

any other purpose. Our charge would be that he had violated a portion or all of section C.01.307, if it came to a court action. We do not make this information public. Nor do we notify anyone else as a matter of fact and have not up until the present.

Mr. VALADE: Is that true even though a new drug has been accepted and it has been discovered that there are some secondary effects which have been drawn to the attention of the directorate, or do you then advise the medical or pharmaceutical bodies in this nation?

Dr. MORRELL: No, and it is quite common, as you may know. A drug is in the market for some time with wide use on a large number of patients—it may have been millions, and by a great number of medical practitioners, many thousands—and you will discover, or someone will discover a side reaction or a contra-indication which was not revealed when the new drug submission was made. Our law requires the manufacturer to give adequate direction for use. Also the act itself in section 9(1) prohibits anyone from labelling, advertising or promoting a drug in a matter that is false, misleading or deceptive or likely to give an erroneous impression regarding its safety.

So, falling back on this law and this authority, we have required all manufacturers to give adequate directions for the use of their products, and the term “adequate directions” would certainly require them to give warnings of side effects or contra-indications. The law makes this the responsibility of the manufacturer. Our responsibility is to see that he does do so. So that the manufacturer then sends out a warning, or puts it in a package circular his directions for the use and a notation of any new contra-indication or new undesirable side effect so that the doctor himself can be aware of all of the dangers that are known about the drug at any given time.

Mr. VALADE: I should like to follow up this discussion with one further question, Dr. Morrell. Have you in the past communicated by letter or advised those medical or pharmaceutical bodies or organizations representing these medical professions of any of the new developments in regard to drugs?

Dr. MORRELL: We do communicate with the pharmacists and the doctors in respect of drugs. One of the most common bits of information we give them is information about a drug put in the “prescription only sale” category. It is, of course, essential for these people to know and we issue an annual card which is sent to I think every practicing doctor and every practicing pharmacist in the country to inform them as to what drugs now may be sold retail only on doctor's order. This I think is the main communication we have had with the medical profession as a whole in the past.

In recent months we have, of course, sent several letters—I think three, but two anyway—directed to individual doctors, or at least to the medical profession, in respect of thalidomide, in one case, and other drugs in respect of which we had some information regarding possible certain associated side effects that were undesirable. We have informed them of these things.

This is a new policy in so far as the administration of the act has been concerned. We have always, up to this year at least, considered that it was the manufacturers' responsibility to inform the profession or the public, and in the case of the public, to warn on the label of any reasons for dangers in respect of the use of a drug.

Mr. ORLIKOW: Mr. Chairman, I should like to ask one question, without being critical, in respect of the thalidomide incident. Having regard to the system of holding the manufacturing company responsible for doing the investigation work in regard to drugs and in the light of what happened with the use of thalidomide, is a new policy necessary, and if so what does the department think should be adopted in this field? I raise this question because I know