

*Food and Drugs Act*

of insomnia. In Canada, at least, it was not recommended for nausea or morning sickness in pregnancy. At that time there was no hint of any significant side effects at all, let alone any association with malformations in children.

The material submitted was found to comply wholly with the requirements of the law and the manufacturers were so advised. On the advice of the prescription drug advisory committee, on which is represented the medical profession and the profession of pharmacy, the drug was placed on prescription. This meant that it could only be dispensed under medical supervision. The decision was in accordance with the general policy of the advisory committee to require all sedative drugs to be sold only under prescription.

The first indication of significant side effects associated with thalidomide appeared in the scientific literature after the new drug submission had been accepted. Information in this regard developed very slowly and it was not until the spring of 1961 that reports from Great Britain pointed clearly to a possible association of what is termed peripheral neuritis with thalidomide. Peripheral neuritis is a nervous disorder involving tingling in the hands and feet and is a relatively common side effect in the drug field. Evidence suggested that if administration of thalidomide was stopped at the first appearance of peripheral neuritis, the condition would disappear. Accordingly, the food and drug directorate concurred in a similar step being taken in Canada as had been taken in Great Britain, namely that the company would amend the information sent out to doctors by the inclusion of a specific warning with respect to peripheral neuritis.

I mention this aspect of the situation to highlight the fact that a warning to doctors is the usual method of alerting the medical profession to possible side effects in the use of drugs. This is the procedure followed in the case of all drugs with obvious effectiveness and has a direct bearing on development which took place towards the end of 1961. Before turning to these, however, I should like to re-emphasize that peripheral neuritis is not an unusual or unique side effect of drugs. In the spring of 1961, there was no evidence in the scientific literature of any possible connection between peripheral neuritis and phocomelia or malformations in children.

A second aspect of Canada's experience with thalidomide relates to the steps taken in early December, 1961, to warn doctors of a possible association of thalidomide with phocomelia, and to advise them not to prescribe the drug for premenopausal women pending further clarification. This was done

[Mr. Monteith.]

as the result of reports received by the drug companies from West Germany indicating that a pediatrician in that country suspected the involvement of thalidomide in cases of phocomelia. The companies were not able to give any idea of the number of cases involved nor the extent of scientific evidence available to support these suspicions.

In view of this, the usual procedure was again followed. After consultation with the food and drug directorate, a warning was sent by each of the two drug companies to every doctor in Canada of this possible side effect of thalidomide. In this connection, I might point out that the cases of thalidomide-associated malformations reported in Canada during the past summer had obviously been the result of taking the drug prior to the first information of possible danger being made available to the government and to the medical profession early in December, 1961. No other course of action at that time could have prevented these cases. Up to the present time to our knowledge, there has been only one case of thalidomide-associated abnormalities where the drug could have been taken after the warning to doctors. We have made inquiries and are advised that the drug in this particular case was not obtained on prescription or with the knowledge of the attending physician.

All of us have the greatest sympathy and compassion for the unfortunate victims. When tragedy strikes a child or the unborn child, we are all particularly touched. But we have a responsibility to control our emotions and deal objectively and effectively with the situation.

The government has proposed to the provinces the sharing of the cost of special programs to assist these children. We have asked the provinces to undertake special investigations and we are co-operating with not only the provinces but also specialists in the field of rehabilitation to see what can best be done.

As announced in the house last April, I requested the Royal College of Physicians and Surgeons of Canada to establish a special committee to consider objectively and critically our procedures respecting new drugs. While I have not as yet received their report, I expect that it will be available in the near future.

In addition, last May, Canada took an important initiative at the world health assembly in Geneva. Our delegation initiated and co-sponsored a special resolution designed to promote greater international co-operation in the drug field, and particularly to secure regular exchange of information on the safety and efficacy of pharmaceutical preparations. As our experience with thalidomide has