Health Services which sets forth (Volume I, p. 649) the pharmacist's essential professional functions over and above dispensing, to which might well be added numerous other professional responsibilities which evolve upon him as a member of the community health team.

With respect to the dispensing function itself, he refers to counting, razor blades and '. . .transferring pills from one bottle to another', without reference to identification, storage, knowledge of dosage, side reactions, therapeutic incompatibilities, etc., etc.

Bass indicates the percentage of compounded prescriptions as 1%. The national average is approximately 5%, although it may be acknowledged that the percentage is undoubtedly lower in certain pharmacies who cater to volume-drug prescriptions and discourage patients with compounded prescriptions since they are time-consuming (and therefore expensive) to fill. This practice usually extends to 'service prescriptions' (e.g. Welfare, Compensation Board, Indian Health, D.V.A., etc.) which are administratively time-consuming (and therefore expensive) to fill and are also discouraged in pharmacies whose predominant appeal is to price rather than professional service.

Bass concluded from his equation of the pharmacist's function with the mere techniques of dispensing and his debasement of the latter, that a two-year course could, and should, replace the present four-year university course. Recognition of the role of the pharmacist in the provision of a *complete* pharmaceutical service to the public precludes such a possibility. The need of the community for pharmaceutical service could not be satisfied by mere technical training as opposed to professional education.

The Role of Provincial Pharmaceutical Associations
(Brief, pp. 9-10; Evidence pp. 1293-4, 1302)

Bass states: 'All their legislation is geared for the protection of their members and NOT the protection of the public'. Examination of the Pharmacy Acts and Bylaws and/or Regulations thereto of the provinces does not support this contention. It might be added that many pharmacists strongly express an opposite view: namely, that the Pharmacy Acts offer them no protection whatsoever from the (few) charlatans and pharmaceutical 'quacks' amongst them.

Bass states that the pharmacist's '...every action is controlled by various provincial associations which, through their disciplinary committees, help to control prices'. He alleges, in support of this statement, that he, himself, was so disciplined but obtained a court judgement in his favour and charges, by quoting from the judgement, completely out of context, that the Council of his provincial association operated '...on a basis of their own convenience.' Perusal of the Reasons for judgement of the Honorable Mr. Justice Ruttan (Supreme Court of British Columbia No. X 28859, 25th May, 1959) reveals Bass' innuendal reference to be an apparent attempt to mislead.

During the course of the Council Inquiry which led to Bass' erasure from the register for misconduct in the practice of his profession (the alleged sale in his pharmacy of pre-packaged 'kits' containing a dropper and hypodermic needle) he requested an adjournment of the inquiry to endeavour to call a witness (a pharmacist formerly employed by him) who had moved to the United States. Council refused an adjournment. Mr. Justice Ruttan granted Bass' appeal on the basis of this refusal, there having been no contest by Bass of the substance of the charge itself. He (Ruttan) conjectured that one of the reasons for Council's refusal to grant an adjournment may have been that Council was not scheduled to meet for several months and did not want to hold a special meeting in the interim. He concluded that, if this was so, Council was gearing its handling of disciplinary matters '...to its own convenience...' and hence the comment quoted out of context in Bass' brief to the Committee.

The case itself had nothing to do with prices, as Bass implies and, further, the judge's reference to '...its (Council's) own convenience...' was predicated upon the conjectured possibility that the time lapse till the next regular meeting, rather than the evidence then before them, was the motivation for refusal to grant an adjournment. This was not so.

'Like price for like quantity' policy
(Brief, p. 11; Evidence, pp. 1308, 1311)

Bass states '...provincial associations get together to prevail on the drug manufacturers to cooperate with them in their own, selfish interest.' and he quotes, in support of this statement, a 'Dear Pharmacist' letter from a pharmaceutical manufacturer, drawing particular attention to the excerpt:

> '2. 'Like prices for like quantities' are offered to both retail pharmacies and hospitals. This is in accordance with the Canadian Pharmaceutical Association's resolution:'

Far from being in the pharmacist's '...own selfish interest...' the resolution of C.Ph.A. which is referred to, and is endorsed by this Association, is very much in the public interest. It is the Association's contention that the low level of prices at which many manufacturers sell their products to hospitals, government institutions and dispensing physicians is made possible by the unnecessarily high level of prices charged the retail pharmacist for the same products in the same quantities. Thus, the non-institutionalized patients who obtain prescriptions from the retail pharmacist (the majority of the population) are forced to subsidize drug costs for those who receive their prescription drug requirements from an institution or dispensing physician.

It is not the contention of C.Ph.A. or this Association that the adoption of a 'like price for like quantity' policy by manufacturers would result only in the raising of institutional prices but rather that, concurrently, a reduction in prices to the retail pharmacist (and therefore to the consumer) would be effected; in short a 'levelling off' of the multiple price differential to the direct benefit of the majority of the public who receive pharmaceutical services from the retail pharmacist.

Physician-pharmacist 'kick-backs'
(Brief, P. 8; Evidence, p. 1305)

Bass charges that pharmacists' 'kick-backs' to doctors are a factor tending to increase drug costs to the public, though he admits to having no proof to substantiate such a charge. There is a specific prohibition against such practices by pharmacists in the 'Standards of Pharmaceutical Practice' Bylaws of the B.C. Pharmacy Act:

> 'No pharmaceutical chemist shall enter into any arrangement or agreement with a practitioner for the purpose of dividing, splitting or otherwise sharing charges for professional services rendered.'

Any evidence of such practice by a pharmacist in this province would be dealt with immediately by disciplinary inquiry. Further, it is our understanding that such practices by medical practitioners are set forth as unethical and would no doubt, on evidence, be dealt with by medical licensing bodies.

Generic VS Brand name drugs
(Brief, p. 9; Evidence, pp. 1285, 1299, 1306)

Conflicting statements appear between the Brief and Evidence in this matter. Bass proposes in his Brief that legislation should be enacted to

permit 'generic dispensing' which, he claims, would lower drug costs. In Evidence, however, he states he uses very few products from so-called 'generic houses' and, further:

'...I am not fully convinced of the quality of products from generic houses'

His position in this matter is hard to evaluate.

Dispensing VS Front-store subsidization
(Brief pp. 5 and 12; Evidence, p. 1312)

Once again a conflict of views is presented. On page 5 of the Brief Bass charges that front-store subsidization of the dispensary is wrong and a result of poor management, while on page 12 he states 'The dispensary should not subsidize front store sales'. His position in this matter, also, is hard to evaluate.

Prescription Economics
(Brief p. 13)

We find the mathematical calculations leading Bass to conclude a pharmacist enjoys '$20.00 an hour profit' inexplicable and invalid. I would refer the Committee to the Survey of Dispensing Costs by W. W. Fee (copy enclosed).

I trust that these notes may be of some assistance to your Committee.

Yours sincerely,
Douglas A. Denholm, B.S.P.,
Registrar.

APPENDIX "D"

PARKE, DAVIS & COMPANY, LTD.
Montréal 9, Quebec,

NOVEMBER 24, 1966

Dr. Harry C. Harley
Special Committee on Drug Costs and Prices
House of Commons,
Ottawa

Dear Doctor Harley:—

When we appeared before your committee on November 3 to present our Brief and answer questions, Dr. William D. Howe asked me to provide the Committee with the following information—What does Parke, Davis & Company charge for a completely finished product, manufactured in Detroit and ready for use, which is regularly imported into Canada, and to other Parke-Davis locations in the world? This would be before excise taxes, transportation, etc. In other words, what is the net f.o.b. price? Parke, Davis & Company, Detroit, were asked to supply this information based on five products.

(1) Tuberculin Tablets, purified protein derivative, 10 or 20 test package, intermediate strength—Canada, $1.23; Italy, $1.25

(2) Tuberculin Tablets, purified protein derivative, 100 test package, intermediate strength—Canada, $2.50; Italy, $2.55

(3) Tuberculin Tablets, purified protein derivative, 10 test package, second strength—Canada, $1,23; Italy, $1.25

(4) Histoplasmin—Canada, $1.85; Italy, $1.89

(5) Hapamine—Canada, $2.50; Argentina, $2.55; Mexico, $2.55

The foregoing values are expressed in U.S. Dollars, and the products are all biologicals and are the only biologicals which are regularly imported into Canada, and are the only sales that were completed in 1965 to locations in other international areas.

We trust that this is the information you require.

Sincerely,
PARKE, DAVIS & COMPANY, LTD.,
C. A. Rogers,
Vice-President and Managing Director.

APPENDIX "E"

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 tbas	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 & codeine phosphate gr.½)		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.	Merck 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 & codeine phosphate gr. 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

BONN

Trade Name	Generic Name	Strength	Manufacturer	Original Size	Foreign Price	$ Canadian Equivalent
1. Chloromycetin	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.	Hoffmann-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]	Merck Sharp & Dohme	100 tabs	29.33	7.91
6. Librium	Chlordiazopoxide	10 mgm.	Hoffmann-La Roche	100 caps	11.60	3.13
7. Equanil	Meprobamate	400 mgm.	Wyeth & Co.	100 tabs	not sold	
8. Enovid	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] Decadron, 0175 mg not sold
[2] Butazolidin, 100 mgm. not sold

D Mark = $0.27 Canadian
December 1966

BOSTON

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[1] units	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.	Hoffmann-La Roche	50 caps[2]	3.50	3.78
7. Equanil	Meprobamate	400 mgm.	Wyeth & Co.	100 tabs	5.80	6.26
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

$1.00 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.....	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.

APPENDIX "F"

HOUSE OF COMMONS

First Session — Twenty-seventh Parliament

1966 - 1967

SPECIAL COMMITTEE
ON
DRUG COSTS AND PRICES

SUBMISSION
of
THE GOVERNMENT OF THE PROVINCE OF ALBERTA

February 14, 1967.

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CHAPTER I

INTRODUCTION

My name is Henry B. Steele. I am associate Professor of Economics at the University of Houston, Houston, Texas.

I am delighted to have the opportunity of making this presentation on the behalf of the Province of Alberta. I am an academic economist and have been engaged in studies of drug industry economics and policy problems during the last six years. I have written three articles on drug industry economics and regulation (10, 11, 12)[1] which have appeared in professional economics journals, and I am currently writing a book on drug industry economics and regulation. I have also written papers on the supply and distribution of physicians' services (22, 23). In my research I have been continually hampered by lack of precise and authoritative data on drug costs and prices, the subject of the present inquiry by your Committee. In fact, the only evidence of any sort regarding drug costs has been provided as a result of governmentally sponsored investigations. I have studied all the publicly available records, hearings, and reports, to date, of drug investigatory bodies in both the United States and Canada, as well as much of the material from the United Kingdom. Much useful information has been presented regarding the Canadian drug industry. Nevertheless, I am continually forced to resort to the data on United States drug production costs as of about 1960, whenever it is necessary to draw conclusions regarding the relationship of drug prices to production costs. While these figures relate to very important drugs, it is unfortunate that they relate to only a few drugs, that they relate to a period now several years in the past, and that they relate to the United States rather than to Canada.

An investigating committee charged with the responsibility of studying drug costs and prices certainly needs to be provided with

[1] Numbers in parentheses appearing throughout this submission designate the appropriate sources in the List of References which follow the Appendices.

concrete statistical information on computed costs and methods of cost allocation by the companies producing drugs. In its submission to the Royal Commission on Health Services, February 12, 1962, the Province of Alberta reprinted a chart from the Report of the Subcommittee on Antitrust and Monopoly of the Committee of the Judiciary of the United States Senate hereafter referred to as the Kefauver Subcommittee showing factory cost, royalties, and gross margin above production costs for producing tetracycline capsules by Upjohn and Bristol, with the comment:

> ".....we might well ask the question: If the records of Upjohn and Bristol enabled the Kefauver Committee to put this information concerning revenue cost spreads on the public record in the United States, why is it considered so objectionable to put the same information upon the public record in Canada?" (3a).

The question is as relevant today as it was in 1962. In all fairness, it should not be suggested that obtaining this cost data is an easy task; the chief reason why it is difficult for public bodies to insist upon being supplied with such data is the sturdiness of the "trade secret" dogma--that it would put firms at a disadvantage to have their cost data made public for the edification of their rivals.

In this application, the "trade secret" dogma probably has somewhat different roots than are generally put forth. I have been teaching courses, conducting research, and doing consulting work in the areas of industrial organization and the public regulation of industry for over ten years, and I have become convinced that major firms in many industries are able to inform themselves with reasonable accuracy as to the approximate cost conditions under which their rivals produce. I admit that this is a general impression based on accumulated experience rather than on documentary proof. Nevertheless, it is a very consistently confirmed impression. Hence it strikes me that only in a limited sense are production cost statistics "trade secrets," the revelation of which would damage the firm's ability to maintain its share of the market with respect to its rivals. This is particularly true in the drug industry

since such disclosure is of crucial interest to competitors only if they wish to engage in rather sharp price competition, and the drug industry is not notorious for severity of price competition. Above and beyond this, however, there is without doubt an intense reluctance on the part of the firm to release data which would confirm the surmises of rivals regarding one's cost position. There may be a certain illusion among firms such that while the firm has a good idea of its rivals' costs, it regards the secrecy of its own as being better established. I believe this to be an illusion on the part of the firm, and I suggest that while it may be generous to be chartible to the illusions of the producers, it is socially much more useful to obtain and make public all the facts in the matter. After all, if a subject is to be investigated, the materials with which it is concerned must be identified and evaluated.

On the other hand, producers may more often have valid reasons for objecting to the disclosure of their costs on grounds that it may be edifying to consumers, rather than to rival producers. There may be reasonable grounds for such reluctance. Variable costs may be small relative to total costs. The nature of capital costs may not be understood clearly by the public. Informed opinions as to reasonable rates of profit may vary; uninformed opinions vary even more widely. The nature of risks faced may not be understood. The relationship of risks to an appropriate rate of profit is a very complex matter. Finally, there may be an irrational hostility to profit as such, regardless of the rate of return on investment. Despite all this, the facts should be made known, particularly in view of intense and widespread public concern over drug prices. The industry certainly has command of resources which allow it to defend itself; it is only fair that the public be supplied with the facts which will enable policy makers to determine whether or not the economics of the drug industry are in fact defensible.

At present, however, a student of the cost and price relationships in the Canadian drug industry has no adequate source of information to allow him to reach definite and comprehensive conclusions. This is true

regardless of whether he has been conducting his studies in Toronto, Texas, or Taiwan. Considerably more information is available on cost-price relationships in the United States drug industry as of the early 1960's. To what extent is one justified in extrapolating cost data from the United States into the Canadian market? In the absence of definitive Canadian cost data, the question cannot be answered. It would appear to be incumbent upon Canadian producers to demonstrate that the comparisons are significantly in error, by producing definitive computations of their current cost situations. Otherwise, it is clearly preferable to base conclusions on objective data, even if of limited relevance, than to speculate completely in a vacuum.

It is not proposed that United States market data will be substituted en masse for Canadian; where Canadian data is available it will be employed. Where market circumstances differ between the two countries, attempts will be made to allow for such differences. Actually, the similarities between the drug industries in the two countries are much more striking than the differences. This is also the finding of the Restrictive Trade Practices Commission:

> "Conditions in the drug industry in Canada are related to and are influenced by conditions in the industry in the United States; in fact, in many respects the Canadian market may be considered as simply an extension of the United States market." (2a).

Since Frosst was acquired by Merck in 1965, no Canadian drug firm of any size has remained under Canadian control. About 90% of the Canadian drug industry, it is well known, is controlled by foreign investors, and although relative sales volume data for individual firms is not available, it is clear that the majority of the market is controlled by subsidiaries of American firms. Furthermore, some European-based firms are major factors in both the United States and the Canadian markets. According to the Pharmaceutical Manufacturers Association of Canada brief, 36 of its 57 member firms are based in the United States. I am at present unable to confirm how many, if any, of their members are Canadian-owned; the number would appear to be from three to six. (6a)

The major firms which have testified before this Committee have been unanimous in characterizing the drug industry as an international industry, in the world-wide context of which the Canadian market must occupy a secondary position because of its small size. There is no doubt that the United States market is by far the world's most important because of its large size and high per capita income. Because of the absolute character of patent protection in the United States, the size of its market is all the more attractive, and it is obvious that this patent protection, coupled with high domestic demand, acts to increase the level of world drug prices as a whole. Not only is the United States the most attractive location for a drug manufacturer, but the prospect of obtaining a U.S. drug product patent must be a potent incentive for a particular type of research in other countries where absolute patent protection is not granted. United States patent protection provides the basis for both directly and indirectly limiting competition in both United States and world markets by making the spontaneous or independent development of price competition anywhere in the world to some extent less likely. (Similarly, the absence of the patent privilege for drugs in Italy has to some extent made for greater price competition not only domestically, but throughout the world.) It is thus to some extent Canada's misfortune to be in such close proximity to the world's most lucrative drug market; the high prices south of the Canadian border are not only preserved when the border is passed, but apparently are in most instances actually magnified. There may be a few valid economic reasons why prices might be higher in Canada. There would be certain downward pressures created on Canadian prices if United States drug prices could be reduced. The present problem, however, is to attempt to reduce those Canadian drug prices which may be unreasonably high, by unilateral action by Canada. Unfortunately, both the ways in which the Canadian market is related to, and separated from, the United States market, tend to keep Canadian prices high. Since the present discussion is merely devoted to illustrating the ways in which United States drug industry economics are

relevant to Canadian drug industry economics, the specific details of these interrelationships will be reserved for later discussion at the appropriate times. To summarize the similarities and differences between the drug industries in the two countries, the following tabulation may be instructive:

A. Similarities:

1. The same firms do the great majority of ethical drugs sales in both countries. About 80% of the active ingredients in drugs sold in Canada are imported in bulk form, the great majority of these coming from the United States, and hence produced under United States cost conditions.

2. Tabletting, bottling, and other costs associated with the conversion of the bulk active ingredient into finished dosage forms, are minor factors in total cost and these costs should not vary greatly between the two countries.

3. Outlays for other purposes than production costs apparently follow similar trends. Although very little research is done in Canada, international firms apparently adopt accounting practices which result in charging both parents and subsidiaries for some portion of total research costs. The extent to which the methods chosen are appropriate is another question, but some such allocation arguably makes international cost comparisons more valid than they would be in the complete absence of any allocation. The very much larger outlays for sales promotion also apparently follow the same pattern. For example, the Report of the Kefauver subcommittee showed that 22 of the largest drug firms doing business in the United States in 1958 (both domestic and foreign-based) reported that 24.8 cents in each sales dollar was devoted to selling activities. (5a). The PMAC submission shows that 30.0 cents in the sales dollar of 41 of its members was devoted in 1964 to selling activities. (6b). It is with regard to the international impact of selling activities, however, that the influence of the United States industry on the Canadian industry is most direct. American drug firms promote brand names, not generic names. So do their Canadian affiliates. United States medical

journal advertising is intense; since there are many more U.S. medical journals than there are Canadian, many American journals are read in Canada, and the Canadian physician is correspondingly exposed to the advertising message on behalf of brand name products made and promoted in the United States, with predictable implications for prescribing practices. (2b.) Also, non-professional magazines may convey brand names to the public.

4. In both countries, the institutional structure of the markets in which drugs are sold to patients are broadly similar. Brand name advertising and other sales promotion tactics induce the physician to write the great majority of prescriptions by brand name, and these prescriptions are largely dispensed by retail pharmacies. A substantial minority of drug purchases, however, are made by hospitals, by public agencies, and by other buyers with more bargaining power than the captive patient. Most importantly, in neither country is there any system of comprehensive national health insurance which provides for, or influences the cost of, prescription drugs, since the presence of such a system would greatly complicate any international comparisons.

B. Differences:

1. In the United States, retail pharmacists add a 66 2/3% mark-up over invoice cost, in order to arrive at prescription charges. In Canada, a dispensing fee may be added to the 66 2/3% mark-up, or a "professional fee" may be added to invoice cost. There is also an eleven per cent federal sales tax at the manufacturer's level, from which purchases by hospitals and other public agencies are exempt.

2. There are differences in applicable tariff rates, and in Canada special "anti-dumping" duties may be imposed under certain circumstances.

3. In the United States, patents may be obtained on drug products as well as drug processes, and there are no statutory provisions in the Patent Act for compulsory licensing of drugs, even if the patent is abused. In Canada the laws as written give the consumer more protection. Drug products produced by chemical processes cannot be patented as such, only

in conjunction with a patent on the process by which they are produced. Furthermore, not only does the patent law specifically provide for compulsory licensing in case of the abuse of a patent, but this remedy is also available for drugs generally unless in a particular case the Patent Commissioner sees good reason not to grant the license.

4. The Canadian Trade Mark Act contains a provision whereby a Canadian affiliate of a foreign company can prevent the importation into Canada of products purchased in the foreign country even though they bear a trademark identical with that of the Canadian affiliate, provided that the Canadian affiliate owns the particular trademark. This eliminates the possibility of legally importing many brand name drugs which may be selling at lower prices outside Canada.

5. The Food and Drug Directorate in Canada and the Food and Drug Administration in the United States have broadly similar powers and responsibilities. It appears, however, that the requirement that all prospective marketers of a "new drug" provide the same type of experimental and clinical testing evidence does impose unnecessary burdens on subsequent suppliers of compounds identical with those previously cleared for marketing by earlier applicants.

6. Resale Price Maintenance has been outlawed in Canada but is still in effect in most states in the United States.

One last prefatory comment is in order. In my presentation I may appear to be critical of the relative inefficiency of resource allocation which results from allowing the pharmaceuticals industry the same exemption from special economic regulation which is routinely accorded to all those industries which naturally tend to function competitively in a free market environment. But if the drug industry is left to itself, it will inevitably display elements of both monopoly and rivalry. Spokesmen for the industry continually refer to the extreme degree of competition among firms. Unfortunately, the "competition" referred to is of the cost-raising type rather than the price-reducing type. This might more properly be referred to as "rivalry" rather than "competition," since the latter term has the connotation, not only in economic theory, but also in general usage, of price competition.

In this regard I wish to make it clear that, as an economist, I have the highest regard for freely competitive private enterprise markets and the efficiency with which they allocate resources. Indeed, last year, together with several other academic economists, I was characterized by Fortune magazine as a "professional guardian of free enterprise." (8) However, my admiration for efficiently functioning free markets makes me all the more sensitive to the drawbacks of markets which do not possess those characteristics requisite to enable the unrestricted operations of demand and supply to produce efficient results. I regard the great majority of product markets in both Canada and the United States as being more or less workably competitive, but the market characteristics of the pharmaceuticals industry are such as to make it virtually a foreign body in an otherwise workably competitive economy.

In which respects does the drug industry depart from workable competition? A brief summary must suffice at this point.

(1) Essential to the effective operation of a free market is the ability of the buyer to choose among suppliers on the basis of an adequate knowledge of the price and quality of the alternative products which they may provide him. But in ethical drugs, the buyer has no practicable means of gaining access to knowledge of the range of price and quality alternatives in the market; indeed, his purchasing agent, the prescribing physician, is constantly over supplied with biassed information and misinformation which facilitates confusion and ignorance of prices.

(2) The price-conscious buyer should be able to identify the lowest-priced seller and purchase from him without artificial impediments. Instead, the possessor of a newly-written prescription is unable to buy any but the specified drug, regardless of price. The willingness of the price-conscious physician to prescribe lower-priced drugs may be compromised if he has been exposed to repeated attempts to disparage low priced drugs on the part of representatives of brand name drugs who contend that low price means low quality. And even if

a generic prescription is written, the buyer has no power to compel the dispenser to sell him a reasonably priced generic drug instead of substituting a less reasonably priced brand name equivalent.

(3) There must be freedom of entry into the industry by new firms, such that high profits being made by existing firms will attract new competitors who will, by engaging in price competition, drive profits down to competitive levels. But freedom of entry in drugs is greatly lessened by the existence of the patent privilege, the trademark device, and the necessity for newcomers to match the enormous advertising outlays of existing rivals.

(4) There should be an adequately large number of competitive sellers offering buyers genuine alternatives in terms of product price and quality; none of the sellers should be so large that he overshadows the magnitude of his competitors and poses a potential threat should they incur his displeasure. In drugs, restricted entry limits the number of sellers, and while there are few if any genuine product monopolies, the size of the major firms is certainly appreciably greater than that of their smaller generic-name competitors.

(5) A market is not workably competitive unless all firms act independently--there must be no overt or tacit collusion, no passive acquiescence in prior decision arrived at by others and established by mutual consent. While the Restrictive Trade Practices Commission Report did not charge the drug industry in Canada with any illegal overt collusion, there are two circumstances which act to hamper independence of action. First, there is the practice of price leadership and the pricing of new medications at exactly the same levels charged for existing substitute drugs. Second, there is the fertile field of patents. While an individual patent confers a monopoly, the scope of the monopoly privilege is limited. But in an industry with complex technology, the efficient production of a drug may require the use of processes controlled by rival patent-holders.

The negotiation of the resulting cross-licensing agreements requires the mutual compromise of patent monopoly positions, and may well stimulate such meetings of the minds as will lead to the development of a greater sense of community of interest in policies regarding prices, production, and participation in world markets.

There is another respect in which the implications of the usual free market arguments need to be examined in the light of the nature of demand in the prescription drugs market. In a purely competitive market, buyers are protected in that they need pay no more than the competitively determined supply price for any product. But it deserves equal emphasis that they must pay no less than this price. Resources are not efficiently allocated unless the buyer is obliged to pay the full cost of the goods he demands, since in demanding them he is requiring the economy to employ scarce resources to produce to suit his desires, when these resources might be used equally efficiently in other pursuits. The true cost of employing a given level of resources in producing a certain product is the value of the alternative output which is lost by necessarily foregoing the employment of the same resources in producing another product. But this argument is most directly relevant only where the nature of demand is such that the desire for the good is voluntary; that the buyer should be willing to bid for a particular good or service in accordance with the positive benefit or satisfaction which he derives from its purchase. If demand is not voluntary, however, then the consumer cannot in the same sense be held liable for payment of the full cost of services rendered to him, since he did not voluntarily require that the economy devote scarce resources to serving him which could be provided only at the cost of sacrificing the output of other goods which these resources might have produced. This is not to say that the drug buyer should not, after all, bear the full cost of the drugs which he requires, since he is perhaps deriving benefit from them in the sense of avoiding prolonged suffering rather than enjoying positive satisfactions. Still, there is a difference between paying the full cost of financing an activity deliberately engaged in, as compared with one forced by accident

or misfortune upon the buyer through no real fault of his own. Considerations such as this do not necessarily justify assumption by the state of all responsibility for medical care--far from it. But a rational awareness of the risks and uncertainties of health care might, for example, induce a prudent man of sufficient means to participate in a voluntary health insurance program. The requisite means, however, will depend not upon the "full competitive cost" of drug supply, but upon the actual prices charged under far from purely competitive market conditions. Unless drug prices are reasonable, the possible full costs of drug therapy under a comprehensive health insurance program may be so great that excessively high premiums would be required, and the costs of drug therapy would not constitute an insurable risk for practical purposes. These are considerations which should be kept in mind when assessing the effects of the great variety of drug industry activities and expenditures on the cost of drugs, when such costs are borne in their entirety by individuals involuntarily afflicted and whose earning power and ability to pay may be seriously affected by the very condition which makes medication necessary.

In the absence of consumer knowledge of the market, and of workable competition among sellers, the firms are subject to only two limitations in their ability to exploit the drug buyer: self-restraint and public constraint.

Self-restraint is a sentiment essentially foreign to the efficient operation of a commercial enterprise; indeed, in a sharply competitive market, excessive self-restraint would lead to the demise of the firm. In drugs, self-restraint has probably seldom been a barrier to high prices and profits. Upjohn made over 30 per cent on its net worth after taxes in each of the deep depression years 1930-1935 in the United States. (4a) Still, self-restraint may have been more prevalent during the years before the second world war. But in the post-war era it became increasingly apparent to investors that the profit possibilities were simply too great not to be fully exploited. While it is very difficult for small firms to enter the drug market, it is possible for larger firms to merge with existing pharmaceutical firms, and for bulk

chemical and fine chemicals producers to integrate forward to the drug making and selling level. This was characteristic of the first postwar decade in the United States. As was amply documented in the Kefauver hearings, the change in the composition of the industry intensified the emphasis on sales promotion. The quantity of promotional matter increased sharply, and there were many physicians and medical educators who testified that the decline in its quality was no less marked. Many argued that Gresham's law was applicable to the new rivalry in selling efforts: that bad advertising drove out good. Some argued that the industry should be saved from itself: that it was necessary only for one or two less-than-scrupulous firms to deluge the physicians with advertising appeals of inferior quality, and all the rest had to follow suit. The offending firms were never specifically singled out. Still, the great majority of the unfavorable references were confined to a handful of firms. At any rate, the intensified rivalry which characterized the North American drug market in the 1950's probably removed the factor of industry self-restraint from the realm of possible solutions to drug policy problems.

Public constraint has offered the drug consumer only an inadequate safeguard. In the United States, drug administration laws have been passed only in times of acute crisis when public sentiment is temporarily aroused. Between crises, the government's attitude seems to be as permissive and uncritical as that of the general public, whose sentiments consist largely in the belief that "miracle drugs" are made by full-time miracle workers who can do no wrong. But miracle drugs can produce "miracle diseases." Dr. Walter Modell of the Cornell University Medical School commented that some 40-odd new diseases had been identified as brought about by the untoward effects of drug therapy. (9a). And a pharmaceutical atrocity like thalidomide can produce a whole "miracle generation." While crises like these spur action, interest soon wanes thereafter. But the drug interests are always alert to possibilities for minimizing the impact of control legislation.

In both Canada and the United States, food and drug legislation has been directed--and rightly so--at insuring the safety and quality of drugs. But too little attention has been directed to the problems of insuring the economic health of drug consumers. An adequate and comprehensive program of public constraint must include measures designed to keep drug prices at competitive levels and thus prevent the exploitation of the drug buyer. The problem at present is to determine which measures would be most appropriate.

CHAPTER II

THE DETERMINANTS OF DRUG COSTS AND PRICES IN THE CANADIAN MARKET -- AN ECONOMIC INTERPRETATION

Since the Committee is given the responsibility of making a study of drug costs and prices, major emphasis will be placed upon an analysis of the determinants of drug prices and costs; the relationship (if any) between the two under present circumstances, and the sort of relationship which might prevail under altered circumstances. As an economist specializing in the study of industrial organization and the public regulation of industry, my perspective is more general and more oriented toward the public interest than to the special interests which are the appropriate concern of spokesmen for drug firms and trade associations. Nevertheless, my orientation is first and foremost to economic realities, the most important of which is the profit motive.

A systematic analysis of drug prices and production must proceed in terms of an investigation of factors influencing supply and demand. Broadly speaking, supply is influenced by the costs of production, promotion, and distribution; by the channels of distribution; by the arrangements in terms of which production costs are allowed to influence pricing and production; and by the laws affecting the cost and availability of imports, the techniques of promotion, the difficulty or ease of entry into the market by new drugs and new firms, the taxation of drugs, and the ability of sellers to temper competitive pressures. Demand is influenced by the acuteness of the buyer's need for the product, his ability to pay (individually or through access to welfare case status), and the extent to which sales promotion efforts have the power to influence the physician and thus control the demand for a given drug.

The remainder of this chapter accordingly will be devoted to a discussion of the determinants of drug supply, drug demand, and drug price levels. The analysis will be organized under the following headings:

A. Factors Influencing the Supply of Prescription Drugs
   1. Costs incurred by manufacturers
   2. Costs incurred by distributors
B. Factors Influencing the Demand for Prescription Drugs
C. Market Price as Resulting from the Interaction of Supply and Demand

A. Factors Influencing Supply of Prescription Drugs

1. Costs Incurred by Manufacturers.

The costs incurred by drug manufacturers may be broken down into several broad categories:

(1) basic or fundamental research;

(2) applied research;

(3) product development;

(4) manufacturing the active ingredient;

(5) preparation of finished dosage forms;

(6) sales promotion activities.

Each cost category will be discussed and costs actually incurred and the activities undertaken under each heading will be contrasted to the scope of activities and level of costs appropriate to an efficiently competitive drug industry.

a. Basic Research

Basic research is an activity which inherently involves a distribution of benefits such that all of the advantages may not be captured by the agency incurring the costs. In economic theory, situations in which there are inequalities between private and social costs and benefits are referred to as "externalities" in that the private agency responsible for a particular activity need not be held internally accountable for all of the costs incident to the activity; nor may it reap internally all of the benefits. The most prominent examples currently discussed are "external diseconomies" resulting from waste disposal by means which may minimize private cost to the disposing firm, but which impose social costs upon the economy at large through the avenues of air pollution, water pollution, etc. Basic research provides a good example of an "external economy" in the sense that the agency undertaking the research may incur all of the costs of the operation, which then become private or internal costs to the firm, but the usually far-reaching benefits of successful basic research projects can seldom be captured in their entirety by the agency doing the research. Some of the benefits may be realized by competitors in the same industry, some by the

developers of new products and new applications in other industries, and some may be realized by the economy at large. Hence, basic research is the sort of activity which is not ideally adapted to the type of cost-vs.-revenue calculations which a private firm must make. A drug firm which engages in truly fundamental research must ask itself the following questions:

(1) What is the risk of failure of a given project?

(2) If the project is successful, will the findings ever be commercially applicable?

(3) Will the resulting findings ever lead to patentable discoveries?

(4) Will the time horizon between initiating the research project and its fruition in the sales of commercially marketable products be sufficiently short that the discounted rate of return on the investment will justify the outlays?

(5) Will the "gestation period" of product development for patentable discoveries be short enough that patent protection will be commercially profitable?

(6) Will the discoveries prove to be of equal or greater benefit to the rivals of the firm?

(7) Will the discoveries prove to be of greater application in industries outside the pharmaceuticals field?

(8) Will the discoveries pose the threat of obsolescence to presently profitable products?

Fundamental research is always a highly risky activity--for each success there are a multitude of failures; this is the nature of basic research. Furthermore, the sort of information resulting is often not patentable in the form in which it is obtained, and the "gestation period" between path-breaking basic research and the embodiment of the results in successful innovations is typically of considerable, but unpredictable length. The combination of high risk and long gestation period is in itself enough to discourage the typical firm from undertaking very much basic research. This is particularly true in an industry like drugs, where the rate of return which can be made by investing funds in applied research, product development, and sale promotion is very high. If the firm can make in the range of 15 per cent per year on funds invested in relatively shorter-run activities like the

above, the expected returns from fundamental research activities must be extremely high in order to make them seem worthwhile after discounting these expected returns at the firm's internal opportunity cost of funds of 15 per cent for a period of perhaps ten years or more prior to any payoff. When to this is added the risks that rivals in the industry, or firms in other industries, or the society generally, may stand to reap the major rewards of basic research, it is understandable that drug firms do as little truly fundamental research as they appear to undertake. (5b) Indeed, this is true of private industry generally. It must be admitted that problems of measurement are difficult. It is difficult to define basic research and to separate it from applied research meaningfully. No statistics are available which distinguish between basic and applied research carried out by private and public agencies in North America. The only estimates known to me which cover all industries and distinguish between basic and other types of research are those made by David Novick of the RAND Corporation for industry expenditures (both publicly and privately financed) on research and development in the United States in 1959. (4b) Dividing his analysis of these activities into four stages on the basis of an increasing degree of certainty of payoff, and a decreasing potential for long-range social benefits, Novick allocated an estimated total expenditure of ten billion dollars as follows: Basic Research, one per cent; Applied Research, three per cent; product development (development, testing, evaluation, pilot plant production), 26 per cent; Product Application (application research, applied testing, applied evaluation), 70 per cent. Most research is concentrated in a few industries (aircraft, electronics, chemicals) and much of this is financed by the federal government. When one takes into account the amount of basic research done in universities and by foundations, it is very likely that the great majority of basic research is undertaken and/or financed outside the sphere of private industry, as is economically only reasonable.

In order to embark on a given long-term basic research program

which because of its nature is believed to be of possible benefit only to the pharmaceuticals industry, a drug firm would have a greater degree of assurance of the commercial value of the program in proportion as its market position approaches long-run, unconditional monopoly of the entire industry. If the basic research is also expected to have application to the chemicals industry generally, then the firm might be reluctant to invest an adequate amount of resources to the extent that its market position falls short of long run monopoly control of the chemical and pharmaceuticals industries. If, however, significant benefits are likely to accrue to a number of other industries and to society generally, the "external economies" become so important that only an agency specifically endowed to undertake basic research (whether philanthropically endowed or financed by society generally) can be expected to assume the costs of a comprehensive program on the assumption that the benefits accruing to those who finance the agency will be commensurate with the costs.

Regarded from a slightly different perspective, basic research is simply not a very dependably profitable investment from the standpoint of a firm allocating its funds between different activities on the basis of expected net rate of return over time. At any given point in time, a profitable firm will always have many competing uses for funds which offer higher average expected net returns than fundamental research. This certainly does not mean that profitable drug firms will completely shun fundamental research, but this consideration implies that they will, for perfectly logical business reasons, allocate only a fraction of the funds to basic research which the long-run social and economic importance of the activity justifies. It is no exaggeration to say that fundamental research is ultimately a philanthropic activity, in that it always has a potential for benefitting society generally. Hence privately endowed universities and foundations as well as publicly financed agencies may most appropriately be expected to undertake the greater part of a nation's truly fundamental research effort. Indeed, the public is largely

responsible for the magnitude of the basic research effort in a nation. From the public comes not only the few philanthropists who endow universities and research foundations, but also the initiative to authorize publicly financed research programs and facilities, and to permit subsidization of private research through such devices as the recent 150% tax writeoff for increases in certain types of research investment in Canada. The PMAC Submission indicates agreement with this position:

> "Appropriately enough, basic research is carried out in the universities, while applied research is the province of industry." (6c).

The implication is clear, however, that since basic research is not the province of industry, the cost of drugs is not a reflection of any great expenditure by firms on fundamental research. And of course it is fundamental research which in the long run is socially the most productive form of research.[1]

Under efficiently competitive conditions, therefore, private drug firms would not be expected to devote any significant share of available resources to basic research, since it would not prove sufficiently profitable to the individual firm. The industry would instead be dependent upon publicly available results of basic research done by more broadly-financed organizations. And from all appearances, the amount of fundamental research undertaken by North American drug firms does not bulk very large in relation to total revenues. But this does not mean that private drug firm activities give rise to no distortion in the spectrum of basic research efforts. It may be the case that too little basic research in areas relating to health and therapy is done by non-industry sources, in part because the ability of the industry to pay high salaries due to the high profitability of drugs under present market conditions results in drawing too large a part of the very small

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1. In its recent presentation to this Committee, representatives of one major pharmaceuticals company claimed that their firm had undertaken truly fundamental research in Switzerland over a period of five years without any tangible results as yet forthcoming. If this is the case, this company might well be commended for its persistence in what at present appears to be a truly philanthropic gesture in the interest of fundamental research. This commendation would have to be qualified, however, in that as part of the company's budget, this research has been paid for entirely by purchasers of medications, who are probably not in an ideal position to afford subsidy of basic research which may benefit the entire world. This is one major criticism of drug industry research generally.

pool of qualified investigators and technicians away from public employment in basic research and toward private employment in applied research, product development, and product application. (The major drawback, perhaps, of the fact that Canadian drug firms do little research in Canada is not that the quality of available drugs suffers, but that Canada loses many of its highly trained research workers because of lack of opportunities for domestic employment.) In order to rectify the situation, it may be desirable not so much to attempt to increase the amount of basic research done by private firms, as to take steps to reduce the ability of these firms to drain off very scarce human resources for employment in less productive capacities than they might be assuming.

b. Applied Research.

Applied research takes a variety of forms in the drug industry. Basically, however, drugs are a branch of the chemicals industry, and in chemicals, applied research is rationally viewed as a means of implementing a profitable marketing operation. Applied research is risky, but less so than fundamental research. It may be productive, but again the total potential is less than in the case of basic research. There is less likelihood that the benefits of successful programs will accrue to parties other than those undertaking the applied research, although this possibility cannot be ignored. But on balance, applied research is likely to be less slighted than basic research by private firms. (This is not to say that applied drug research by public or non-profit organizations is necessarily totally inappropriate, but since such bodies as universities are naturally best adapted to basic research, it may be desirable to institute particular types of non-profit projects if it is considered appropriate to supplement the applied research efforts of private drug firms. And public patent policy becomes a more important issue when applied research is undertaken. Should public discoveries be unpatented, or, if patented, be freely licensed without royalties?)

What sort of applied research expenditures would be incurred by drug firms operating in an efficiently competitive market? To the extent that competition drives prices down closer to the level of production costs, it might be suggested that this would seriously limit such efforts on the part of firms. Reserving judgment for the moment in regard to the possible desirability of limiting applied research efforts, let it be instead pointed out that 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. According to the PMAC Submission to this Committee, the ratio is around 7 per cent. (6d). Novick estimated that about three per cent of research and development expenditures are devoted to applied research; the ratio is no doubt greater in drugs, but even if we assume that it is about ten times as great, the cost of applied research is still only about 2 per cent of the sales dollar. But we cannot proceed to speculate on the appropriate level of applied research outlays in an efficiently competitive drug industry without specifying what changes have been assumed in order to produce efficient competition. It is not profitable to discuss in detail the conjectural effects of possible changes in market structure, but it is essential to observe that competitive performance will not be obtained without a reduction in the power of a patent holder to limit entry into a particular drug market. To the extent that this power to limit entry is being reduced in Canada in at least some drug markets, the stage of efficient competition is being approached.

In an effectively competitive drug market, the character rather than the level of applied research is more likely to be altered. The direction and emphasis of research is clearly influenced by the nature of the patent system, by the impact of the patent system upon the organization of the industry, and by the effect of the activities of the industry on research outside the industry. In fact, the direction of research is no doubt greatly altered by the mere existence of the patent privilege for drugs. The prospect of patent monopoly stimulates research

efforts in the direction of patentable discoveries and inventions, and in so doing correspondingly acts to reduce the proportion of research in areas where no patents can be obtained. This discriminates at the outset in favor of applied research and against basic research. It also discriminates among different avenues of applied research. It clearly results in the placing of an unduly intense emphasis on chemotherapy. While chemotherapy will long be a fruitful area for research, it is inescapable that the complementary fields of nutrition, public health, biochemistry, and preventive medicine have been relatively underinvestigated. Antibiotics provide the most obvious illustration. Fear has been expressed that antibiotic therapy may eventually prove to be a blind alley because of overuse and the development of resistant strains of micro-organisms. A case could easily be made that too much effort has been expended in activities which tend to make micro-organisms increasingly resistant to control, and too little has been done to attempt to make man naturally more resistant to micro-organisms.

Any patent system, by biassing efforts toward applied research, will reduce the amount of basic research findings which can be applied, and ultimately depress the productivity of applied research. Much has been made in recent years of the "increasing cost" of drug research for new discoveries. But to speak of increasing costs is just an indirect way of referring to decreasing productivity of efforts. The nature of the patent system--its application to products and/or processes--will further influence the direction of applied research. A patent law which protects new products, either directly or through process patents, will bias applied research in the direction of devising new products rather than investigating the properties of old ones. As the archetype of applied research in drugs, let us take the methods by which new drugs are discovered or contrived. As Professor George Wright has explained in his Submission to this Committee, the molecular engineering approach is favored over the multiple screening method because new compounds are generally patentable, while the discovery of new uses for older compounds is not. (7b).

To the extent that patent reform reduces biases of these types, fewer impediments to the efficient allocation of resources by drug firms to applied research will exist. In an effectively competitive drug industry, there will be a greater variety of fundamental research findings on the basis of which applied research can be conducted. The potential improvements in nutrition, public health and preventive medicine from research efforts will become more readily capable of attainment. The bias in favor of devising new compounds instead of evaluating the properties of existing compounds will be reduced. Whether the total level of expenditures on applied research would be reduced or increased in an effectively competitive drug industry is a matter of uncertainty, but the expenditures would be more productively invested.

Let us contrast this with an appraisal of current practice. The major contributions of North American drug firms in the postwar period have been in the field of applied research--the discovery and development of the so-called "broad spectrum" antibiotics. For these drugs, no truly fundamental research was involved. The basic discovery had been made in England in 1928, the problems of large-scale production had been solved by government scientists during the second world war, and it was common knowledge that many moulds occured in nature, some of which might be capable of yielding new antibiotics. All that remained to be done was to collect and analyze soil samples, a rather tedious trial-and-error process of a routine but exacting nature, which the technicians involved could hardly have found intrinsically very stimulating. But since no new fundamental research was involved, the returns to more and more intensive exploitation of the same basic method have continually declined, very sharply since the mid-1950's, as is admitted by industry analysts.

But not all of the antibiotics marketed were of equal quality, nor did they represent comparable inputs of research effort. The drug patent, by providing the prospect for at least a limited period of monopoly

control of a given substance which could be assigned an abstract brand name and then advertised as a unique entity, inflated the amount of applied research done, and redirected it toward the overly intensive exploitation of approaches known in the past to have produced profitable drugs. Since the number of such known approaches is limited, it is within the capacities of major firms to explore several of them, and since this is known by all firms, the research programs of the large firms tend to duplicate, at least in part, the programs of their major rivals. This is evident not only from the testimony of doctors during the Kefauver hearings, but is also witnessed by the near-simultaneous discovery of several major drugs by two or more firms. This represents a compounded misallocation of resources; not only are scarce talents diverted from basic to applied research, but wasteful duplication of effort appears to be the rule rather than the exception. (A certain amount of duplication of effort may be desirable, but not on the scale encountered in drugs.) These disadvantages of patent-induced research are further compounded when the proven profitability of marketing patented drugs leads firms to engage in the increasingly well-known game of molecular manipulation, with the object of devising a patentable deviant of an existing patented drug, which can serve as the vehicle of an intensive sales promotion campaign in the hope of profit.

Hopefully the new manipulated drug will be at least in some regards superior to the drug which it is intended to supplant, but the essential purpose is to get another product on the market which can be promoted in rivalry with its substitutes, regardless of the actual comparative therapeutic merits of the drug. During the Kefauver hearings, two physicians who had served as medical directors for major North American drug firms testified to the extent to which therapeutic considerations were subordinated to profit possibilities. Dr. A. Dale Console, former medical director for Squibb, upon being asked whether there was much drug research which produces nothing worthwhile and is not intended to, responded:

> "I think the majority of it is in that category...and I should point out that with many of these products, it is clear while they are on the drawing board that they promise no utility; they promise sales. It is not a question of pursuing them because something may come of it. It is quite clear there is no point in pursuing this: that you won't end up with a product that has any real value; but it is pursued simply because there is profit in it." (4c).

Dr. Console also noted that imitative research could crowd out legitimate work.

> "When a 'crash program' comes along in which some product is being pushed in order to get it out before a competitor gets it out, it is not unusual for a worthwhile research program to be postponed so that the people can be taken off it to be put on the 'crash program.' Very frequently some of these programs are never picked up again. So that I think that good research is actually hampered by this type of thing." (4c).

Dr. Haskell J. Weinstein, former medical director of the J. B. Roerig division of Pfizer, indicted the industry for wasting the time of their research staffs:

> "Their talents should not be expended on patent-bypassing chemical manipulations, on ridiculous mixtures of drugs, or inconsequential additives to established drugs. Since the number of well-trained capable scientists is severely limited, their potential should not be wasted. The long-term benefits of the appropriate utilization of the abilities of these skilled individuals would be immeasurably greater." (4d).

Hence patents have not only induced a distortion between basic and applied research, but in making the latter budgets relatively too large, have induced wasteful duplication of effort and the misdirection of effort toward rivalry-oriented molecular manipulation, the development of often irrational combinations of existing drugs which lack flexibility and compound the problems of dosage and toxicity, and the devising of additives which represent often questionable and perhaps unnecessary flourishes in the direction of increasing the absorption rate of a drug, guarding against side effects, and the like.

As a concluding example of molecular manipulation and the "battle of the additives," let us take the drugs related to erythromycin, discovered in 1952 by Lilly. Dr. Harry F. Dowling of the University of Illinois Medical School explained the ensuing exercise in product development

rivalry to the Kefauver Subcommittee. (4e). Pfizer in 1953 concocted a closely related analog, carbomycin, which affected the same bacteria as erythromycin, but proved less effective in human disease than in the test tube, and was finally withdrawn from the market in 1960. In 1956, Pfizer introduced another closely related analog of erythromycin, oleandomycin; and in 1957, a modification of oleandomycin, triacetyloleandomycin, which was highly advertised as a major breakthrough in that the same oral dose as oleandomycin brought somewhat higher concentrations of the drug in the bloodstream. Lilly countered this in 1958 by modifying its original erythromycin to market it in the form of its propronyl salt, which was claimed to produce a higher concentration of the drug in the blood than triacetyloleandomycin. Resources were therefore spent in producing five drugs to serve the purpose of one, since slightly higher doses of erythromycin would have been as effective as the later derivatives.

c. Product Development

In this category a great many activities are included. The development of new products requires experimental testing to determine pharmacological activity and toxicity in laboratory animals, the determination of appropriate dosage forms, the conducting of initial clinical trials, the obtaining of permission from the Food and Drug Directorate of the Department of National Health and Welfare to market the new drug, the construction of pilot plant facilities, and related activities. Also included in development would be subsequent product application work in connection with long-run evaluation of the total effects of the drug, possible improvements in dosage forms, revisions of brochures, and the like.

In an efficiently competitive drug industry, profit prospects from marketing new drugs would be modest, and extreme haste in development would not be a great temptation. Development activities could proceed at a pace appropriate to the importance of careful drug evaluation. To eliminate or minimize the effects of proprietary bias in

evaluation, it would be desirable to have clinical testing carried out under other auspices than those of the discovering firm. Minimization of bias would result from having evaluation undertaken by public or other bodies outside the industry. But it would probably not be practicable to require that educational or government agencies perform clinical evaluation of all drugs, even though the total number of drugs evaluated would no doubt be smaller in an effectively competitive industry because of decreased motivation to produce drug copies and minor modifications. Preferable arrangements might be some variant of an evaluation program financed jointly by the entire drug industry. There should be no premium on haste, since each step in development is time-consuming if properly carried out. And the consequences of improperly evaluated drugs are not pleasant to contemplate. Dr. C. D. Leake of Ohio State University has trenchantly noted,

> "There is no shortcut from chemical laboratory to clinic, except one that passes too close to the morgue." (4f).

Under present arrangements, however, a great premium is placed on speed in rushing a new drug through the development phase and into commercial marketing. In order to secure permission from the Food and Drug Directorate, it is necessary to submit a sufficient amount of experimental and clinical data to establish the presumption that the drug is reasonably free from hazards of acute toxicity, and is a reasonably expedient agent in combatting those disorders in which it is claimed to be effective. But it takes time to conduct sufficient experiments and to carry out enough clinical studies to estimate probable toxicity in general use. In the United States, many instances of inadequate experimental work were unearthed by the Kefauver Subcommittee, although it is probable that conditions have improved since the thalidomide-inspired passage of the Drug Amendments Act of 1962. (And, as Dr. Alan Davidson has observed in his submission to this Committee, although no new Canadian legislation resulted, Canada was an indirect beneficiary of the new regulations in the United States). It also takes time to have new drug submissions studied and processed. In drug marketing,

many firms are often working on the same or related products at the same time, and each desires to cut the period between discovering and marketing to an absolute minimum, since the order of priority in market appearance usually determines the relative sales ranking for different brands of the same types of drug. Consequently, the motivation is to limit experimental and clinical work to the minimum acceptable level, to skip stages in product development, such as the pilot-plant stage, and to apply pressure to the staffs of regulatory agencies in such a way as to facilitate rapid approval. For example, Duncan of Lederle disclosed that his firm took the risk--which could have been costly and wasteful--of by-passing the pilot-plant stage in the development of triamcinolone. (13). And disclosures by former Food and Drug Administration employees during the Kefauver hearings gave evidence of the deplorable pressures which drug firms exerted on regulatory personnel, and the disgraceful condoning of such pressures by officials of the agency. (4g).

Another of the symptoms of excessive pressures for rapidly testing an excessive number of new drugs is that the time of the best available researchers is soon completely filled, and less capable, less experienced, less discriminating, and perhaps even less scrupulous individuals must be relied upon to conduct these tests. (While I understand that abuses in Canada have never been as severe as in the United States, similar pressures are likely to exist.)[1] Dr. Maxwell Finland of the Harvard University Medical School produced a very enlightening example at the Kefauver hearings. He cited an instance

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1 Dr. C. Gendron, Medical Director of Cyanamid of Canada, mentioned before this Committee that there were only about 75 available qualified clinical investigators in Canada (7ii), far too few to meet the demands for their services. And yet the scarce time of these men may be wasted if they are induced to participate in drug studies designed to promote drugs rather than investigate them. To quote from the Government of Alberta Brief before the Restrictive Trade Practices Commission in 1961:

"In Alberta, as a result of past experiences, where precipitate promotion interfered with objective clinical evaluation of new products, most clinical consultants refuse to undertake evaluation unless a clear understanding is made that no promotion of a product is contemplated until adequate investigation to allow valid conclusions is completed. In the past, it has happened that active promotion of a drug with its attendant ballyhoo has been initiated in the United States within a few weeks after an investigation has been started at the University Hospital in Edmonton at the suggestion of the drug firms. This inevitably results in the investigator becoming an unwitting party to the promotion." (1j)

where reports by a clinical investigator claimed the successful treatment of 100 cases of staphylococcal pneumonia by a particular drug, without a single mortality. Since the subjects were infants and children, and since under even the best of circumstances, the mortality rate is 50% in children under two years of age, the drug would appear to be a godsend. But upon scrutiny of the cases, Dr. Finland was satisfied that not a single case of staphylococcal pneumonia had been present, and inferred that the investigator had been unable to diagnose the presence or absence of the true disease from the laboratory cultures with which he was supplied. Dr. Finland concluded ominously:

> "This is the sort of thing that I say is dangerous because another doctor who knows how to make a diagnosis of staphylococcal pneumonia will use that drug to the peril of his patient." (4h).

Incompetent individuals should not be expected to conduct such studies; one great advantage of reducing the number of drugs to be evaluated would be a concomitant increase in the average quality of evaluation. Another advantage, less dramatic but in the long run very important, is that by reducing the claims on the time of medical educators, a decrease in the number of drugs to be evaluated would alleviate the competition between teaching and drug research for the time of the medical school faculty member, and increase the quality of medical education.

While the transformation of the drug industry to a more competitive state would tend to lower costs of most functions, it would probably tend to increase the cost per drug of product development by enabling more thorough and responsible evaluation. Total product development costs might not increase, however, since the number of drugs developed might decline as a result of eliminating motivation for producing minor modifications under great time pressure.

d. The Manufacturing of the Active Ingredient.

Precise information on the cost conditions under which the active ingredient in a typical drug is manufactured is not generally available. Such evidence as exists appears to confirm the economist's

natural suspicion that when many firms produce rival brands (or rival molecular versions) of the same compound or family of compounds, there may be excess capacity in that market demand is not great enough to keep the plants of all producers working at full capacity. And excess capacity imposes economic costs. For example, the Pharmaceutical Manufacturers' Association in the United States retained Dean E. V. Rostow of the Yale University Law School to defend the industry's drug price policy and patent privileges before the Kefauver Subcommittee. Rostow contended that although production costs for tetracycline represented only ten per cent of the price to the druggist, such a gross profit margin was not unexpected in view of the rapid increase in demand for the drug. The possibility of very high profits is very likely, contended Rostow,

> "if, as would seem natural, new entrants required some time to perfect their methods of production, so that there was some lag in capacity as compared with demand." (9b).

However it developed that Bristol, which was producing about a third of the total output of the drug, was then operating (1955) at only about twenty per cent of capacity. (9d.) Obviously, such enormous over-capacity increased the fixed costs per unit of production. In a competitive market, this would have forced price reductions in order to increase sales and reduce excess capacity. But tetracycline was produced under very elaborate patent licensing and cross-licensing arrangements, the genesis of which was attacked by the United States Federal Trade Commission, which in 1963 issued its verdict that the patent had been awarded to Pfizer only because of misrepresentation and the withholding of information from the patent examiner by Pfizer and Cyanamid. (14). Hence Bristol maintained its price level and tried to combat excess capacity by producing penicillin jointly with tetracycline. But Bristol did contemplate price reductions on penicillin in order to increase sales, since there was no effective patent control over penicillin. (9d).

In an efficiently competitive drug industry, each stage in the production process would be accomplished at minimum cost, and without

the burdens of persisting excess capacity. In drugs, the facilities required for the production of active ingredients apparently vary considerably. For those active ingredients which can most efficiently be produced by truly large-scale or mass-production methods, production by makers of fine chemicals or even of bulk chemicals would be appropriate. But for many drugs, the amount of investment required to produce the active ingredient, while perhaps large in absolute terms, is relatively modest in comparison to the amount of funds available in capital markets. Relatively small firms can efficiently produce the active ingredients in these cases. Mass production methods are not appropriate for many drugs since the physically minute quantities used in medications require only a small total annual volume of output. (4i). Even so, it may still be more efficient for a small firm to contract with a larger firm for the production of the basic drug. Under competitive market circumstances, relative economies of production versus preparation of dosage forms and distribution should control the functions assumed by different producers at different stages in the industry. If patents were no great barrier to entry into a drug market, raw materials and intermediates could be made by bulk chemical companies, the active ingredient could be produced by fine chemicals producers, and the finished dosage forms could be tabletted and bottled or otherwise prepared by drug makers to be distributed through various channels. Without barriers to entry, comparative costs of each process would determine the allocation of tasks among different firms. As far as financial requirements for drug making itself are concerned, there are no reasons why a large number of relatively small firms might not compete effectively in the market, a situation conducing to efficient price competition.

Under present circumstances, however, there are a number of market factors which distort the picture and introduce other criteria than comparative costs as determinants of the distribution of efforts at various stages of the industry. A relatively small drug maker may find a new drug, patent it, and then be induced to undertake the

production of the active ingredient himself, even though his comparative advantage does not lie in this area because of inexperience, inappropriate facilities and general lack of adaptation of his operation to the manufacturing of fine chemicals. Still, production may be undertaken--at higher cost levels than necessary--in order to prevent the "know how" which is not necessarily disclosed in the patent from being acquired by another firm. Where several firms are producing lots of suboptimal size at higher costs than would be incurred by a single manufacturing chemist supplying all of them from his own production, costs could obviously be reduced by recourse to more efficient practice. Under the circumstances induced by patents, these disadvantages can be overcome only partially by such means as forward integration, usually through merger, where manufacturers of bulk and fine chemicals operate or acquire pharmaceutical houses. Some of these mergers occurred before the era of "wonder drugs," such as Lederle's takeover by American Cyanamid in 1930; but most are of later date, as witness Olin-Mathiesson's absorption of Squibb, Dow Chemical's acquisition of Allied Laboratories and Pitman-Moore, Merck's merger with Sharp and Dohme, Pfizer's development of Roerig, and others. The Canadian scene is certainly no stranger to such mergers, with the acquisition of Ayerst by American Home Products, of Horner by Carter, and of Frosst by Merck being only the more prominent instances.

Patent restrictions are not the only factors stimulating forward integration by merger. The practice of intense sales promotion of drugs under brand names creates economies of large scale marketing at the drug firm level and creates a barrier to entry where production methods are such as to permit entry. The ability of small drug companies to compete with their former peers is reduced by such forward integration, and the power of the merged firms to resist or avoid competitive forces is enhanced. Also it has frequently been surmised that the decline in the standards of drug advertising and promotion had some relationship to the take-over of some previously conservative firms by companies not

specialized to drugs, but accustomed to applying only the sales yardstick when measuring the appropriateness of advertising appeals, such as producers of cosmetics, proprietaries, and "patent medicines."

Where the danger of loss of coveted "know-how" is not relevant, drug firms may contract out the production of active ingredients to producers of fine or bulk chemicals. It is then striking to note the relationship of the price of the bulk drug in comparison with the market value of the substance when embodied in medications and sold to distributors. Ratios in the vicinity of one hundred to one are not unknown.[1] The reason for this is simply that there is price competition between the firms which manufacture the active ingredient, but for patent and other reasons, there is none in the sale of the finished product. In a purely competitive industry this could not happen. With competition, the price of the finished drugs would decline to be more in line with production costs for the active ingredient.

It is difficult to generalize about the effects of present industry arrangements on the level of manufacturing costs for the active ingredients in view of the virtually complete absence of empirical evidence on costs and utilization of capacity. It is true, however, that investment in excess capacity means that earnings as a percentage of net worth are depressed below the levels which would obtain under optimal capacity-output relationships, such as would of necessity tend to prevail under price competition. Hence a moderate rate of return on investment may not indicate competition, but merely excess capacity. Similarly, if a firm argues that since profits amount to only about ten cents per dollar of sales, the complete elimination of profits would cut prices only ten per cent, it should be kept in mind that the costs occasioned by the existence of excess capacity also have their share in the sales dollar, and such costs could by and large be eliminated through

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1 Empire estimated that it could sell bulk diazepam at $170 per kilogram while the value of a kilogram of diazepam embodied in dosage forms is about $20,000.00, a ratio of about 125 to one (see pages 40 and 41 of this submission).

adopting reforms which, by compelling firms to operate more efficiently, required them to forego the luxury of excess capacity.

Evidence on the cost of active ingredients in bulk form to Canadian drug firms is partially obscured by the fact that about 80 per cent of such ingredients is imported, usually from foreign affiliates, and the prices set in inter-company transactions of this sort may not reflect the true cost of production of the substance. There are several reasons for this. First, the valuation is likely to include an unknown margin of profit to the foreign affiliate, over and above allocated full production costs, hence overstating the latter. Second, the effect of drug tariffs should partially offset this tendency, since a high valuation would mean, other things being equal, a high tariff liability. Regardless of the value for tariff purposes, however, the tariff should be distinguished from the level of production costs. Because of the low ratio of production cost to price, even tariffs of 20 to 25 per cent add only a very small amount relative to consumer price. Information given by the Minister of National Revenue to this Committee indicates that customs duty accounts for only 2.5 per cent of the consumer price for drugs imported in an unfinished condition for further manufacturing in Canada, or in bulk for full or partial packaging in Canada. For goods made predominantly from Canadian materials, with some imported materials and supplies, the ratio was .7 of one per cent. (7c). However, if competition reduces price levels, this ratio will correspondingly increase. Third, the effects of the dumping duty which may be imposed on certain drugs might be to make the foreign parent set a relatively high price on active ingredients exported in bulk form to Canadian subsidiaries, reasoning that if a lower price were set, revenues would be lost through dumping duties paid, while a higher price would merely increase the reported profits of the parent at the expense of the Canadian subsidiary. This is the view put forth in the Report of the Restrictive Trade Practices Commission (1a) and is obviously correct to the extent that valuations for dumping duty purposes are set in excess of manufacturing

cost plus a profit allowance reflecting the rate of return on the manufacturing operations per se experienced by the parent. But in an integrated operation it is very difficult to say what part of the company's overall profitability is due to the operation of various stages in its production process. Hence the precisely relevent value for dumping duty purposes cannot be determined in the absence of any independent market for the good in question. In practice it seems that where the dumping duty potentially applies, active ingredients in bulk form would usually be valued at manufacturing cost plus a 50 per cent markup. This is low in terms of the profits generally realized by the industry; the Minister of National Revenue cited a study showing that in the United States gross profits on drugs from 200 per cent to 1200 per cent are common. (7c). Under these circumstances it would appear that the application of the dumping duty is not likely to result, in itself, in any great inflation of parent company profit levels at the expense of those of Canadian subsidiaries. But if an increase in competition in the industry were to occur and gross profit margins were to decline, an examination of the dumping duty provisions might be in order. Specific reforms are discussed in Chapter III on this submission.

It may tentatively be concluded that the production cost of imported bulk drugs may be overestimated. The prices charged for such imports necessarily include a profit markup over cost which may be substantial. For those drugs subject to dumping duty, an additional motive exists to insure that customs valuations are high relative to costs. Hence in measuring the production cost of bulk drugs by reference to the price charged by exporters it must be realized that such prices may be substantially in excess of actual costs.

e. Preparation of Finished Dosage Forms.

The technology of the preparation of finished dosage forms, and the modest capital requirements of such operations, make this stage of the industry ideally suited for efficiently competitive market performance. The compounding of finished dosage forms typically involves

what are technologically routine and elementary processes for most dosage forms. For tablets, the tabletting and bottling of the preparation involves technically trivial operations, which are carried out at very low cost. For other dosage forms, such as injectables, processes may be more involved and costs appreciably higher. Still, for the typical pharmaceutical preparation total "factory costs" (making the bulk ingredient and producing the finished, packaged dosage forms) are a very small part of the wholesale price, and an even smaller part of the retail price. There is no reason why very small firms could not contract out the manufacture of the bulk powder and then tablet and package the finished dosage forms on the basis of a very modest total investment. Hence brisk competition between many small sellers of pharmaceutical products could develop if production costs were the only barrier to entry into the drug field. In most major industries, it is precisely this element of production cost--the technological economies of large scale, capital-intensive production--which provides the major barrier to entry, and hence preserves the market power of existing firms.

But if patents and sales promotion patterns were not present to prevent entry into drug making, pressures would develop to transform the drug market into a structure with a relatively large number of relatively small producers selling largely identical products and producing efficiently at low price levels consistent with low production costs and only competitively determined rates of return on investment.

While available evidence is largely fragmentary, it seems to indicate that the costs incurred by all firms for producing standard capsule forms and packaging them are very low relative to the prices charged by the brand-name firms, and that much of the price competition which does exist between brand-name and generic-name versions of the same drug comes about because for such drugs the absence of tight patent control over manufacture and/or sale of the bulk powder enables small firms either to produce or to obtain the bulk powder at the low prices which reflect only the competitive supply price of the bulk powder. The firms then tablet and package the drugs and sell them at low prices reflecting low costs of production. This is virtually the

only instance of vigorous price competition in the entire industry. It does, however, show the sort of pattern which might develop if barriers to entry were removed, and numerous small competitive firms were to enter the market for producing existing drugs.

In an efficiently competitive industry the relationship between production costs and market prices is close and direct. Indeed, the acid test for a workably competitive industry is that reductions in cost be necessarily passed on to the consumer as corresponding price reductions. This is the point at which the available evidence on the relationship of drug costs to prices should be assembled. First, the cost evidence presented so far to the Committee will be evaluated, and then other cost and price data relating to the Canadian market will be considered in conjunction with the cost-price relationships developed for the United States during the Kefauver hearings.

The Hoffman-LaRoche submission to the Committee consists chiefly of an attack on the Canadian patent law and an indictment of several small firms which applied for compulsory licenses, in the course of which some interesting data on costs and prices is divulged. At best, this data is approximate and gives only rough orders of magnitude, but it is worth examining. The submission relates that Bell-Craig, in its application for a compulsory license for chlordiazepoxide (the so-called "Librium") maintained that while it could not estimate its probable cost of manufacturing the drug very accurately, this was largely irrelevant to the selling price. Roche agreed without comment. (15a). The implication is clearly that prices need not be related to costs, and that cost is so small relative to price that substantial variations in cost would have no significant effect on expected profit margins.

Roche contended, but did not explain, that the minimum price for this drug could not go lower than $1300 per kilogram, which is presumably the minimum supply price representing cost plus the minimum acceptable profit. (15b). Roche estimated Bell-Craig's price for the drug when sold in dosage form at $3000 per kilogram; Bell-Craig estimated

that it would probably sell no more than 60 kilograms per year. Roche indicates that it sold in Canada 3424 kilograms of the drug through 1965; since it was first introduced in 1960, average sales per year for Roche were about 685 kilograms, or about 11.4 times as great as Bell-Craig's expected sales. (15c). Roche further stated that its average price received per kilogram was $4400. Presumably this is the cost to the retailer; if the druggist adds to this a 2/3 markup and then superadds a dispensing fee, we might be safe in roughly doubling the cost (as is consistent with the submission of the Canadian Pharmaceutical Association to this Committee, see Appendix A to the present submission) and obtaining a cost of $8800 per kilogram to the consumer. But what is the factory cost to Roche and to Bell-Craig? Roche feels that Bell-Craig would be no longer interested in producing if the price falls to $1300 per kilogram, (7hh) but the $1300 itself may include some rate of return on investment. If it is in the neighborhood of 25% on sales price, before taxes (as would not seem unreasonable in view of the small outputs contemplated by Bell-Craig) then the production cost plus other business overheads would be about $1000 per kilogram. Since Roche produces over 11 times as much in the Canadian market alone, its costs of production are surely much less than this, perhaps on the order of $500, or 50% of Bell-Craig's costs for the smaller output. (Roche indicated agreement with both Bell-Craig's and Empire's admissions that their costs of production would be substantially higher per unit than those of Roche, because of smaller volume of sales.) (15d). As a very rough comparison, then, for which no accuracy can be claimed, Bell-Craig was proposing to sell for $3000 a drug which it could produce for $1000--a markup over production cost of about 200%. If druggists sold Bell-Craig's product for $6000, the constructive total markup over cost would be 500 per cent. For Roche, production costs of roughly $500 would contrast with revenues of $4400, a markup of 780 per cent relative to Roche's revenues, and constructively 1660 per cent relative to price to the consumer. (Naturally the druggist does not impose a 1600% markup; his markup is only 100 per cent. The constructive markup over cost at retail is

computed only in the interest of contrasting production cost and consumer price.)

In another application for license, Delmar indicated that its price for selling the bulk drug would be $450 per kilogram. For a small volume operation, perhaps half of the price would have to be profit in order to provide an acceptable rate of return on the appropriate investment, so that the cost of manufacturing the bulk chemical, before profits might be somewhere in the area of $225 per kilogram. If the profit rate were only 25%, the cost would still be merely $337.50 per kilogram. If we assume that Roche's production costs were about half of Delmar's, we obtain a range of from $112.50 to $168.75 per kilogram. Even if it were as much as $200 per kilogram, there would still be a gap of $300 between estimated bulk drug production cost, and the estimated factory cost of $500 per kilogram. Is a $300 per kilogram margin for preparation of dosage forms reasonable? Roche does not indicate the dosage form mix contemplated in terms of its receipts of $4400 per kilogram. However, if we assume that the kilogram is embodied in 100,000 capsules of 10 milligrams each, some rough indication of the cost of capsuling is indicated by Strong Cobb Arner's quotation of $1.70 per thousand tablets for making tetracycline hydrochloride, where the basic drug and the empty capsules are supplied. (16a). This would be $170.00 for 100,000 capsules. That the order of magnitude is reasonable is apparent when it is realized that the contract price quoted surely includes a substantial allowance for profit. On the other hand, some allowance for losses during dosage form preparation should be made, as well as for the costs of capsules and perhaps other containers, plus the possibly higher costs of preparing other dosage forms.

When Empire requested a license on Roche's diazepam (the so-called "Valium"), the applicant estimated manufacturing costs of about $68 per kilogram, which, with the addition of "overhead and profit" would allow it to sell to others in bulk at $170 per kilogram. (15e). The nature and the amount of the overhead is not specified; presumably the

overhead is manufacturing overhead; if not, the full production cost may be only $68 per kilogram. Let it be assumed, however, that the production cost is in the realm of $100 per kilogram. If Roche's cost is only about half this great, a manufacturing cost of $50 per kilogram is to be compared with Roche's average revenues of $10,000 per kilogram, and the presumable price to the consumer of $20,000 per kilogram. With so low a production cost, the margin of error in cost estimation matters relatively little. If we assume that Roche's other factory costs--tabletting and packaging, etc.--are $300 as is the estimated instance of chlordiazepoxide, the cost per kilogram is only $350. This estimate could be off by about 2/3 and the factory cost of $1000 would still be only 10 per cent of the revenue realized--a 900 per cent markup at wholesale and a 1900 per cent markup at retail. If the lower cost figure is correct, the markups are closer to 2800 per cent and 5700 per cent respectively. There would seem to be some room for price reductions. Empire planned to sell at prices about 40 per cent below those of Roche, and with its lower cost structure it could probably reduce prices much farther.

Let it be stressed that these markups quoted are estimated markups over factory cost only, and not net profit margins. What they measure is the gap between the cost of production and the price to druggists and to consumers. The gap will be filled in part by costs of distribution and general and administrative overhead. Research and development may also add to the total. But this still leaves a lot of room for sales promotion and profits. In a competitive industry the gap would not be nearly so pronounced.

Two other observations were made on the costs of chlordiazepoxide. Roche cites Micro's admission that its costs of making the bulk drug would be about $460 per kilogram (15f) which compares closely with Delmar's estimate of $450. But Mr. Leslie Dan of the Canadian Drug Manufacturers quoted costs for this substance of $150 per kilogram in Switzerland and $81 in Italy. (7d). In view of these foreign prices, it

seems quite likely that Hoffman-LaRoche, a Swiss-based firm, could make the material in Switzerland at a cost of under $150 per kilogram. Transportation costs should be negligible, and the addition of customs duties should not increase the cost to over at most $200 per kilogram. Hence the earlier estimate of $500 total cost of preparing finished dosage forms seems reasonable, when taken in conjunction with Mr. Dan's statement that costs of preparing dosage forms run between $1.00 and $2.00 per thousand capsules.

Professor George Wright, in his brief, "Canadian Drug Patents," refers to an unnamed drug which has similar costs: the patent holder claims a value of $3,528 per kilogram, while the licensee contests that it is $150, and Dr. Wright observes that the drug can be bought from Europe for $72.00 per kilogram. He gives a further example: pentaerythritol tetranitrate sells under a brand name (presumably Warner-Chilcott's "Peritrate") for about $2.70 per hundred tablets to the druggist, and presumably is dispensed for about $5.40 per hundred 20 milligram tablets. A Canadian-owned company (presumably Empire, Dr. Wright's company) is quoted as selling under the generic name at a price of 55 cents at wholesale, and presumably about $I.10 to the drug buyer. The cost of the latter is said to be 21 cents per hundred; the cost of the more expensive version might be as much as 26 cents. The brand name firm imposes a markup over production cost of 940 per cent to the druggist, and the markup above the retail price is presumably 1980 per cent. The generic seller's markup over factory cost is 162 per cent, and the equivalent retail price is equal presumably to a 424 per cent markup. Interestingly enough, the brand name version is not patented, and both firms buy the raw material from the same supplier. What accounts for the price difference? Dr. Wright submits that it is inefficiency. For an unpatented drug, it probably depends upon sales promotion efforts aimed at brand name prescribing, which it may be argued falls within the category of inefficient use of resources.

This would seem to be a comprehensive review of the sum total

of data on production costs (rather than prices or aggregate balance sheet breakdown) relating to particular drugs, which has so far been presented to this Committee. This fact speaks for itself. (I will add any available later information in later drafts.)

The only other available data on drug production costs in Canada comes from the Green Book and relates to cost levels as of 1958-1959 (2c). Most of the data given represent not actual factory production costs, but instead costs of the bulk chemical as imported. It is instructive to survey certain of these reported costs or import prices and compare them with the revenues received from sales of finished dosage forms as of 1958-1959 prices and 1965 prices. (The latter comparison is of interest only to the extent that 1965 production costs are related to 1958-1959 production costs.) Because of the large possible margins of error associated with making estimates related to these data, and because the material is not necessarily up to date, only a few drugs will be analyzed with respect to the cost-price relationship. These drugs consist of those for which cost data were obtained and published in both the Green Book and the Kefauver Subcommittee Report: chloramphenicol, tetracycline, and meprobamate.

Although the "broad-spectrum" antibiotics all sell at virtually identical prices, production costs appear to differ greatly, at least on the basis of available cost information. Chloramphenicol seems to be the lowest in cost, it being possible to produce this drug synthetically rather than through fermentation. The Green Book cites that reported costs of manufacture of the drug in Canada in 1958-1959 were about $90 per kilogram, although it is not clear whether this cost refers to the operations of Parke-Davis, of Fine Chemicals, or to both operations. Fine Chemicals sold the bulk drug to other manufacturers for $200 per kilogram plus a royalty which at that time had not been determined. Imports from Europe during 1959 were reported at prices between $60 and $250 per kilogram, excluding duty. (2d). Since chloramphenicol is sold in 250 milligram capsules, one kilogram of the

drug should yield 4000 capsules. With a liberal allowance of 5 per cent for wastage in processing, a kilogram should still suffice for 3800 tablets. At this time, Parke-Davis was selling 100 capsules to the druggist for $34.02, and the druggist was presumably retailing this quantity for about twice this sum, or $68.04. Hence a kilogram in dosage form would yield a revenue of $1292.76 to the manufacturer, and $2585.52 to the retailer. The estimated production cost in Canada was $90 per kilogram; the factory cost, however, would include tabletting and packaging costs. Data on these costs were not obtainable in the Green Book; however a computation of these costs was made by the Kefauver Subcommittee staff and applied to chloramphenicol. (4j).

It is of interest to look in some detail at the Kefauver Subcommittee staff's estimate of Parke-Davis costs for a 100-capsule bottle of 250 milligram chloramphenicol capsules. Parke-Davis in 1960 had a contract with Farmitalia of Italy under the terms of which it was to buy up to 30,000 kilograms of this drug at a price of $30 per kilogram. Since only 6,000 tons had been purchased under this contract through July 11, 1960, it may be inferred that the buyer found he could make the drug more cheaply in Detroit--that is, at less than $42 per ton, since the import duty was apparently $12 per ton. To this raw material cost, the Subcommittee staff added actual cost data for capsuling and packaging tetracycline capsules, as reported by Upjohn: for a bottle of 100 capsules, capsules and other materials would cost 17 cents; production labor and overhead, 13 cents; packaging materials, 6 cents; packaging labor and overhead, 5 cents, for a total of 41 cents. For Parke-Davis's capsules actually made from the Italian bulk drug, estimated costs per bottle of 100 were 79 cents for raw materials, 41 cents for finishing and packaging, and 32 cents for the import duty, a total of $1.52 per bottle. (If production costs in Detroit were $42 per kilogram the costs for the production of chloramphenicol from domestic United States produced chloramphenicol would be the same as for Italian bulk raw material produced drugs.) This $1.52 per bottle of 100 tablets is

a cost only 5.0 per cent of the wholesale price of $30.60 in the United States, and 3.0 per cent of the retail price of $51.00. It would be only 5.5 per cent of Parke-Davis's claimed average revenue of $27.50 per bottle. Even if the cost of making the drug in Detroit were twice as great as the Italian price, a cost of $60 per kilogram would still increase costs to only $1.99 per bottle.

Turning now to Canada, let us assume that because of the smaller volumes produced, it cost Parke-Davis $90. per kilogram to produce the drug. (Fine Chemical's output must have been considerably less than that of the patent-holder; if the $90 cost stated in the Green Book refers to Fine Chemical's cost, that of Parke-Davis could have been substantially lower.) If we assume that finishing and packaging costs in Canada were the same as in the United States--41 cents per hundred tablets, or .41 cents per tablet, then the total factory cost of chloramphenicol would be $105.58 per kilogram (3800 tablets). The sales revenue at the wholesale price level at that time of $1292.76 would imply a 1125 per cent over factory cost; the retail price would imply an equivalent markup by both manufacturer and retailer of 2350 per cent over factory cost.

It is interesting to note that Fine Chemicals found it necessary to sell for $200 the kilogram of chloramphenicol which it had produced for perhaps $90; this gives some support to the estimates mentioned above of assuming that about half the sales price of a drug by a small firm would be the necessary profit margin. For firms which bought chloramphenicol at $200 per kilogram and then experienced finishing and packaging costs of .41 cents per capsule, the total cost of producing 3800 capsules from the kilogram would be $215.58; when sold to the retailer at $1292.76, and resold by the retailer at $2585.52, the implied markups over factory cost would be 500 per cent and 1100 per cent, respectively. Since 1960 chloramphenicol prices have declined, in part no doubt because of compulsory licenses granted under section 41(3) of the Canadian Patent law, and the June 1965 price levels

for the drug would result in total revenues of $896.80 per kilogram as sold to the druggist and $1793.60 as sold to the consumer. The implied markups over factory costs are now 317 per cent, and 734 per cent, respectively. (This of course assumes that factory costs are still the same today, which is probably not the case. Costs may have increased or decreased, depending upon whether or not possible increases in price levels for materials purchased have been offset by possible improvements in methods of production.)

For tetracycline, the Green Book reports a wide range of costs. Bristol imported the bulk drug from its United States parent company at prices of $90 per kilogram in 1958 and about $140 per kilogram in 1959. Bristol sold to Squibb and Upjohn at prices reported by the buyers as $336.57 for Squibb and $414.50 for Upjohn. Pfizer imported its drug from its United States parent at prices ranging from $156.71 to $525.36 per kilogram. Cyanamid reported production costs in its Canadian plant of $644.15. Gilbert imported the drug in bulk for $300 per kilogram. (2e). It is impossible, without further information, to reconcile these various figures. Royalties play an unknown, but probably significant, role. The Green Book suggests that the costs reported are accurately reported, and that Bristol's costs show that tetracycline can be manufactured at costs relatively quite low in comparison with some of the reported costs. One might conclude that where prices are extremely high relative to factory production costs, a very wide range of costs are consistent with profitable operation.

Fortunately, in the Kefauver hearings, Bristol's actual production costs for tetracycline were made public. A bottle of 100 capsules of 250 milligrams each cost only $1.67 to produce. If 41 cents of this total is alloted to finished and packaging, the cost of the drug itself is $1.26; hence the drug cost in 3800 capsules should be $47.88, which is Bristol's equivalent factory cost of one kilogram of tetracycline when converted into capsules with a 5 per cent wastage allowance. Bristol also paid $1.03 royalty to Pfizer on a 100 capsule bottle, but as mentioned above, while the payment of the royalty increased

Bristol's cash expenses of doing business in tetracycline, royalties paid do not constitute a cost of production but are more in the nature of a levy on product profitability. Bristol's total expenses, including royalties, would be $102.60 for 3800 capsules which would sell in the United States, at prices current at that time, for $1162.80 to pharmacists, and for $1938.00 to consumers. This is equivalent to a markup of 1033 per cent over factory costs plus royalties in the price to the retailer, and an implied markup of 1789 per cent by the pharmacist over the factory cost plus royalty.

In Canada, the bulk drug prices paid which were reported ranged from Pfizer's $156.71 per kilogram for imports, to Cyanamid's $644.14 reported production cost per kilogram. Assuming that Upjohn packaging and finishing cost of $.41 per hundred tablets can be applied total factory costs per kilogram would be $172.29 for Pfizer's lowest import costs, and $659.73 for Cyanamid's production cost. In terms of 1959 prices, Pfizer's markup over factory cost would have been 650 per cent (with the retail price representing a constructive 1400 per cent markup); Cyanamid's only about 100 per cent (300 per cent at retail). Since Pfizer's patent was declared invalid by the United States FTC in 1963, considerable price competition has developed in this drug in North American markets, and the Canadian price had fallen by 1965 to $18.00 per bottle of 100 capsules of 250 milligrams each to the druggist. Current cost levels in Canada are almost impossible to estimate. Canada Pharmacal recently quoted a price of $30.30 per thousand 250 milligram capsules of tetracycline. Total revenue per kilogram would accordingly be no more than $115.14 which would be an absolutely maximal estimate of the firm's factory costs (See Appendix D, page 1.) In 1965 the price of 3800 capsules of tetracycline to the retailer was $684.00 and presumably twice that much to the buyer at retail. Hence the presumed maximum cost was such as to yield a markup of 494 per cent over maximum estimated factory cost on sales to retailers; the retailer's price was such as to yield a constructive markup of 1088 per cent over maximum factory cost.

The only other drug for which records of both Canadian and United States costs are available is the tranquilizer meprobamate. The Green Book indicates that the price of the drug varied between $6.00 per kilogram and the $29.12 at which one large firm purchased from its United States parent company--an example of the extent to which intercompany-transaction prices can artificially diverge from market prices. (2f). One kilogram could yield 2500 tablets of 400 milligrams each. Allowing for a wastage of 2 per cent, 2450 capsules would be the net output. At a price of $6 per kilogram, the packaging and finishing costs of $8.33 for 2450 tablets would bring the factory cost up to $14.33 per kilogram, neglecting any royalties which might be due. The packaging and finishing costs are based on the tabletting charge of $2.00 per thousand the the bottling charge of $1.40 per thousand, as given in the Report of the Kefauver Subcommittee. (5c). The prices charged to the druggist for a bottle of 500 capsules of 400 milligrams each varied from Ayerst's $31.50 to Empire's $7.50. (2g). Ayerst's total revenue would then be the equivalent of $154.35 per kilogram while Empire's would be $36.75. Assuming that a seller could obtain the drug at $6 per kilogram and sell it at Ayerst's price, the markup over factory cost would be 977 per cent; if sold at Empire's price, only 156 per cent. The constructive markups at retail over factory cost would be 1854 per cent and 412 per cent respectively. Assuming that one may compare these costs with prices of from $26.25 (Horner) to $3.75 (Empire) to the druggist in June, 1965, the markup over cost would be 798 per cent for Horner and only 28 per cent for Empire. At retail, the constructive markups over factory cost would be 1696 per cent and 156 per cent.

These estimates of the relationship of prices to costs are presented simply because there is a need for such a comparison, there are no other data available on which to base such a comparison, and it is preferable to make the most of the existing data rather than to present no cost-vs.-price evidence whatsoever. The relevance of the costs of 1959 to the prices of 1965 is simply unknown. What is of interest

is to note that factory costs may be less than ten per cent of the price to the druggist on the basis of these estimates; even if actual costs were twice as great, they would still be one-fifth or less of the price--a truly remarkable ratio in view of the experience of other industries. Of course it is true that not all products sold by drug firms have such large gross profit margins; furthermore, gross profit margins exceed net profit margins because of the necessity of incurring other expenses than factory costs. Nevertheless, it would be impossible under efficiently competitive conditions for any significant drug to sell for very long at prices ten times or more in excess of production costs; and it may be contended that the types of expenditures which fill in almost the entirety of the gap between the gross profit margin and the net profit margin are largely wasteful and are expended chiefly in order to keep the gross margin unnecessarily wide rather than to perform essential production and distribution functions.

An approximation of the gross margin of a drug firm may be obtained by comparing the cost of goods sold to total sales revenue. Unless the firm's income statement can be carefully audited, the economist cannot be certain whether costs and revenues are being appropriately allocated or otherwise accounted for. Nevertheless, if we consider the 1965 income statement submitted to this Committee by Smith Kline & French, it appears that only about 16 per cent of sales revenues were accounted for by the actual cost of goods sold. By way of contrast, sales promotion outlays were about 38 per cent of sales, and research and development only about 7 per cent. (7e). To be sure, other companies may have higher ratios of costs of goods sold to sales revenues. But one cannot be confident that unadjusted income statements provide a sufficiently precise measure of the ratio of the exact factory and other genuine production costs incurred, to the precise sales revenues obtained from selling these particular drugs. This is particularly problematic when dealing with the operations of international companies. For example, Parke-Davis claims that its 1965 cost of goods sold was 47.5 per cent of sales revenue for its Canadian operations, (7f),

but in its submission it includes its 1965 Annual Report to stockholders, which indicates that the cost of goods sold ratio for all operations in all countries was only 36.3 per cent of sales. The discrepancy is sizeable and one may infer that it is advisable to interpret financial statements of domestic subsidiaries of foreign parents with considerable caution. In other submissions to this Committee, Frosst indicated a ratio of 29.8 per cent (7g) while Roche designated 61.7 per cent of sales as the "cost of sales" which includes everything except research and development, administration, and royalties and interest charges, and hence includes an unknown component of sales promotion and other costs. (7h).

Even allowing for differences in definitions and measurement, the statistics presented to the Committee on "Key Business Ratios in Canada" in 1965 from Dun and Bradstreet of Canada, Ltd., (7i) show that the ratio of the cost of goods sold to sales is lower in the drug industry than it is in any of the fifty other manufacturing industries listed, with the single exception of soft drinks. The drug industry ratio of 49.1 per cent is 36 per cent lower than the ratio of 73.7 per cent for all manufacturing firms, and 26 per cent below the ratio of 69.1 per cent for all companies grouped together. This large gross margin also permits a relatively quite high ratio of profits to tangible net worth (preferred and common stock plus net surplus minus intangibles): 21.93 per cent, which is the sixth highest ratio among the 51 Industries listed. Since a total of 224 firms were included in arriving at the ratios for the "pharmaceutical preparations" industry, it is likely that the relatively higher cost of goods sold ratios for the smaller firms increased the industry ratio to 49.1 per cent, a level which may be above that of the average of the largest firms considered as a group. Conversely, the inclusion of the smaller firms may have had a depressing effect on the ratio of profit to tangible net worth.

Further indications of the low level of production costs relative to prices may be obtained by a study of the relationship of prices to the druggist and bid prices in competitive bidding for sales to hospitals and public agencies. As investigations in both Canada and the United States have shown, competitive bidding may very greatly reduce the price of unpatented drugs, or drugs the patents for which have been widely licensed, while reductions in price for patented drugs are typically very slight. In the United States, the Military Medical Supply Agency has been able to purchase a bottle of a thousand 25-milligram tablets of the tranquilizer reserpine for as little as 51 cents, while the price of the patent holder, CIBA, was $39.50 to the druggist. CIBA itself when questioned by the Kefauver Subcommittee about this price spread, claimed that it had not recovered out-of-pocket costs on its low bids, but this is hard to accept, particularly in view of CIBA's subsequent even lower bids. Later during the Kefauver hearings, McKesson and Robbins indicated that its full cost of producing for this drug was 63 cents; the larger volumes sold by the patent holder might have enabled it to experience costs lower than 50 cents. (11, p. 215.)

In Canada, the Green Book shows that the University Hospital in Edmonton, in response to tenders in 1959 was able to obtain a 43.2 per cent discount off the regular hospital price (which in turn was about 8 per cent below the price to the retail pharmacist) for Bristol's brand of tetracycline for an order of 20,000 bottles. For Schering's brand of prednisone, the discount off regular hospital price (which in this instance already reflected a 49 per cent discount off the price to the pharmacist) was 76.9 per cent, the order size not being specified. In the case of the latter drug, where patent protection had not been obtained, the price to the hospital was only about 12 per cent of the price to the druggist. (11).

Appendix D to this submission consists of several schedules relating to the prices of certain drugs to various buyers in Alberta in 1966. The drugs concerned belong to four groups; Antibiotics,

Corticosteroids, Ataractics, and Oral Anti-diabetics. The prices given are those quoted by various brand name and generic name suppliers to the University of Alberta Hospital at Edmonton, and in the case of ataractics, to the Alberta Department of Health. Prices are also given, where available, to wholesalers, retail pharmacists, and final consumers. Manufacturing cost data is taken from the Green Book for those drugs for which it was available at that time.

An analysis of these data will reveal several interesting features. Table I, below, indicates the contrast between the maximum percentage discounts off consumer list price allowed on various drugs by brand name and by generic name drugs.[1] For brand name antibiotics, discounts allowed range from 55 to 86 per cent; for generic name antibiotics, the only observation reported shows a discount of only 34 per cent. One reason for the smaller discount allowed by the generic seller is his relatively much lower consumer list price; it should not be assumed that because the discount allowed off list price is smaller for the generic firm, the brand name firm's price is lower. On the contrary, reference to Table II will indicate that the ratio of the lowest price quoted by a generic name drug supplier to the lowest price quoted by a brand name supplier, for purchases by the University Hospital at Edmonton is only 23 per cent in the case of tetracycline.

Table I shows that in the case of corticosteroids, the largest discounts allowed by brand name drug sellers ranged from 46 to 96 per cent; for generic drugs, three observations were recorded, at 29, 40, and 83 per cent. For ataractics, the range was from 43 to 91 per cent for brand name drugs, and from 30 to 39 per cent for generic drugs, on price quotations to the University Hospital at Edmonton. For quotations to the Alberta Department of Health the discounts were larger in all but two instances, ranging from 61 to 91 per cent for brand name drugs. The

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1 In Table I, only the maximum percentage discount allowed from consumer list price by one particular seller among all listed sellers of a particular drug is ordinarily listed. To obtain prices for comparable quantities, the per unit price of the quantity closest in magnitude to the basis for the Hospital or Government bid (usually 1000 tablets) is adjusted proportionately.

larger discounts received by the Alberta Department of Health apparently do not reflect larger quantity purchases, since the prices quoted are generally for lots of a thousand, regardless of total order size. It may be due simply to the greater potential bargaining power of the larger agency. For oral antidiabetics, two sellers of brand name preparations of tolbutamide quoted identical discounts of 70 per cent to both agencies, and for phenformin one seller quoted prices implying discounts of 55 and 66 percent to the two agencies. Comparative data for generic sellers of oral antidiabetic drugs are lacking.

Table II shows that in no instance did the lowest price quoted by the brand name supplier undercut the lowest price quoted by a generic name supplier as far as the data in Appendix D are concerned. For tetracycline, tolbutamide, and meprobamate the lowest generic price was only about one-quarter as high as the lowest brand name price. For dexamethasone, promazine, and prednisolone the generic prices were respectively about two-fifths, three-fifths, and four-fifths as high as the brand name prices. Only in the case of prednisolone did the brand name price closely approach the level of the generic name price.

Table III shows the ratio of the manufacturing cost for a drug reported in the Green Book to the 1966 list price to the consumer, for 15 brand name drugs, 13 of which are sold by major firms. As mentioned before, the degree of comparability between the price and cost data is unknown because of the time elapsed since the cost data were compiled. Table III shows that the range of manufacturing costs as a percentage of consumer list price is from seven-tenths of one percent to 31 per cent, with a median of 12 per cent. Seven of the ratios have a value of less than ten per cent, five lie between 11 and 20 per cent, two between 21 and 30 per cent, and the highest is 31 per cent. Table III does not necessarily constitute a representative sample of prescription drugs, but consists instead of a listing of cost price data for all drugs for which cost data is given in Appendix D. except for those drugs previously discussed

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TABLE I

I. BRAND NAME DRUGS:

Name of Drug	Name of Firm	Maximum Percentage discount from retail list price allowed to purchasing agency: (1966)	
		University Hospital Edmonton	Alberta Dept. of Health
Antibiotics:		per cent	per cent
Erythromycin	Abbott	68	
"	Lilly	55	
Novobiocin	Merck	55	
Tetracycline	Nadeau	86	
Chlortetracycline	Lederle	77	
Chloramphenicol	Intra	77	
Cycloserine	Roche	77	
Corticosteroids:			
Prednisone	Schering	96	
Prednisolone	Schering	91	
Triamcinolone	Lederle	55	
Dexamethasone	Merck, Schering	52	
Methylprednisolone	Upjohn	46	
Tranquilizers:			
Promazine	Mowatt and Moore	91	91
Chlorpromazine	Poulenc	80	84
Trifluoperazine	SKF	49	
Hydroxyline	Pfizer	51	
Tranylcypromine	SKF	46	65
Thioridazine	Sandoz	57	67
Triflupromazine Hcl	Squibb	46	70
Phenylzine Dihydrogen sulfate	Warner-Chilcott	43	61
Meprobamate	Wyeth	68	60
Promethazine	Poulenc	59	68
Prochlorperazine	Poulenc	50	68
Chlordiazepoxide	Elliott-Marion	68	
"	Roche	63	67
Diazepam	Roche	55	63
Oral Antidiabetics:			
Tolbutamide	Hoechst; Horner	70	70
Phenformin	Arlington-Funk	55	66

II. GENERIC NAME DRUGS:

Antibiotics:			
Tetracycline	Gilbert	34	
Corticosteroids:			
Prednisone	British Drug Houses	83	
Prednisolone	Bell-Craig	40	
Dexamethasone	Gilbert Gil	29	
Tranquilizers:			
Promazine	Gilbert	30	
Meprobamate	Gilbert	39	

Source: Appendix D.

TABLE II

Ratio of lowest price quoted by generic name drug supplier to lowest price quoted by brand name drug supplier, to the University Hospital, Edmonton, Alberta, 1966

Tetracycline	23 per cent
Prednisolone	81
Prednosone	97
Dexamethasone	42
Promazine	65
Tolbutamide	28
Meprobamate	25

TABLE III

Drug	Producer	Ratio of Manufacturing Cost Reported in Green Book to 1966 List price to consumer
Antibiotics:		
Erythromycin	Upjohn	12 per cent
"	Merck	29
Cycloserine	Roche	30
"	Lilly	31
Tranquilizers:		
Promazine	Wyeth	9
"	Intra	15
"	Mowatt and Moore	18
Chlorpromazine	Poulenc	15
Perphenazine	Schering	7
Trifluoperazine	SKF	1
Hydroxyline	Pfizer	0.7
Thipridazine	Sandoz	17
Triflupromazine	Squibb	9
Meprobamate	Wyeth, Horner	4

These lower prices to hospitals and public agencies reflect several factors: (1) certain economies of large scale selling, such that some costs are reduced for such transactions; (2) the hospital's exemption from federal sales tax in itself should allow hospital prices to be reduced by about ten or eleven per cent below the price to the druggist; and (3) the presence of potential price competition among sellers, which usually becomes effective to the extent that small generic-name sellers are able to compete with the large firms. Usually this is possible only in the absence of patents.

It has been argued that sales to pharmacists at high prices make possible the sales to public agencies at lower prices, and hence the former sales "subsidize" the latter. If by this it is meant that the latter sales are actually made at a loss, then I believe the contention to be generally incorrect. Production costs are apparently so low that very substantial reductions can be made without eliminating profits. Furthermore, a company can always add to its total profits by selling goods at special low prices, provided that these prices are above marginal or out-of-pocket costs incurred in order to make the sale, and further provided that the lower prices received on the particular transaction do not affect prices received in other markets. To the extent that firms have excess capacity they may be more keenly motivated to increase the rate of output and spread the overhead cost of excess capacity over a larger level of production by taking special orders at price levels exceeding out-of-pocket costs incurred by such orders.

Again, if costs of making sales through hospitals are lower than through druggists because of large unit purchases, then there is no discrimination between distribution channels if the same general schedule of quantity discounts is available for both types of distributors. (Discounts offered do not have to be identical, since hospital sales may involve cost savings over and above those relating to quantity purchased alone.) On the other hand, the exemption of hospitals

from sales tax does act to discriminate between distributive outlets--but this is not due to actions taken by the drug firms. Still, price differentials may easily exceed those which would be due to the combined effects of large quantity orders and sales tax exemption. But the seller who charges the highest price he can obtain in two separate markets is not necessarily subsidizing one market at the expense of the other because he can exact a higher price from one type of buyer than from the other. In economic terms he is just taking advantage of the separation of the two markets to discriminate in price between buyers. If he cannot make a profit in one market, there is no reason why he should lose money just to subsidize it, when he can simply refuse to bid at competitive levels--as many large firms apparently do in the bid markets. (The contention that firms are willing to lose money on bids in order to get their drugs used in hospitals and convince physicians of their quality is probably to be rejected as a rationalization for low bids. The myriad of other sales promotion activities will ensure that the doctors become aware of all brands.)

The bid market is separated from the retail prescription market in that public agencies which buy drugs at low prices do not resell them at slightly higher prices to pharmacists. The demand for drugs on the part of retail pharmacists is derived from the demand of the drug buyer, which of course is extremely inelastic with regard to price. Retail pharmacists can afford to pay high prices because they can charge high prices to buyers, in the interests of maximizing profits. The demand on the part of hospitals and other public agencies is differently constituted. Being non-profit agencies, they operate within a general budget, and while they are not directly concerned with selling individual items in accordance with scales of particular charges, they are concerned with lowering total operating costs and keeping within budgets. Their purchasing agents may also take a professional interest in economical buying. But the most important distinction between the demand for drugs on the part of the retail pharmacy and the public agency is that the latter can solicit price competition among sellers, while the former have little ability to do so, and also relatively

little interest because they can readily pass on higher prices to drug buyers. With demand much more elastic in the bid market, drugs produced at a given cost level will sell at prices much closer to costs. With certain costs lower in the bid market, such as some distribution costs (and the sales tax), supply prices will be lower. Hence with more elastic demand and lower supply costs in the bid market, it is to be expected that bid prices will be lower, to the extent that rival suppliers can be induced to engage in price competition with each other. But if the possession of patents precludes the entry of rival suppliers from the market, the demand situation in the bid market may be as inelastic as in the retail market.

f. Sales Promotion Activities.

Economists are fond of making a distinction between informative (or factual) advertising, and persuasive (and perhaps less than factual) advertising. In an efficiently competitive drug industry, advertising practices and other sales promotion strategies would be adapted so as to take advantage of the structure of information needs and the abilities of the individuals involved to absorb information, in order to minimize the costs of providing the necessary information. The fact that ethical drugs are ethical in the sense that they cannot be bought over the counter, but must be prescribed by physicians would seem to minimize the temptation to engage in advertising since advertising direct to consumers would not be productive of sales. Three characteristics of physicians are also important. They are highly trained at medical schools. They are on the average extremely busy--there are many demands upon their time. And on the average they are very prosperous, with income levels well above the median. Because of his interest and training, the physician is quite capable of appreciating and responding to purely informative technical and factual releases concerning drugs, and need not be enticed and cajoled into responding to the sort of purely persuasive advertising appeal to which so many physicians have publicly objected, and which Dr. Howe of this Committee has declared to be

insulting. (7j)[1]. Since doctors are busy, the time that they can spend in reading and evaluating information on drugs is limited. In brief, it is in the physician's interest in every way professionally, financially, and as a citizen--to keep well informed on developments in drugs. This can best be accomplished by disciplining the flow of information, making factual communications more concise, limiting purely promotional propaganda and superflous communication, and eliminating entirely the possibility of misinformation. Physicians should rely on completely unbiassed sources of information, and since they profit from the availability of good medications, should be expected to pay the costs of being supplied with adequate drug information. Through the purchase of official compendia and subscription to independent newsletters, the conscientious physician could keep abreast of at least the most important developments in his specialty with less time spent and more confidence in the quality of the information conveyed than is now the case.

Drug firms have defended their sales promotion outlays as "postgraduate medical education." But it is inescapable that commercial bias is the fundamental principle informing this "education", and such conditions should be recognized as insupportable. If drug information were provided by unbiassed sources, there would seem to be no purely economic or therapeutic reason for drug firms to incur any sales promotion outlays in connection with physicians as prescribing agents, as long as the firms refrained from engaging in mutually offsetting sales promotion campaigns designed to facilitate rivalry in the absence of price competition. How is adequate drug information to be provided by

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1 A rather different view was taken by the Canadian Pharmaceutical Manufacturers Association in their 1961 brief; there is no need to characterize it since it speaks for itself: "Visually, the so-called flamboyant pictorial style used in journal advertisements is not as unusual as it may appear to the uneducated eye. An advertisement to gain readership must be more than a box of black type. It must carry a pleasant layout of copy, and to a higher intellect such as a professional man this layout must be in extremely good taste." (emphasis supplied) (2i).

independent sources? Admittedly, official compendia are published infrequently and hence may not include the latest drugs. Even this may not be a drawback if, as has been suggested, new drugs typically owe their success more to skillful promotion than to true advantages in use. Independent newsletters may be more timely; one such publication, The Medical Letter is already in existence, published in the United States. It has been suggested that such a publication be undertaken under public auspices; such a recommendation was made in the Hall Commission report, and such a publication actually exists in the United Kingdom, where it is made available free of charge to the physician. The latter feature may be desirable in view of the deplorable performance of doctors in the United States, only about 15 per cent of whom bothered to subscribe to The Medical Letter.

No matter how the information service is financed, it will result in savings if it is combined with reforms to lower drug prices and eliminate the ability of drug firms to promote their products as extravagantly as is their custom. The costs of even an elaborate drug information reporting system, such as has been proposed where doctors would be obligated to relay information on adverse reactions to a central data centre, would surely fall far short of present levels of outlays on promotion. At present, drug firms subsidize the physician by providing him with information and propaganda, the bulk of which may be unwanted as well as in varying degrees biassed and misleading.[1] The cost of this sales promotion is naturally passed on to the drug user in higher prices. Hence the physician is subsidized at the cost of the patient, a subsidy not needed by the physician (since he could pass on

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[1] Many examples of misleading advertisements were unearthed during the Kefauver hearings. One of the best came from Upjohn. A circular, "Ulcerative Colitis," was mailed to physicians, featuring two full-page X-ray photos clearly designed to imply a dramatic recovery in a patient before and after the use of the advertised drug. Upon inquiry to the firm's medical director, it developed that the two X-rays were of entirely different persons with qualitatively different disease conditions, neither of whom had even been treated with the advertised drug. (9c).

his own costs of keeping well-informed in his fees charged), largely not wanted, and arguably not justified, since it represents a transfer of income in favor of a high-income group and at the expense of a group whose income is not only on the average lower, but whose ability to pay is reduced by precisely the circumstances responsible for seeking medical treatment: at least temporarily imparied earning ability, and increased expenses. If the physician assumes the costs of keeping himself informed, while these costs will be passed on to the patient, they will be much smaller in total amount than the thousand or more dollars per year per physician which drug firms are said to spend on marketing. If the information services are supplied at public expense, physicians and patients together will be subsidized by the taxpayer, which is at least a less objectionable arrangement than subsidy of physicians by drug buyers alone.

It is plausible to assume that some, perhaps many, of the drug firms themselves are discontented with competitive needs to mount expensive advertising campaigns in order to maintain market position. If these expenses were not made, profits would increase since the drug buyer would in general not have his bargaining power increased by the ceasation of advertising, and there would be no reason to reduce prices just because marketing costs had declined. It is therefore not surprising to learn from the PMAC Submission to this Committee that the member firms are unhappy with their high marketing and distribution costs, and are even interested in the development of an independent medium to disseminate drug information. In this area, perhaps, industry and reformist sentiment are approaching some reconciliation. The development of an independent information system would allow the virtual elimination of drug firm sales promotion budgets. But in itself it would not enforce such elimination. To the extent that it is the profitability of selling drugs at inflated prices which justified and motivates marketing outlays, reforms would be needed to institute genuine price competition which would eliminate excessive profit margins and thus eliminate both the

ability and the desire to engage in sales promotion rivalry. Even under actively competitive market arrangements, selling costs would probably not be reduced to zero, but if they were cut from 30 per cent of the sales dollar to about 3 per cent, then other things being equal, the sales price to the druggist would be cut by 27 per cent. If the druggist has a pricing policy which results in approximately doubling the manufacturer's price, the price to the drug buyer could be cut by the same 27 per cent. But the institution of price competition would be likely to cut profit margins as well, and force a reduction of excess capacity and its accompanying costs, together with reductions in the less productive areas of the research and development budgets. It is not possible to predict how large a reduction in prices may be compelled by drug reform, but the scope of such price cuts is not limited to the size of the sale promotion budget, the most frequent target of drug price criticisms.

It is, however, in the area of marketing activities that the most conspicuous wastes of the drug industry become apparent. Physicians justifiably complain about the great bulk of direct mail advertising. As Mr. Lawrence Wilson pointed out before this Committee, the most unfortunate result of deluging the doctor with attractively printed trivia is making it unlikely for him to be able to detect any valuable information which may be buried in the great mass of propaganda. (7k). Hence, the effect of redundant advertising in increasing drug prices may be less socially harmful than its side-effect of rendering more difficult the enlightened practice of medicine. According to the PMAC Submission, even if we accept the cost categorizations which the manufacturers' own spokesman has devised, sales promotion expenses accounted for 30 cents in the industry's sales dollar, as previously stated. The cost of research accounted for only about 6.7 cents; hence 4.5 times as much was spent on sales promotion as on research. Was this justified? under present market circumstances, certainly so. It is my view that executives in the drug industry, judging by the performance of those who have appeared before investigating committees

in Canada and the United States, are extremely shrewd and astute, and are superlatively capable of managing their firms in the interest of maximizing profits and the value of the stockholders' investments. Hence I take it that it is the experience of the industry that sales promotion is much more effective than research in producing profits--for every added dollar in sales revenue, 30 cents will be expended for sales promotion as compared with about 6.7 cents for research.[1]

There are several reasons for this. First, basic research will be relatively small in amount because of the external economies associated with it. Second, even applied research and product development are relatively unproductive except during the periods following major breakthroughs achieved in fundamental research, so it is not profitable to channel any very large share of available funds into this sort of activity. Third, and probably most important, sales promotion can substitute in large measure for both genuine price competition and for productive research. These points deserve considerable attention.

As was observed by several physicians during both the Canadian and United States hearings, a drug embodying a genuine advance in therapy advertises itself. If highly effective and thus of real value, physicians themselves rapidly spread the news. This was the experience with insulin, penicillin, cortisone, and the sulfa drugs. But, in the words of one of these physicians,

> "the more a drug has to be peddled, the more one begins to wonder why." (9e).

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[1] In view of these facts, one must admire the persistence of industry spokesmen in asserting that research costs are the reason for high drug prices. It is amusing to note that firms do not allocate the same share of their submissions to this committee to these two activities as they do in budgeting expenditures. In the PMAC brief, of a total of 92 pages of text, 11 were spent on research and 9 on marketing, which adds up to 5.5 times as much emphasis on research relative to marketing in the submission as in the budget. Cyanamid devoted 15 pages to research and 10 to marketing in an 80-page submission, or 23.3 times as much emphasis on research relative to the firm's ratio of expenditures on research to marketing costs. Cyanamid devoted 31% of its sales dollar to marketing and 2% to research.)

Dr. A. Dale Console, former medical director for Squibb, was most explicit about the relationship between unproductive research and the advertising budget:

> "advertising is called upon to make successes of research failures...The problem arises out of the fact that they market so many of their failures." (4q).

Almost any drug will sell, if promoted intensely enough, at least for a while. 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. The chief reason for the high turnover rate among drugs is, I suspect, to be explained along these lines: advertising alone can sell physicians on a drug, if intensive enough, but any number can play at the advertising game, especially when brand names can be used to obscure the relationship between or even the identical nature of nominally unique substances. The greater the accumulated experience with a given drug, however, the more likely it is that its untoward actions will become known. However, if the rate at which new products is introduced is as great as the rate at which publicity is given to the mischief caused by existing products, the sales of the new products will increase as that of the old products declines, so that the total cash flow need not suffer.[1]

On the other hand, as any businessman knows, advertising rivalry can substitute--perhaps entirely--for genuine price competition. Price competition is a good servant to the consumer, but a harsh master to the producer. Hence sellers tend to avoid it as much as possible under normal circumstances, and it generally prevails only where it is

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[1] In the United States, brand-name sellers had to be compelled by law to give proper prominence to generic names in advertising. But brand-name sellers do have their uses for generic names. A firm, for example, may advertise by brand name, but issue warnings under the generic name only. Pfizer and Wyeth adopted this opaque tactic for a triacetyloleandomycin warning. (9f).

forced upon them by the structure of the market: numerous small sellers, none dominant; no collusion; no barriers to entry of new firms or expansion of existing firms. Where sellers are fewer and larger; where barriers exist to entry by new firms; where legal devices exist to facilitate a community of interest in price and production policies--under these circumstances, the forces which compel producers to undertake active price competition will be so weakened that rival firms will attempt to maintain or enlarge their share of various product markets by raising costs instead of lowering prices.

Advertising is inherently less destabilizing an arrangement than price competition. Some segments of the market may be loyal to a given brand even in the absence of advertising; other segments can be induced to prescribe only by increasingly provocative sales appeals. In general, sales can be increased by increasing advertising coverage, attracting new buyers while retaining the old, and perhaps even reinforcing their allegiance to the product. In the case of price competition, however, even though there may be a substantial segment of the market which is not highly price-sensitive and would buy the product at relatively high prices, in order to attract additional and price-sensitive customers, the prices which all customers pay must be reduced. Under such conditions, the controlling considerations relate to the price sensitivity, or price elasticity, of the total market demand for the product, and the expected price elasticity of the net demand schedule which the prospective price-cutter estimates that he will face after all his rivals have consummated their reactions to his price reduction. Only if demand promises to be quite sensitive, or relatively elastic, in response to price reductions, will a particular rival feel justified in gambling on a price cut. Even so, one or two moderate price reductions will ordinarily be sufficient to traverse the region of sufficiently elastic demand and hence to exhaust the possibility of further consumer-benefitting price reductions by the rivals.

The major difference between the two strategies is therefore that price competition benefits consumers through lower prices and higher output, while it reduces the profit levels of producers to competitive

rates--an outcome consistent with maximum efficiency of resource allocation in an economy. But rivalry in extravagant marketing campaigns raises costs and prices, benefits advertising media at the expense of consumers, and possibly also at the expense of company profits, and keeps the total consumption of the products of the industry at relatively low levels. In fact, the effects on profits of the two strategies may be the same in the long run: initially high rates of return on investment serve as a stimulus to efforts to increase output and market share; price reductions will directly reduce profits to equilibrium competitive levels; increased advertising budgets, which are mutually offsetting in the same way as competitive price reductions, except that they do not reduce costs to consumers and increase quantities produced and consumed, may eventually reduce profits to no more than competitive levels. Hence, monopoly prices may not necessarily mean monopoly profits, but simply excessive sales promotion budgets. A monopolist does not always make monopoly profits--he does so only to the extent that he is efficient, and one of the great attractions of monopoly is that it reduces or largely eliminates the penalties which a competitive market imposes on inefficiency.

It should be noted in passing that while price competition benefits consumers and while advertising rivalry may benefit no one except to the extent that it attracts more resources into the advertising industry, it is not suggested that monopolistic rivals are motivated by the desire of private gain at the public expense, while competitive producers are motivated solely to serve society. The producers' motivations do not differ. Competition is always a competition in the hope of establishing a monopoly, but where the structure of the industry rules out the possibility of monopoly, the ambitions of competitors must fail of fulfillment. The task of public policy is to adapt market structures in such a way as to preserve the vigor of competition while securing the public against the dangers of monopoly power on the part of the too-successful competitor.

But in the marketing context of the drug industry, excessive sales promotion budgets serve still another important function, in addition to bolstering the market appeal of products of indifferent quality, and substituting for price competition: they create a major barrier to entry. In most industries where the market is shared by a relatively small group of non-competitive rivals, the number is kept small by virtue of the economies of large-scale production, such that the capital requirements for new entry into the industry on a sufficiently large scale to permit efficient low-cost mass production are in themselves a formidable barrier to entry. In drugs, the bulk powder of the active ingredient in unpatented drugs can often be obtained or produced at very low cost, and certain finished dosage forms can be prepared and sold at prices no more than about ten per cent as great as the prices which the major brand-name firms are able to impose. But the nature of the prescription drugs market is such that the availability of these lower-priced drugs must be brought to the attention of the prescribing physician. Here is a case where merely informative, as opposed to persuasive, advertising is needed. But the vast scale of advertising by the major firms tends by its very bulk to obscure the existence of informative price lists sent out by small firms who do little if any advertising.[1] Hence, the drug firms have created economies of large-scale marketing where none exist in production, and by this means have prevented the products of small lower-priced generic name sellers from coming to the attention of the physicians.

This is serious enough. But there is yet another way in which massive sales promotion puts the small firm at a disadvantage. Eventually, the existence of reasonably-priced drugs may come to the

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[1] Mr. Seymour Blackman of Premo Corporation testified during the Kefauver hearings that his firm had tried to market its products in competition with major firms, but the contest was an unequal one, since his modest sales promotion efforts attracted no more attention than might be given to "a spark in a vast conflagration" of advertising messages. (4k).

attention of the physician, and he may wonder how it is possible for a tiny firm to undersell a giant by perhaps a ten-to-one price ratio. Here is where the large firm has a great advantage. One reason why major firms spend so much on travelling salesmen (detailmen) is that their sales messages, unlike those contained in journal and direct mail advertising, are not communications of record.[1] The testimony given by several physicians and medical educators during drug industry hearings in North America leads one to suspect that one of the most indispensable functions of detailmen is their ability to disparage, with relative impunity, the quality of the products produced by small generic-name sellers. I say "with relative impunity" because disparagement of the quality of a competing product is considered illegal, not only under common law, but specifically under the Trade Mark Act in Canada and under Section 5 of the Federal Trade Commission Act in the United States, where "unfair methods of competition in commerce" are prohibited. This sort of activity could not be carried on as safely or effectively through the media, of communications of record. This may be one of the major reasons why major drug firms spend about as much on detailmen as on all other types of sales promotion combined. (6d).[2]

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1 During the Kefauver Hearings, Dr. Frederick Meyers of the University of California Medical School testified as follows regarding the names in which drug firms adapt sales promotion strategies to the opportunities offered by different media:

> "they conform to the minimum standard of the medium being used at the time. If a medical journal has a certain standard they will meet it, their detail men, their salesmen who are subject to no such discipline, will slide down a few notches, for example"

2 The disparagement, in general terms, of the quality of low-priced drugs is not, of course, limited to detailmen. High officials of major firms and trade associations have used investigatory hearings as a forum for disparagement efforts; the present Committee has been exposed to an unusually vivid account of the alleged shortcomings of so-called "copiers" and "counterfeiters", and at unusual length. But such efforts are probably most effective as between detailmen and individual physicians over a long period of time. The following instances are illustrative of the uses of disparagement:

(1) Dr. Solomon Garb testified before the Kefauver Subcommittee: "Although our students had been told by their teachers that generic names were preferable to brand names, in the first year of the project, a single session with a detailman apparently convinced about half the students that brand name prescriptions were better...In essence, they pointed out that products made by an unknown manufacturer may be impure, or of erratic potency..." (4m)

(2) Disparagement may be directed at one particular drug. Dr. Howe of this Committee stated that a detailman criticized the efficacy of a rival brand of penicillin relative to that of his own firm after having searched drug store prescription records to ascertain which brands Dr. Howe had prescribed. (7m)

If the physician can be induced to suspect the quality of all low-priced drugs, then the potential price competition which could develop in areas where drugs are unpatented is largely nullified. Not completely nullified, fortunately, since there are some areas in the drug market where better-informed purchasing agents buy from qualified sellers on a price basis. But the individual physician is vulnerable to having his confidence in low-priced drugs undermined by disparagement since he is not in a position personally to evaluate the quality of the drugs he prescribes. As in any case where the buyer lacks full information on the nature of the product at the time of purchase, selling efforts take on some of the aspects of a "confidence game" where the buyer is induced to take the seller's word that not only is his product satisfactory but far superior to those of his rivals. Naturally the past reputation of his firm is portrayed in a favorable light, while the unknown and hence allegedly dubious reputation of smaller sellers is hinted at. Since the technical details of producing safe and effective drugs are within the province of competence of both large and small sellers,[1] the "reputation"

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[1] In an effort to misdirect attention from generic names to brand names, the National Pharmaceutical Council in the United States published an educational booklet entitled "Twenty-Four Reasons why Prescription Brand Names are Important to You". Dr. Walter Modell, Professor at Cornell University Medical College and chairman of the Formulary Committee of the New York Hospital, gave his critique of the book:

"Everything in here is true. These are just a list, as I said, of truisms. Reliability does provide all of these things, but these are not secrets. Anyone who is conscientious can do this."

Contending that all the alleged superiorities of brand name drugs made by the larger firms over generic drugs sold by smaller firms were specious, Dr. Modell insisted that the capabilities claimed to be monopolized by brand name firms were in fact the common property not only of small firms as well as large, but even of well-trained individual pharmacists who might extemporaneously compound drugs. (4n).

to which the saleman refers is determined almost wholly by the impack of massive and long-term advertising and other sales promotion devices. Hence a low price in itself becomes associated in the physician's mind with low quality. Only an agency which is able to determine for itself the quality of the products of both high and low price sellers will become immune to disparagement efforts. This is the most important reason for insisting upon providing the Food and Drug Directorate with sufficient authority and funds to guarantee the quality of all drugs offered on the Canadian market.

Actually, there is very little reason to suppose that low price means low quality. Both brand and generic name drugs must meet official standards listed in authoritative compendia. Experts have testified that there is no therapeutic gain realized by producing to purity standards exceeding official standards. (4n). The products produced by brand and generic name manufacturers are subject to the same inspection procedures; each will be held to the same standards. A small producer is even more strongly motivated than a large producer to conform to requirements, since the impact of a given fine for violation will be much more serious to his finances. This danger should outweigh any financial advantages which might be realized by economizing on the content of the active ingredient or on quality control. Official standards will specify a certain range of tolerated fluctuation about stated potency, for example, 90 to 110 per cent. But the cost of the active ingredient in a given drug is typically only a small part of total cost, and the cost saved by orienting the production process to produce an average content of 90 per cent rather than 100 per cent stated label potency would only save a fraction of this small part of total cost; furthermore it would result in the production of a substantial number of violative drugs and would expose the firm to fines and other sanctions by the inspectors--which would clearly not justify the risk.

Nor is quality control so costly as to be a monopoly of the larger firms. One of the few differences in the defenses adopted by drug

firms in the Canadian and United States investigations is the relatively greater emphasis on quality control expressed at the Canadian hearings. Efforts to justify high drug prices by reference to the magnitude of research budgets are, to say the very least, overstated; but efforts to justify prices in terms of the cost of quality control border on the ludicrous. Admitting the difficulty of isolating quality control costs as distinct from general manufacturing costs (which raises the question as to why the firms are so interested in the distinction), the estimates of quality control costs as a per cent of the sales dollar in 1960 in Canada are given in the Green Book as ranging from 1.21 per cent to 4.2 per cent for samples of from 22 to 35 of the largest firms. (2j). For smaller, lower-priced firms the ratio would probably be somewhat higher, but would still not be a controlling factor in costs. Neither small nor large firms can dispense with quality control; the production of marketable products requires it. Yet large firms discuss their quality control programs in such a way as to suggest that (1) as a philanthropic gesture they are gratuitously undertaking to provide the public with quality-controlled drugs, while smaller firms need not do so; and (2) that quality control in the drug industry is different and superior in kind from quality control in other industries. Neither suggestion is valid. Once a firm decides to produce drugs and sell them in an inspected market, it becomes impossible to do without some means of quality control. During the fermentation of a batch of ingredients designed to produce antibiotics, constant quality control is a necessity, not in the interests of pampering the eventual drug buyer by over-insuring quality per se, but for the purpose of avoiding contamination and hence sustaining a loss on the entirety of the work in process. Furthermore, quality control is of more than passing importance in other industries as well. In the automobile industry, for example, the quality of moving parts produced subject to very close tolerances, such as crankshafts, is a matter of not inconsiderable importance to car buyers. Yet car makers do not feel compelled to justify

the prices of automobiles by constant reference to quality control costs; these costs are after all incurred in carrying out routine and mechanical processes which are largely taken for granted. That drug firms publicly celebrate their inability to take processes for granted may--or may not--be cause for reassurance.

Moreover, most small firms buy drugs in bulk form from large firms, and merely tablet and package the finished dosage forms. They may even simply package bulk tablets, or even merely put their label on unlabelled bottles of finished dosage forms. Pejorative comments by larger firms may often imply some criticism of their own bulk drugs or finished dosage forms, as sold by smaller firms.

Possibly the best argument why quality differences might be expected to exist between high priced and low priced drugs is the contention that the Food and Drug Directorate is underfinanced, understaffed, and unable to make sufficient inspections. It is in the interest of the higher-priced producers to overstate this case. It is also true that a shortage of inspectors implies insufficient inspection of the facilities and products of large as well as small producers. Hence the remedy to the problem of insufficient inspections is not to prohibit or discourage by propagandistic activities the sales of drugs at lower prices. This would merely increase the monopoly power of large firms in those few areas of the market in which price competition exists, and would accordingly increase that part of the profits of the large firms which constitutes monopoly returns. Furthermore, it would not remedy the insufficient scale of inspection of large firms.

The obvious remedy is to provide fully adequate inspection. It has been objected that this would cost too much. But the benefits are certain greatly to exceed any costs. I do not have available any data which would allow a cost-benefit analysis in the Canadian context, but the statistics relating to the United States indicate clearly the order of magnitude of prospective costs and benefits. In 1958, the net profits before taxes earned by the 22 largest drug firms in the United

States amounted to $562 million. Food and Drug Administration Commissioner Larrick estimated that it would take a budget increase of $3,418,000 to obtain adequate inspection. A reduction in drug prices sufficient to cut drug firm revenues by $7.121 million would of course cut before-tax profits by $7.121 million. With the tax rate at 52% at that time, this reduction in pre-tax profits would have cut tax receipts by $3.705 million. The net gain to the country would therefore have been the $7.121 million saved by the drug buyers, minus the $3.703 million in reduced tax receipts, or the needed $3.418 million. Thus, if adequate drug inspection could establish confidence in lower priced drugs to the degree that the resulting competition would lower major drug firm prices by enough to cut total profits by as little as 1.27 per cent before taxes (if total profits are about 20% of gross receipts, prices might be cut by as little as ¼ of one per cent), the savings realized would pay for the expanded enforcement program. In addition, the substantial benefits obtained from the elimination of inferior drugs would have to be included in appraising the value of an expanded enforcement program.

Further drawbacks of the practices of massive advertising and brand-name prescribing include the consequences of such additional confusing of market information which results in not only obscuring the low-priced drug alternatives from the physician's view, but also in making it more difficult for the physician to identify the full range of substitute medications available for treating a given disorder. Suitably devised (and advertised) generic names might provide some guide in identifying pharmacologically related compounds; heavily advertised brand names suggest no such relationship, and the limiting case of confusion would occur when the physician may serially prescribe two or more brand name versions of an identical substance because the brand-name disguise has deceived the physician as to the identical character of the drugs. (on economic grounds alone, I regard contentions that different firm's preparations of chemically identical compounds are therapeutically significantly different as overstated and without real merit. If there

are different ways in which to capsule form, for example, of a particular drug can be prepared which significantly affect the therapeutic potential of the drug in treating certain disorders, it is not to be expected that firm A will produce a dosage form which is adapted to treating disorder X, firm B will produce one which is adapted to disorder Y, and so on. Instead, to the extent that there are significant market potentials in treating each of these disorders, or forms of a given disorder, each firm will tend to produce all of the varieties of the dosage form preparation. Differences may exist, but they are likely to represent secondary or marginal product differentiations.)

That aspect of sales promotion which takes the form of the distribution of free samples benefits not only from having rival brands of the same drug being given different brand names, but also different colors and shapes. It is certainly enterprising of generic producers to duplicate the forms and colors of brand name drugs; other things being equal, it would increase the degree to which price competition might develop between different sellers of the same drug. While such duplicates might plausibly be called "copies", it is rather an unscrupulous use of language to call them "counterfeits" unless they illegally reproduce another firm's trademark or other uniquely distinguishing imprint on the dosage form itself.[1]

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[1] In this regard, it is rather amusing to observe that two types of public relations activities of major drug firms work rather at cross-purposes, and that this contradiction has apparently escaped detection by the co-ordinators of public relations strategies. On the one hand, disparagement--usually in general terms--is not limited to detailmen, but is engaged in by drug industry spokesmen from the vantage point of a variety of forums, and is directed against the quality of generic products. On the other hand, in order to create a sympathetic image of the large company as being persecuted by illegal competition, the danger of drug counterfeiting is repeatedly urged upon the public, and possibly the danger is exaggerated. Perhaps the intention is to confuse in the popular mind the image of the small firm as relatively unknown competitor, and as clandestine counterfeiter. Nevertheless, if one takes the trouble to pursue the implications of such pronouncements, it follows that one is safer to insist on generic drugs than upon brand name equivalents. Since counterfeiters would find it more profitable to produce ten-dollar bills than copper cents, it follows that the high-priced drugs of major firms would naturally be preferred subjects of counterfeiting, instead of the low priced generic drugs.

2. Costs Incurred by Distributors

In relation to profits and sales promotion outlays, distribution costs do not appear to be extremely high: the PMAC submission assigns a cost of 4.0 per cent of the sales dollar to distributing and warehousing costs. Naturally, not all of the distribution costs are included in this figure; only those distribution costs incurred by manufacturers are covered. Apparently the smaller firms rely more heavily upon wholesalers than the larger firms; nevertheless, no firm is said to rely entirely on its own facilities for all distribution of its products. Hence the 4.0 per cent of the manufacturer's sales dollar covers an unknown percentage of total industry distribution costs.

It is asserted that the large areal extent and low density of population in Canada necessarily means high distribution costs. While this is undoubtedly a factor, it is noteworthy that no attempts have been made by drug firms to make quantitative estimates of the influence of this factor on distribution costs. In the same general sense it is also asserted that the bilingual character of Canada tends to increase marketing costs. Again, while there is some point to this assertion, one is left in doubt as to the actual cost impact of this factor. Clearly, the mere facts that a country is large, thinly populated, and bilingual does not justify any and all levels whatsoever of marketing and distribution costs. It may justify some level of additional costs over, say, comparable costs in the United States, but no evidence beyond mere assertion has been provided.

a. Wholesale Distribution.

Distribution costs incurred by wholesalers cannot be estimated from available data, but it appears that net operating profits of drug wholesalers are not high, so that distribution costs would be closely related to the wholesaler's total revenues less cost of goods sold. For 1957, for example, drug wholesalers made a net profit of 1.45 per cent on sales, and ranked seventh among eleven types of wholesalers in regard to height of profit ratio on sales. While the profit ratio tells us nothing in the absence of data on turnover, the relatively low ranking compared with other retailers is probably

significant. (2k). Wholesalers spent only 0.14 per cent of total sales in advertising, and again ranked seventh of the eleven types of wholesalers in this regard. Little interest has been expressed in the efficiency of the performance of the drug wholesaler and this may indicate reasonable satisfaction with the performance provided. In an efficiently competitive drug industry, the wholesaler would receive an operating margin which would reflect the market value of the distribution services rendered. At present, for those drugs sold through wholesalers, the share of the wholesaler in the drug buyer's dollar would appear to be about eight and one-third per cent. Assuming that the suggested list price is $1.00, the price to the druggist will be 60 cents, and the price paid by the wholesaler will be 50 cents. But the prescription surveys of the Canadian Pharmaceutical Association show that the average prescription price represents a doubling of the druggist's cost, hence the prescription will be dispensed for $1.20, and only 10 cents of this is kept by the wholesaler.

Of all the businesses engaged in the drug industry, the wholesaler operates in the most competitive market, relatively speaking. Drug manufacturers have their markets protected by patents, trademarks, tariffs and dumping duties, sales promotion practices, fewness of numbers and large average size. Druggists have a protected 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. There are relatively many relatively small wholesalers, and no real barriers to entry. If unsatisfied with the performance of wholesalers, drug manufacturers can integrate forward and sell directly to retailers. Similarly, groups of retailers, or even larger individual 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. This is not to say that there cannot be inefficiencies in drug wholesaling, but one would expect to find fewer at this stage of the industry than at any other.

b. Retail Distribution

Efficient competition in the retail distribution of prescription drugs would require price competition among sellers. Pharmacies are inherently rather small-scale in nature, and although reasonably numerous in urban areas, monopoly problems might arise in isolated areas unless there are alternative sources of supply, such as might be provided by mail-order service. Capital requirements pose no major barrier to entry, but no other barriers should be present if performance is to be competitive. All sellers should act strictly independently in regard to pricing policies; no formal or informal arrangements which would facilitate uniformity of action on price policies should exist. No need for keeping excessive inventories should be present. Prescriptions should be written in such a way as to facilitate the ability of drug buyers to stimulate price competition among pharmacists. The requirement that prescriptions be written generically would serve both purposes. Public inspection of drug products should be adequate to insure the quality of all drugs on the market. No such practices as "coding" prescriptions should exist. There should be no barriers to the dissemination among buyers of information on the prescription drug prices of individual pharmacies. Buyers must be free to seek out the lowest-price seller, both for the original dispensing of a prescription, and for refills. Under these circumstances, prices would be reduced, inventory costs could be cut, the average quality of drugs improved, the efficiency of retail distribution of drugs increased, and the disadvantage under which the drug buyer presently labors could be greatly lessened.

Under the existing circumstances, the market disadvantage of the drug buyer is extreme. The physician acts as the purchasing agent for

the patient, but does not pay for the drug. Hence the physician is not motivated to prescribe the least costly preparation[1] (or even to become aware of price) except to the extent that he may prudently calculate that the lower the drug bill, the more certain the expeditious payment of his own fees. (It is even possible that the doctors who prescribe the more expensive drugs may be accorded the greater prestige.) The patient who is burdened with a high-priced brand name prescription has no alternative at present but to pay the full price, or fail to purchase the drug, and thus be deprived of the benefit of the medical advice for which he is charged. To reduce the impact of possible ignorance of or indifference to drug prices on the part of the physician, two approaches might be pursued. Firstly, dissemination of information on the typical cost of a course of treatment with different medications. This might be a regular feature in articles evaluating the relative advantages of different drugs which would appear in independent newsletters. Legislation might also be passed to require that all drug advertisements prominently feature suggested retail prices, but there are disadvantages since it would not be legal to require that these prices be actually charged, it might facilitate price stabilization, and it might induce sellers to quote relatively higher prices than they expected that the average retailer might charge. On the other hand, some guide to prices is perhaps better than none; and the physician who is sensitive to the economic health of his patients could perhaps become aware of the relationship between suggested list prices and actual patient charges at various pharmacies, and convey to his patients information on the relative

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1 Dr. J. W. Reid, a medical practitioner in Halifax, made the following statements during the Restrictive Trade Practices Commission hearings:

> "...if I knew what the cost of a drug was, I might not prescribe it...".

But then qualified his answer:

> "I must say that we do become familiar with the cost of a drug as time goes on, and it does cause us a little thought, perhaps, but it does not interfere with prescribing." (1b).

markups or "professional fees" of different pharmacies.[1] Secondly, direct action should also be taken to institute price competition and thus reduce the level of all drug prices, so that even non-price-conscious physicians would not run the risk of imposing economic burdens on patients by prescribing in ignorance of relative prices. Such actions would include eliminating all the various barriers which make it difficult for small, lower priced producers to compete in the market with large and higher priced sellers. These measures are discussed at length in Chapter III of this presentation.

Optimal economic efficiency in the dispensing of drugs would require that the mark-ups which the retailer places on drugs be determined by price competition among sellers.[2] Hence the mark-up should be at the minimum rate above cost which is consistent with the retailer's cost of distribution, including a competitively determined rate of return on an appropriate level of investment in inventories and other facilities. In general, the larger the volume of business of an individual seller, the smaller his investment per dollar of annual sales, and the lower the rate of necessary markup over cost. The druggist who lowers prices beneath the levels of his rivals may find that the resulting increase

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1 As a college professor, I am concerned in the only other market I know of which bears any resemblance to prescription drugs. Professors may be said to "prescribe" textbooks for their students. But students have certain alternatives not open to drug buyers, such as textbook sharing or the second-hand market. I am personally quite conscious of the cost of textbooks to students and try to minimize such costs by selecting lower-cost books, minimizing the number of required texts, and using paperbacks where possible. In one instance I succeeded in having the University purchase a number of copies of a reading book which was placed on reserve in the library for student use on the premises. At that time I was employed by one of the wealthiest universities in the United States in terms of endowment per student, and hence considered this arrangement not inappropriate.

2 Mr. Turnbull of the Canadian Pharmaceutical Association made the following statement to this Committee:

"I would respectfully suggest that each individual knows the value of his own service and places a monetary fee on that" (7kk).

In a truly competitive market, however, it is the market and not the seller himself which places an equilibrium price on the services rendered by the druggist.

in business volume reduces costs so as to more than justify the price reduction. If genuine competition exists, the method by which the markup is arrived at will be relatively unimportant, since competition will require that the amount of the markup be very nearly equal among competing sellers. Under imperfectly competitive circumstances, however, there are advantages in having a "professional fee" added to drug cost, rather than having the cost subject to a flat rate markup. If generic prescriptions are received, the flat rate markup induces the substitution of brand name equivalents for the specified generic drug, since the profit margin in applying the same markup to the higher cost good is greater. But if a "professional fee" is added to each order, regardless of the cost of the drug to the retailer, this bias disappears.

As to the actual status of price competition among retail druggists in Canada, it seems to be distinguished by its almost complete absence. The very last paragraph in the Green Book concludes:

> "It is, however, clear that there is virtually no price competition in the sale of ethical drug products at the retail level. Price competition among suppliers is the factor which is normally relied upon to control the prices charged by suppliers and to ensure that consumers can purchase at reasonable prices. In the case of ethical drugs, no such control exists." (2m).

Hence monopoly power at the manufacturing level is accompanied by lack of competition at the retail level to put the drug buyer at a double disadvantage. Structurally, however, the constitution of the retail market would seem to be much more conducive to price competition than that of the drug manufacturers. There are a large number of small pharmacies, and there are no purely economic barriers to entry such as would be posed by large capital investment requirements. What barriers do exist are apparently more in the nature of legal and, as it were, quasi-guild restrictions. In the last dozen or so years I have been largely engaged in studies of industrial organization and the public regulation of industry so as to restrain monopoly power and promote competition. As far as the United States is concerned, my attention has been continually drawn to certain of the activities of organizations of druggists which relate to eliminating, or at least minimizing the vigor of price competition on drug store products, including of course

prescription items. In spite of myself, I have been compelled to admire the persistence and single-mindedness of these groups in pursuing the goal of abolishing price competition on drug store sales. Other organizations of numerous small sellers have been less active and militant--such as those representing variety store, auto supply stores, department stores, and even retail food sellers. In fact, the organized druggists have carried much of the load for the other retailers; the role of the National Association of Retail Druggists in securing the passage of state and national so-called "fair trade" laws in the United States in the 1930's is notorious.[1]

Naturally, no seller enjoys price competition. But why druggists in the United States should be so much more active and successful in opposing it, when many other groups had as much or more to lose by it, and yet did not present the same highly organized united front against it, has persistently puzzled me. If there is an answer, I suspect that it is related to the attitudes cultivated among pharmacists by membership in their professional associations, particularly the notion that it is "unethical" to refer in any way to prices charged for prescription drugs.[2]

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[1] This can readily be verified by reference to any good textbook on industrial organization. For example: "But the gadfly of all the organized business-interest groups is commonly recognized as the National Association of Retail Druggists; the NARD has had more to do with the success of the fair trade movement than any other single organization." (17) "Moreover, well-organized dealers like druggists can use fair trade to increase their margins. Acting together using or threatening to use black lists or white lists, promising to push some products or threatening to put them under the counter, they can persuade manufacturers to set fair trade prices at levels which will increase the retain markup. The National Association of Retail Druggists have used fair trade as a weapon in its long campaign to assure its members of a markup of at least 50 per cent." (18).

[2] In 1959, a druggist in Toronto had displayed a sign which advertised prescriptions at ten per cent off. Four local druggists wrote the Ontario College of Pharmacy as follows:

> "We, the undersigned, feel very strongly about the ethics of this pharmacist and would like to have him remove the notorious streamer at once. We would like to have him follow the Code of Ethics as enunciated in the Ontario Pharmacy Act or cease to carry on in this disreputable conduct. We feel that this method of going business is not desirable and ask that the infringement committee convene at once to handle this situation." (2n).

Clearly, the lack of price competition among pharmacists is a major factor in the high cost of drugs, and it must be faced by this Committee. I do not hesitate to admit that while I admired the late Senator Kefauver for his effective challenge to drug industry abuses in the United States, I admire the Canadian investigations still more for their explicit consideration of the possible role of the druggist in influencing the high level of drug prices in Canada. It is clear that the investigators in the United States did not wish to provoke the opposition of the highly organized retail druggists--at least, not at the same time they were fighting the lobbying efforts of the drug makers. But the Report of the Restrictive Trade Practices Commission is quite explicit as to the fact of lack of price competition among druggists. (1c, 2o).

This lack of competition appears to be traditional, if for no other reason than the severe disadvantages the drug buyer suffers in the market. The father of modern economics, Adam Smith, noted in The Wealth of Nations, back in 1776, that "Apothecary's profit is become a bye-word, denoting something uncommonly extravagant." (19). And at that time, when the professions of physician and pharmacist had not yet been generally separated, the control of the prescriber-compounder-dispenser over the patient must have approached the absolute. Even when physicians and pharmacists became separate groups, the patient was still largely at the mercy of the pharmacist, who generally compounded the medicinals which he sold. In North America it was not until the early years of the nineteenth century that certain apothecary shops began to specialize in producing larger quantities of medicinals for sales to other apothecaries. This might have given rise to the possibility of some price competition between resellers of purchased medicinals, but there is no evidence of any sort of price competition until the advent of the "cut-rate" drug store in the 1880's, and even then the price competition referred to other drug store goods than prescriptions. (20). Hence, although the pharmacist might realize high profit margine on prescriptions during this era, these margins reflected not so much his inventory investment as a merchant, as it did his compounding skills and services as a professional

man. (The Adam Smith quotation above is followed by a section in which high unit profits are related among other things to the skills in practice of the apothecary.) Although the ratio of prescriptions compounded to prescriptions merely dispensed probably continued to decline slowly throughout the last hundred years or so, as the manufacture of drugs became increasingly widespread, it is only within the last decade or so that the ratio has become insignificantly low...five per cent or less (1d). The pharmacist's function has changed from that of active compounding to passive merchandising; many of his skills have become largely obsolete as a result of the "revolution" in the drug industry.

In less custom-oriented professions, or in a more competitive environment, the obsolescence of the pharmacist's unique function would have reduced his market importance and his remuneration. This had not happened in North America. But before enlarging upon the present situation and its implications, recall that a monopolist does not necessarily make monopoly profits. Nor does a group which wishes to legislate away or otherwise rule out price competition necessarily enjoy the hoped-for benefits of high earnings. It may be possible to maximize net profit per unit sold, but unless completely effective ways to prevent new entry into the market can be found, new firms will be attracted by the high unit profits which are protected by custom, law, or agreement. As new firms enter the market, average sales per firm decline, and an equilibrium may be reached where so many new sellers have been attracted into the industry that the decline in turnover has reduced profits on investment to no more than competitive levels. Only at this point will new entry cease.

In the United States, where resale price maintenance laws were enacted under the euphemism of "fair trade," the results have been largely disappointing to the sponsors, not only because of adverse decisions by some state courts, but because of an inability of druggists and others to limit entry and prevent turnover from declining. (21). This situation compels misallocation of resources since high unit margins mean

increased prices and reduced sales, but the low turnover per store means that each dealer typically has excess capacity; hence total investment is excessive relative to the amount of business being done. Lower prices would increase production and consumption, eliminate excess capacity, and result in rates of return on investment which are no smaller than previously earned. In the United States, drug stores, like other fair traders, have suffered from increased entry, although they have some advantage over other sellers in that state boards of pharmacy may be able to some extent to limit the number of pharmacists and hence the number of potential entrants into the market. Canada has wisely achieved the abolition of resale price maintenance, and one would expect price competition except perhaps in a few of the larger metropolitan areas. On the contrary, it appears that pharmacists are able to levy even higher charges for their services than can their counterparts in the United States. The conventional markup in both countries is 66 2/3 per cent over invoice cost, but the superimposition of a "professional fee" in Canada increases the retailer's unit margin. The imposition of this surcharge for higher-priced prescriptions, where imposed, is persuasive evidence of the ineffectiveness of price competition.

If this situation prevails even in the absence of resale price maintenance, the problem is deep-seated and the solution at best is likely to be a very long run matter. Education might help in developing a more enlightened attitude on the part of pharmacy schools, students, and control boards, but the basic problem is one of injecting price competition into drug retailing. Efforts to educate pharmacy control boards to the idea that it is unethical, not ethical, to discourage price competition and hence overcharge the sick, may or may not be successful. To the limited extent that such lower-cost outlets as hospitals and public agencies can be substituted for traditional outlets, the problem will be alleviated. However, a more satisfactory solution must await the adoption of the maximum practical liberalization

of the traditional restrictions limiting entry into drug retailing. This liberalization should be such as to constitute recognition that the traditional pharmacist's distinctive functions are being altered away from professional competence in compounding and toward skills in merchandising. This, more than anything else, would probably bring about new entry into the market by those who are not traditionally opposed to price competition. In many lines of trade, sellers were inefficient and distribution methods stagnant and unprogressive until competition developed from such sources as supermarkets and mail-order houses. Drug "supermarkets" are by their nature more suited to large urban centers, but the encouragement of mail-order pharmacy, where feasible, would do much to spur competition in more thinly settled areas where druggists may have local monopolies. (Needless to say, the obstacles in the way of achieving such reforms are formidable, but hopefully not prohibitive.)

B. Factors Influencing Demand for Prescription Drugs

It is the nature of demand for prescription drugs which makes the industry an inappropriate vehicle for the unregulated exercise of market power by sellers. Instead, the industry is regarded in every nation as a candidate for some degree of regulation in the public interest. Different shades of emphasis, however, are placed on regulation to insure the safety, quality, and reasonableness of price for the products sold. Basic to an understanding of the economics of the drug industry is the fact that prices have virtually no relationship to costs. This is a point which deserves considerable emphasis. It is of course contrary to the industry position.

It is broadly true to say that in any industry price is determined by the relationship of supply to demand. In a purely competitive market, price is determined by the relationship between the supply price of a good, defined as the cost of producing a given volume of output (where costs include a competitive rate of return on necessary investment) and the demand price which the market is willing to pay in order to purchase a given volume of output. As long as the determinants

of supply and demand are substantially independent of each other, there is no circularity involved. Supply price depends upon properly defined production costs, and the demand price depends upon the consumer's need for a product and upon his income level. The relatively small number of prospective consumers who are both wealthy and needy will constitute the highest demand-price segment of the total market demand, but this will typically account for only a small part of total demand in most industries. In order to market higher quantities, prices must be lowered, since the more numerous group of potential buyers have more moderate incomes and/or more moderate needs or desires for the product. Only at very low prices will those with low incomes and/or lesser degrees of interest in the product be actual purchasers in the market.

On the supply side, if the expected price is very low, only a small output will be forthcoming, since only the most efficient producers can make and sell goods profitably at a low supply price. As the expected price to be received by sellers increases, higher cost (less efficient, less favorably situated, or otherwise less advantageously constituted) producers will enter the market. Hence, in a competitive market, the demand price which the consumer[1] has to pay will continually decrease with increases in the rate of output and sales, while the supply price at which the newly-entering firm can profitably sell continually increases with increases in the rate of output and sales. Equilibrium is reached at that level of output where supply price is equal to demand price. In a competitive market of this type, the price is thus determined by an equality between (1) the demand price of the consumer who, while actually in the market, is least anxious to buy; and (2) the supply price of the firm which is least able to earn profits after covering its total costs, which include an allowance for the competitive

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[1] To be precise, the crucial demand price as output increases is the price at which the least interested consumer in the market at that level of output is just indifferent between buying the product and not buying it. To sell that rate of output, price has to decline to the point where the least interested buyer will purchase the last unit of output produced.

rate of return on capital invested. Hence the market price reflects, at the same time, what the good is worth to the buyer with least urgent wants, and what it costs the highest cost producer actually operating to make it. Under these circumstances, the buyer whose demands are urgent and whose income is high gets a great bargain, and sellers whose costs are very low (who are most efficient, for a variety of reasons) will make substantial profits. This system is economically optimally efficient in that the industry produces a given output at the lowest possible total cost. Why does the consumer with the most urgent demand pay no more than the consumer with the least urgent demand? Because the good is being sold in a purely competitive market; hence if there were any attempt to charge richer buyers higher prices and poorer buyers lower prices, there would be no obstacle to the poorer buyers reselling at only slightly higher prices to richer buyers. Arbitrage would soon establish a common equilibrium price. Only if there are barriers to such resale would richer buyers be compelled to pay higher prices. Such barriers are of course incompatible with a purely competitive market, but they do exist in other markets--for example, the market for medical services, where an indigent charity patient cannot resell his brain surgery to a wealthy patient. Where such barriers exist, different buyers may pay different prices for the same goods or services, even where the cost of supplying all buyers is the same. This amounts to price discrimination in the economic sense, and it results in an inefficient allocation of resources in that a given level of output may be sold, in the limiting case, at an absolute maximum total cost to buyers, the difference in receipts between the purely competitive market and the market with perfect price discrimination being equal to the monopoly profits realized by the seller. Such price discrimination seems to be practiced in the drug industry between, for example, antibiotics in human pharmaceuticals and in livestock feed supplements.

Another question arises. Why does the market have room for both efficient and inefficient firms? Why do not the efficient firms drive the inefficient out of business? Simply because the total market demand at the equilibrium price level happens to be great to be supplied

entirely by the most efficient firms. Hence the excess of total demand over the amounts which can be supplied by the lower-cost firms has to be supplied by firms with increasingly higher costs of production. This implies that the efficient scale of production for a lower-cost firm is small relative to the entire market. This is in fact one of the previously mentioned structural requirements for pure competition--that there be numerous relatively small firms. If economies of large scale production existed, such that one or a very few efficient firms could supply the entirety of market demand, then pure competition becomes impossible and the market devolves into a situation characterized, at one extreme, by monopoly, or more probably into a market conferring varying degrees of monopoly power on the sellers individually.

In the case of monopoly by a single producer, the structure of market demand is still the same as in pure competition, but now it is surveyed by a hypothetical single monopolist who regards it as his private preserve, to be cultivated without the necessity of sharing it with other sellers. Such might be the position of a patent monopolist producing a unique drug. The seller is now in a position to set the price and output jointly in such a way as to maximize his profits. The resulting price and output will depend largely upon the sensitivity of demand to the price level--the so-called elasticity of demand. If demand is very insensitive to the level of prices (very inelastic), prices will be very high and output relatively low. If demand is highly sensitive to price levels (highly elastic), price will be lower and output higher. Typically the monopolist will have a supply position determined by economies of large scale production, such that average production costs decline until output rates become high relative to total market demand. This is not necessarily the case, however, and if the optimum size of plant is small relative to the profit-maximizing output, as seems to be the case in the drug industry, the firm might build several moderate sized plants (or employ a large number of standard sized process facilities, like the fermentation vats used in antibiotics) or perhaps license his patented process to others to produce and/or sell,

maximizing his profits in terms of the royalty and other licensing conditions which he imposes.

In the case like this, and assuming the existence of the very inelastic demand which is typical of prescription drugs, while the market price of the least urgently necessitous individual, this price will nonetheless be absolutely quite high in view of the urgency of demand on the part of all buyers of drugs. What is in some ways even more important, the price will be greatly in excess of the average cost of production of the product, allowing an excessive profit margin to the seller. Resources are misallocated to the extent that prices are high, output is low, excess capacity therefore is likely to exist, and the profit received by the seller is much more than the minimum level necessary to elicit the supply of his productive services--in other words, greatly in excess of the supply price of his output in a competitive market.

Monopolists are notorious for charging "what the traffic will bear," which is just another way of saying that the full demand price is exacted. Naturally, as long as the act of purchase is voluntary, no one will literally pay more than what a good or service is ultimately worth to him. But under either pure competition or pure monopoly, or any other market structure where there is no price discrimination, market price paid by all is equal only to the full demand price paid by that buyer who, while actually making a purchase, is the least interested buyer for that good presently in the market. Under pure competition, output will generally be so great that the price paid is relatively low; under monopolistic circumstances, output will be restricted and the price paid will be relatively higher. Similarly, the chances of the typical buyer getting a large "free" or "surplus" increment of "use value" over and above the amount he paid for the purchase are much greater under pure competition than under monopoly. The chief difference, however, is the relationship between price and cost of production. Under pure competition, the price paid is equal to the full cost of production (including a competitive rate of return on investment) of the last producer whose output is required to satisfy

total market demand--hence the demand price is equal to the competitive supply cost. But under monopolistic circumstances, the price is equal to what the traffic will bear, and is often far above production cost.

Hence when the drug makers argue before public bodies like the present committee that the consumer is paying no more than the good is worth to him, the only appropriate response is: of course not! In the absence of compulsion, he simply could not be induced to pay more for anything than it is worth to him, no matter how great the monopoly power of the seller. The real question is: what is the relationship of price to cost of production? The greater the relative gap between price and cost of production, the less competitive, more monopolistic, and more inefficient in the allocation of resources, the market will be.

As mentioned above, in analyzing the demand for drugs, it must be kept in mind that income levels are of co-ordinate importance with physical needs. In any marketplace, money talks, and sellers mean business, not chivalry--which is as it should be at this stage, if resources are to be properly allocated. But this argument is compelling only where markets are competitive and demand is strictly voluntary. While demand for a drug is price-inelastic to the extent that the need for it is urgent, demand relative to the ability to pay, or the income-elasticity of demand, is often more important than price elasticity. This is especially true for low-income patients, and for those requiring constant medication for chronic disorders. It is well known that individuals with severe inflammatory diseases and low incomes sometimes do without food in order to buy drugs. (4p). Ideally, the total potential market for a drug or a group of related drugs is measured by the total need for medication on the part of all individuals afflicted by all the various disorders which are capable of being treated best by the drug or group of drugs. Economically, the total effective amounts demanded at the level of market price charged may fall short of total physical need in the case of individuals with low incomes and no access to public care. Equally importantly, effective demand may exceed ideal total physical need to the extent that individuals not suffering from those disorders for which the drug or

drugs are of use, may nevertheless be treated with them. For any given drug it then follows that the actual relevant market is comprised of the total effective demand for medication on the part of all individuals who can be induced to consult physicians, and who are afflicted by those disorders for which doctors may be inclined or persuaded to prescribe the particular drug. It is with the matter of persuading the physician to prescribe, of course, that sales promotion executives are constantly preoccupied.

Changes in the effective demand (i.e., prescriptions written and purchased as written) for individual drugs are brought about by direct mail advertising, medical journal advertising, the bestowing of free samples, the purchase of exhibit space at conventions, the financing of symposia, and the incessant insistence of detailmen. While advertising cannot manipulate the total incidence of disease, it can shift effective demand from one drug to another, within, or even among, differing drug groups. (In a sense, certain types of advertising can create demand. Articles planted in newspapers or magazines may mention the name of a drug which is alleged to be efficacious in treating a given condition, and thus make more people who suffer, or imagine that they suffer, from such conditions aware that drug therapy can be purchased.) Two of the greatest drawbacks of sales promotion in drugs stem from these characteristics of demand. First, physicians may be oversold on a drug because of intensive advertising, minimization of data on adverse reactions and maximizations of claims, such that it is prescribed entirely too widely, often for minor disorders where it can do no good, and may cause positive harm. Antibiotics are usually cited in this context. But other drugs may be overused and it is particularly serious when the drug is given for chronic, rather than acute, condition. Mr. Mark Nickerson, Professor at the University of Manitoba Medical School, estimated that the sales of adrenal steroids in Canada and the United States was about $250,000,000, and commented,

> "...personally I feel that I am being very liberal when I say that fifty million of that was needed." (1e).

Second, and closely related to the first drawback, is that patients themselves often insist on unnecessary drug administration. Dr. J. P.

Gemmell of the University of Manitoba Medical School commented on the seriousness of this phenomenon, concluding that:

> "I almost feel the public has transferred its belief in doctors to its belief in drugs." (1f).

This may have serious consequences for the medical profession. Dr. Walter Modell of Cornell University Medical School predicted that if an aimless proliferation of mediocre and possibly dangerous drugs continued to flood the market with adverse results on the quality of medical practice, then when the public lost its faith in drugs it would also lose its faith in doctors, and during the ensuing phase of "therapeutic nihilism" would desert allopathic physicians in favor of non-chemotherapeutic healers. (9g).

When markets are imperfectly competitive the question of income redistribution assumes a degree of importance perhaps co-ordinate with that of resource allocation. Under pure competition only the necessary costs of production are being financed by purchasers' funds, plus profits which go to producers in proportion to their efficiency, and can therefore be regarded as a direct reward for efficiency and an indecement for further efficiency. At least this puts funds in the hands of the most efficient producers who might be expected to invest these funds in the most productive channels. But where there is no discipline on the level of costs, and where monopoly profits are large in sum, income is being transferred from consumers to managers and stockholders. If managers make inefficient use of these funds, a levy is being exacted from consumers to subsidize inefficiency. And the sort of income redistribution which is incident to a transfer of income from consumers to stockholders depends chiefly upon the incomes of consumers; it can safely be assumed that the incomes of stockholders are on the average well above the median. If the good sold is an expensive luxury, the degree of income redistribution is perhaps not too pronounced. But if the good is a very expensive necessity, it is likely that the average income levels of buyers is comparable to that of the general population, and that the relative impact on the budget of such purchases becomes increasingly severe as income levels of buyer decline. Hence there may be an increase in the inequality of

the income distribution which is not compensated for in terms of allocating more investable funds into the hands of the more efficient firms.

Even in an efficiently competitive market, however, the incidence of the costs and benefits of privately financed individual health care would be characterized by "external economies" of the type which was discussed in connection with basic research. Let us contrast the cost and benefits from public health measures with those associated with private health care. The costs of the former are very largely by taxes. Here, the general tax paying public has, according to the incidence of taxation of the people, borne the cost of measures which benefit the entire public. The costs of the latter, if borne entirely by the afflicted individual, involve an external diseconomy to the individual, and an external economy to the society. A person who pays the costs of combatting his own illness has not only conferred a "negative benefit" upon himself in the form of the avoidance of further suffering, but has also benefitted society by eliminating the danger of its being exposed, perhaps, to contagion, and also by restoring his own productive services to the uses of society in co-operative production. When this argument is combined with the unexpected, involuntary, and uncertain impact of drug and other health care costs, it reinforces in a sense the case for private health insurance. But it may also be used to justify some undeterminable degree of public subsidy of the indigent through limited public health insurance programs. This is not to say that the monetary value of the excess of social benefits over private costs in the private health care sphere can be measured, and this total excess in dollar terms allocated to subsidizing insurance for the poor, but it does provide a basis for arguing that such activities bring public as well as private benefits. The use of the above perspective enables the point to be made more emphatically; to the extent that external economies result from private assumption of personal health care burdens, there are external diseconomies to the individual who seeks adequate care; but to the indigent person who hopes to get by with foregoing care, it is

paradoxically an external economy. If he endures a prolonged contagious illness and infects others, he has borne only part of the total social cost of his illness, the rest of which has been shared by the persons infected.

An illuminating contrast may be developed by comparing the relative effects on the distribution of income of (a) medical practioner fees, and (b) drug costs, if we assume (1) that these costs are covered by private health insurance, and (2) that these costs are borne entirely by the patient personally.

If the patient is covered by a comprehensive health insurance policy, the costs of both physician fee and drugs will be shared between the patient and all of the insured on the basis of premiums paid. Under ideally comprehensive insurance (including payments for incomes foregone, as well as costs incurred, through illness) the patient would pay no more per year whether sick or well, hence he would be truly insuring himself, paying a relatively small but certain charge in order to avoid the danger of an uncertain but possibly quite large expense. The costs of sickness would be borne by the insured individuals in proportion to the ratio between premiums paid and total incomes. The total incidence would probably be somewhat regressive, in that the premium would represent a larger share of a low income than a high income. But the regressivity would be milder than in the case where a poor but uninsured individual becomes sick and incurs medical expenses in excess of his premium if insured.

If the patient is not insured, however, the impact of medical fees and drug costs, for a representative cross-section of patients, will show a widely different incidence. Let us first consider the impact of physician fees on the income distribution of patients.

In the course of doing research on two papers regarding the economic determinants of the spatial distribution of physicians in the United States (22, 23) I came to no firm conclusion regarding the extent of the time-honored practice of the physician of "tempering the wind to the shorn lamb" by charging relatively lower fees to poor patients

and recouping them through relatively higher fees to affluent patients. My impression, however, is that it remains an appreciable factor in the United States, but I admit that I have no evidence for Canada and hence no basis for assuming that Canadian practices differ from, or resemble those in the United States. To the extent that doctors follow this practice, they do indeed exert a Robin Hood influence on the distribution of income, transferring the incidence of relative expenditures from the poor to the rich. What is often overlooked, however, is that the medical Robin Hood must of necessity confine his activities largely to the sick; hence it is as if this Robin Hood were robbing the hospitals of the wealthy in order to distribute his largess among the inmates of the hospitals of the poor. But illness can be a burden even on the wealthy, and this sort of redistribution of income, while it takes from the rich and gives to the poor, takes entirely from those of the wealthy who are least able to afford it. Presumably a modern day Robin Hood would still be solicitous of the hospitals of the poor, but he would be more likely to rob the country clubs.

If, however, the private individual must bear the burden of drug expenses, then the direction of the Robin Hood effect is reversed. The rich and the poor pay the same price, and while the physician presumably realizes no net gain from undercharging the poor and recouping from the rich, the drug firm makes monopoly profits from all classes of buyers, wealthy to indigent. (I have seen no statistics on the value of drugs given by drug firms to charities which would persuade me that this amount is other than insignificant. Free samples may be used to an undetermined degree as starter doses, such that by preventing the sale of a few capsules it is stimulating the sale of several times as many.) Hence income is drained away from those who might well be the relatively poorest members of each income class--from the poorest of the rich as well as the poorest of the poor--and into the hands of drug firm stockholders, the average member of which group should be well able to provide for himself, thanks in large measure to the phenomenal rise in drug stocks brought about by the miracle drug

revolution of the past twenty years.

These points are worth making, even at the expense of some repetition, because of the almost complete neglect of these issues, particularly by drug industry spokesmen. Even if there were no private health insurance, the drug buyer purchasing from a purely competitive drug industry would pay chiefly for the cost of producing the drugs he uses. From an imperfectly competitive industry, the buyer is financing not only the comparatively small level of drug production costs, but large outlays on marketing and large profits before and after taxes. He is also financing a small amount of research. Drug spokesmen have defended the price of drugs by reference to research costs thousands of times, but to the best of my knowledge have never once raised the question of the propriety of having these costs financed entirely by the sick. To the extent that such expenditures are wasteful, they should not be financed at all; but in proportion as they benefit the general public, the justification for financing them solely out of the funds of the currently ill becomes increasingly questionable, especially in view of the unequal incidence of illness between and among age and income groups. Admittedly, this over-simplifies the problem; furthermore, its identification is not tantamount to its solution. Nevertheless it is a real problem and is a serious one.

C. Market Price as Resulting from Interaction of Supply and Demand

What does the above description of the nature of supply and demand imply for the pricing policy of the firm? A purely monopolistic seller could set prices in such a way as to maximize profits, but since the price chosen depends upon an estimate of demand, it is possible that the monopolist may either underestimate or overestimate demand. When Lederle began in December 1948 to market the drug chlortetracycline (under the more euphonious name "Aureomycin") it was in a limited sense a monopolist since this drug had in respects a broader range of activity than penicillin, and hence was the first so-called "broad spectrum" antibiotic. It was originally priced in the

United States at $15 for a bottle of sixteen 250 milligram capsules, which at the traditional markup of 66 2/3 per cent would bring the price to the patient up to a handsome $25. Now, the introduction of this drug had been preceded by a very costly sales promotion campaign, including the distribution of a controversial $2 million in free samples. (Lederle disputes this sum and maintains that the amount was closer to $200 thousand. Perhaps the lower figure is the cost, and the higher figure the sales price, for the same amount of drugs.) One can only infer that Lederle fully intended to achieve mass market sales, and had certainly made careful price and cost calculations accordingly.

But Lederle must have miscalculated; the price of $15 must have been above the profit-maximizing level, for in February 1949 the price was reduced to $10. ($16.67 to the consumer.) In March 1949, Parke-Davis introduced a competitive broad spectrum antibiotic, chloramphenicol, the so-called "Chloromycetin." This qualified Lederle's monopoly of the broad spectrum market, since the two drugs were in many applications capable of being substituted. In a purely competitive market, chloramphenicol would have been priced in relation to its cost, probably at a level much closer to $1 than $10. And if there had been even a scintilla of price competition, Parke-Davis would have priced its drug at no more than, say, $9.95. Instead, it chose to match Lederle's price of $10 to the very cent.

However, the broad spectrum antibiotics do not stand by themselves as unique entities. Penicillin actually has a broad spectrum of activity itself, and it might have been more appropriate to term the other drugs "broader spectrum" antibiotics. When chlortetracycline first appeared on the market, 10 million units of penicillin in bulk cost $9.50. By early 1950, competitive reductions in its price had reduced the cost to $4.75--a drop of 50 per cent in one year. The reason for the decline in the price of penicillin is simply that it was not subject to patent monopoly control, and its production increased rapidly as many firms entered the market, the resulting increase in supply relative to demand causing prices to decline

correspondingly. By February 1950, Lederle and Parke-Davis both reduced their broad-spectrum prices by the same amount, from $10 to $8. This may have been in response to the price decline in penicillin; if so, had there not been an unpatented, competitively priced antibiotic, this price reduction might never have been made. At any rate, it is indicative of the oligopolistic practice of price leadership that both firms cut prices by the same amount and at the same time. Neither went to $7.95, for example.

In April of 1950, Pfizer entered the market with another broad spectrum contestant, oxytetracycline, which it priced at a 5 per cent differential with regard to the prices of the other drugs. But not five per cent below; no, five per cent above, at $8.40. Still, after Pfizer's entry, price competition may for once have developed. In May of 1950, Lederle and Parke-Davis cut prices from $8 to $6, Pfizer failing to match the price cut until November. By September of 1951, the price of 10 million units of penicillin had fallen still further, from $4.75 to $3.75, a decline of 21.1 per cent. Pfizer cut the price of oxytetracycline then from $6.00 to $5.10, a reduction of 15%. This time it was the other two firms who failed to match the price cut until November, 1951. Neither undercut Pfizer. Between November 1951 and August 1960, six nominally different broad spectrum antibiotics found their way to the market. Five of these were different brand names for the same substance, tetracycline. The sixth, demethylchlortetracycline, was a marginally different compound. Each seller predictably placed his product on the market at the identical price of $5.10, even though demethylchlortetracycline contained 150 milligrams of the active substance instead of 250. Finally, after almost nine years of identical prices, Pfizer reduced priced to $4.35, a 15 per cent cut. This move was widely interpreted as a bit of political strategy, since it came only one month before the industry was scheduled to testify before the Kefauver Subcommittee on its antibiotics pricing and other policies. During the nine-year period of price rigidity in the broad spectrum field, the price of penicillin had fallen by no less than 92 per cent--from $2.50 to $.21 for 10 million

units. It is reasonable to suppose that during this period the costs of producing broad spectrum antibiotics declined by approximately as much as the cost of penicillin, the production methods employed being largely similar. (5d). In fact. the costs of chloramphenicol probably declined by even more, since the patent holder discovered a way of making the drug synthetically. A comparison of the price decline of 90 per cent in penicillin during 1951-1960 with the rigid price level for broad spectrum antibiotics measures the effect of patent protection, restriction of entry, and lack of true price competition in the latter market.

Drug industry spokesmen assert that their pricing practices result in declining levels over a period of time, with very few increases. That this is the case supports the hypothesis that monopolistic, rather than competitive, pricing is the rule in drugs. The price of a new drug is initially set at the profit maximizing level, and this price is typically precisely matched by large firms producing patented therapeutic equivalents. Prices of patented drugs may decline when the prices of unpatented substitutes fall, or when producers not yoked by patent restrictions are allowed to compete in the market. But the fact that most drug prices have held constant, or even declined moderately in the face of rising cost trends is apparently a source of pride to drug firms. If anything, it merely indicates the degree to which their prices are insulated from competitive forces. A purely competitive firm would be compelled to raise its prices each time its costs increased, since its profit margins are always at minimum acceptable levels. That drug prices have held constant or have declined during a period of increasing costs suggests that while early profit levels may have been exorbitant, subsequent profits may have been merely excessive, and still later profits are certainly not below competitive levels, or else prices would have been increased.

Other examples of the inherently non-competitive nature of drug pricing can be given. When the first oral antidiabetic drug, tolbutamide, was introduced in the United States market, the price was set at the same level as that of insulin, despite the fact that it was

almost certainly much cheaper to produce tolbutamide than to obtain and process the animal pancreas from which insulin is extracted. (5e). Also, cost reductions have been achieved without any of the cost savings being passed on to the consumer. In 1952 the Upjohn Company discovered a much cheaper microbiological process for producing corticosteroid hormones, but Upjohn continued to charge the same prices as those listed by its rivals, some of whom were producing by the more costly process. (5f). When Parke-Davis discovered a cheaper synthetic method for producing chloramphenicol, it failed to reduce its prices below those of its rivals. Other examples could easily be given.

Since prices bear almost no relationship to costs, the argument that high prices are temporarily necessary in order to recoup research costs for new drugs is suspected. The firm will price so as to obtain the highest price consistent with profit maximization for each drug; the fact that some hypothetical method of research cost allocation should indicate that all research costs had been recouped by January 1, 1967, would not under any circumstances in itself lead to a reduction in price. Price declines might result from reductions in demand, but not, apparently, from reductions in actual process outlay costs, and certainly not for expirations of arbitrary cost allocations. In any event, firms do not specifically allocate research overhead to individual drugs, so the entire argument is without any substance. And even if prices were lowered when allocated research costs had been recouped, the reduction--while welcome--would not be very great since the ratio of research costs to the sales price is so low. Research costs are probably recouped in a time period closer to seventeen months than to the seventeen years of patent protection.

CHAPTER III

The Influence of the Legal and Regulatory Framework on Canadian Drug Prices

Why is the level of Canadian drug prices apparently the highest in the world? Since drug pricing is based chiefly on demand, applying the rule of "what the traffic will bear" would to a first approximation suggest that drug prices would be highest in those countries where per capita income is the highest. And this impression is confirmed by the PMAC's otherwise rather pointless demonstration of the ratio between hourly wage rates and drug prices in various countries. The higher the income, the greater is the demand and the higher the price that can be exacted. Wage rates serve to indicate indirectly the level of per capita income. But since per capita income is still somewhat lower in Canada than in the United Stated, this factor alone would not explain higher Canadian prices. While prices are basically related to demand, from one country to another, other factors are also important and will have to be considered.

Let us begin by considering a North American-based company which possesses product patent control on some drug which it wishes to produce and sell internationally. It will attempt to estimate demand in each country and set prices accordingly. High incomes mean high ability to pay, but the presence or absence of rival producers and competitive products will qualify the firm's ability to discriminate in price solely on the basis of relative per capita income. Factors which influence the policy adopted by a single producer with respect to possible rivals (or even price competitors) are as follows: presence or absence of process and product patents in the foreign country; tariffs, quotas, or other impediments to free foreign trade; presence or absence of price controls on drugs; the status of the existing drug industry in a given country, and similar factors. Of these, by far the most important is patent policy, since it will most directly influence the ability of different companies in different countries to compete with a product for which shipping charges, owing to small bulk, are very low, and where manufacturing costs are so low relative to price that customs duties ordinarily would not act as a major deterrent to drug imports.

A company may decide to produce all of its output of a drug domestically and simply sell the finished product in foreign countries, perhaps at price levels much lower than those charged in the very city of manufacture. Or it may pay to establish factories abroad, not necessarily because the wage rate is lower abroad (productivity per hour may also be lower; besides, wages are only a minor part of costs) but because there may be a higher tariff on imported finished drugs than imported raw bulk drugs, and the cost of converting the powder to finished dosage forms may be less than the difference in applicable tariff rates. There is probably little point in the contention that drugs can be sold at lower prices in some foreign countries because production costs are lower abroad. Production may not even be undertaken in the country; if it is, the costs when adjusted for productivity differences may be higher than in the home country. The basic reason for lower prices in such countries is simply lower per capita income; lower wage rates cause low prices by reflecting low incomes, not low production costs.

In Canada there are five major elements in the legal framework which influence the level of drug prices directly and indirectly:

A. the patent and trademark laws

B. tariffs and anti-dumping laws

C. the federal sales tax

D. the Food and Drug laws and

E. legal sanction for the practice of brand-name prescribing.

Each of these elements will be discussed below.

A. The effects on drug prices of the patent and trademark laws.

Drug buyers in Canada are fortunate in that (1) drug product patents may not be obtained independently of process patents, and (2) drug patents are subject to compulsory licensing under normal circumstances. In contrast, patent protection is absolute in the United States. Why, then, have Canadian drug prices remained at higher levels than those charged in the United Stated?

There are four respects in which the present state of Canadian patent law contributes to high drug prices. First, relatively few applications have been made for compulsory licenses, and none of the firms which have been granted licenses have been truly major factors in the international or even domestic drug industry. Second, applications for licenses to import have been refused. Third, since the products of firms selling under compulsory license are usually marketed under generic names, or under little-advertised brand names, the burden of securing a market in competition with the highly promoted brands of major firms, taken in conjunction with the habit of brand-name prescribing, and the disparagement activities of major firms against generic name drugs, puts even the successful applicant for a compulsory license in at best an inferior position in the market. He may undercut his rivals by selling at prices only a tenth as high as theirs, and yet not be able to gain even a tenth of the market. Such an outcome would be unthinkable in any sort of competitive market, and must be attributed to sales promotion and prescribing practices, which are supported by patent exclusivity. Fourth, if a firm produces or imports a drug which is covered by a Canadian process patent, the burden of proof is on the producer or importer to show that the drug was produced by a non-infringing process, and costly and vexatious legal problems abound here.

1. Paucity of Applications for Compulsory Licenses

The first of these reasons is probably the most important. If major firms were awarded compulsory licenses to produce drugs patented by their rivals, the number of major sellers with brand names acceptable to physicians would increase, and the likelihood of price competition would similarly increase. If Parke-Davis were awarded a compulsory license on a Pfizer drug patent, Pfizer, however, would be most likely to retaliate by demanding to be licensed under a Parke-Davis patent for some other drug, and the number of drugs being sold by many major firms would increase rapidly, with price competition becoming increasingly likely. The major firms, however, are well aware of this, and since the Canadian market is only a small part of the total world

market of most of these firms, they hesitate to take actions which might at best increase sales in only perhaps five or ten per cent of their total market, which might eventuate in profit-destroying price competition in Canada, and which would also make for hard feelings among the companies in other markets and disrupt the community of interest in world market stability. It is instructive that compulsory licenses have been obtained chiefly by wholly Canadian firms. If, however, the entire North American market were thrown open to compulsory licensing, the profit prospects of obtaining a license to market a rival's product in a market as large as that of the United States and Canada combined would very likely be too great a temptation for the major international firms to resist. This is particularly true as between the United States and Canada, since journal advertising in the United States would also be read in Canada to a considerable extent. Hence, the adoption of compulsory licensing in the United States would be of very great benefit to Canada.

Unfortunately, this is not likely to happen, The best solution would then seem to lie in the area of enabling those presently price-competitive elements of the Canadian drug market--chiefly the small, Canadian-owned firms--to be able to compete more effectively with the major foreign patent-holding firms. Measures should also be taken to induce new entry by price competitors. If about 90 per cent of the Canadian drug industry is presently controlled by firms which do not choose to take advantage of compulsory licensing, then steps should be taken to increase the viability of the existing competitive segment of the market, and to introduce new competition, if necessary from abroad, in the interest of lowering Canadian drug prices.

2. Failure to Grant Licenses to Import

Second, the failure to grant compulsory licenses to import prevents Canadians from being able to buy foreign drugs at low prices. The reluctance to grant licenses soley for importing is probably due

to the notion that Canada would gain more by having drugs produced domestically than by being able to buy drugs more cheaply. Naturally this is contrary to the principles of international trade and the theory of comparative advantage. But such theories do not impress practical men, who would rather explore the costs and benefits expected from adopting alternative policies. Accordingly, if Canadian drug prices could eventually be cut by 50 per cent, which is by no means impossible, consumers would realize annual savings of about 100 million dollars, even at present rates of consumption. In contrast to this, the industry only employs about 10,000 people in Canada; the industry would by no means be destroyed by a 50 per cent price decline, since costs can be cut by more than 50 per cent; and even if drug industry employment were to decline, it is overly pessimistic to assume that those who become umemployed could not find other, and probably more productive jobs. Above and beyond this, a practical man might have doubts about the extent to which a foreign-owned captial-intensive industry is an unequivocal asset to a country.

As regards employment, wages and salaries paid by drug firms represent only about 30 per cent of the value of output, while in most industries it is closer to 70 per cent. As comparing two domestically owned industries, the ratio of wages to value of product is not too significant, particularly if the industries are competitive, since the addition to total national productivity of a dollar of wages would be about the same as that of a dollar of rent, interest, or profits. But in a monopolistic industry profits (and hence dividends and retained earnings) may be inflated relative to wages. And if the industry is foreign-owned, the dividends will be withdrawn from the direct stream of spending within Canada. To the extent that earnings are retained and reinvested in the industry, the effect is but little different, since foreign claims on Canadian-based facilities are increased, and the basis for the future earning, and possible repatriation, of profits and dividends is increased.

The practical man may argue that the real danger lies in the monopolistic nature of the industry, and not in the fact that it is foreign-owned--after all, dividends received by foreign stockholders may be spent in buying Canadian exported goods. True. However, this is a return to the theory of comparative advantage--scorned by practical men--and it is inconsistent to argue that, on the one hand, Canadians benefit by paying high prices for drugs since this allows some domestic production of drugs, and on the other hand to maintain that the dividends exported by foreign-owned drug plants do not penalize the Canadian economy since they probably lead to increased demand for Canadian exports by stockholders. In one case, only the direct effect of a single aspect of the matter--wages received by Canadians employed in foreign-owned drug plants--is appraised; in the other case there is an appeal to consider both the direct and indirect effects of dividends sent out of the country. Of course it is preferable to analyze both the direct and indirect effects of all aspects of a situation. In general international monopoly, like any monopoly, is a burden on the world economy, although the incidence of this burden may vary from country to country. But there is no general presumption that investment in foreign subsidiaries per se is necessarily a net burden or net benefit to the economies of any of the countries concerned.

The point should be stressed, however, that the chief beneficiary of the patent monopoly is the stockholder. The price of anything of value is determined by supply and demand. If supply is short relative to demand, price goes up. When a drug firm gets a patent on a profitable new drug, its expenditures on research, on marketing, and on production will go up. So will its profits. But while the existence of a profitable drug industry provides for the employment of many research scientists, salesmen, production workers, and even management executives, the wages and salaries earned by these men will not be increased by the profitability of the new product. They are members of competing groups, competing against each other for employment in drugs and in other industries. If the drug firm's demand for research workers increases, the increase in their wages will be

limited by the extent to which research workers are willing to leave other industries and work in drugs, and also by the extent to which students are motivated to enter research training in the prospect of good job opportunities. If there were only a dozen or so qualified research workers in the drug industry, they would have a sort of monopoly on research ability and could demand higher salaries as the profits of drug firms went up. But since the number is large relative to the demand, competition among research workers for job opportunities in drugs will keep drug research wages from rising above the level of such wages in similar occupations in industry as a whole. Furthermore, the fact that high earnings today stimulates training and increases supply in the future tends to limit the increase in research salaries, even if total employment opportunities continually expand. The same is true of drug firm executives; if a company president demands a salary increase because of the increased profitability of the firm, he can always be replaced by an executive of comparable ability, recruited from another industry if need be. But the patent creates an artificial scarcity of the capacity to derive benefit from the invention, and this capacity is vested entirely in the ownership of the patent by the stockholders of the firm. The surplus of drug revenues over the corresponding costs of obtaining drug labor, and materials and research, and sales, and management services at competitive market prices and salaries, is reaped entirely by existing stockholders as the return to the truly "scarce" factor in drug production. Hence the most striking thing about the drug industry is the vast increase in the market value of the stocks of the most successful companies, such as Smith Kline and French. There has been no corresponding fantastic increase in production worker wages or management salaries. Hence the country of residence of the stockholders of a drug firm will always be a factor of some importance in estimating the international incidence of drug industry prosperity.

3. Possible Patent Reforms

What, precisely, is the advantage of issuing compulsory licenses to import drugs, in contrast with other ways of weakening the

power of the patent privilege? A range of possible remedies is conceivable:

a. complete abolition of all drug patents, as recommended in the Report of the Restrictive Trade Practices Commission;

b. allowing compulsory licenses for imports;

c. facilitating the process of obtaining compulsory licenses;

d. amending the patent law to put the burden of proof in infringement suits on the plaintiff; and

e. amending section 19 of the Patent Act to allow provincial governments and their agencies to use drug patents upon payment of reasonable compensation, a power presently reserved to the Government of Canada.

The securing of the four latter reforms might make the more radical step of abolition of drug patents unnecessary. Let us consider the implications of these reforms.

a. Abolition of drug patents

The abolition of all drug patents would surely be the most direct single measure to secure new entry and price competition. This would admittedly have the disadvantage of creating international difficulties between Canada and countries committed to drug patents, and the danger of repercussions cannot be discounted. Other costs of patent abolition might also be urged: the possible reduction in research outlays in Canada; the diminution of the stimulus to improve processes which is provided by drug patents; and the possible return to secrecy instead of disclosure on the part of drug inventors. However, since so little research is actually done in Canada, the maximum possible reduction would not be very great. And it is possible that research in Canada might merely be diverted from private to public channels with probable increases in the value of the results. As to the next point, it is likely that the existence of patent protection for drug processes does stimulate development of alternative processes, but it is not certain that this incentive is necessary, nor that the inventions so devised are superior--all that is required to surmount the patent barrier is that the processes be different. As to the return to a policy of secrecy,

it may be observed that almost all Canadian patents are foreign-owned and have already been patented in the country of the inventor, so that the granting of a Canadian patent is not necessary to provide disclosure of the details of the invention to interested Canadians. Furthermore, the "know-how" may remain secret even though the patent discloses the nature of the process. (lg). Genuine secrecy, however, Professor Fritz Machlup of Princeton University has declared, is not really possible in the drug industry, even in the absence of patents, for a variety of reasons including the ability of technicians to analyze and duplicate drug products.

b. Permitting Compulsory Licenses to Import in Conjunction with other Reforms.

If prospective importers were licensed to import drugs produced by Canadian patent holders in return for the payment to the patent holder of reasonable royalties, the potential for competition would be greatly increased. Presumably the international repercussions would be less severe since patents are not abolished, and royalties are paid on quantities imported. This solution has much to recommend it, since it would introduce competition for those drugs which can be produced more cheaply abroad than by domestic compulsory licensees.

Other reforms could be instituted in conjunction with the licensing of imports. The facilitation of the process of obtaining compulsory licenses is a necessary part of any patent reform program which retains compulsory licensing. The time and expense to applicants should be cut to the minimum; if this minimum still proves burdensome, patent licenses should be issued as of right. This is the recommendation of the Ilsley Commission, and it seems highly appropriate. The amending of section 41 (2) of the Patent Act to put the burden of proof on the plaintiff in an infringement suit would probably lead to more competition through the importation of drugs produced abroad by non-infringing processes. Since such imports would be royalty-exempt, they might be sold at even lower prices on the domestic market than the drugs imported by compulsory licensees. But placing the burden of proof on the plaintiff would not completely eliminate the danger of legal harassment

of importers by patent holders. The only way to accomplish this would be to amend the Patent Act.

Section 19 of the Patent Act could be amended to allow provincial governments and their agencies to use any drug patent in return for payment of reasonable compensation, a right which is presently limited to the Government of Canada. This recommendation of the Hall Commission is highly appropriate since it would further safeguard the Canadian drug buyer against restriction of supply and high prices. These four reforms should jointly achieve the same goals as the abolition of patents. If they do not succeed in stimulating price competition and price reductions, then as the Hall Commission indicated in its report, there would be no alternative but to abolish patents.

One final point remains. Applications for compulsory licenses may also be discouraged because of the necessity of a new firm to engage in expensive sales promotion in order to obtain business in competition with sellers of established brand name products. To be forced to engage in such outlays, of course, would reduce or eliminate the ability of the licensee to undersell the patent holder. The solution to this difficulty lies in requiring that brand names for drugs be outlawed and that drugs be advertised and sold only under generic names, coupled with the name of the seller. This aspect of reform will be discussed below under section (5), the effect on drug prices of laws supporting brand-name prescribing.

4. Drug Prices and Trade Mark Reform

Certain provisions in the Trade Mark Act serve to insulate still further the Canadian drug industry from competition in the world market. A foreign parent drug company, in the United States, for example, may be selling a drug at a much lower price in the United States than its Canadian subsidiary is charging in Canada, although both companies are selling the same drug under the same trade mark. Canadian prices could be lowered if it were possible for independent Canadian importers to buy drugs from wholesalers in the United States, pay import duties, and sell the drugs in Canada at a lower price than that

specified by the Canadian subsidiary of the United States manufacturer. This is prevented by the present provision of the Trade Marks Act, which permits the owner of a Canadian trade mark to monopolize the importation and distribution of any product bearing this mark, whether or not any production of the product is carried on in Canada.

This could be corrected by adopting the Hall Commission's recommendation that Section 20 of the Act be amended to specify that no infringement could be claimed where the drugs in question are produced by a related company. (Section 2(r) of the Act defines related companies as "companies that are members of a group of two or more companies, one of which, directly or indirectly, owns or controls a majority of the issued voting stock of the others.") The only retaliation would then be for the Canadian subsidiary to take out a new trade mark for its drug, but it would hesitate to do so to the extent that sales promotion efforts in both the Canadian and United States markets had made the trade-marked name itself a valuable business asset, which would occasion a capital loss upon name change. (see Appendix D for a discussion of the arguments advanced by the Patent and Trade Mark Institute of Canada against patent and trade mark reform.)

B. The Effects upon Drug Prices of the Tariff and Anti-Dumping Laws

Tariffs are intentionally designed to protect domestically situated producers by imposing an import tax burden on foreign goods, thus increasing the cost of imports and raising the prices at which they must be sold in order to justify importation. Except perhaps in the very long run, tariffs tend directly to increase domestic prices by encouraging higher cost domestic producers at the expense of lower cost imports. Hence the complete eradication of drug tariffs would be the most expedient tariff measure for maximizing the potential decrease in Canadian drug prices. But if it is desired to retain protection for domestically situated producers, in the hope of some long-run benefit on the price level, or for the sake of advantages which are considered to outweigh the price-increasing effects of import taxes, the customs laws should then be such as to give protection only to those drugs which are actually being produced at any given time. It would then be

appropriate to revise these laws to accomplish the following goals:

1. the application of tariffs only to those drugs of a class or kind actually produced in Canada;
2. the application of anti-dumping duties only to those drugs of a kind actually produced in Canada;
3. the valuation for customs and anti-dumping duty purposes of imported drugs at levels which are not so high as to motivate foreign parents of domestic subsidiaries to take a disproportionately large share of the total profits of the integrated operation in the foreign country; and
4. the imposing of a schedule of tariff rates no higher than is needed to afford domestic drug plants the minimum necessary protection.

Each of these will be discussed in the following paragraphs.

1. Applying Tariffs only to Drugs of a Class or Kind Actually Produced in Canada

The amending of the tariff laws so as to restrict the application of drug tariffs to drugs of a class or kind actually produced in Canada would aid the cause of price reduction (though in itself it of course would not insure price reductions) by reducing the cost basis of importers, and hence permitting some decrease in price. At the same time, since these drugs would by definition not be of a class or kind made in Canada, the operations of domestic drug makers would not be disrupted. It might be desirable to abolish tariffs on all drugs of a kind not made in Canada, except that since many drugs which are not chemically identical are actually largely substitutable for one another, the exempting from tariffs of individual drugs not made in Canada might be prejudicial to the ability of therapeutically similar but chemically not identical drugs made in Canada to compete in the market with tariff-exempt imports. Nevertheless, "class" should not be defined so broadly that, for example, all antibiotics are considered to belong to a certain class such that tariffs would be imposed on every imported antibiotic if even a single antibiotic were made in Canada. Rather it would be preferable (although admittedly difficult) to define "class" by making an exhaustive enumeration of all drugs which are therapeutic

substitutes for drugs made in Canada, and then exempting from tariffs any drugs not on the list. In addition, the change in the law would not prevent the establishment of new domestic drug plants since tariffs would become applicable to imports of any drugs of a class or kind produced by domestic plants as soon as domestic production were to be established.

2. Applying Anti-Dumping Duties only to Drugs of a Kind Actually Produced in Canada

The existence of the anti-dumping duty tends to motivate foreign parents of Canadian subsidiaries to impute a larger share of total profits to the parent by setting prices to the subsidiary at levels high enough to avoid all possibility of being subject to the anti-dumping duty. Clearly, the determination of the price below which the duty will be imposed is a matter of great importance. To set too high a price would be to penalize the Canadian subsidiary and add to the total costs which it must recoup in prices, thus adding yet another factor which conduces to higher prices. But setting too low a price will result in lower tariff revenues and less protection to domestic Canadian producers, although at the same time this may reduce costs and thus permit (but not insure) some price reductions. Complete abolition of the anti-dumping duty would eliminate this particular parent-subsidiary complication from arising, but of course would leave domestic producers open to the threat of dumping. It would seem desirable to limit the application of the anti-dumping duties to drugs of a kind made in Canada. At present, while most of the pharmaceutical drugs used in the preparation of dosage forms in Canada are not themselves made in Canada, most pharmaceutical preparations containing these pharmaceutical drugs are considered to be of a class or kind made in Canada for dumping duty purposes. Hence although the active ingredients in a drug are not made in Canada, dosage forms containing these drugs may be subjected to anti-dumping duty in order to protect sellers of dosage forms rather than the non-existent manufacturers of the basic drugs from which the dosage forms are prepared. Drug prices are therefore increased by the amounts of anti-dumping duty paid, or by

the increase in invoice prices necessary to eliminate the danger of anti-dumping duties, not only for drugs made in Canada, but for all other drugs of a general class which are made in Canada. It would seem desirable to limit the application of anti-dumping duties to drugs of a kind made in Canada, in order to eliminate the possible price-increasing effects of the possibility of imposition of anti-dumping duties on all drugs of the same class sold in Canada. This would maintain the protection afforded the actual manufacturer of the basic drug, but not the protection now enjoyed by the seller who, rather than making the basic drug, merely imports it or its ingredients. This difference in treatment can be defended on grounds that it is the manufacturing of the basic drug which is primarily to be protected because of the greater investment of the manufacturer in more specialized facilities, and the greater flexibility of operation of the importer of finished dosage forms or ingredients thereof.

3. Valuation of Imported Drugs for Tariff Purposes

The reduction in the scope of anti-dumping duties would eliminate many of the instances in which valuation problems for imported drugs arise. The goal of valuation for customs purposes of those imported drugs which are still subject to dumping duties, at levels which are not so high as to motivate foreign parents of Canadian subsidiaries to take too large a portion of the combined profits of parent and subsidiary in the foreign country, would be most expeditiously arrived at by setting this value equal to production cost plus an allowance for gross profit. Gross profit would include allowances for general and administrative overhead, selling costs, and net profits. To simplify the administration of this rule, some maximum allowance for gross profit should be stipulated. This is now done for some items of import. For example, the maximum gross profit allowance for imported car parts of a class or kind not made in Canada

is five per cent. If after appropriate study a maximum rate of perhaps ten per cent were to be adopted for drugs, the motivation for foreign parents to charge high prices to Canadian subsidiaries to avoid anti-dumping duty would be removed. If, for example, a drug cost $1.00 to produce, invoice costs to Canadian importers of less than $1.10 would not be subject to dumping duty. If invoice costs were over $1.10, then the actual invoice cost would naturally be the basis for the regular tariff duty. But by setting only a reasonable maximum allowance for gross profit, foreign parent companies would not be inclined to set high invoice prices to subsidiaries to avoid anti-dumping duty.

4. Reduction of Tariff Rates to Minimum Levels Consistent with Protection of Domestic Producers

Finally, the tariff rates imposed on drugs should be no higher than is necessary to afford domestic producers the minimum protection considered necessary. A careful evaluation of the entire schedule of tariffs on drugs is needed, such as was proposed by the Hall Commission. The Tariff Board has recently finished a study of the chemicals items tariffs, which however specifically excluded pharmaceuticals. Still, many fine chemicals used by the drug industry were evaluated, and the Tariff Board should be directed to make a similar study for drugs.

There are two respects in which one might be skeptical about the value of customs reform in achieving reductions in the price of drugs. First, it may be asked whether or not a reduction in tariffs would be passed on to the consumer in the form of lower prices, or whether the net effect would be to reduce tariff revenues and leave prices unchanged. The answer would appear to be that tariff reduction, by itself, would not necessarily lead to price cuts because of the presently non-competitive nature of the industry. If, however, tariff reductions are only one part of a concerted program to make the industry more competitive, then the nature of the resulting competition will force drug firms to reduce prices as their total cost levels are reduced.

A second objection is that even if price reductions did follow as

a result of tariff reductions, the resulting price declines would be very small. Minister of National Revenue Benson has made a statement to this effect to the Committee:

> "Not only are customs markups low as compared with industry profits, but also the factory costs to which they apply are low in relation to the total costs incurred in marketing pharmaceuticals. Thus the values for duty now prescribed under section 38 of the Customs Act are low in terms of normal selling prices in the industry, and for this reason there is some doubt that any lower valuation would greatly reduce the price of drugs in Canada." (7n).

Again, it must be admitted that if tariff reductions alone were relied upon, the effect would very likely be negligible. But if other measures are also employed to create price competition, prices would decline and the size of the tariff relative to consumer prices would become greater. Industry profits and the total cost of marketing drugs would be forced to decline, so that values for duty purposes would become a larger part of the lower price levels prevailing under competition.

C. The Effect on Drug Prices of the Federal Sales Tax.

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. An eleven per cent manufacturer's sales tax would thus increase the price to the wholesaler by eleven per cent; and the wholesaler, who can be depended upon to impose his traditional markup, will raise his price to the retailer by the same eleven per cent. The relationship between the retailer's cost and his price has been disputed. If the druggist simply marked up his cost for the drug by the traditional 66 2/3 per cent markup, the impact of the tax would then be to increase the final consumer price by eleven per cent. If, on the other hand, he superimposes some fixed charge to the marked-up cost, the net effect on the price to the buyer would be an increase of less than eleven per cent; to the extent that the ratio of the fixed charge to the cost-plus-markup was relatively large, the price increase to the buyer might be appreciably less than eleven per cent. If, however, the average prescription were priced in such a way as to make the price to the buyer exactly twice as high as the cost of the "ingredients" to the druggist (this is the relationship

shown in the Canadian Pharmaceutical Association's annual surveys) then the eleven per cent sales tax on the manufacturer would on the average be passed on to the consumer as an eleven per cent price increase. (See Appendix A for a detailed discussion of the impact of the sales tax on the consumer price under different assumptions regarding the method of pricing prescriptions.)

The presentations submitted to this Committee have been practically unanimous in recommending the abolition of the sales tax as a way of reducing the price of drugs. But it must be stressed that the act of tax abolition, taken by itself, would not necessarily have the slightest effect on prices. Prices are determined by demand, and if drug sellers are able to exact $11.00 from the drug buyer for a particular item, why should they reduce the price to $10.00 just because the manufacturer now pays 55 cents less in taxes on a price to the distributor of $5.55? He could quite readily just pocket the extra 55 cents and not change the price to the distributor. And even if he reduced the price to $5.00, the wholesaler and/or the retailer might simply widen their margins correspondingly and the net price to the consumer would be unchanged. To be sure, the present publicity being given to the high price of Canadian drugs, and the suggested remedy of sales tax removal, has no doubt focussed so much attention on this issue that it would be difficult for sellers not to pass on at least a good part of the tax savings to buyers. But arguments against the immediate reduction of prices because of higher-priced existing inventories, although valid in themselves, may be used as a delaying tactic, and price cuts may be postponed until public awareness of their possibility has abated. By the time that the higher-cost inventories have been sold, smaller price reductions than are justified may be made because of this abatement of interest. And even if full price reductions are made, the knowledge on the part of sellers that extensive sales can be made at prices eleven per cent higher may act as an incentive to subsequent price increases to restore prices to former levels. All of this is speculation, but the uncompetitive nature of the drug industry suggests that such speculation is not entirely idle. Drug industry spokesmen have

clearly been stressing the price-increasing effect of the sales tax in order to distract attention from drug firm marketing costs and profits. Sales tax abolition is certainly justified on many grounds, but must be only one part of a comprehensive reform program to introduce genuine price competition into the Canadian drug industry.

D. Effects on Drug prices of Food and Drug Laws and their Administration

The Canadian food and drug laws appear to provide adequate authority for public inspections of the facilities and products of drug sellers. But it has been argued that sufficient funds and staff to guarantee adequate inspection have not been appropriated. The necessary funds should by all means be supplied. One of the greatest advantages of the major firm is its ability to disparage the quality of the products of lower-priced generic sellers. That it can successfully do so despite the fact of federal inspection is proof of its ability to disparage the possible scope of the efforts of inspections as well. If sufficient funds are appropriated to make the adequacy of the inspection program obvious to all, these disparagement efforts will become manifestly specious. Such an expanded inspection budget is an essential part of a drug industry reform program, since the awarding of licenses to import will increase imports of low cost drugs, and the drug industry can be expected to mount a titanic effort to disparage the quality of imported drugs and hopefully prevent their prescription. It is my understanding that the present level of drug imports has already prompted the assignment of drug inspectors to some Canadian embassies in drug exporting countries, so that foreign factories can be inspected as well as their products.

Steps should also be taken to eliminate any unnecessary barriers to the marketing of "new drugs" by a large number of firms. Where a new drug has been cleared for marketing on the basis of experimental and clinical information compiled by an original applicant, the identical drug should automatically be cleared for marketing by any firm demonstrating the ability to produce an identical drug, regardless of possible differences in the processes of manufacture. To act otherwise is to prolong the monopoly power period of the original applicant, and to impose unnecessary

burdens on later applicants.

E. The Effect on Drug Prices of the Laws Supporting Brand Name Prescribing

Brand name prescribing adds very greatly to the cost of many drugs, and is engaged in not because medical schools teach brand name prescribing (this is not their practice) but because of the great volume of brand name sales promotion to which they are exposed. One way of reducing drug costs by making it possible for the druggist to dispense the generic equivalent of the brand-name drug being prescribed is to amend provincial pharmacy acts to permit such so-called "substitutions."[1] This was of course done in Alberta in 1962. See Appendix E where the statute is reproduced. The Alberta law authorized "substitution" provided that the physician did not specify that no substitutions were to be made. But even with this law in force, it is by no means certain that the average pharmacist would have substituted lower-priced drugs for brand-name drugs since his profit margin on the former is likely to be much lower than on the latter. Indeed, even if a prescription is written generically, it will usually pay to fill it by substitution of a brand name drug at higher prices. According to a survey conducted some years back by Drug Merchandising 62 per cent of generically written prescriptions are filled with a brand name product, and only 30 per cent are filled with a generic product. (1h). Very many drugs are subject to patent monopoly so that generically written prescriptions must necessarily be filled with a brand name product. For other drugs which are sold under both generic and brand names, the demand for the unadvertised generic name product may be so small that its distribution

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[1] To an economist, the notion that any meaningful "substitution" has taken place when one company's embodiment of a particular chemical is selected rather than that of another, is a curious one. And indeed, in the United States the economist's view coincided with that of state pharmacy boards until relatively recently. One of the most fascinating developments unearthed by the Kefauver hearings, and one of the least publicized, was the success of the National Pharmaceutical Council's crusade to change the meaning of substitution. Substitution used to mean dispensing the wrong drug, not a different brand name. In 1953, when the crusade began, only four states in the United States had any kind of anti-substitution laws. By 1959, 44 states had written into their law books the new approach to substitution. Fortunately, a similar attack on hospital formularies proved much less successful. (5g).

is limited largely to hospitals or major cities. Hence, for many reasons, even the mandatory requirement that all prescriptions be written generically would not necessarily result in cost savings for any very large fraction of prescriptions.

A genuine solution of this problem must await the outlawing of brand names for drugs. If drugs had to be marketed under the generic name, coupled with the name of the manufacturer, the power of massive sales promotion to "educate" the physician to prescribe only a certain brand name would be eliminated, and the ability of identical substances to masquerade behind different brand-name disguises would be at an end. Furthermore, generic names would soon be disciplined. If Lederle had to sell "Declomycin" under the name "Demethylchlortetracycline-Lederle" and Sandoz had to sell its euphonious "Mellaril" as "Thioridazine hydrochloride-Sandoz," drug firm spokesmen would soon drop arguments that generic names cannot be simple, and begin to make every effort to simplify them. A further advantage would be that Canadian physicians who read medical journals published in the United States would not be subjected to advertising appeals which could be translated directly into prescribing in Canada the brand names advertised.

It would be far more rational to advertise by firm name than by brand name. The alleged virtue of prescribing by brand name is to secure the high quality products made by the reputable firm. But the brand name does not identify the firm; instead, it refers to absolutely nothing but itself, stressing uniqueness and abstraction. It is probable that many physicians do not know which firm produces many of the brand names which they prescribe; indeed, with the striking proliferation of brand names, it could hardly be otherwise.

It should be kept in mind that the physician's hesitance to prescribe generically is relative, not absolute. They readily abide by hospital formulary agreements. Presumably this reflects greater confidence in the hospital pharmacist and the facilities at his disposal than they have in the retail druggist. Adequate public inspection of drug products should result in all pharmacists being equally worthy of confidence.

The outlawing of brand names is probably essential to any rapid reduction in Canadian drug prices. When reasonably priced generic drugs begin to be imported, their impact on the market will be determined by the willingness of physicians to prescribe them, as well as by their probable success in obtaining sales on tender from hospitals and public agencies. If the doctor is not aware of the generic name of a particular brand name drug, it will not be convenient to prescribe it generically. And advertising certainly minimizes the attention devoted to generic names relative to brand names. Beyond this, the practice of brand name sales promotion creates a presumption in favor of brand names and against generic names, which is miseducational in the sense that it conflicts with what medical students are almost universally informed in medical schools is rational prescribing practice. Newly graduated physicians will not be subject to efforts to make them forget generic names. For older physicians, it is likely that the "magic" of brand names will not long survive the passing of such names. Depending upon the intensity of price competition, and the rapidity with which it develops, the ability of major firms to finance extensive sales promotion will sharply decline as prices and cash flows fall, and the present advertising-induced disadvantage under which the generic name seller labors will be greatly reduced. As the ability of public inspection to keep all low-quality drugs off the market is established, there will be less fear of prescribing generically.[1]

Other laws conducive to promoting an environment supporting brand name prescribing and the suppression of price competition would include provincial legislation limiting operation of drug stores to registered pharmacists, and limiting the dispensing of prescriptions to

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[1] This carefully cultivated suspicion of the quality of generic name drugs is largely unjustified; many generic name drugs are no doubt superior to brand name drugs. In the United States, FDA records show that irregularities have repeatedly arisen in connection with the drugs produced by brand name firms. A generic name is no indication of low quality. It is equally true that a brand name in itself is no guarantee of acceptable quality.

licensed pharmacists, physicians, dentists, and veterinary surgeons. obviously it is possible for entry to pharmacy to be limited by requiring unnecessarily lengthy academic preparation, the passing of examinations of arbitrary difficulty, and the imposition of apprenticeship requirements. While no one wants incompetent personnel to dispense prescriptions, the requirements for success in pharmacy today probably put a higher premium on merchandising skills than on compounding and other technical skills. Requirements could be correspondingly altered. To stimulate price competition at the retail drugstore level, it is absolutely essential that it be made possible for persons and firms not subject to possibly arbitrary pressures or penalties imposed by pharmacy control boards to enter the field. The competition provided by discount pharmacies, drug chains, and the equivalents of drug supermarkets and mail order houses should do a great deal to lower drug prices and force the conventional type of pharmacy to become more efficient.[1]

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1 The statements made to this Committee by Mr. S. S. Bass of London Drugs, Limited, Vancouver, at least suggest that improper pressures may be brought to bear on pharmacy owners who engage actively in price competition. (7mm).

CHAPTER IV

The Effect of Drug Law Reform on Existing Canadian Drug Firms

The existing Canadian drug industry is more than capable of dealing successfully with the drug reforms proposed in this submission. The major firms have a tremendous initial advantage over new entrants selling under generic names or unknown brand names in that their intensive sales promotion campaigns have secured for their brand name drugs the good opinion of the medical profession, and the custom of disparagement has placed generic name sellers at a great disadvantage. If brand names are outlawed, the name of the seller will still stand established firms in good stead. But it is to be expected that the availability of compulsory licenses to import, in conjunction with the other proposed reforms in drug laws and in the distribution system, will force existing large firms to respond to the challenge of price competition. It is a challenge which they are well able to meet, since their production costs are very low, and probably lower than those of most of the importers because of their larger volumes of output. To meet the low prices of imported drugs, it will be necessary to reduce marketing costs greatly, and to settle for the lower rates of return on investment which are everywhere imposed by competition. It will, in a salutary sense, force the firms to become much more efficient in their overall Canadian operations.

The total sales volume of the major firms will be maintained to the extent that they reduce their prices to meet the competition of imported drugs. It is to be expected that the chief impact of these imports will be to drive the prices of the major firms down a little closer to their costs, which are no doubt low enough to allow a great deal of price reduction. The impact on employment and investment in Canada will probably not be severe since the principle of tariff protection for the domestic industry is not being abandoned. Furthermore, since much of the industry's employment is concentrated in the Montreal and Toronto areas, the chances that any displaced workers will find employment elsewhere is correspondingly great.

In summary, it is to be expected that the major effects of drug reform will be to reduce the prices, selling outlays, and profits of existing large drug firms, rather than to decrease greatly their share of the market. Output can be maintained to the extent that they are willing to cut prices to meet the challenge of imports, and this will maintain output and employment for Canadian-based plants. Even research may not suffer much if fiscal incentives and subsidies to research continue to expand.

CHAPTER V

Summary of Recommendations

1. Compulsory licenses to import should be granted, subject to the payment of reasonable royalties. These licenses should provide for the importation of semi-finished and finished dosage forms as well as bulk drugs.
2. Section 41(2) of the Patent Act should be amended to put the burden of proof of infringement of drug process patents on the plaintiff.
3. Every effort should be made to further expedite the process of acting on compulsory license applications. If reasonable expedition cannot be achieved, such licenses should be issued as of right.
4. Section 19 of the Patent Act should be amended to allow provincial governments and their agencies as well as the Government of Canada to use any patented drug, subject to the payment of reasonable compensation.
5. The Trade Marks Act should be amended to allow the importing of trade-marked drugs which have been produced by a company related to the company possessing the Canadian trade mark.
6. The schedule of tariffs on drugs should be reviewed by the Tariff Board, with a view toward:
   (a) Limiting the liability of drugs to tariff duties to those drugs of a class or kind actually made in Canada, and
   (b) reducing applicable rates to the minimum level consistent with the provision of the desired level of protection for domestic producers.
7. Liability for anti-dumping duty should be limited to drugs of a kind actually made in Canada, where "kind" is defined in terms of the active ingredient.
8. The valuation for customs purposes of imported drugs should be based on production cost plus a maximum allowance for gross profit (or invoice cost, if higher) in situations where it is not possible independently to ascertain fair market value.
9. The federal sales tax on drugs should be removed.

10. The Food and Drug Directorate should be provided with sufficient authority, funds, and staff to enable it to carry out an inspection program adequate to prevent the marketing of substandard drugs and establish confidence in all drugs sold in Canada.
11. Unnecessary barriers to the marketing of new drugs by additional firms should be eliminated. Where a new drug has been cleared for marketing on the basis of adequate data compiled by an original applicant, the same drug should be approved for marketing by any firm capable of producing the identical drug. Similarly, unnecessarily onerous burdens in the way of supplying drug information which merely duplicates existing known information should not be imposed.
12. The publication of a governmentally sponsored newsletter evaluating drugs, similar to the Prescriber's Journal in Great Britain should be considered, particularly if widespread subscription by Canadian physicians to presently or prospectively published independent newsletters of this type fails to develop.
13. Every reasonable effort should be made to inject more price competition into drug retailing. Serious consideration should be given to the liberalizing of the requirements for operating drugstores and dispensing prescriptions, so that the development of lower priced outlets for drugs such as discount pharmacies and mail order houses can be encouraged.
14. If the above reforms do not succeed in reducing drug prices to competitive levels in a reasonable period of time, drug patents in Canada should be completely abolished.

All of which is respectfully submitted

Henry B. Steele

on behalf of the Government of Alberta

February, 1967

APPENDIX A

An Analysis of the Effects of the Eleven Per Cent Federal Sales Tax on the Price to the Patient for Prescriptions priced by Different Methods.

I. General Analytical Framework.

Let the manufacturer's sales price to the wholesaler, prior to the imposition of the tax, be an amount designated by the letter C. (This is the price per unit.)

Let the wholesaler's markup be the conventional 20% above his cost of C per unit. Hence the wholesaler's price to the retailer, per unit, is C(1.20).

Let the retailer's markup be assumed initially to be simply 66 2/3 per cent above the price which he pays the wholesaler. Hence the price to the patient would be C(1.20)(1.667). If we let this price be represented by the letter P, it is obvious that P=2C. Hence the markups of wholesaler and retailer have doubled the manufacturer's pre-tax price.

If a sales tax of eleven per cent be imposed on the manufacturer's sales price to the wholesaler, the manufacturer can pass the entirety of the tax forward to the wholesaler by raising his price by eleven per cent. The wholesaler's price then becomes C(1.11).

The wholesaler can then realize an increased absolute gross profit margin per unit by maintaining his usual markup of 20 per cent on his increased price from the manufacturer. The price to the retailer will then be: C(1.11)(1.20).

The retailer can similarly realize an increased absolute gross profit margin per unit be persisting in the imposition of his customary markup of 66 2/3 per cent on the increased price from the wholesaler. The price to the patient would then be C(1.11)(1.20)(1.667). Let us refer to this post-tax price as P*.

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We now have to answer two very important questions: (1) What per cent increase in the price to the patient was brought about by the imposition of the 11 per cent sales tax at the manufacturer's level? (2) How is this increase in price accounted for by (a) actual tax revenues; (b) the increase in the wholesaler's gross profit margin; and (c) the increase in the retailer's gross profit margin? The answers to these questions can be supplied by a very straightforward analysis.

The first question can be answered by computing the increase in the price to the patient. The ratio of P to P* gives us the percentage change in the patient's price as a result of the tax. This ratio is as follows:

$$(1) \qquad \frac{P^*}{P} = \frac{C(1.11)(1.20)(1.667)}{C(1.20)(1.667)} = 1.11$$

Hence the eleven per cent sales tax, shifted forward in full by the manufacturer, and pyramided by the wholesaler and retailer, results in an eleven per cent increase in the price paid by the patient.

To answer the second question, let us assume that the value of P is $1.00 and hence P* is $1.11. This would mean a pre-tax manufacturer's price of $ .50, and a price of $ .60 to the retailer. The patient's dollar would be divided as follows: 50 cents to the manufacturer, 40 cents to the retailer, and 10 cents to the wholesaler. But after the tax is imposed, the manufacturer increases his price of $ .50 by 11 per cent, of 5.5 cents, so the wholesaler pays $.555. If the wholesaler adds his customary 20 per cent margin, the price to the retailer increases by 11.1 cents, to $.666. When the retailer imposes his 66 2/3 per cent markup, the consumer price increases by 11 cents to $1.11. The consumer now pays 50 cents to the manufacturer, 44.4 cents to the retailer, 11.1 cents to the wholesaler, and 5.5 cents to the government in taxes. Although the manufacturer's receipts have not increased, the retailer's gross profit margin has gone up by 4.4 cents, and the wholesaler's gross profit margin has increased by 1.1 cents. Only 50 per cent of the increase in the price to the patient has been captured by the taxing authority; the other 50 per cent has

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been allocated to increasing the gross profit margins of distributors. Sales tax receipts are only 4.9% of the post-tax price. ($.055/$1.11).

II. Effect of different prescription pricing methods on the relative price increase caused by the sales tax.

A. Different Pricing Methods employed by pharmacists in Canada:

1. Retailer's cost plus 66 2/3 per cent markup.
2. Retailer's cost plus 66 2/3 per cent markup plus dispensing fee.
3. Retailer's cost plus "professional fee."

It has been reported that some pharmacists do not charge professional or dispensing fees in cases where the retailer's cost plus the 66 2/3% markup would yield an absolutely high markup. (Testimony of Mr. W. Isaacson of the Council of the Ontario College of Pharmacy and proprietor of retail pharmacies in Toronto, as reported in the 1961 Restrictive Trade Practices Commission Hearings, p. 2967.) If the drug were not so highly priced, a dispensing fee of perhaps 50 to 75 cents might be added to the cost plus markup. Alternatively, a "professional fee" of perhaps $2.00 to $2.25 or more might be added to the retailer's cost. It is obvious that the role of the sales tax in increasing the price to the patient may vary as between different methods.

Let us apply each method to the "average" prescription in Canada during 1965, which according to testimony presented before this Committee on June 14, 1966, by Mr. J. C. Turnbull, Executive Director of the Canadian Pharmaceutical Association (page 57 of the Hearings) was priced at $3.32 on the basis of preliminary figures for the 24th Annual C.Ph.A Pharmacy Survey for 1965.

1. Retailer's cost plus 66 2/3 per cent markup. If the price to the patient of $3.32 represents a 2/3 markup over retailer's cost, the retailer must have paid $1.992, and the wholesaler's cost must have been $1.66, or 50 per cent of the price to the patient. The tax paid by the manufacturer must have been 11/111 of $1.66, or 16.4 cents,

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so that the net receipts by the manufacturer would have been $1.496. In this case, the price in the absence of the sales tax would have been twice $1.496, or $2.992. The price increase occasioned by the tax is of course 11.0 per cent, as before ($3.32/$2.992), and the ratio of taxes collected to the price paid by the patient is $ .164/$3.32, or only 4.94 per cent. (It is doubtful, however, if a price of only $3.32 would be regarded as sufficiently high to justify omitting a dispensing fee.)

2. Retailer's cost plus 66 2/3 per cent markup plus dispensing fee. If a dispensing fee is charged, one must know the average retailer's cost for the typical prescription in order to compute both the markup and the average dispensing fee. According to Mr. Turnbull's statement, cited above, the average ratio of retailer's cost to prescription price in 1964 was 50 per cent. (Hearings, p. 58). Hence a prescription priced at $3.32 would involve a cost of $1.66 for materials. Adding the 2/3 markup to $1.66 brings the price up to $2.77, and the difference between $2.77 and $3.32 could be interpreted as an average dispensing fee of $ .55.

If this be assumed the case, the price in the absence of the tax can readily be computed. If the retailer's cost was $1.66, the wholesaler's cost was $1.38 (5/6 of $1.66) and the sales tax paid by the manufacturer was 13.7 cents (11/111 of $1.38). The manufacturer's net after taxes was therefore $1.243. In the absence of the tax, the retailer's cost plus 2/3 markup would be twice this sum, or $2.486. Adding 55 cents to this sum, we arrive at the price of $3.036 for the average prescription of 1965 if there had been no sales tax. Hence the increase in price occasioned by the sales tax, under this particular method of pricing, is 28.4 cents, and the relative price increase is $3.32/$3.036, or 9.6 per cent. The ratio of taxes collected to the price paid by the patient is $ .137/$3.32, or only 4.13 per cent.

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3. Retailer's cost plus "professional fee." If we a assume, rather conservatively, that the typical "professional fee" charged by Canadian pharmacists during 1965 was $2.00, then for the average prescription of $3.32, this would represent a retailer's cost of only $1.32 for purchases from wholesalers. The wholesaler's cost for this amount would be 5/6 of $1.32, or $1.10. The tax paid by manufacturers on this sum would be 9.25 cents (11/111 or $.933). The net to the manufacturers would therefore be $ .841. In the absence of taxes, the retailer's cost for this amount, as purchased from wholesalers, would be $1.009. Adding the $2.00 "professional fee" to this sum, the prescription price would be $3.009. Hence, the increase in price brought about by sales tax, under the "professional fee" system, would be 31.1 cents. The relative price increase is $3.32/$3.009, or 10.0 per cent. The ratio of taxes collected to the price paid by the patient is $ .0925/$3.32, or only 3.28 per cent.

B. Relative effects of sales tax on prices of more expensive and less expensive prescriptions according to method of pricing.

An eleven per cent sales tax will always increase retail prices by eleven per cent if the retailer uses the conventional 2/3 markup alone. Similarly, the sales tax receipts will always be only 4.96 per cent of the post-tax price.

If pharmacists always add a dispensing fee of a given amount to the 2/3 markup over retailer's costs, the effects on prices will vary according to the magnitude of the retailer's cost for a particular prescription. Assuming a conservative dispensing fee of 50 cents, the ratio between P* and P will be given by the following expression:

$$(2) \qquad \frac{P^*}{P} = \frac{C(1.11)(1.20)(1.667) + .50}{C(1.20)(1.667) + .50}$$

If the cost of ingredients C is zero, obviously there is no price increase. But for every one-cent increase in C, the numerator of expression (2) will increase by 2.22 cents while the denominator will increase only by 2.0 cents. Hence for every one-cent increase in C,

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the incremental price increase is eleven per cent, but the average price increase will be a great deal lower than this at very low levels of C. Only as C becomes increasingly large will the average price increase approach the ultimate level of eleven per cent. Similarly, if C is zero, taxes collected are zero, and the ratio of taxes collected to retail price is zero. But as C becomes larger and larger, the amount of taxes similarly increases, and ultimately for extremely high values of C, the ratio will be the same 4.96 per cent mentioned in connection with equation (1) above. The table below gives some sample values for prescriptions with various levels of ingredient costs at the manufacturer's level:[1]

Ingredient costs at manufacturer's net after-taxes price levels:	Percentage increase in Prescription Price Caused by sales tax	Ratio of tax receipts to Prescription Prices after taxes
$ .10	3.1 %	1.5 %
.50	7.3	3.4
1.00	8.8	4.0
1.50	9.4	4.3
2.00	9.8	4.5
2.50	10.0	4.6
3.00	10.1	4.7
5.00	10.6	4.8
10.00	10.7	4.8

If pharmacists add a $2.00 "professional fee" to their invoice cost, the effects on prices of the sales tax will still vary directly with the level of cost to the pharmacist, but not as markedly as in the case of the 50 cent dispensing fee. The ratio between P* and P is now given by expression (3):

$$(3) \qquad \frac{P^*}{P} = \frac{C(1.11)(1.20) + 2.00}{C(1.20) + 2.00}$$

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1 As the value of C becomes infinitely large, the effect of the $ .50 dispensing fee becomes completely negligible. Hence, neglecting the $ .50 in both numerator and denominator, expression (2) becomes equivalent to expression (1).

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Again, if the cost of the ingredients is zero, there is certainly no price increase. But for every one-cent increase in C, the numerator of expression (3) will increase by 1.332 cents, while the denominator will increase by 1.2 cents. As in the case of expression (2), for every one cent increase in C, the incremental price increase is eleven per cent, but the average price increase will be a great deal lower than eleven per cent at low values for C. But as C becomes increasingly large, the increase in the total price will approach its ultimate level of eleven per cent. The effect is retarded, however, in expression (3) relative to expression (2) in that the total price includes a component which does not vary with the value of C of $2.00 in the former instance and only $ .50 in the latter instance.

The same comparison between expressions (2) and (3) also holds with regard to the ratio of taxes collected to the after-tax price. This ratio will approach 8.26 per cent as the value of C becomes extremely large, but it will approach this level more slowly than if the fixed fee component were only 50 cents instead of $2.00. The table below gives some sample values for prescriptions with various levels of ingredient costs to the retailer:

Ingredient costs at manufacturer's net after-tax price levels:	Percentage Increase in Prescription Price Caused by Sales Tax	Ratio of Tax Receipts to Prescription Prices after taxes
$ .10	0.6 %	0.5 %
.50	2.5	2.1
1.00	4.1	3.3
1.50	5.3	4.1
2.00	6.0	4.8
3.00	7.1	5.5
5.00	8.3	6.4
10.00	9.4	7.2

III. Evaluation of the Effects of the Sales Tax as applied to Prescription Drugs.

Basic to the analysis of any sales tax is the extent to which it is pyramided. 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

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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. Where one method of distribution is universally followed, the pyramiding process will occur most smoothly. If some sellers deal with fewer intermediate distributors, other things being equal, they will be able to sell at lower prices than sellers who deal with more middlemen. The present application of the sales tax to prescription drugs makes a substantial, although in all probability not perfect, allowance for this situation by computing the tax on the basis of a 49.3 per cent discount below retail price for transactions between manufacturers not selling in wholesale quantities to independent wholesalers, and such non-wholesale dealers.

Beyond this, the exemptions given to such dispensers as public hospitals and charitable institutions, and to certain particular drugs, introduces a discriminatory factor between different types of dispensing outlets, and/or different drugs. Whether or not such discrimination is socially desirable is a question of equity rather than of economic efficiency. To the extent that tax pyramiding is substantial (and from all indications this is the case for prescription drugs), the sales tax is inefficient in that it induces distortions in relative prices charged (or relative profit margins received) between sellers utilizing different distribution channels, and between exempt drugs as compared with non-exempt drugs. The first sort of distortion should be substantially, although probably not completely, offset by the tax treatment accorded to certain non-wholesaler transactions, but this treatment does not affect the price advantage of hospitals over retail pharmacies. The second sort of distortion, that between exempt and non-exempt drugs, is similarly not affected by any mitigating provisions in the tax laws.

A second question relating to efficiency of any sales tax is this: since the object of revenue taxation is to raise funds for public use, and the price-increasing effect is an undesired by-product,

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it would be desirable to minimize the ratio of the price increase to the tax revenues received per unit. To do this, it is expedient to tax at the retail level only, in order to minimize pyramiding, and to tax goods the demands for which are very sensitive to price such that sellers cannot raise prices much without pricing the good entirely out of the market. (Such goods are said to display a high degree of price elasticity of demand.) The prescription drugs sales tax meets neither requirement. Since it is applied at the manufacturers' level, it is pyramided upward at the distributor's level or levels. And since the price sensitivity of demand for prescription drugs is notoriously low, the price-raising effect of imposing a tax will be proportionately very great. For many types of drugs, the price inelasticity of demand is probably nearly perfect, such that the entirety of the pyramided price increase can be passed forward to the consumer without reducing the quantity sold in the market. Indeed, it is for this reason that computations of the price-increasing effects of the sales tax on drugs can be made with considerable confidence.

Under these circumstances, a sales tax applied at the retail level would raise more tax revenues and increase prices by no more than the same tax applied at the manufacturer's level. If the manufacturer's price to the wholesaler were $1.00, the wholesaler's markup would increase the retailer's cost to $1.20, and the 2/3 retail markup would raise the price to $2.00. An eleven per cent sales tax at retail would yield 22 cents in tax revenue and increase the price by the same 22 cents, to $2.22. An eleven per cent tax on the manufacturer's price of $1.00 would raise only 11 cents in tax revenue, but the pyramided price increase would produce the same $2.22 price to the patient. (This example is purely illustrative and should not be taken as a recommendation for Federal retail sales taxation.)

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In conclusion, it would seem that the sales tax on prescription drugs has nothing to recommend it. This is hardly surprising since it is difficult to conceive of defending a tax on illness. However, elimination of the tax by itself will not insure any reduction in drug prices; unless active competition is introduced into the market, prices may remain at the levels produced by the tax. While the tax is shifted forward by sellers, the elimination of the tax may not give rise to any "de-shifting", but simply increase drug manufacturers' net receipts by eleven per cent. Thus it is imperative that the elimination of the sales tax be seen as part of a more general program to reduce drug prices by increasing competitive forces in the market, rather than as a reform capable of being introduced in isolation from other reforms.

APPENDIX B

Comments on the Submission of the Pharmaceutical Manufacturers Association of Canada

The Submission to this Committee of the PMAC deserves careful reading since it has been very carefully prepared. Adequate comment would require a document several times as lengthy as the original submission. Hence only a few of the most important areas can be analyzed.

I. The Significance of International Comparison of Drug Prices in Terms of Their Equivalent in Hourly Wages.

If this measure has any significance, it should purport to show how long the working man must labor in each country in order to buy a supply of each drug. While this might be of some academic interest, it has nothing to do with the costs of producing, shipping, and selling drugs in a given market. But it does not even have anything to do with the working man's real wages in terms of drug purchasing power. Nothing, that is, unless the working man is a druggist. The prices shown are prices to the retailer, not the patient. Presumably it is easier to obtain data on prices to the druggist than to the consumer. But by choosing druggist's cost the effect is without doubt to understate Canadian prices relative to other world prices because of the comparatively much higher retail markup in Canada, which seems to average 100 per cent, as compared to 66 2/3 per cent even in the United States, and in Great Britain only 18 per cent plus a dispensing fee of about 17 pence. Hence the statistics show nothing concerning relative prices to the consumer, whether he is laborer or capitalist.

As the Consumers' Association of Canada has aptly pointed out in its brief to this Committee, PMAC seems to be endorsing the Marxist concept of the labor theory of value in this comparison. Even so, it would show only half of the picture. What is needed is also the number of labor hours necessary to produce a given drug in a particular country. If labor were the only factor of production, one would have

to neglect capital, land, management, and other possible classifications of productive factors. However, orthodox Marxists are willing to do just this, so PMAC is not innovating an entirely new economic theory. All PMAC needs to do is to compute the number of hours necessary to produce each drug in each country, subtract this from their figure on the number of labor hours expended in financing the comsumption of each drug, and the difference will represent the number of labor hours of "surplus value" extorted from the worker by the drug maker. Is this criticism to be taken seriously? It must, if PMAC's statistics are to be taken at face value.

As indicated in the test of the Alberta submission, the computation actually shows that prices are higher in those countries in which per capita income is higher. This is no doubt the case because consumers can afford to pay higher prices in countries in which incomes are greater.

The relationship between drug costs and per capita income cannot be ascertained precisely on the basis of information given in the PMAC brief, since the price indices computed therein are merely simple arithmetic averages of unweighted prices instead of having been weighted by the total expenditures of consumers in each country for each drug. As the Consumers Association of Canada Brief appropriately observes, this procedure "violates the central tenets of index number theory by taking as an index an unweighted average of drug prices." (7o). Still, if PMAC advocates the use of an unweighted index for computing the cost of drugs in terms of labor hours, it should have no objection to the use of an unweighted index for computing average money prices of drugs in the selected countries. If we compute the average price, in Canadian dollars, of the seventeen drugs listed by PMAC on pages 3 and 4 of Appendix F of its submission, we have a measure of the relative money costs, in terms of 1964 Canadian dollars, of the "average" drug purchased from this group of 17 drugs, in each of the eight countries. If we compare these average drug prices with average per

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capita income (in 1964 Canadian dollars) in each of these countries, there is apparent a generally direct relationship between the height of drug prices (in constant 1964 Canadian dollar terms) and the height of per capita income (also converted to 1964 Canadian dollar equivalents, by use of the statistics on national income and population for 1964 as given in the United Nations Statistical Yearbook for 1966.) The relationship is given below:

	Average drug price	Per capita income, 1964
United States	$ 4.64	$ 3485
Canada	4.45	2502
France	3.59	1869
Germany (Federal Republic)	3.56	2145
Holland	3.73	1615
Sweden	3.28	2640
United Kingdom	3.03	1935
Italy	2.85	1116

It can be seen that prices are highest and lowest in the countries with highest and lowest per capita incomes, respectively. Between these extremes there is some variation, but only Sweden, with sixth highest average prices and second highest per capita income, is significantly out of line with the general relationship. (The co-efficient of Spearman Rank-Order Correlation is .500. Perfect correlation would be represented by a co-efficient of 1.00.) It is true that the computed averages are not entirely comparable in the cases of Italy, Sweden, France, Holland, and the United Kingdom, where price information is not given for all 17 of the drugs. But this criticism applies also to the PMAC presentation.

A slightly different way of making the comparison between drug prices in Canada and in other countries (which reduces, but does not eliminate the statistical shortcomings of the previous computation) is to take the price of each drug in each foreign country (expressed in Canadian dollars) and divide it by the Canadian price of the drug, expressing the price ratio as a decimal fraction. For each country the

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average price ratio is then computed by taking the unweighted arithmetic average of the ratios for each of the drugs separately. The results of the computation show clearly that prices in Canada are higher than in any of the other countries except the United States:

	Ratio of drug prices in each country to drug prices in Canada	Index of foreign drug prices in terms of Canadian drug prices
United States	1.062	106.2
Canada	1.000	100.0
Germany (Federal Republic)	.840	84.0
Holland	.833	83.3
Italy	.770	77.0
Sweden	.767	76.7
France	.725	72.5
United Kingdom	.670	67.0

It is interesting to note that Professor P.C. Briant, in explaining the PMAC labor value computations before this Committee failed to defend in principle the labor-hours basis of the index, and betrayed implicit lack of confidence in the value of an unweighted index in responding to a criticism by Dr. Howe regarding the validity of the index. During the proceedings, Mr. Laidlaw, as counsel for the Committee, asked Dr. Briant the following question: ".....It seems to me that your hypothesis is...entirely wrong. If butazolidin reaches the consumer in the United Kingdom at a special price, it reaches the consumer in Canada at three times that price, what has the Canadian earning capacity to do with it?" Dr. Briant responded with the surprisingly critical statement, "I did not really start out with the hypothesis that this is the proper way to measure comparative costs." If this is the case, one wonders why the proper way to measure costs was not employed, and what precisely was the intention in presenting the data in the form chosen by PMAC. (The next statement by Professor Briant may have some bearing on this point, as he added: "I did start

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out with the assumption that we are interested in maintaining a pharmaceutical manufacturing industry in this country....." (7p)

With regard to the relative value of weighted vs. unweighted indices, Dr. Briant implicitly revealed his preference in responding to a criticism of the PMAC data by Dr. Howe, who had presented a list of 58 drugs the retail prices of which were from three to twenty times as high in Canada as in the United Kingdom. Dr. Briant computed that, for the fifteen drugs (in the PMAC list of 17) which were actually sold in the U.K., comparative money prices to the consumer for the unweighted sum of "a basket of 15 of these drugs" (7q) were $66.91 (in Canadian dollars) in the United Kingdom and $111.40 in Canada, showing that prices were 66.5 per cent higher in Canada. (For what it is worth, the equivalent labor hours were computed by Dr. Briant to be 15.5 per cent higher in the United Kingdom.) For the 58 drugs in Dr. Howe's list, the unweighted sum total cost of buying one dosage-pricing unit of each drug at the consumer price level was $130.05 in the United Kingdom and $599.72 in Canada. Hence prices in Canada were 361.1 per cent higher than those in England. Again, for what it may be worth, Dr. Briant computed that the equivalent labor hours required to purchase the drugs was only 41.7 per cent as great in the United Kingdom as in Canada.

Dr. Briant then found it "statistically reasonable" to combine the 17 drugs in the original PMAC list with the 58 drugs in Dr. Howe's list to obtain an index for all 75 drugs, by "weighting the index relatives by the relative market shares" of each drug. (7r) It is not explained why it is statistically reasonable in one context to use a weighted index, while in all other contexts the use of unweighted indices is apparently regarded as requiring no particular justification. Interestingly enough, the introduction of market share weights makes a substantial difference. Since Dr. Briant had previously been comparing an unweighted index of 15 drugs with an equally unweighted index of 58 other drugs, one would suppose that mere

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consistency would require the computation of an unweighted index for the entire group taken together. If this procedure were followed, it would appear that money costs in Canada would be 261 per cent higher than in the United Kingdom, while, if relevant, even equivalent labor hours costs would be only 54 per cent as great in the United Kingdom as in Canada. But if one adopts the weighting procedure advocated (in this context only) by Dr. Briant, relative money costs are only 151 per cent greater in Canada and equivalent labor hours are 91 per cent as great in the United Kingdom as in Canada. It is this last comparison which Dr. Briant stresses--that 91 per cent is only "somewhat lower" than the Canadian standard of 100 per cent. What deserves emphasis, however, is that if timely adoption of the weighting procedure had not been resorted to at this point, the "blended" index of 75 drugs would still have shown equivalent labor hours to purchase drugs in the United Kingdom as only about 54 per cent as great as in Canada.

The point is not that it is an error to employ weights in the "blended" index, but that it is erroneous to use unweighted indices in all other contexts. Moreover, the precise effect of either weighted or unweighted indices on the computation of equivalent labor hours to purchase drugs is irrelevant since the magnitude being measured is strictly irrelevant. At best, a lower ratio for Canada than for other countries would indicate nothing more than the simple fact that Canadian labor is relatively more productive, per hour, than labor in other countries, such that Canadian wages permit workers to buy given amounts of any particular good with fewer labor hours expended. But the extent to which Canadians are able to translate their relatively[1] greater productivity per labor hour into a greater command over goods

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[1] Since one of the principal determinantes of wage rates is the amount of capital investment per worker employed, this may indicate indirectly the relatively more capital-intensive methods of production prevalent in Canada.

and services on the market depends upon the degree to which the products of different industries are priced competitvely (i.e., relatively close to production costs) or monopolistically in different countries. It might be of some limited interest to compute weighted indices of relative labor hours required to purchase a variety of different goods in different countries, produced by competitive as well as monopolistic industries, comparing drugs with raw materials durable and non-durable consumer goods, foodstuffs, and the like.

Breakdown of the Prescription Dollar

In Section 2 of the PMAC Submission it is asserted that the manufacturer's portion of the prescription dollar is only 37.5 per cent. This would appear to be understated, but the true share is a matter of conjecture. PMAC refers to the 1964 annual survey of prescription prices conducted by the Canadian Pharmaceutical Association which stated that the average price of a prescription was $3.47, and the cost of the ingredients to the pharmacist was $1.73, or exactly 50 per cent of the price. PMAC then concludes, not too explicitly "when additional allowances are made for wholesale distribution and federal sales tax the manufacturer's portion of the average prescription is $1.30 or 37.5 cents of the average prescription dollar." (6e). Apparently the computation was made as follows: from $1.75 deduct the wholesaler's markup of 20 per cent over his invoice cost, which would amount to 1/6 of the price to the druggist, or 29 cents. This leaves $1.44 as the price to the wholesaler, which includes 11 per cent sales tax, the deduction of which would require that $1.44 be reduced by 11/111, or 14 cents, yielding PMAC's $1.30 net to the manufacturer.

The difficulty with this procedure is that it assumes that all drugs sold pass through the hands of wholesalers. To the extent that manufacturers sell direct to various classes of buyers, they bypass wholesalers. As manufacturers they therefore perform also the wholesaler's function on these sales, incurring extra costs, but also

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receiving an extra share of the sales dollar. The costs incurred in performing wholesaling functions appear to be included in the table on page 2.2, "Manufacturer's portion of the prescription dollar" presumably under the heading "distributing and warehousing costs," but the additional revenue from selling the drugs at the higher price obtained by selling direct rather than through wholesalers is omitted. Hence the manufacturer's share of the consumer's prescription dollar is understated. What is the approximate magnitude of the understatement? This would depend upon the relative share of sales made direct to retailers (at an average discount of presumably 40 per cent below suggested list price to consumers) and the share of sales made to wholesaler (at a discount of presumably 50 per cent below suggested list price to consumers.) The only information we have is that volunteered by Dr. Briant (7s) to the effect that in 1964 sales by PMAC members were divided up as follows: $23.5 million direct to retailers; $49.9 million to wholesalers; $27 million to hospitals; $3.2 million to government buyers, and $1.15 million in export sales. Hence only about 47.6 per cent of total sales were made through wholesalers. If we then assume that manufacturers realized 40 per cent of suggested consumer list price on roughly 50 per cent of their sales, and 50 per cent of list on the other half of their total sales, the manufacturer's share in the prescription dollar should be increased by one-half of the 29 cents deducted to allow for the wholesaler's margin, or 14.5 cents. This would increase the drug firm's share of the sales dollar to $1.445, or about 41.6 cents in the sales dollar, indicating an understatement of about 11.1 per cent in the PMAC Submission.

The validity of this computation depends upon the accuracy of the figures quoted by Dr. Briant and the representativeness of the Canadian Pharmaceutical Association survey. The consistency of the latter survey with the Submission of the Canadian Pharmaceutical Association before this Committee in June, 1966, is not established,

since in the latter presentation it was asserted that 62 cents, rather than 50, in the consumer's drug store dollar were accounted for by payments to drug manufacturers and distributors. (The discrepancy between 50 and 62 cents remains unexplained, since the elucidation in paragraphs 7.6 and 7.7 of the CPA Submission is less than enlightening.) (7t). Other fragmentary evidence exists to suggest that both the estimates of 37.5 per cent and 41.6 per cent of the consumer's prescription dollar may be on the low side. For example, Lederle in the United States in 1958 submitted that the manufacturer received 51 per cent of the prescription dollar. (3b). While the comparable figure for Canada would probably be lower because of the sales tax and the higher markup imposed by the druggist, it is still surprising to note the difference of from 10 to 13 percentage points in the drug maker's share of the consumer dollar.

The Reasons for Multiple Pricing

On pages 5.4 and 5.5 of the PMAC Submission some of the factors responsible for price discrimination between retail pharmacy, hospital formulary, and government bid markets are adumbrated, but not analyzed, in a section entitled "The Reasons for Multiple Pricing." Two valid reasons for price differences are stated: the sales tax exemption to hospitals and quantity discounts for large purchases, but the quantitative importance of each of these factors, taken by itself, is not indicated. It is also suggested that firms wish to have their products used in hospitals in order to allow physicians to become acquainted with them, but this consideration would seem at best a very minor factor in view of the comprehensiveness of drug industry sales promotion efforts along other lines.

The last mentioned factor is "The competitive situation." Interestingly, emphasis is not upon competition among major brand name firms, but with the producer of the "so-called generic equivalent." Also, the reference to competition is limited to hospital and government markets: "the original manufacturer has to decide whether to abandon the hospital or government market, or to reduce his price to a

level which will meet" that of a generic producer. The paragraph concludes: "In effect, he is forced to compete for business, often based on quite general specifications, against naturally cheaper, and it may well be, inferior, products. He will do this to maintain an important market or to protect the reputation of his product; in the event of the failure of a so-called equivalent formulation doctors may well blame the drug itself." (6f).

This paragraph is of interest to the student of competition in the drug industry for several reasons:

(1) It betrays the extent to which major drug firms consider themselves above the necessity of competing in the market on a price basis. In a competitive market, firms naturally expect to be "forced to compete for business" and if the products of competitors are "naturally cheaper," the decision of "whether to abandon" a given market will be made by the price-conscious buyers themselves, not the higher-cost seller. Furthermore, the art of competing is seen in terms of arriving at price levels "which will meet," not undercut, those of rivals.

(2) It also conveys the frame of mind of major sellers insofar as they do not expect to have to compete on a price basis except with generic firms in hospital and government markets. One wishes the PMAC Submission would explain why "the competitive situation" is limited to these areas. Why is the possibility not mentioned that major firms might not find a competitive situation developing between themselves in making sales to pharmacies, hospitals, and government agencies? Why is the further possibility not mentioned that major firms might have to compete on a price basis against generic firms in the pharmacy market? Is it because under present market circumstances these possibilities are too remote to warrant mention?

(3) It illustrates the propensity of the brand name firm to indulge in blanket disparagement of the quality of the products of

generic name sellers, and the skillful manner in which such a propensity can be exercised. For example, the following negative impressions of generic products are conveyed in this paragraph:

(a) The generic seller is by implication an "unfair" competitor because he has managed to avoid the now "sunk" costs of research and marketing. Actually it is a sign of economic efficiency to operate a low cost levels, and it is indicative of poor business judgment to allow past or "sunk" costs to influence one's present pricing policies, particularly in a competitive market.

(b) By referring to the "so-called generic equivalent" and "A so-called equivalent formulation" and to "naturally cheaper, and it may well be, inferior, products" PMAC is by implication disparaging any and all generic drugs without sufficient justification.

(c) By referring to the brand name version of a drug as "the drug itself" PMAC is implying that there must be a difference in kind between generic name and brand name drugs, which is also without justification.

Recommendations by PMAC

Several of the recommendations of PMAC are clearly in the public interest, if adopted as part of a more comprehensive reform and adequately implemented. The abolition of the federal sales tax on drugs is an excellent recommendation, but it does not necessarily follow that consumer prices will be reduced accordingly unless other reforms are also taken, as explained in the body of the Alberta submission.

The recommendation that an independent source of drug information for doctors and pharmacists be established is also worthy of support, provided that the source of this information remains truly independent of the drug industry. The further recommendation that more comprehensive statistics on drug costs, prices, and expenditures be collected is also praiseworthy, provided that the statistics collected and published are in all respects accurate and unbiassed. The same is

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true regarding the provision to physicians of reliable data on drug therapy costs.

On the other hand, it is hard to take seriously any reference to a program for voluntary drug price restraint. And the suggestion that the problem of drug costs is not high prices, but low incomes, should be vigorously repudiated. These are two problems, not one. Drug prices are high to the affluent as well as to the indigent because they are well in excess of production cost. The problem of high drug prices should be attacked as such, just as the problem of low incomes should be approached as an entirely separate problem, whether or not critically low incomes happen to be received by the healthy or the afflicted. PMAC recommends a wider availability of programs for drug insurance prepayment, which would "provide an effective vehicle through which government can help those who need assistance." (6g). This sounds plausible, but unless there is some control over drug prices, private insurance programs and expanded government aid will simply increase the effective demand for drugs without in any way exerting a disciplining influence over prices. The result will be increased drug prices, sales and profits.

In fact, private and public drug insurance plans and public welfare and assistance programs may prove to be impediments rather than useful expedients in the solution of the problem of high drug prices--unless the insuring agencies and the public organizations providing assistance can secure and exert bargaining power in order to discipline drug prices and charges. A common feature in most legislation of the "medicare" variety is the provision of funds which will increase effective money demand for health services without at the same time providing adequately for an increase in the supply of these services, or even for securing a more efficiently produced and reasonably priced provision of the existing supply. It is certain that if demand increases while supply remains substantially constant, prices will

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increase. This is all the more true if suppliers are not competitive and look upon the provision of more funds for health care as providing them with a guaranteed increase in their market. Hence public policy should take steps to stimulate new competition in the drug market at the same time that it undertakes measures for increasing the availability of public funds for drug care for the indigent.

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APPENDIX C

COMMENTS ON THE SUBMISSION OF THE PATENT AND TRADEMARK INSTITUTE OF CANADA

In this Submission, the Patent and Trademark Institute of Canada recommends that the legal privileges afforded drug patent holders be greatly strengthened by the repeal of Section 41 of the Patent Act, and by drafting new patent legislation "defining objectively the obligations to the public of 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 license." (7u). This would make it possible for the obligations to be narrowly defined, and even for the statutory requirement of royalties high enough to deprive the Canadian public of the benefit of genuine price competition between patent holder and compulsory licensee. In contrast, present legislation serves the interest of Canadian consumers by specifying that compulsory licenses on drug patents shall be granted unless the Commissioner sees good reason to the contrary, and by awarding royalties at rates permitting the supplying of the public at the lowest possible price consistent with rewarding the inventor. Furthermore, in this submission it is recommended that no changes be made in the Trade Marks Act which would put drug trademarks on a different footing than other trademarks. Since no recommendations are made as to the proper method of reforming drug trademarks without introducing some distinction in treatment between drugs and other trademarked goods, it is to be inferred that no change in the Trade Marks Act is to be desired.

One is reminded of the Submission of the American Bar Association before the Kefauver Subcommittee in the United States, in which every patent reform provision contemplated in the proposed Drug Industry Antitrust Act was rejected as undesirable--not from the point of view of public policy, but from an over-riding concern with the preservation of the body of patent law in the United States. It would be unfair, and an over simplification, to characterize the attitude of

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patent attorneys toward patent reform as an instinctively conservative reaction in the direction of protecting obvious vested interests in the subject matter of their profession. The roots of their opposition are more ramified and more complex. Still, it is doubtful if the Patent and Trademark Institute is qualified to deal with problems of patent reform from a purely objective and disinterested perspective.

Nor is the Institute qualified to deal with the economics of the patent system as it affects competition in the drug market. Mr. Smart, in speaking for the Institute before this Committee, was explicit on this point: "We, as members of the Institute to which we belong, are not concerned with and are not knowledgeable on the economic aspects of the subject." (7w). The Submission itself, furthermore, is more than modest in claiming that it comes to grips with the major problems of drug costs and prices with which this Committee is concerned. In the introduction to the Institute's brief it is stated that "While we do not deal directly with drug costs and prices we feel that in relation to our object of promoting clear legislation which is easy to understand and administer we are, in relation to patented and trade marked drugs at least, dealing with a factor of cost...Thus, while our submission is mainly directed to the state of the law, it is not wholly without relevance to the subject of costs and prices." (7x). The more important object would seem to be to promote legislation which is in the public interest; clarity, although desirable, should be a secondary consideration. (For that matter, if the minimization of patent litigation costs and uncertainties is of paramount importance, it would seem that this could be done most effectively by abolishing drug patents.)

As was pointed out at some length in the report of the Ilsley Commission, the system of patent law as a whole has many critics and is subjected to many criticisms. Most of these criticisms become more pointed when directed to drug patents. Some of these criticisms

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seem particularly compelling to economists, who are professionally concerned with promoting competition and controlling monopolistic forces. While most of the countries in the world grant process patents[1] on drugs, the great majority of them regard the granting of product patents on drugs as contrary to humane public policy and hence insupportable. Of those countries granting both product and process patents, only Panama, Belgium, and the United States have been sufficiently indifferent to the interests of the consumers as to make no provision for compulsory licensing of food and drug patents under appropriate circumstances. The basis in public policy for denying product patents is the principle that no one should be entrusted with absolute monopoly power over products essential for human health and life. In chemical industries, however, owing to the ease with which

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1 Even an economist who has been retained by counsel for a trade association of drug makers may not be able to resist expressing his reservations concerning the suitability or expediency of existing patent law. Prof. E.V. Rostow, Dean of Yale University Law School, when appearing before the Kefauver Subcommittee on behalf of the Pharmaceutical Manufacturers Association of the United States, stated: "I recall a meeting of a committee of the American Law Institute where Judge Learned Hand remarked that one of the strongest impressions he had of his many years on the federal bench was that the patent law had some fundamental defects. His view is supported by a good deal of evidence, including the studies of scholars, and some useful papers prepared for this and other congressional committees. We need much more information, and much more research and study about the conditions of creativity of American science, before we can be sure that our patent law, and other arrangements for encouraging and rewarding creativity in science, are in fact adequate and effective. (9i).

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process patents could be by-passed through the devising of new (and hopefully improved) processes, it was felt to be in the public interest to allow drug process patents and hence to improve the prospects for rapid technical progress. As L.J. Robbins has observed, "The limitation of protection for chemical products in general as well as pharmaceutical products in particular, to process claims, is essentially a continental European conception, and is tied up with social thinking in the 19th century during the industrial revolution. It became a matter of practically unassailable dogma that if the public is to receive the benefit of new chemical or pharmaceutical products at a reasonable price and in amounts sufficient to meet the demand, that this could only be accomplished by restricting the inventor to his process, so that others will be encouraged to invent new and improved processes which will make the product cheaper and available in greater quantities." (24). With these considerations in mind one can better evaluate the positions taken by the Institute regarding drug patents and the Patent Act.

It is contended that abolition of drug patents would occasion at least three difficulties. One of these consists in the difficulty of identifying a drug patent. This is apparently a very good point, and if it is decided to abolish drug patents, great care should be taken in drafting the law to insure that drug patents are very inclusively defined. It is in such an area as this, rather than in the field of establishing public policy goals, that the assistance of the Institute in drafting reform legislation would be invaluable. A second difficulty is said to reside in the necessity of making patent abolition apply to drugs patents already granted but not yet expired. In itself, this should occasion no real difficulty; the Institute seems to be concerned, rather, with possible inequities rather than technical legal difficulties. The sentence, "The alternative, that of making the legislation retroactive, would give rise to difficulty of compensation to the patent holders and applicants whose rights were legislated out

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of existence posing almost insurmountable problems of assessment and valuation or the imposition of what would effectively be legislative confiscation without compensation." (7y) seems to raise some problems which are more apparent than real. In an economic sense, patents confer privileges, not rights. If the social value of the process patent device in drugs is to stimulate more rapid invention, then the virtue of the patent privilege resides not in the reward which it gives to the possessor of an existing patent, but in the incentive which it gives others to by-pass the patent. In other words, the patent system should be regarded as designed to improve technology not so much because of existing patent protection, as in spite of it. The abolition of drug patents would presuppose a conviction upon the part of the public that drug process patents were not an expedient means of promoting such technical progress; hence the privilege which the patent conferred upon past possessors was undeserved. Under these circumstances it is an open question whether abstract equity would not be better served by seeking to recover damages from previous patent holders than by awarding compensation to those whose monopoly privileges have been terminated earlier than expected. In the United States it is an established principle of antitrust law that in the exercise of the regulation of prices charged by monopolists such prices may be lowered without entitling the monopolist to compensation because the reduction in price lowered the discounted future value of prospective monopoly p profits and hence reduced the market value of the monopolistic firm as an entity. It has been held that the expectation of the undisturbed exercise of monopoly pricing powers and the capitalization of anticipated future monopoly profits therefrom does not create a property right to compensation when such market values are destroyed by price regulation. The same principle should in all fairness be applied to patent monopolists, particularly if and when the time arrives when it is decided that drug patents are contrary to the public interest.

A third objection is more serious, namely, the threat of international retaliation. This is the most important reason why

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licenses to import may be preferable to the complete abolition of drug patents. The Institute asks this question: "Since the proposal does have international implications it is fair to ask how such measure would affect Canada's image abroad." (7z). It is likely that Canada's "image" will be enhanced in the minds of those throughout the world who feel that it is only just to protect the drug consumer against economic exploitation.

In recommending the abolition of section 41 of the Patent Act, the Institute advances a number of reasons for its position. First, it is alleged that since 1923 the science of chemistry has advanced so greatly that the "philosophy" behind section 41 is no longer valid. Second, it is submitted that the advance of science has rendered the words of the statute no longer clear and precise, but instead subject to a variety of plausible interpretations. The point of the illustrations given in support of the second contention is that the current interpretation of section 41 (1) by the courts makes it "booby-trapped with special requirements for validity which are frequently impossible to meet." (7aa). In support of the first contention some rather more substantive issues are raised. It is alleged that at the time section 41 was passed, the promise of chemistry was envisaged in terms of process improvements rather than the devising of wholly new products. Since that time, it is argued, synthetic chemistry has become more important, and compounds not occurring in nature can be routinely synthesized, while diminishing returns have set in for process innovations, such that a fundamentally new chemical method is said to be extremely rare. Reference is made to a decision of the Supreme Court of Canada in which it was held that the inventive virtue for a given drug resided in the discovery of the useful properties of the product rather than in the method of producing it. The conclusion is that what was in 1923 "regarded as the inventive merit, namely the process, is out of place in a later day and age which regards the discovered intrinsic properties of the product as the seat of inventive merit." (7aa). This discussion

raises the question that under these circumstances neither the product per se not the process is regarded as constituting invention. This suggests the possibility that drug developments may become fundamentally unpatentable under conventional patent laws. This brings to mind one of the major criticisms of patent law--that it rewards certain types of "inventions" quite lavishing and cannot be adapted to rewarding other types of productive creativeness. Judged from this perspective, some of the complaints against the obsolescence of the "wording" of section 41 (1) of the Patent Act may be interpreted more broadly as implying that increasing emphasis on proof of the useful properties of a newly discovered compound may make drug patent protection of the conventional type practically unobtainable regardless of ingenuity in wording a statute.

In response to these observations, it may be argued that the purpose of section 41 is to protect the consumer against exploitation by drug patent holders. If the science of chemistry has advanced so greatly since 1923, the "philosophy" behind section 41 referred to by the Institute may be more valid than ever, particularly if the collective economic power of the major drug firms in the world drug industry (but not necessarily of individual firms taken singly) has greatly increased as a result. Secondly, it may then be desirable that judicial interpretation of section 41 (1) has made it increasingly difficult to secure a drug patent, since the inventive merit in what it has been considered is in the public interest to make patentable--the process innovation--has allegedly decreased. And it is by no means certain that it is in the public interest to make what is currently increasingly regarded as the inventive merit--the discovery of the useful properties of a compound--routinely patentable.

Some very useful observations are made by the Institute in regard to improving the patent law to make more adequate provision for the public interest in respect to food and drugs. Since section 41 (1) prohibits the patenting of new compounds only when produced by chemical processes and intended for food or medicine, it prevents the possibility

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of compulsory licensing of foods or drugs not made by chemical processes. Further, it does not allow for the compulsory licensing of patents on products or processes not originally intended for food or durg applications but subsequently discovered to have such applications before the period of patent protection has expired. The aid of the Institute would be invaluable in this context as well, in drafting legislation which would provide for compulsory licenses in each of these instances.

The Institute expresses the opinion that the repeal of section 41 (1) would serve a useful purpose in encouraging technological advance in drugs; beyond that, it is asserted that the importance of the patent incentive "is, if anything, greater in relation to the medical arts than it is in relation to the other useful scientific arts." (7bb). Any number of physicians and medical technicians who have devised diagnostic aids or surgical inventions and innovations and have been above patenting them might well take exception to this statement.

The language in which the Institute denounces section 41 (3)[1] constitutes a recognizable rhetorical landmark in these proceedings: "In short, the intent of this section as interpreted by the courts is to take from the patentee and give to anyone who make application the right to, for practical purposes, a virtual free ride on the patentee's coat-tails unless the Commissioner of Patents sees some as yet undefined "reason to the contrary."" (7cc). If patent holders actually do feel thus thwarted it is perhaps an indication that section 41 (3) is being interpreted in accordance with the intent of protecting drug consumers by promoting competition. The best expression of the contrary attitude--that the world owes the drug patent holder a living--is to be found in

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1 The best recent example of this is the invention of the "mechanical heart", devised by a team of researchers from Baylor Medical College in Houston, Texas and a local engineering school. Dr. Michael DeBakey spoke for the entire group when he characterized as unthinkable the notion of obtaining a patent on this life-saving device.

Cyanamid's unusually colorful Submission to this Committee. A parable is developed at some length in which the virtues of the "Innovator" are proclaimed in bold contrast to the parasitic character of the "Copier." Space is lacking in which to supply an economic interpretation of this ethical parable. To an economist it is obvious that the word "innovator" should be replaced by "monopolist" and the word "copier" should be replaced by "competitor." This may be the most concise way in which to deflate the atmosphere of moral indignation created, and place things in a true economic perspective. (For example, the Copier is castigated since he "obtains his bulk active ingredient on the world market at the lowest possible price"[1] as if there were some more logical way of doing business efficiently.) (7dd). The Hoffman--La Roche Brief engages in the same sort of earnest discussion of "originators" and "copiers" and contains many revealing remarks (such as "competition, which is meaningless if it is not equal" (7ff) which suggest that monopoly privilege has become such a way of life that the firm is really disoriented to the realities of a competitive market.

The Institute rejects the recommendation of the Hall Commission that section 20 of the Trade Marks Act be amended to eliminate the possibility of infringement proceedings when goods bearing the same trademark but produced by domestic and foreign related companies, are sold in competition in the domestic market. The grounds for rejecting this recommendation are not entirely clear. On the one hand it is urged that the public interest in the integrity of trade marks is great, and

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1 During the Proceedings before this Committee, Mr. Bertrand of Cyanamid was asked by Mr. O'Keefe: "Is your firm always an innovator and never a copier?" The reply was in the affirmative. (7ee). But outside observers might not be so charitable. C. E. Silberman has observed that Cyanamid's Lederle division is so versatile that it is not limited to innovating wholly new departures in drugs, but can also mount a molecular-manipulation effort to keep abreast of the developments of others. This is perhaps not "copying" in the narrow sense of the Cyanamid parable, but it is not fundamental innovation either. (13)

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probably greatest in the area of drugs. On the other hand, the nature of this public interest is not satisfactorily specified. It is emphasized that a trademark is a badge of origin for a particular good, certifying its quality and the conditions of its manufacturer. This can only be true in a very general sense; otherwise different trademarks would have to be applied to goods produced in different plants, in different grades or qualities, and by different methods, even if the same firm were the producer. Mr. Smart came closer to identifying the commercial value of the trademark (as possibly distinct from the differential use value of the trademarked product to the consumer relative to that of another product bearing another trademark) when he stated: "A trade mark is something that has validity because of something that is in the minds of the public in relation to it." (7gg). Hence the value of a trademark to a firm is created by successful advertising and sales promotion strategies which differentiate the trademarked product from the products of other sellers. The precise value of the trademark to the buyer, however, is difficult to determine.

As the law now stands, it appears that trademarks do not necessarily function as a badge of origin--not only with regard to plant of manufacture, but even with regard to country of manufacture. It appears that if a Canadian firm does not own the trademark registration but merely uses the mark as a registered user, the sale of goods bearing the same trademark, but produced abroad rather than in Canada, would not consitutue trademark infringement. Furthermore, the Institute observes that any company which found its Canadian subsidiary was being injured by importation of identically trademarked wares from related companies abroad would thereupon change the trademark used by the Canadian firm. This is surely a possibility, but it may occasion some cost, particularly in the case of a Canadian subsidiary of a United States firm where the trademarked name of the firm's product is well-known in Canada through intensive advertising in North American media read and heard in both countries. In such a case, changing the name

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and trademark of the Canadian product would cost the subsidiary the accumulated "good will" associated with the widely known and persistently advertised brand name. However, it is surely logical that such a step be taken, if the virtue of the trademark resides in its being a unique badge of origin.

The Institue is also of the opinion that reform is unnecessary since there is nothing in the Trade Marks Act to prevent a Canadian importer from purchasing abroad finished drugs from a related company of a Canadian firm and then selling them in Canada under the importer's own label. However, there is nothing in the Trade Marks Act which compels the related company to sell to the Canadian importer for repackaging purposes--this might not be consistent with the foreign affiliate's view of the fitness of things. More importantly, even if the importer obtained the very highest quality finished drugs from the foreign trade mark holder, if he sold them under his own (presumably less well known) brand name, he would be likely to sell less and to be forced to charge a lower price because he would not be selling them under the foreign firm's widely advertised brand name.

Finally, the Institute suggests that there is no need for reform in the Trade Marks Act because section 30 of the Combines Investigation Act may be invoked in cases of the abuse of trademarks. It is hard to take this recommendation seriously since the expense, delays, and general cumbersomeness and uncertainty of such proceedings would make this remedy in every sense of the phrase a last resort.

Appendix D

DRUG PRICES IN ALBERTA ANTIBIOTICS

1	2	3	4	5	6	7	8
Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Erythromycin 250 mg.	Erythrocin Abbott	$4.96 to 5.02 per 100 g.b. 177(1)	$40.55/100	$27.03/100		$18.35/100	
	Ilosone Lilly		$40.55/100	$24.33/100		$14.50/100	
Novabiocin 250 mg.	Albamycin Upjohn	$14.64/100	$50.50/100	$30.30/100		$25.60/100	
	Cathomycin Merck	$6.91/100 g.b. 181(2)	$50.50/100	$30.30/100		$22.75/100	
Tetracycline 250 mg.	Achromycin Lederle	$644.15 kg g.b. 169 $340.00 kg (2)	$540/16 $29.50/100	$17.70/100		$13.05/100	
	Tetracyn Pfizer	$156.71 to $525.36 kg g.b. 169	$30.00/100	$21.99/100		$16.20/100	
	Tetrex Bristol	$140.00 kg or $3.50/100 g.b. 169	$30.00/100	$18.00/100		$16.22/100	
	Muracine Nadeau	N.A.	$32.00/100	$16.00/100		$4.60/100	
	Canada Pharmacal					$30.30/M	

(1) Green Book: Department of Justice, Ottawa, 1961, Report on Manufacture, Distribution and Sale of Drugs by Director of Investigation and Research, Combines Investigation Act.
(2) The theoretical cost of the drug in 100, 250 mg. capsules at Merck's buying price (i.e. $276.50 per kilogram) would be $6.91.
(3) Cost of 88% crude aureomycin refined and chemically converted to Achromycin. See R.T.P.C. proceedings Vol. 15 p.1651
(4) See also chart reproduced in Submission of Alberta to Hall Commission showing Upjohn's and Bristol's costs and selling prices for tetracycline capsules.
(5) Ditto

ANTIBIOTICS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
	Empire Generic	NA	$20.60/100	$12.36/100			
Tetracycline 250 mg	Gilbert Generic	NA	$6.00/100	$4.50/100	$3.75/100	$3.96/100	
Chloro-tetracycline 250 mg.	Aureomycin Lederle	$476.51 kg	$5.40/16 $29.50/100	$3.24/16 $17.70/100		$15.95/100	
Chloram-phenicol 250 mg	Chloromycetin Parke, Davis	$90.00 kg or 2¼¢ each or $2.25/100	$39.40/100	$23.60/100		$12.50/100	
gb 168	Enicol Intra		$39.40/100	$23.82/100		$9.00/100	
	Mycinol Horner		$39.40/100			$9.50/100	
	Empire Generic		$15.70/100				
Cycloserine 250 mg	D-Cycloserine Hoffmann, La Roche	$14.76/100 g.b. 178	$49.10/100	$29.46/100		$21.36/100	
	Seromycin Lilly	g.b. 178 $5.96/40 $71.93/500	$19.50/40 $233.34/500	$11.70/40 $140.00/500			

CORTICOSTEROIDS

Generic Name	Brand Name	Manufacturer's Cost (1)	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Prednisone 5 mg	Meticorten Schering		$7.10/30 $22.70/100 $109.00/500	$13.62/100		$9.25/1000	
	Prednisone British Drug Houses		$4.20/100 $20.00/500	$2.52/100		$6.75/1000	
	Delta Cortef Upjohn		$3.00/30 $22.70/100	$16.34			
	Paracort Parke, Davis		$4.20/100			$1.20/100	
	Colisone Frosst		$4.20/100	$2.80/100		$6.95/1000	
	Prednisone Intra		$7.20 ? $4.20/100	$4.50/100 ?		$1.33/100	
	Prednisone Empire		$4.00/100 $18.00/500				
	Prednisone Gilbert		$11.00/500	$8.80/500		$7.74/500	
	Prednisone Bell-Craig		$3.50/100 $13.50/500 $23.50/1000			$2.10/100 $8.10/500 $14.10/1000	

(1) Manufacturer's Cost is left blank because the Statement of Material Collected by the Director of Investigation and Research, Combines Investigation Act, does not cover Corticosteroids.

The United States Senate Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary (the Kefauver Committee) fully investigated Corticosteroids and at page 17 of its Report of May 8, 1961 the following statement is made:

" On a per tablet basis, the consumer using either prednisone or prednisolone bearing the brand name of one of the major pharmaceutical firms will pay approximately 30 cents for a pill which is sold to the druggist for some 18 cents and which can be produced for 1.5 cents or less. An arthritic patient will frequently remain for long periods on a dosage of about 100 of the 5-milligram tablets a month; thus he pays $30 a month for his medicine, for which his druggist paid around $18 but which cost around $1.50 to produce."

CORTICOSTEROIDS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Prednisolone 5 mg	Meticostelone Schering	$1.57/100 (1)	$22.70/100 $109.00/500	$13.62/100		$10.00/500	
	Generic Bell-Craig		$3.67/100			$2.20/100	
	Generic Empire		$6.00/100 $27.50/500				
	Generic Gilbert		$11.50/500	$9.20/500		$8.09/500	
Triamcinolone 4 mg	Aristocort Lederle		$38.39/100	$23.00/100		$17.27/100	$17.27/100
	Kenacort Squibb		$38.40/100	$25.60/100		$18.65/100	
Dexamethasone 0.75 mg	Decadron Merck		$29.80/100	$17.88/100		$14.50/100	
	Generic Gilbert		$43.00/500	$34.40/500		$30.72/500	
	Generic Empire		$12.50/100 $57.00/500				
	Deronil Schering		$29.80/100 $140.00/500			$14.50/100 $44.50/500	

(1) Green Book p51: "No detailed information was obtained about cortisone or any related product. However, for comparative purposes, it may be noted that evidence before the recent senate committee in the United States was to the effect that, for Schering's prednisolone sold under the name meticortelone, the cost of manufacturing 100 tablets (five mg.) was $1.57. The selling price to a retail druggist was $17.90 and the suggested retail price was $29.83. The list or suggested selling price of the same tablets in Canada is $33.13." Note: Schering's present list price is $22.70/100.

CORTICOSTEROIDS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Methyl-prednisolone 4 mg	Medrol Upjohn		$29.00/100	$17.40		$15.66/100	

TRANQUILLIZERS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Promazine 25 mg	Sparine Wyeth	$0.0950/100 g.b. 198	$5.25/50 $45.00/500	$4.37/100	$3.71/100	$3.03/100	$21.00/1000
	Intrazine Intra	$0.0950/100 g.b. 198	$6.50/100			$1.83/1000	$19.50/1000
	Pro-Tran Mowatt & Moore	$0.0950/100	$4.75/50	$2.85/50	$2.42/50	$0.86/100	$8.58/1000
	Generic Empire		$1.50/100 $4.50/500				
	Generic Bell-Craig		$1.60/100 $5.00/500			$5.70/1000	
	Generic Gilbert		$4.00/500	$3.20/500		$2.81/500	
Chlor-promazine 25 mg	Largactil Poulenc	$53.00 kg or $0.133/100 g.b. 186	$8.90/100 $38.30/500 $68.00/1000	$5.34/100	$4.54/100		$11.00/1000
50 mg	"	$0.265/100	$12.80/100 $55.30/500			$2.54/100	$20.00/1000
25 mg	Generic - Empire		$16.00/500				
50 mg	Generic - Empire		$6.70/100 $28.00/500				$3.00/1000

TRANQUILLIZERS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Chlor-promazine 25 mg	Generic Bell-Craig		$2.09/100 $22.00/500 $40.00/1000			$ .10/1000	
50 mg	Generic Bell-Craig		$2.70/100 $11.00/500 $21.00/1000			$12.60/1000	
25 mg	Generic Gilbert		$6.60/500	$5.28/500			
50 mg	Generic Gilbert		$2.35/100 $10.00/500	$1.88/100 $8.00/500		$7.04/500	
Perphenazine 2 mg	Trilafon Schering	$5.10/1000 g.b. 194	$4.30/50 $8.60/100 $37.90/500			$2.32/100 $20.49/500	$19.85/1000
Trifluo-perazine 1 mg	Stelazine SKF	$1.15/1000 g.b. 201	$4.75/50	$2.85/50 $25.80/500		$4.65/100	2 mg. $32.00/1000 5 mg. $43.20
	Triflurin Paul Maney		$3.80/50			$1.70/100	
	Triperazine Gilbert		$3.50/100	$2.80/100		$2.46/100	
Hydoxyline 10 mg	Atarax Pfizer	$.043/100 g.b. 190	$6.16/100 $27.55/500	$3.70/100		$3.00/100	
25 mg	Atarax Pfizer		$11.00/100 $49.70/500			$6.72/100	$44.78/1000

TRANQUILLIZERS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Tranyl-Cypromine 10 mg	Parnate SKF		$4.25/50	$2.55/50		$4.58/100	$30.00/1000
Thiori-dazine 100 mg	Mellaril Sandoz	$33.40/1000 g.b. 201	$12.50/50 $100.00/500			$85.50/1000	$65.80/1000
Triflu-promazine HCl 25 mg	Vesprin Squibb	$11.39/1000 g.b. 201	$13.50/100	$8.10/100		$7.36/100	$41.00/1000
Phenelzine Dihydrogen Sulphate 15 mg	Nardil Warner - Chilcott		$8.00/100 $38.00/500 $80.00/1000	$5.05/100 $48.00/1000	$4.08/100 $40.80/1000	$4.55/100	$31.00/1000
Meprobamate 400 mg	Equanil Wyeth	$.018/50 g.b. 192	$5.00/50 $43.75/500 $85.00/1000	$26.25/500 $51.00/1000	$22.31/500 $43.35/1000	$13.90/500	$34.12/1000
	Miltown Horner	$1.80/500 g.b. 192 (1)	$43.75/500				
	Generic Bell-Craig		$1.60/100 $6.25/500 $11.30/1000			$1.05/100 $3.90/500 $6.90/1000	
	Generic Empire		$1.60/100 $6.25/500 $11.30/1000				
	Generic Gilbert		$5.00/500 $9.75/1000	$4.00/500 $7.80/1000		$3.52/500 $6.86/1000	

(1) At the date of the Green Book (1961) Miltown was a product of Ayerst.

TRANQUILLIZERS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Imipramine H.C.L. 25 mg	Tofraine Geigy	N.A.	$12.60/100	$7.56/100	$6.43/100	$7.56/100	$42.36/1000
Fluphenazine 1 mg 2 mg 5 mg	Moditen Squibb	N.A.	1 mg $19.00/100 2 mg $25.00/100 5 mg $43.00/100			$10.27/100	$97.88/1000 $150.00/1000
Levome-promazine 25 mg 50 mg	Nozinan Poulenc Poulenc	N.A.	25 mg $12.60/100 $63.00/500 50 mg $17.60/100 $88.00/500			$56.70/1000 $79.20/1000	$41.50/1000 $59.50/1000
Promethazine 25 mg 50 mg	Phenergan Poulenc Poulenc		25 mg $5.50/100 $27.50/500 50 mg $9.90/100			$23.00/1000 $41.00/1000	$17.50/1000 $31.50/1000
Oxazepam 10 mg 15 mg 30 mg	Serax Wyeth		10 mg $8.00/100 15 mg $10.00/100 30 mg $14.50/100			$18.71/500 $23.39/500 $33.93/500	$46.78/1000 $46.78/1000 $67.80/1000
Prochlor-Perazine 5 mg 10 mg 25 mg	Stemetil Poulenc	N.A.	5 mg $7.00/100 $35.00/500 10 mg $9.00/100 $45.00/500 25 mg 12.00/100 60.00/500			$17.50/500 $22.50/500 $30.00/500	$21.00/1000 $30.00/1000 $38.00/1000

TRANQUILLIZERS

Generic name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Nortriptyline 25 mg	Aventyl Lilly	N.A.	$6.50/50 $13.00/100 $31.50/250	$3.90/50 $18.60/250		$36.72/1000	$36.28/1000 Lilly, July 14/65 10 mg-$28.80/1000 25 mg-$55.80/1000 $53.00/5000
Chlor-diazepoxide 5 mg 10 mg 25 mg	Librium Roche	N.A.	5 mg $9.00/100 $40.00/500 $76.00/1000 10 mg $12.00/100 $54.00/500 $102.00/1000 25mg $18.50/100 $83.00/500 $157.00/1000	5 mg $5.40/100 $24.00/500 $45.60/1000 10 mg $7.20/100 $32.40/500 $61.20/1000 25 mg $11.10/100 $49.80/500 $94.20/1000		$28.50/1000 $38.20/1000 $58.80/1000	$34.00/1000 $52.00/1000
	Protensin Elliott-Marion	N.A.	5 mg $8.50/100 /500 /1000 10 mg $10.85/100 /500 $97.50/1000 25 mg $18.00/100 /500 /1000			$29.75/1000 $31.50/1000 $54.25/1000	
	Bell-Craig						

TRANQUILLIZERS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital, Edmonton	Price to Alberta Department of Health
Amitriptyline H.C.L. 25 mg.	Elavil MS & D	NA	$12.50/100 $60.20/500			$6.75/100 $32.50/500	$47.50/1000
Trimipramine 25 mg 100 mg	Surmontil Poulenc	NA	25mg: 12.60/100 63.00/500 100mg: 38.00/100			$3.50/100 $31.50/500 $57.00/1000	$45.00/1000 $135.00/1000
Desipramine H.C.L. 25 mg.	Pertofrane Geigy	NA	$13.20/100 $66.00/500			$7.92/100 $39.60/500	$56.50/1000
Diazepam 5 mg 10 mg	Valium Roche		5 mg $7.95/100 $67.92/1000 10 mg $12.90/100 $110.28/1000	5 mg $13.50/100 $113.20/1000 10 mg $21.50/100 $183.80/1000		$5.96/100 $50.99/1000 $9.68/100 $82.79/1000	$41.82/1000 $67.88/1000

DIABETES DRUGS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital, Edmonton	Price to Alberta Department of Health
Tolbutamide 0.5 gram	Orinase Hoechst		$6.25/50 $59.40/500			$42.00/1000	$4.20/100 by tender
	Mobenol Horner		$6.25/50 $59.40/500			$42.00/1000	$4.20/100 by tender
	Canada Pharmacal					$11.75/1000	
	Generic Gilbert		$9.50/500 $18.25/1000				
	Generic Empire		$5.00/100 $23.00/500 $44.00/1000				
Chlor-propamide 250 mg	Diabinese Pfizer		$12.11/100 $57.00/500		$6.06/100 $28.50/500	$5.90/100 $28.24/500	$5.00/150
Phenformin H.C.L. 50 mg.	DBI-T.D. Arlington-Funk		$17.25/100	$10.35/100		$7.80/100	$5.89/100

APPENDIX E

1962

CHAPTER 61

An Act to amend The Alberta Pharmaceutical Association Act

(Assented to April 5, 1962)

HER MAJESTY, by and with the advice and consent of the Legislative Assembly of the Province of Alberta, enacts as follows:

1. The Alberta Pharmaceutical Association Act, being chapter 232 of the Revised Statutes, is hereby amended.

Section 2 amended

2. Section 2, clause (c) is amended
(a) by striking out the word "or" at the end of subclause (i) and by adding the word "or" at the end of subclause (ii),
(b) by adding immediately after subclause (ii) the following new subclause:
(iii) in the Food and Drug Act (Canada) or the regulations thereunder;

New section 45

3. The following new section is added immediately after section 44:

Prescription by generic name

45. Where a prescription refers to a drug or drug combination by a brand name or a name other than its generic name, a pharmaceutical chemist, in dispensing the prescription, may use a drug or drug combination that is the generic or brand name equivalent of that named in the prescription unless the prescriber indicates otherwise
(a) by designating the name of the manufacturer, or
(b) by specifying that no equivalent is to be dispensed.

Coming into force

4. This Act comes into force on the day upon which it is assented to.

Printed by L.S. WALL, Printer to the Queen's Most Excellent Majesty,
Edmonton, Alberta, 1962

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HOUSE OF COMMONS

First Session—Twenty-seventh Parliament

1966-67

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

Chairman: Mr. HARRY C. HARLEY

PROCEEDINGS

No. 34

THURSDAY, MARCH 2, 1967
THURSDAY, MARCH 9, 1967
FRIDAY, MARCH 10, 1967
TUESDAY, MARCH 14, 1967
THURSDAY, MARCH 16, 1967
MONDAY, MARCH 20, 1967
TUESDAY, MARCH 21, 1967

INCLUDING

(a) Second and Final Report to the House
(b) List of Witnesses Heard
(c) Index of Briefs, Statements and Correspondence
(d) List of Documents Tabled
(e) List of Appendices

ROGER DUHAMEL, F.R.S.C.
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OTTAWA, 1967

25730—1

SPECIAL COMMITTEE ON DRUG COSTS AND PRICES

Chairman: Mr. Harry C. Harley

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

and

Mr. Brand,	Mr. Howe (*Wellington-Huron*),	Mr. O'Keefe,
Mr. Clancy,	Mr. Hymmen,	Mr. Orlikow,
Mr. Côté (*Dorchester*),	Mr. Isabelle,	Mrs. Rideout,
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Mr. Goyer,	Mr. Mackasey,	Mr. Tardif,
Mr. Howe (*Hamilton South*),	Mr. MacLean (*Queens*),	Mr. Whelan,
		Mr. Yanakis—24.

(Quorum 10)

Gabriel Savard,
Clerk of the Committee.

REPORT TO THE HOUSE

MONDAY, April 3, 1967.

The Special Committee on Drug Costs and Prices has the honour to present, as its Second and Final Report, the annexed document.

Respectfully submitted,

HARRY C. HARLEY,
Chairman.

25730—1½

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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.

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

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

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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 tc 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 approach 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".

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 Chapter VII, Item 6 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 individua' 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 sma'l 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

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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.

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

[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.[a] 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

[a] 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.

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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 has been operating for over eight years. Under the U.K. programme, 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 such provincial governments as wish to participate, a study of the feasibility 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

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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 drugs 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 va'ue 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 wou'd 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.

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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. ¼)		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.	Merck 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. ¼)		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

Bonn

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	Norethynodrel 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

Boston

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

25730—6½

MARKETING EXPENSES (1956) 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.)	$ 16,844,023	$ 12,176,898	$ 4,667,125
(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)	4,694,292	3,367,367	1,327,025
(c) Advertising and Promotional Expenses	11,238,255	9,980,809	1,257,446
TOTAL	$ 32,977,381	$ 25,724,814	$ 7,252,567
2. How much Did You Spend on the Following During the Year:			
(a) Medical Exhibits and Space	290,257	190,368	99,889
(b) Medical and Pharmaceutical Journal Advertising	2,331,287	2,113,000	218,287
(c) Direct Mail Advertising	2,230,429	2,008,000	222,429
(d) Samples (This refers to promotional samples only and does not include sales samples, etc.)	3,000,840	2,792,969	207,871
(e) Other:			
(i) Product	1,704,459	1,298,888	405,571
(ii) Non-Product	404,221	321,619	102,602
TOTAL	$ 11,469,459	$ 10,125,844	$ 1,343,615

30750—61

MINUTES OF PROCEEDINGS

THURSDAY, March 2, 1967.
(50)

The Special Committee on Drug Costs and Prices met *in camera* this day at 9.50 a.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout, and Messrs. Asselin (*Richmond-Wolfe*), Brand, Enns, Harley, Isabelle, MacDonald (*Prince*), Mackasey, MacLean (*Queens*), Orlikow, Rynard, Tardif, Yanakis (13).

In attendance: Mr. A. M. Laidlaw, Q.C., of Ottawa, Legal Counsel for the Committee.

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

Resolved,—1. That the supplementary submission to the Comittee by the Pharmaceutical Manufacturers Association of Canada be printed as an appendix to the Committee's Minutes of Proceedings and Evidence (*See Appendix "A"*).

2. That a letter dated February 24, 1967, addressed to the Chairman of the Committee and signed by Mr. J. E. Halliday, Chairman of the Canadian Conference of Pharmaceutical Faculties, and Mr. F. Norman Hughes, President of the Canadian Association of Deans of Pharmacy, University of Toronto, containing a statement re: *The Extent of Pharmaceutical Education required by Modern Pharmacists*; and re: *Safety Factors provided by Pharmaceutical Services*, be also printed as an appendix to the Minutes of Proceedings and Evidence (*See Appendix "B"*).

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

Resolved—That a letter dated February 20, 1967 to the Chairman of the Committee from Dr. M. Pernarowski, Ph.D. of Vancouver, Associate Professor, the University of British Columbia, and the enclosed copy of speech made by him at the University of British Columbia be printed as an appendix to the Minutes of Proceedings and Evidence (*See Appendix "C"*).

The Committee discussed the availability of the Evidence given on February 14, 1967, when the brief of the Province of Alberta was presented.

Ordered—That a copy of the unedited transcript be made available for the information of the Members.

The Committee discussed the format of the report to the House.

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

Resolved—That the "Second and Final Report to the House" submitted by this Committee be reproduced in booklet form; and that 1,500 copies in English and 1,000 copies in French of that booklet be printed.

On motion of Mr. Isabelle, seconded by Mr. Brand,

Resolved—That the Chairman be authorized to arrange for the employment of a steno-typist to assist in the completion of the Committee's work and that such steno-typist be employed on a casual basis at the salary rate of the Members' stenographers.

The Committee proceeded to the consideration of Chapter VI of a draft report to the House.

At 12.30 p.m., the Committee adjourned until after the Orders of the Day.

AFTERNOON SITTING
(51)

The Committee reconvened *in camera* at 4 o'clock p.m., the Chairman, Mr. Harry C. Harley, presiding.

Members present: Mrs. Rideout, Messrs. Brand, Harley, Hymmen, Isabelle.

In attendance: Mr. A. M. Laidlaw, Q.C., Legal Counsel for the Committee.

The Committee resumed consideration of Chapter VI of a draft report to the House.

At 4.50 the members being called in the House for a vote, the Committee adjourned until 8 o'clock p.m. this evening.

EVENING SITTING
(52)

The Committee met again *in camera* at 8.30 p.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Messrs. Brand, Enns, Harley, Hymmen, MacDonald (Prince), MacLean (Queens), Orlikow and Rynard.

In attendance: Mr. A. M. Laidlaw, Q.C., Legal Counsel for the Committee.

The Committee resumed consideration of Chapter VI of a draft report to the House.

At 10.15 p.m., the Committee adjourned to 8 p.m. Monday, March 6.

THURSDAY, March 9, 1967
(53)

The Special Committee on Drug Costs and Prices met *in camera* today at 3.06 o'clock p.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout and Messrs. Brand, Harley, Howe (*Hamilton South*), Hymmen, Isabelle, MacDonald (*Prince*), Mackasey, MacLean (*Queens*), O'Keefe, Orlikow, Rynard, Yanakis (13).

The Committee considered a draft report to the House.

At 5.55 p.m., the Committee adjourned to 8.00 o'clock p.m. this evening.

EVENING SITTING
(54)

The Committee reconvened at 8.15 o'clock p.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout, and Messrs, Brand, Sarley, HOWE (*Hamilton South*), Hymmen, Isabelle, Mackasey, MacLean (*Queens*), O'Keefe, Orlikow, Rynard, Yanakis (12).

The Committee resumed consideration of a draft report to the House.

At 10.20 p.m., the Committee adjourned to 1.00 o'clock p.m., Friday, March 10, 1967.

FRIDAY, March 10, 1967.
(55)

The Special Committee on Drug Costs and Prices met *in camera* today at 1.10 o'clock p.m. The Chairman Mr. Harry C. Harley, presided

Members present: Mrs. Rideout and Messrs. Brand, Harley, Howe (*Hamilton South*), Isabelle, Mackasey, MacLean (*Queens*), O'Keefe, Orlikow.

The Committee resumed consideration of a draft report to the House.

At 3 o'clock p.m. the Committee adjourned to 9.30 a.m. Tuesday, March 14.

TUESDAY, March 14, 1967.
(56)

The Special Committee on Drug Costs and Prices met *in camera* this day at 9.55 a.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout, Messrs. Brand, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), Isabelle, Mackasey, MacLean (*Queens*), O'Keefe, Orlikow and Mr. Rynard (11).

The Committee resumed consideration of a draft report to the House.

Agreed,—That a letter from Mr. J. J. Frawley, Special Counsel, Executive Council of Alberta, dated March 8, 1967, with reference to a statement quoted in Dr. Steele's brief be printed as an appendix to the Committee's Minutes of Proceedings and Evidence (*See Appendix "D"*)

At 12 o'clock noon, the Committee adjourned till after the Orders of the Day.

AFTERNOON SITTING
(57)

The Committee reconvened *in camera* at 4.15 p.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout, Messrs. Brand, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), Isabelle, Johnston, MacLean (*Queens*), O'Keefe, Orlikow and Mr. Tardif (11).

The Committee resumed consideration of a draft report to the House.

At 6 o'clock p.m. the Committee adjourned to 8 p.m.

EVENING SITTING
(58)

The Committee met again *in camera* at 8.10 o'clock p.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Messrs. Brand, Forrestall, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), Mackasey, MacLean (*Queens*), O'Keefe, Orlikow and Mr. Rynard (10).

The Committee resumed consideration of a draft report to the House.

At 10.10 o'clock p.m. the Committee adjourned to 9.30 a.m. Thursday, March 16 at 9.30 a.m.

THURSDAY, March 16, 1967.
(59)

The Special Committee on Drug Costs and Prices met *in camera* this day at 9.45 o'clock a.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout, Messrs. Brand, Enns, Harley, Howe (*Hamilton-South*), Howe (*Wellington-Huron*), MacLean (*Queens*), Orlikow and Mr. Rynard.

The Committee resumed consideration of a draft report to the House.

At 12.15 p.m. the Committee adjourned until after the Orders of the Day.

AFTERNOON SITTING
(60)

The Committee reconvened *in camera* at 3.45 p.m., the Chairman, Mr. Harry C. Harley, presiding.

Members present: Mrs. Rideout, Messrs. Brand, Enns, Harley, Howe (*Hamilton South*), Howe (*Wellington-Huron*), Isabelle, Johnston, MacLean (*Queens*) and Mr. Orlikow (10).

The Committee resumed consideration of a draft report to the House.

At 6 o'clock p.m. the Committee adjourned to 8.00 o'clock p.m. this evening.

EVENING SITTING
(61)

The Committee reconvened *in camera* at 8.30 p.m., the Chairman, Mr. Harry C. Harley, presiding.

Members present: Mrs. Rideout, Messrs. Brand, Enns, Forrestall, Harley Howe (*Wellington-Huron*), Hymmen, Isabelle, Johnston, MacDonald (*Prince*), MacLean (*Queens*), and Mr. Orlikow. (12).

The Committee resumed consideration of a draft report to the House.

At 9.45 p.m. the Committee adjourned to 8.00 o'clock p.m. Monday,March 20.

MONDAY, March 20, 1967.
(62)

The Special Committee on Drug Costs and Prices met *in camera* this day at 8.10 o'clock p.m. The Chairman, Mr. Harry C. Harley, presided.

Members present: Mrs. Rideout, Messrs. Asselin (*Richmond-Wolfe*), Harley, Howe (*Wellington-Huron*), MacDonald (*Prince*), Mackasey, MacLean (*Queens*), Orlikow, Whelan and Mr. Yanakis. (10).

The Committee resumed consideration of a draft report to the House.

At 10.10 the Committee adjourned to 1 o'clock p.m. Tuesday, March 21.

TUESDAY, March 21, 1967.
(63)

The Special Committee on Drug Costs and Prices met *in camera* this day at 1.05 o'clock p.m., the Chairman, Mr. Harry C. Harley, presiding.

Members present: Messrs. Asselin (*Richmond-Wolfe*), Forrestall, Harley, Howe (*Wellington-Huron*), Hymmen, Johnston, MacDonald (*Prince*), Mackasey, MacLean (*Queens*), Orlikow, Tardif, Yanakis (12).

The Committee resumed consideration of the draft Report to the House.

On motion of Mr. Forrestall, seconded by Mr. Orlikow,

Resolved (unanimously),—That the Report to the House be adopted and that the Chairman be ordered to present it as the Committee's Second and Final Report.

On behalf of the Committee, Mr. Orlikow expressed to the Chairman the grateful appreciation of the Members for his able and sympathetic manner in which he presided over the meetings, and for his assistance in the preparation and adoption of the final report.

At 2.05 o'clock p.m. the Committee adjourned *sine die*.

Gabrielle Savard,
Clerk of the Committee.

APPENDIX "A"

SUPPLEMENTARY SUBMISSION TO THE HOUSE OF COMMONS SPECIAL COMMITTEE ON DRUG COSTS AND PRICES BY THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION OF CANADA, FEBRUARY 1967

As the Committee is no doubt aware, various witnesses who closed out the hearings gave testimony on several critical issues that is in conflict with evidence presented by Dr. Irwin Hilliard, the Canadian Medical Association, the Canadian Pharmaceutical Association, the Patent and Trademark Institute, and PMAC. Accordingly, we respectfully request that the Committee receive and give consideration to this supplementary submission in lieu of a further formal appearance by PMAC.

In his testimony, Mr. David Henry, director of investigation and research under the Combines Investigation Act, proposed that drug prices could be lowered by means of licensing imports. His proposal depends on the assumption that FDD can guarantee the safety and efficacy of all imported drugs. As Mr. Henry himself stated, if the FDD cannot provide this guarantee, "then the exercise comes to an end." The Directorate, of course, was never constituted to perform such a mommoth task. Dr. C. A. Morrell, testifying before the Committee on Drug Safety when he was FDD Director-General, said rightly that you cannot put "government-approved" on a drug.

His successor, Dr. Chapman, told your Committee in his last appearance that it is essential to inspect all imported drugs for purity and quality. But surely it is equally imperative, as has been pointed out by both Dr. Hilliard and the chief of FDD's pharmaceutical chemistry division, Dr. L. Levi, that safety should be considered in terms of efficacy. This, of course, applies not only to imported drugs but also to the question of compulsory licensing of secondary domestic manufacturers. Unless a secondary manufacturer can prove to FDD the clinical equivalency of his product, then he cannot rely on the medical information developed and provided by the originator through experience with his own preparation.

The problem of therapeutic equivalency is still an area of great complexity and limited knowledge, as evidenced in the recent announcement by the United States' Food and Drug Administration of a major research program with an initial expenditure of $5 million. In the public interest, we therefore urge the Committee to step warily in making any new recommendations that would create fresh problems in this area, at the same time repeating our wholehearted endorsement of the Hilliard Committee proposals which should be vigorously applied through new legislation or regulations.

Mr. Henry and Dr. Henry Steele, the associate professor of economics from Houston University who appeared on behalf of the Alberta government, have

posed the question whether, in fact, we should have a drug industry in Canada. PMAC is confident that the Committee will take into account what effect the Committee recommendations will have on the research-based industry here, its substantial investment and employment capacity, and its R & D expenditures which have increased so markedly over recent years. They have tripled in the last five years and now represent the highest research expenditure of any industry in Canada. There are many reasons why international drug companies will want to make Canada an ever more important base of operations; political, economic, scientific and man-power reasons. But proper patent protection is an essential adjunct to these, and the companies must understandably view their future plans on an international basis.

In this connection, we would mention that the Department of Industry is at present conducting a special survey of the chemical industry to assess its contribution to Canada, and will include the pharmaceutical sector. In addition, the Economic Council of Canada is currently making a major survey on the effects of patents and trademarks. The findings of both these bodies will certainly have an important bearing on national policies concerning our industry.

The long-term advantages to Canada of a strong research-based drug industry far outweight any temporary price reductions which could result from further emasculation of drug patents. If greater price competition among manufacturers is to be encouraged then it must be on an equitable basis; the copiers should pay fairly for the benefits they receive. This means that, contrary to the present situation condemned by many witnesses both in and outside the industry, there should be a qualified tribunal to judge licence applications and assess royalties. The latter must ensure that the originator receives adequate compensation for his costs of research, product introduction and servicing which the licensee does not have to carry.

Prices must be assessed in the light of the profits necessary to finance the expansion of a high-risk industry. Taking note of this, the Hinchliffe Committee, for example, stated: "The cost of research must be provided in the prices of proprietary (prescription) medicines, and a good profit record is essential if the industry is to be encouraged to invest capital in continued development projects. The pharmaceutical industry is one which has to face unusual risks. The sudden discovery of a new therapy anywhere in the world can put a product, on which a great deal has been spent, off the market overnight."

The drug industry in Canada is one which has re-invested a very large part of its earnings into further growth. International research-based companies have brought a great deal of investment capital into Canada. They have made a significant contribution to the country's industrial development and, as we have indicated, should be expected to make a still larger one. Unless the Committee adopts the position that direct foreign investment per se is a bad thing, these companies cannot be faulted on their corporate citizenship in this area. A crucial fact is that about 80 per cent of the manufacturer's sales volume is represented by payments and investments made in Canada. If Canadians were to be solely dependent on imports, then the importers would be obliged to meet the heavy

costs of medical information, packaging, distribution and marketing, thus swelling their prices. There is no safe short cut from the custom house to the sickbed.

In answer to criticism of our level of marketing expense, we have already stated in our brief that companies would be happy if they could reduce expenditures. This is difficult owing to the competitive situation, as evidenced by the large number of new-product introductions, which in turn is indicative of therapeutic progress. We have proposed the establishment of an independent source of drug information covering both therapeutic value and cost of treatment and the new Compendium of Pharmaceuticals and Specialties of CPhA is a promising step in this direction. But its usefulness as a main source of information would depend upon its acceptance by physicians. This proposal notwithstanding, the detailman remains the key factor in two-way information between company and physician. The Canadian Medical Association stated in its brief: "We do not agree with those who malign the detailman, but we favor his retention in his current capacity with additional training to make him still more useful."

As a final comment on marketing, we would quote Sir Derrick Dunlop, chairman of the British Ministry of Health Drug Safety Committee, who has stated: "It is probable that without the mass-marketing techniques which are so often bitterly assailed, few of the drugs on which modern medical practice depends would be affordable at all."

Misunderstandings concerning the comparative value of applied versus basic research have led to some critism of the industry's efforts. The point surely is that industry research, whatever the label, has resulted in Canadians, along with the other people in the world, benefiting from a wide range of therapeutically effective drugs. Industry, university and government need each other as partners if the brilliance of the basic scientist is to benefit mankind by products, not just concepts. Industry has already ably demonstrated its ability to transform concepts into commodities.

Looking to the future and the advent of medicare, we would like to emphasize again the need for widespread availability of programs for drug insurance of prepayment, with priority given to government support for those citizens unable to meet the cost. We might add that whether the organizers of such programs be government or private agencies, it is evident that the strength of their buying power will enable them to negotiate on prices and so confine the cost of these programs through the cooperation of all concerned.

But no such system should be allowed to justify the limitation of the physician's right to prescribe a specific drug preparation for his patient, or the forcible reduction of any group to the level of second-class citizens by the imposition of anything less than the highest qualify of medical care. This, of course, has been a *sine qua non* of the British National Health Service. From a purely economic viewpoint, it is worth noting the following finding by the Hinchcliffe Committee on the cost of prescribing: "We reject substitution as a practical method of securing economies in the drug bill."

We suggest that Nobel Laureate Ernst Chain summed up the matter succinctly when he said: "The public must understand that the pharmaceutical industry is life saving and as such fulfils a public function of very great importance...I cannot visualize how the industrial pharmaceutical research laboratory could adequately be replaced by another non-industrial structure, and those who wish to abolish it by nationalization for theoretical-reasons, or impede notably its freedom of action, must know that in taking such steps they are conjuring up a major health hazard, much more dangerous than a virulent epidemic. No pharmaceutical industry—no new drugs; this, in a nutshell, is the situation." ("Academic and Industrial Contributions to Drug Research," the Trueman Wood Lecture, Royal Society of Arts, London, June, 1963.)

In concluding our submission, may we adjure the Committee not to sacrifice progress to any doctrinaire concept of economic efficiency. There remain many unconquered areas of disease—heart disease, cancer, viral infections. Nobody would claim that the research-based drug industry will win these battles alone. It will have to be a team effort, and industry will certainly have to be a member of that team if vital new drugs are to be found, developed and made available.

We are sure that the members of the Committee will want to keep the research-based drug industry at effective strength in Canada, so that the best drugs are made available to the people as soon as possible, regardless of international difficulties. This is not a plea for the status quo. Nor is it a plea for protection. It is a plea for very careful weighing of the real issues involved in any act of public policy. The situation is not, and should not be, static. Change and progress are essential. In the interests of safety, both therapeutic and economic, it is of prime importance that no harm be done. Let us be sure that we move in the right direction.

Appendix "A"

STATEMENT ON THE BRIEF OF THE ALBERTA GOVERNMENT

We regard it as unfortunate that the evidence of Professor Henry B. Steele was heard in the very last session of the Committee. His written submission contains several assertions which we feel need to be further clarified.

The major assertion is on page 103, within the Chapter III A 2, namely, that the granting of compulsory licences for the import of patented drugs could eventually cut prices by 50 per cent and thereby save Canadian Consumers $100 million.

But a considerable part of the consumption of $200 million consists of drugs which are not patented, and which accordingly are already subject to the "open price competition" which Professor Steele advocates.

We attach a broad analysis of this $200 million. We estimate that the patented drugs which in practice would likely be subjected to licensed competition from imports would amount to about $40 million. This includes such drugs

as Hoffmann-LaRoche's chlordiazepoxide ('LIBRIUM') and diazepam ('VALIUM') and Smith Kline and French's trifluoperazine ('STELAZINE') for which compulsory licences exist or are likely to be granted, and which therefore are or will be subject to "open price competition."

Even if the prices of this $40 million could be cut by 50 per cent, the saving would be only $20 million. This is quite different from the $100 million prospect which Professor Steele holds out.

You will doubtless have noticed that Professor Steele shows by his extensive quotations that he studied the Hoffmann-La Roche submission very carefully. He must therefore have seen that Roche explained, in paragraph 30 (c) (Minutes of Proceedings and Evidence No. 11, page 765) and elsewhere, why the Hall Report recommendation to licence imports could not have any further marked influence on the price of drugs.

The essence of Roche's explanation was that the cost of manufacturing the active ingredient is a very small part of the total costs, most of which must in any case be incurred in Canada, and that the compensation for the grant of a licence is at present a declared "pittance." It is true that Professor Steele's Recommendation 1, on page 123, says "subject to reasonable royalties." But the general presumption of his submission is that he does not think that reasonable royalties" should be very different from the present awards.

There are, in fact, no factual grounds for belief that enabling licensees to import would increase the number of their applications markedly. That should be clear to the Committee from the evidence of the group that calls itself The Canadian Drug Manufacturers and other firms such as Micro Chemicals, which actually have made such applications. Though they naturally advocated many things which they hope would advantage them, they notably did not press for licences to import.

The Roche evidence shows that licensees do not in fact willingly cut the price by anything like 50 per cent when they get a compulsory licence. They want as much as possible of a margin created by the patentee's heavy costs built into the price and they freely admit that they are not interested in licences for the many smaller selling drugs. Even so, their own evidence before the Committee shows that they find it difficult to survive, let alone to expand; hence their various pleadings for Government assistance. These basic facts would be unaffected by whether imports were licensed or not.

Professor Steele's Chapter IV may very well indicate that he realizes all this. It is by no means clear that he hopes or expects that the existing originators would continue to do business in Canada notwithstanding a 50 per cent reduction of their turnover. But he is silent as to why they should be prepared to create the market for new drugs by a heavy investment in providing information to doctors, in face of the certainty that it will be immediately invaded by compulsory licensees.

Professor Steele himself stresses how difficult it is for the small Canadian firms to enter even an established market. It should follow that it would

practically be impossible for them to establish a market for a new drug. He would seemingly therefore create a vacuum in which no "launching pad" could exist for new drugs. He nevertheless suggests that in such a situation some prospect would remain for natural expansion of drug research in Canada. It is difficult to imagine that he really believes that.

In the course of Professor Steele's appearance before the Committee he explained that the 50 per cent could be made by eliminating:

(a) Nine-tenths of the promotion costs	29%	
(b) Profits	10%	
(c) The Federal Sales Tax	11%	(now 12%)
Total	50%	

This merely emphasizes as regards (a) that no new drug could effectively and quickly be brought to the notice of doctors; and as regards (b) that the prospects for the hope for expansion of the small Canadian-owned firms would be exceedingly dim. The Sales Tax has no part of Professor Steele's argument in Chapter III A 2 concerning import licences, and must be presumably regarded as in irrelevant afterthought.

Professor Steele also fails to discuss a main theme of the Roche submission, namely how the past capital of the international firms in Canada arose or was provided, and what practical prospects there are for the small Canadian-owned firms to be able to replace them while making drugs generally available to the Canadian consumer. It may very well be that the cross-examination by the Committee of the Canadian Drug Manufacturers about this dilemma has caused Professor Steele to add Chapter IV to his arguments.

SUMMARY OF APPENDIX "A"

1. 1966 sales of "ethical pharmaceutical products" in Canada amounted to approximately $200 million.

2. Since Professor Steele's proposed cut in manufacturers' prices is, according to his testimony to the Committee, to be related only to "prescription drugs", all sales of over-the-counter products (OTC) such as vitamins, nutrients, cough and cold preparations, analgesics, etc. should be deducted. Very few of these products would be patented. 1966 sales of OTC products amounted to approximately $50 million.

3. It should be noted that the remaining $150 million includes not only sales of prescription products manufactured and distributed by the international drug companies, but also those by the Canadian-owned (generic) companies.

4. It should also be noted that the $150 million referred to above comprises not only the sales of patented prescription products but also the sales of:

(a) *unpatented* products (example: phenylbutazone)

(b) products, in respect of which the Canadian patent has *expired* (example: sulfisoxazole) or has been *invalidated* by a court of law.

(c) products, in respect of which compulsory licences under Section 41 (3) of the Patent Act have been granted many years ago and which are being distributed today by numerous "generic" companies (example: chlorpromazine and chloramphenicol)

(d) those products for which the sales volume is so small that competition cannot really exist in the market.

In respect of (a), (b), and (c) there is, of course, already what Professor Steele has termed "open price competition" and consequently Professor Steele would not have envisaged a 50 per cent price cut in respect of these products.

5. Since the testimony of the CDM before the Committee clearly indicates that they are mainly if not only interested in large volume products, one should look at the reality of this problem by considering only the widely prescribed patented prescription products.

The 1966 sales volume of the top 50 "Ethical Pharmaceutical Products" in Canada amounted to approximately $60 million. This includes all products down to a volume of approximately $600,000. If we conduct from the $60 million the sales of the products referred to in 4(a), (b) and (c) plus the sales of the unpatented OTC. products, there remains only a sales volume for 1966 of approximately $40 million which could be subjected to Professor Steele's "50 per cent cut".

APPENDIX "B"

STATEMENT ON THE TESTIMONY OF THE FOOD AND DRUG DIRECTORATE

There has been much misinterpretation in the lay press of the testimony of Dr. R. A. Chapman, Director-General of the Food and Drug Directorate. One particular statement on page 4 of the "Summary of Data on Drugs" presented on Janyary 26 by Dr. Chapman has been singled out by news writers:

"The following conclusions can be drawn from the data shown in Appendices I to V.

(i) There does not appear to be any significant difference between drugs sold under a generic name and those sold under a brand name. Similarly imported drugs appeared to be of the same general quality as domestic production."

We can understand why observers would seize upon such statement in the light of the long-standing controversy over generic and brand names. However, we feel that Dr. Chapman's generic and brand names. However, we feel that Dr. Chapman's statement is unfortunate, in that it has created confusion in an area that sorely needs clarification. The primary consideration is not nomenclature, but clinical equivalency. FDD, by Dr. Chapman's own admission, makes no attempt to compare the clinical equivalency of these two groups. The broad implications of Dr. Chapman's statement could lead your Committee to erroneous conclusions.

We remind you that PMAC has never said that the origin of a drug is necessarily indicative of its quality. We have stressed, however, that we can vouch for the integrity of PMAC member companies and their efforts to produce high quality products. As Dr. Chapman himself told your Committee: "The responsibility for the quality, efficacy, and safety of a drug must rest with the manufacturer."

Dr. Chapman in his testimony has told the Committee that drugs imported from abroad are not all of satisfactory manufacture: "Continued vigilance by the Food and Drug Directorate in the area of drug importation is imperative, for we found that there are many Euorpean companies who do not have proper production facilities and, applying merely patent specifications, fail to achieve the same accuracy and precision of analytical quality control as the original manufacturer." (p.p. 7-8 of "Some Observations on Drug Control in Europe"—presented to the Committee on January 26)

Dr. Chapman has pointed out the very dangers we have emphasized and the awesome problems of policing imports.

Our contention that manufacturers with the proper motivation to produce top quality drug products will do so better than those who are in the market for a quick profit by cutting corners was amply confirmed by Dr. Chapman in his written statement of January 31, 1967.

Much testimony before your Committee indicates that some persons tend to minimize the importance of proper formulation apparently under the impression that as long as the proper quantity of the active ingredient is present in the drug product, the therapeutic action will necessarily follow. This conclusion of course is scientifically unsound. The art of pharmaceutical formulation is one of the most valuable assets of the pharmaceutical manufacturer.

PMAC does not contend more than the fact that it is possible to put some highly unsatisfactory drugs on the Canadian market today if a manufacturer or importer wants a quick profit and does not care too much for his reputation.

This is confirmed by Dr. Chapman in his statement to the Committee on January 26: (pages 3 and 10), wherein he points out that "it would require many times the present resources of the directorate to conduct limited tests on each lot of drugs to confirm compliance with label claims alone."

The situation is complicated by the fact that Food and Drug Directorate does not know the country of origin of the basic ingredients used in the manufacture of drug products as evidenced by an answer given by the Honorable A. J. MacEachen, Minister of National Health and Welfare, to a question by Dr. Isabelle (*Hansard*, Feb. 15, p. 13067).

It is our belief that Dr. Chapman's testimony is not in conflict with PMAC testimony, but rather is subject to widespread misunderstanding and misinterpretation.

APPENDIX "C"

STATEMENT ON THE BRIEF OF THE CONSUMERS ASSOCIATION OF CANADA

One has the right to expect that a brief purporting to present the view of Canadian consumers will approach its subject in an objective and well-informed manner. This brief, however, appears rather to plead a predetermined case, based on the recommendations of the Restrictive Trade Practices Commission and the Hall Commission, even though several of these recommendations run counter to the laudable concern of the CAC for better assurance of drug quality.

Throughout the brief there is a tendency to prejudge the issue by the use of pejorative terms. For instance:

1. "The consumer is the captive in this chain of events." (Minutes 1171) This seems to mean that the consumer buys the drug his doctor prescribes.

2. "...companies spend more to mis-inform than to inform the physicians." (Minutes 1177) This is a grotesque overstatement of any position.

3. "The physician is bombarded daily with propaganda from pharmaceutical houses." (Minutes 1178) Another considerable over-statement. Much of the six or seven pieces of mail the physician receives per business day has an advertising content, but much of it, too, is essential scientific information.

4. "...rivalry of competition takes the form of promotional gimmicks and selling campaigns and minor product variations" (Minutes 1185) This, again, is a highly coloured and unbalanced description of the competition by product innovation which has resulted in the present availability of a large number of therapeutically effective drugs.

5. Referring to savings from the abolition of the sales tax: "...their being passed on to him (the consumer) hinges on the effectiveness of competition in the drug industry." In view of the declaration of numerous companies that they would pass on these savings in their own prices, this is an unwarranted slur on the ethics of the industry.

In addition, there are throughout the brief a number of technical misstatements and unbased assumptions.

1. "The Pharmaceutical Manufacturers Association of Canada...claims that the drugs made or distributed by these firms (independent manufacturers) are of inferior quality." (Minutes 1171)

PMAC does not claim anything of the sort. But it has shown, through the evidence of scientific experts, that there is a real risk of lack of therapeutic equivalency in the products of some non-research based companies. (See also Appendix "B".)

2. "Hospitals pay less for drugs than do most pharmacists." (Minutes 1174) This is true for some products of some companies; it is not a general situation.

3. With reference to the cost of research..."are we being asked to pay more than our share because of our proximity to the American market place?" (Minutes 1176)

Canadians benefit in common with peoples all round the world from the research successes of the pharmaceutical companies, and a share of this cost should surely be met in Canada. Canadians also pay North American prices for drugs—as they pay North American prices for other goods and services.

4. "Some ads distort the therapeutic value of a drug or fail to include necessary data on side effects. The physician either accepts the ad or is forced into a tedious search of the literature in order to determine the true nature of the drug." (Minutes 1176)

In cooperation with the Food and Drug Directorate, PMAC has set up a review board for the advertising of its member companies, to ensure that advertisements carry essential information. Further, few if any advertisements are designed to carry all prescribing information, which the physician has readily at hand.

5. "The association feels that a pharmacist has an obligation to inform the consumer about possible savings (through the purchase of generic-named drugs) (Minutes 1180).

When a physician prescribes a specific preparation it is wrong for the pharmacist to question the professional judgement of the physician with the patient.

6. "...it is surprising to find the PMAC arguing that the costs of drugs in Canada are lower than in most other developed countries. This claim is based on a simple averaging of a selected group of drug prices in terms of labour hours." (Minutes 1184)

In fact, the PMAC brief contained the following statement: "It has been widely maintained that the cost of drugs to Canadians is unduly high in comparison with what is paid in other countries...These comparisons were made in terms of actual prices, translating the foreign currencies into Canadian dollars. They did not take into account either standards of living or earning powers in the countries concerned."

7. "To present a fair picture of the cost of drugs to Canadians, it is, we believe, essential that these factors be related to the prices paid." (Minutes 291)

Interestingly, in his evidence, Dr. English, speaking for CAC, refers to the cost of labour as the first of what he describes as "real costs." (Minutes 1136)

8. The CAC makes a comparison between U.S. and Canadian prices to show the impact of tariff duty and sales duty. (Minutes 1187) This is calculated on the basis that finished goods are imported, not raw materials or even bulk goods. As such, it is by no means representative of the present situation in Canada. In general, Canadian prices are closely comparable with those prevailing in the United States.

9. "When a Canadian subsidiary buys pharmaceutical chemicals or finished drugs requiring further manufacture from a parent company, these goods are valued at the estimated cost of production plus an allowance for profit equal to 50 per cent of the exporters' manufacturing cost." (Minutes 1188)

This use of the word "profit" is inappropriate. It is a customs mark-up for the determination of the fair market value.

10. "The Kefauver Report pointed out that significant discoveries had been made by European pharmaceutical industries in countries which did not offer patent protection, and at that time these advances had outstripped the rate of innovation in the patent-protected United States drug industry." (Minutes 1189-90)

This statement is based on table 38 developed by the Kefauver Committee staff, and its inaccuracy was testified to by the U.S. Commissioner of Patents. For instance, two of the most productive countries, Germany and Switzerland, were listed as non-patent countries, although they do in fact grant significant patent protection to drugs, Patent attorney George Frost characterized the table as "full of errors of fact, errors of law and errors of analysis." He found in it 24 errors of fact.

11. The Consumers Association uses 1960 figures to show that the patent laws do not lead companies to undertake research in Canada. (Minutes 1190)

The CAC might reasonably have tried to find out whether more up-tp-date figures were not available. The expansion of research expenditure in Canada in the past five years has more than tripled.

12. Suspension of patent legislation "would greatly increase competition in the ethical drug industry, thus improving Canada's international competitive stance in pharmaceuticals..." (Minutes 1190)

Since the main result of such action would be to discourage the expansion of the research-based industry in Canada, it is hard to see how it would improve our "international competitive stance."

13. "Extension of FDD powers to include checking of imports under licence and inspection of plants producing final dosage forms would insure the quality of drugs imported under these licences." (Minutes 1190)

Extension of FDD powers in the drug safety field, and a strengthening of FDD staff, are most desirable, but the Directorate, as its spokesmen have themselves said, are not capable of "insuring" the therapeutic quality of all drugs sold in Canada.

APPENDIX "B"

UNIVERSITY OF TORONTO
Faculty of Pharmacy

Toronto 5, Ontario
FEBRUARY 24, 1967.

Dr. H. C. Harley, M.P.,
Chairman,
Special Committee on Drug Costs and Prices,
Parliament Buildings,
Ottawa, Ontario.

Dear Dr. Harley:

This letter is submitted jointly by the Canadian Conference of Pharmaceutical Faculties and the Canadian Association of Deans of Pharmacy. The former is an organization of the eight university schools and faculties and is representative of all members of teaching staffs. The latter is representative of the administrative heads of these same schools and faculties of pharmacy.

Having knowledge that the Canadian Pharmaceutical Association presented a brief to and appeared before your Special Committee, and in consideration of the special area the Committee was charged to investigate, our organizations had not contemplated making a submission. However, in view of statements made to the Committee, and particularly certain statements by Mr. S. S. Bass of Vancouver in a brief and in his evidence when appearing before the Committee on November 17, 1966, it is now deemed desirable to place the following views of our organizations on the record. Because we are aware that the work of the Committee is now in its final stages, we will content ourselves with a very brief statement pertaining to two matters which are directly related to pharmaceutical education.

The Extent of Pharmaceutical Education required by Modern Pharmacists

In his brief (pp. 1319 and 1320) Mr. Bass is critical of the present course of studies and recommends that it be "reduced to two years from the existing five". In the evidence on page 1289 and again on page 1298 there is reference to this subject and what appears to be some measure of agreement by one member of the Committee.

For the record, it first should be stated that the present course of studies comprises four academic years subsequent to senior matriculation (or its equivalent). This is the requirement accepted by the Canadian Conference of Pharmaceutical Faculties. Our organizations adhere firmly to the view that a four-year university course is the minimum essential to the training of a pharmacist.

Of interest, in the above connection, is the fact that a five year baccalaureate programme became effective in 1960 as the minimum requirement in the member colleges of the American Association of Colleges of Pharmacy. In view of

the fact college entrance in the United States is at a level one year below our senior matriculation, this course of studies is considered to parallel the Canadian standard. In Great Britain, effective from September 1965, all entering students are required to take a baccalaureate course of studies. Again considering the entrance level, in this case one year beyond Canadian senior matriculation, this training is of equivalent length to the Canadian standard.

We wish to draw the Committee's attention also to a misconception which appears to exist in some quarters that the present course of studies represents four years of professional training. In point of fact the equivalent of two years is made up of courses in general education and in basic physical, biological and medical sciences which provide an essential background to the professional courses. This background is necessary for a proper understanding of the nature and uses of modern drugs and we support the concept that, as our drugs have become more complex in nature, more specific in their action but at the same time more prone to side effects and adverse reactions, the pharmacist, as the expert on drugs, is becoming more significant in health care for what he knows than for what he does. This belief brings us into direct conflict with the interpretation presented to the Committee by Mr. Bass and which appears to view pharmaceutical services merely on the basis of the physical act performed in dispensing the prescription.

Safety Factors provided by Pharmaceutical Services

We submit to the Committee that the corner-stone of the legislation exemplified in provincial pharmacy acts and in federal drug regulations is the fact that drugs are potent agents and that both indiscriminate use and misuse can be hazardous. It is for such reasons that certain restrictions are placed on their distribution and that certain responsibilities have been placed upon the profession of pharmacy. The modern curriculum has been designed to create an expert on drugs, one who understands the physical, chemical, and biological properties of the drug and its structure-activity relationships, the biopharmaceutical aspects of the various dosage forms, and the pharmacology of drug actions, including undesirable side reactions.

Inasmuch as prescription drugs are not marketed as are other commodities, and to the extent that they thus are removed from unrestricted competition, and also because their servicing requires a substantial measure of professional time and care, such arrangement does make for a built-in additional cost factor. We believe that the matter of the amount of pressure that the pharmacists' remuneration for professional services rendered can withstand before a deterioration of safety standards sets in is one that merits careful consideration.

We have no hesitation whatever in placing our organizations firmly on record as opposing Mr. Bass's appraisal of the individual pharmacist's daily dispensing potential. Without necessarily discounting his contention that he has achieved a higher output by introducing assembly-line methods at his prescription counter, we believe that dispensing techniques do not properly lend themselves to this treatment.

We also wish to express disagreement with Mr. Bass's implication that, because some prescriptions now are dispensed in hospitals and in physician's offices without pharmaceutical service, the idea of lowering pharmacy's standards should be entertained. We disagree specifically with his generalization that "in our Armed Services, prescriptions are dispensed by orderlies" inasmuch as in the majority of DVA and Armed Services hospitals pharmaceutical services are being provided by pharmacists. The fact that patients in many small hospitals across Canada do not receive the same high standard of pharmaceutical service that non-hospitalized patients receive from the community pharmacy is regrettable and calls for renewed efforts by pharmacy to solve professional manpower and other difficulties, including the economic problem, in order to remedy this situation.

We trust that these comments can be brought to the attention of your colleagues on the Committee and that they will prove helpful.

Yours very truly,
J. E. Halliday, Chairman,
Canadian Conference of Pharmaceutical Faculties.
F. Norman Hughes, President,
Canadian Association of Deans of Pharmacy.

APPENDIX "C"

THE UNIVERSITY OF BRITISH COLUMBIA
Vancouver 8, Canada
Faculty of Pharmacy

FEBRUARY 20, 1967.

Dr. H. C. Harley,
Chairman,
Special Committee on Drug Costs and Prices,
House of Commons,
Ottawa, Ont.

Dear Dr. Harley:

It is unfortunate that the Committee didn't question me in more depth when I appeared for the Consumers Association of Canada. The work that I carried on phenylbutazone and reported on in the C. A. C. brief has stirred up much controversy. I can do nothing but stand by the results that I obtained even if these are in conflict with Food and Drug data.

In fairness to the Food and Drug Directorate, the samples which I checked were obtained during the summer of 1965. The work was completed by the summer of 1966 and reported on at the research conference in St. John. I know,

from my years with the Food and Drug Directorte, that there can be differences between lots of drugs but this doesn't detract from the statements I have made.

I am enclosing several copies of a speech that I made here at U. B. C. Unfortunately, I do not have sufficient copies for all the Committee members but you may wish to circulate those that I have enclosed. I have sent one copy to Dr. Brand, who appears to be interested in drug quality.

I would like to thank you and the Committee for the courteous treatment that I and Dr. English received when we appeared last fall. I only hope that we contributed something to the solution of a very complex problem.

Sincerely yours,

M. Pernarowski, Ph.D.,
Associate Professor.

THE QUALITY OF GENERIC DRUGS

Lecture by: Dr. M. Pernaroski Associate Professor, Faculty of Pharmacy, University of British Columbia, Vancouver, B. C.

Pharmacy Refresher Course, 1967
February 16, 17 and 18, 1967

Faculty of Pharmacy
University of British Columbia
Vancouver, B.C.

The pharmaceutical analyst's world is filled with numbers and words that have little meaning to the average person. He speaks of "quality" and "potency", quotes liberally from his pharmacopeia, and confuses all with the subtlety of his art. Because his basic approach to quality control is chemical rather than physiological, his results may be misleading and are often misunderstood. By tradition, he is a chemist. By force of circumstances, he is asked to assess the products that are prescribed by physicians and dispensed by pharmacists.

It should be obvious that we cannot comment on product quality unless we first define certain words that are part of the vocabulary of the pharmaceutical analyst. The dictionary states that quality is a "distinctive trait" or "excellence of character". Potency, on the other hand, is the quality of being "highly efficacious chemically or medicinally." It is at this point that the pharmaceutical analyst comes in conflict with himself. Can he show, by chemical means, that a product is "highly efficacious medicinally"? Many pharmaceutical analysts to speak of "excelence of character", are readily able to comment on the *chemical* characteristics of dosage forms, but will not comment on the therapeutic efficacy of the products they are asked to assess. They know that chemical equivalency is not the same as therapeutic equivalency. They know that the test procedures described in the pharmacopeias and in the scientific literature are, too often, completely unrelated to the processess that occur in the body. Knowing this, they are ready and willing to do two things.

First, by subjecting products to pharmacopeial tests, they can comment on the legal acceptability of these products.

Secondly, by using more sophisticated procedures and relating these to *in vivo* activity, they can show that legally acceptable products do not always meet the criterion of being "highly efficacious medicinally".

I. COMPLIANCE TO PHARMACOPEIAL STANDARDS

Our technology is such that products containing the same drug should be chemically and physically equivalent. But are they? To answer this question, it is first necessary to outline the procedures that the pharmaceutical analyst uses to assess products. For tablets, three basic procedures are used.

1. *Assay*

The analyst selects 20 tablets from a bottle, weighs them, reduces them to a fine power, assays a portion of the powder, and then calculates the amount of drug in a tablet of average weight.

2. *Weight Variation Test*

The analyst selects 20 tablets from a bottle, weighs each of these individually, and then checks for compliance to the standard. For example, if the average weight of the 20 tablets is 200 mg., two of the tablets may deviate from the average by more than 7.5 per cent but none may deviate by more than 15 per cent.

The object of this test is to control dose variation. If a tablet is too light, it will contain too little drug. If it is too heavy, it will contain too much drug.

3. *Disintegration*

The analyst selects six tablets and places these in a tablet disintegration apparatus. Disintegration is considered to be complete if the tablets have broken down into particles that pass readily through a No. 10 mesh screen. The mean maximum disintegration time for compressed and coated tablets is 60 minutes.

There are, of course, certain other tests that are used in specific cases. For the moment, we will set these aside and concentrate on these three basic tests. The first two deal with drug content and weight uniformity. A product could easily pass these tests and still not be therapeutically effective. It is only the last test that even pretends to judge products for their therapeutic effectiveness. However, it is a physical test and, because of this, is subject to much criticism.

Approximately a year and a half ago, I began to test the generic equivalency hypothesis. Our studies are just beginning but the results, to date, to say the least, are interesting. However, before I begin to discuss these, I would like to present some data that was recently released by the Food and Drug Administration in the United States.

The Food and Drug Administration assayed 4,573 drug samples and found that 8.2 per cent failed to comply with minimum standards. (PMA Newsletter,

February 3, 1967, p. 6) It is clear, therefore, that the performance of American industry is less than satisfactory.

We can now turn to the results that we have obtained in our laboratory. During the past year, we have examined 23 brands of sugar coated phenylbutazone tablets, four brands of enteric coated phenylbutazone tablets, twelve brands of prednisone tablets, and four brands of p-aminosalicylic acid tablets.

1. *Phenylbutazone Tablets (Sugar Coated)*

Of the 23 brands, two contained less than 95 per cent of label claim—the legal minimum. One product failed to disintegrate in 60 minutes. This means that 13 per cent of the brands failed to comply with minimum requirements.

2. *Phenylbutazone Tablets (Enteric Coated)*

We examined four brands. One brand failed to disintegrate in 60 minutes. Just to make sure, we checked a second lot of the same brand. It too failed to disintegrate in 60 minutes. This means that 25 per cent of the products tested failed to meet minimum requirements.

3. *Prednisone Tablets*

We checked twelve brands. One of the twelve brands contained more than 110 per cent of the amount claimed on the label—the legal maximum. This means that 8.3 per cent of the products tested failed to meet minimum requirements.

4. *p-Aminosalicylic Acid Tablets*

We checked four brands. All complied with pharmacopeial standards.

During the past year, we checked a total of 43 products. Five of these, or 11.6 per cent failed to comply with minimum standards. We checked far fewer products than did the Food and Drug Administration in Washington but arrived at about the same conclusion—this being that there appears to be something wrong with about eight to eleven out of every one hundred products tested.

II. COMPLIANCE TO PHARMACEUTICALLY ACCEPTABLE STANDARDS

Many pharmaceutical analysts stop their assessment of products at this point. They conclude that if a product is legally acceptable, it must be therapeutically effective. Other pharmaceutical analysts conclude that they do not know this to be a fact and, for this reason, subject products to certain other tests. One of these tests is described in the United States Pharmacopeia and in the National Formulary, another is used by those researchers who study generic equivalency in depth, and the last is used by some drug manufacturers to assess their own products.

Without going into detail, I will outline the nature of these tests and their significance.

1. *Content Uniformity Test*

The weight variation test is assumed to control dose variation. If the granulation that is fed into the tablet machines is properly mixed and if the mix is not disrupted during the tabletting process, this assumption is probably valid. However, if the product is not properly mixed, tablets may pass the weight variation test but certain tablets may contain much more or much less than the amount claimed on the label.

The content uniformity test attempts to control this type of situation. The analyst selects 30 tablets, assays ten individually, and then tests compliance to the standard. If all of the ten tablets contain not less than 85 per cent and not more than 115 per cent of label claim, the product is satisfactory. If one tablet contains less than 85 per cent or more than 115 per cent of label claim, the remaining 20 tablets are assayed. Not more than one tablet out of 30 may contain less than 85 per cent or more than 115 per cent of label claim.

2. *The Dissolution Test*

The disintegration test is a physical test. The dissolution test is chemical in that the analyst must determine the actual amount of drug released from the tablet to the test medium.

In general, a tablet (or tablets) is placed in a basket suspended on the end of a stirring shaft. The basket is then submerged into a specified volume of simulated gastric or intestinal fluid. The analyst sets the stirrer in motion and then samples the medium over a period of time. He can then draw a dissolution curve (mg. in solution versus time) and can calculate a $T_{50\%}$ value, that is, the time required for the tablet to release one half of its drug content.

3. *In Vivo Tests*

There are many in vivo tests. Tablets can be given to a patient, blood samples taken at suitable time intervals, and these blood samples can be analyzed for drug content. It is then possible to draw a graph of drug concentration in the blood versus time. The area under the curve for one product can then be compared with the area under the curve for another product.

Another approach to *in vivo* product testing is based on product failure. The doctor notes that a particular brand does not produce a therapeutic effect. He administers a second brand. This product does produce a therapeutic effect. If an analyst can study the dissolution characteristics of the products, he can calculate $T_{50\%}$ values and use these to assess other products containing the same drug.

We may now turn back to the products we have studied in our laboratory.

1. *Phenylbutazone Tablets (Sugar Coated)*

One of the 23 brands failed the content uniformity test. Another product was so variable that we put it into the unsatisfactory classification. Most phenylbutazone tablets have a dose range of about 7 mg. This product had a dose range of about 25 mg.

We next checked the dissolution characteristics of 12 of the products. Most of the products released their phenylbutazone content to the simulated intestinal

medium quickly but four of the products had $T_{50\%}$ values in excess of 120 minutes. One of the four products failed the disintegration test but the remaining three would be legally acceptable.

To check the validity of our dissolution test, we administered three of these products to three subjects and one patient. The subjects were also given a pharmaceutically acceptable product. After we had completed our blood analyses, we plotted blood curves and then calculated areas under the curve for each of the products. We then calculated a product index in the following way.

$$\text{Product Index} = \frac{\text{Area Under the Curve for Test Product}}{\text{Area Under the Curve for Standard}}$$

We obtained the following results:

Product A	(Standard)	= 1.00
Product E		= 0.76
Product X		= 0.55
Product W		= 0.25

This means that product E yields approximately 75 per cent of the amount of drug to the blood given up by Product A. In the case of Product W, the amount that was released to the blood was so low that the patient would have received equal relief from two Life Savers.

We concluded, therefore, that at least seven of the 23 brands of phenylbutazone tablets were significantly different in one respect or another from those that were uniform and released drug quickly to a test medium or to the blood. This means that 30.4 per cent of the products examined were not equal to the best brands available to the profession.

2. *Prednisone Tablets-*

In 1963, Campagna, et al., (J. Pharm. Sci., 52, 605 (1963) reported the following and I would like to quote from their paper.

> "A 25 year old white married female of Mediterranean ancestry has been under the care of one of us (FAC) for approximately five years. Her clinical diagnosis was familial Mediterranean fever. The prompt use of oral prednisone in amounts of 20 mg. in a 24 hour period for the first 2 or 3 days would promptly abort the clinical symptons...The patient's prescription had been written under the generic name "prednisone". On one occasion, after 72 hours of 5 mg. four times a day, the patient had no clinical effects from the medication. It was discovered...that a different brand of prednisone had been dispensed...The patient was immediately transferred to the brand of prednisone used previously and again within 24 hours there was almost complete resolution of the clinical syndrome."

The late Dr. Nelson, a pioneer and expert in the field of biopharmacy, determined the dissolution characteristics of both products. Both products disintegrated in less than 6 minutes. However, the $T_{50\%}$ value for the clinically active preparation was 4.3 minutes and that for the clinically inactive product was 100 minutes.

In 1964, Levy, et al., (Am. J. Hosp. Pharm., 21, 402 (1964) reported a similar case. The inactive product, in this case, had a $T_{50\%}$ value of 174 minutes. It was noted in this paper that this product disintegrated in less than 3 minutes.

In our laboratory, we have examined the dissolution characteristics of 12 brands of prednisone tablets. Using the dissolution apparatus described in the papers cited above, we found that five of the brands had $T_{50\%}$ values of more than 120 minutes. In two cases, it was difficult to calculate the value because at the end of seven hours in the apparatus, very little of the five mg. in the tablet had gone into the solution.

One of these five brands contained more than the allowable amount of prednisone. Therefore, it is legally unacceptable. However, the other four brands meet all existing standards. I, for one, would not dispense these brands.

This means, therefore, that five (or 41.7 per cent) of the 12 brands are not equal to the best brands on the market.

3. *p-Aminosalicylic Acid Tablets*

I have previously said that all four brands are legally acceptable. Our results were based on products that had been purchased through a local wholesaler (or obtained from the manufacturer). Analyses were carried out as soon as the bottle had been opened.

Many drugs decompose on storage. By carefully formulating a product, such decomposition can be kept to a minimum. We, therefore, set up a stability study for the products tested.

Three of the products were relatively stable under all test conditions. The fourth product was not. For example, after being kept at 30°C and 90 per cent relative humidity for eight days, it lost 5 per cent of its potency. At higher temperatures, for example at 40° C., it assayed at 75 per cent of label potency at the end of ten days.

The first condition, that is, a temperature of 80° to 90° F and a relative humidity of 90 per cent, is not unrealistic. Such conditions are common in many parts of Canada during the summer months. The moral of the story is that one should handle, dispense, and store this product in a dry box, or better still, dispense a product that will withstand normal storage conditions.

We must, therefore, reject one of these four brands even though it met existing specifications at the time that the bottle was opened.

4. *Phenylbutazone Tablets (Enteric Coated)*

I have already said that one of the four products tested failed the disintegration test.

We have administered three of the four products to two subjects. Preliminary results have indicated that the product which failed to disintegrate yielded about 50 per cent-60 per cent of the amount of drug to the blood given

up by Product A—the standard used in our studies on sugar coated phenylbutazone tablets.

One of the other brands did give depressed blood levels. However, at this time, we are not sure if the product is satisfactory or unsatisfactory.

We cannot, therefore, fail more than one of the four brands tested.

III. SUMMARY OF RESULTS

We may now summarize all of our results. We examined 43 products. If I were the Director of Quality Control for the companies concerned, I would not permit the marketing of 14 of these products. This means that 32.6 per cent of the products failed either legally acceptable standards or standards which have been established in our laboratory or by other researchers.

It can be argued that some of the tests that we used in the laboratory are not described in the pharmacopeias or are not considered to be official by the Food and Drug Directorate. Furthermore, it can be argued that biopharmaceutics is still in its infancy and no one really knows its significance with respect to therapeutic activity. I understand both of these arguments and, if I were dealing with something other than a drug, I would not be too concerned. However, because I am dealing with a drug, I will not pass a product unless I am absolutely sure that it is satisfactory in all respects. Personal responsibility is just as important as legal responsibility.

Some of you may have observed that I have studiously avoided a direct comparison of brand name drugs with generic name drugs. You know that many generic houses market drugs only under a brand name. Similarly, many ethical manufacturers market drugs under their generic name. A comparison of brand name drugs with generic name drugs has, therefore, little meaning.

I realize, however, that I cannot avoid the final question. Who manufactured the 14 products that I find unacceptable? I will not list the companies involved but I can make certain generalizations. In pharmacy, we like to refer to "ethical" drug manufacturers. This word carries a certain meaning to most of us. It implies that we trust the products that are manufactured by these companies. Some of us like to be more specific and say that all of the members of the Pharmaceutical Manufacturers Association of Canada are "ethical" manufacturers. I am not too ready to accept this definition but to get myself into a position where I can comment on the products that we have tested I will assume this to be a fact.

Of the 14 products that failed one or more tests two were manufactured by companies that belong to the PMAC. The remaining 12 were manufactured by independent companies. You may draw your own conclusions from these figures.

In conclusion, my concern is with product quality only. We expect a certain level of performance from the students that we teach. We fail students for committing lesser sins in our dispensing laboratories that those committed by the manufacturers of the 14 products I have been discussing. Can we then give our blessing to these products? My answer is "no" because the final responsibility is not to ourselves but to the patients who will receive the medication that we dispense.

APPENDIX "D"

EXECUTIVE COUNCIL

J. J .FRAWLEY, Q. C.

Special Counsel

Ottawa, Ontario
MARCH 8th, 1967.

Miss Gabrielle Savard,
Clerk of the Special Committee
on Drug Costs and Prices,
Room 406, West Block,
OTTAWA, Ontario.

Dear Miss Savard,

Re: Submission of the Province of Alberta

During the questioning of Dr. Steele in the Committee on February 14th, he quoted a statement made by Dr. Walter Modell of Cornell University to the Kefauver Committee concerning new diseases brought about by the untoward effect of drug therapy. The passage in Dr. Steele's brief dealing with this reads as follows:

> "Dr. Walter Modell of the Cornell University Medical School commented that some 40-odd new diseases had been identified as brought about by the untoward effects of drug therapy. (9a)"

Dr. Rynard expressed the view that Dr. Steele's statement was not put in its proper perspective and introduced a wrong impression.

It has occurred to me that it would be best to place before the Committee the full text of what Dr. Modell said to the Kefauver Committee. I apologize to the Committee for not having done so when the discussion was taking place in the Committee.

Dr. Walter Modell, Director of Clinical Pharmacology and Associate Professor of Pharmacology, Cornell University Medical College, appeared before the Kefauver Subcommittee on July 20th, 1961. The part of his testimony to which Dr. Steele was making reference appears at page 317 of Part 1 of the Hearings record:

> "Senator Kefauver. All right, Doctor, proceed.
>
> "Dr. Modell. Thus, there are sins of omission as well of commission as a result of insecurity and lack of precise knowledge of drugs. And the sins—both kinds—are visited on the patients.
>
> "How often is there real trouble? Much too often. It was published in the Journal of the American Medical Association 5 years ago, when it was under the aegis of Dr. Austin Smith, that in one large New York hospital 5 percent—i.e., 1 of every 20 patients, was admitted as the result of the sanctioned and well intentioned use of some drug for either treatment or

diagnosis. Dr. David Barr, then professor of medicine of Cornell University Medical College, stated in this article that reactions to drugs 'could be regarded as one of the commonest conditions encountered.' Drs. Friend and Hoskins of Harvard have pointed out that 40 new diseases or syndromes have resulted from drugs used in therapy and that diseases of medical progress are on the rise. But even these statements do not give the full picture of the difficutles arising from the use of drugs, the poor medical practice resulting from lack of precise and truthful information about drugs. Compilations of toxic reactions do not take into account the number of patients who are undertreated because their physicians are fearful of new drugs they do not understand, patients who, therefore regardless of the merit of the drug they receive, receive token doses only and consequently get substantially less than the best treatment, hence patients who may suffer, whose illnesses may linger, or who may even die because they received inadequate treatment with an adequate drug. There are no data at all on this aspect of the calamity.

The writer will be glad to make the entire volume available to the Committee if that is desired.

Yours very truly,

J. J. Frawley.

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