

Patent Act—Trade Marks Act

the one with regard to which we see the most danger, is simply that of the clinical equivalency of drugs. This point has not been covered. Many citations have been put forward in the debate on this point. We have heard this, that and the other thing. All the citations were good. I should like to put on the record what was said by Dr. Goddard in this respect. He was quoted last night by N.D.P. members. Dr. Goddard, when speaking to the American College of Clinical Pharmacology in Atlantic City, New Jersey, said:

The U.S. pharmacopia and the national formulary provide no biological performance test from which we can conclude whether a particular dosage form of a particular drug will perform as it is supposed to perform in the human.

Over and over again, we have been told by the Food and Drug Directorate that they have the answers. The minister has assured us that they have all the answers, and that these drugs can be tested. Dr. Goddard, Commissioner of the Food and Drug Directorate of the United States, whose formulas we use over and over again, went on to say in that address that there is no test from which we can conclude whether a particular dosage form of a particular drug will perform as it is supposed to perform in the human. He went on to say:

This has not been a wilful omission. Until recently, it just was not considered necessary.

We just cannot fool the people in this regard. Why cannot we be honest and say there is a risk here? Dr. Goddard went on to say:

There are two reasons we can think of which explain this attitude of blissful ignorance which all of us—let me repeat, all of us—have enjoyed thus far. To begin with, there was an assumption that different specimens of a dosage form containing the same concentration of the same active ingredient will behave the same way—

They just do not. Then Dr. Goddard said:

I think it is fair to say that most of us in clinical work now know that such an assumption may be valid for many drugs, but is not valid for all drugs. Considering the vigorous activity in clinical pharmacology and chemotherapy which you and your colleagues carry on, and considering the alleged vast number of checkpoints in our drug distribution system, I have to say I am more than disappointed.

● (3:30 p.m.)

This is the awesome thing which the Minister has hanging over his head. The address goes on:

I am deeply disturbed at our situation today.

I am taking this opportunity, I am using this particular form, to express my misgivings to you and, through you, to all our colleagues in medicine.

What, then, are the elements of this issue which must be vigorously and immediately explored? We know that different drug products which are generically equivalent have been shown to perform differently in vivo. How widespread is this phenomenon? How many different drug classes are involved? How serious is this phenomenon in the public health field? And what does the FDA intend to do about it?

Mr. Schreyer: Would the hon. member permit a question.

Mr. Rynard: Yes, if Mr. Speaker will permit.

Mr. Schreyer: Even agreeing that perhaps the bill is not precise enough in relation to the question of clinical equivalency, would he not admit that the effects of two drugs of the same kind and of the same clinical equivalency would vary in accordance with the receptivity of individual patients?

Mr. Rynard: Given the same clinical equivalency, drugs working on the same person would work in exactly the same way.

This writer goes on to say:

Science has been accumulating a great deal of observable information about drugs over the past 100 years. In the recent past we have sought through good law, reasonable legislation and good science to document this information particularly as to safety and effectiveness. But our documentation falls far short of what we need.

There is the story. We were led to believe in the committee that they had the answers—that they could test a product and arrive at the therapeutic equivalency. The writer goes on to tell us that new kinds of experimental data are needed. I am not saying this in order to be critical or to be smart about it. I am saying it in the hope that the minister will pay heed. I hope, he will, because he is a bright young man. I trust he will act accordingly, because this is our last recourse. The address states:

We need new kinds of experimental data to tell us the minimum concentration of a drug in the blood and urine from which we can deduce that there is enough of the drug available to be viable and to do the job it is supposed to do.

I shall not continue to take up the time of the house on this aspect. But this makes clear the awesome task which the minister has assumed. I am sure he has not thought much about it or he would have shown more responsibility about bringing some of the professors from the pharmacology departments of the Universities before the committee to give evidence. But not one was called.