

Mr. MORRELL: Let us take a hypothetical drug from Pfizer. They will collect all of the information which they have gathered in respect of that new drug, such as the manufacturing procedures, the control procedures, the pharmacology, the toxicology in animals, the pharmacology in animals, the clinical testing, and the composition of the drug right down to the last detail, and they will send this to us as a New Drug Submission. Contained in this is the work of a great many persons; not only those employed directly by Pfizer's plant, wherever it might be, but also persons they have hired, or persons who may have become interested, and who may not even have been paid. The clinical testers or investigators—and there may be dozens or 100 of them—have tried the drug on patients and have made their reports to Pfizer in detail.

We do not want just a testimonial, such as "I tried this drug on six patients and it was excellent". That is of no value to us at all. We want to know what the condition of the patient was, and we want to know his case history. This is what comes to us in the form of a New Drug Submission, and this is what we demand of every new drug, no matter by whom it is manufactured, whether it be Pfizer or a small company. Small companies are sometimes hard put to get the information because it does cost some money.

Nevertheless, in the interests of safety we have to see that they do the same things that the large companies do. But we do know, or our people in the laboratory and in administration do know a great many of these research people from Pfizer and other companies, personally. They know their value, qualifications, and so on. But we do not feel that we can just take a letter from, for example, Pfizer, saying "We have tested this new drug and have found it satisfactory. Therefore, will you agree that it should be sold in Canada?"

We cannot accept that kind of thing. The law demands certain information and we have to say this to Pfizer or to whomever it may be. With the New Drug Submission in one hand and with the law in the other hand, we have to see that all the information demanded by the law is furnished in adequate amount and in adequate quality. And then when we see something missing, or doubtful, or if there is a question in our minds as to what it means, a letter goes back asking for an explanation or for further material or data.

Mr. RYNARD: Once you have passed a drug, it ceases to be a new drug any more.

Mr. MORRELL: It is still a new drug. Again, this is a little difficult to follow. But when we receive a New Drug Submission we write a form letter to the manufacturer saying that we have examined the New Drug Submission. Let us say it is drug "A" manufactured by you, and we find that it complies with the section 308, and so and so. This is notice to the manufacturer that he is at liberty to market that new drug. It is still a new drug because, as you well know,—I am thinking of a certain drug that we talked about yesterday—there is a great deal of evidence which comes out about a new drug even after it has been on the market and used by dozens of doctors upon millions of patients. This is evidence which you cannot have with a New Drug Submission. So it is still a new drug for years after it goes on the market. New things will turn up that never appeared before in connection with the 2,000 to 5,000 patients it was used upon for test purposes. You will get other circumstances.

Mr. RYNARD: Therefore the real test is the clinical trial when it gets out to the doctors and into the hands of the public.

Mr. MORRELL: Finally, I think that is the ultimate test.

Mr. RYNARD: Why should we not have a reference of these drugs to a committee that is in charge, let us say, of university facilities across Canada,