

# The War Amputations of Canada

## Thalidomide Task Force

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# REPORT OF THE THALIDOMIDE TASK FORCE

## SYNOPSIS

### MINISTER'S COMMITMENT

The responsibility of the federal government to provide compensation for the victims of thalidomide was admitted in a statement made to a Special Committee of the House of Commons on January 29, 1963 by the Minister of National Health and Welfare, the Honourable J. Waldo Monteith. The Minister said:

It is our job to ensure that these victims are cared for in the best possible manner . . . [and] their needs are met to the fullest possible extent we can devise . . .

### VICTIMS' NEEDS

The Task Force has been able to determine that the thalidomide victims are currently facing enormous difficulties in many aspects of their lives: education, employment, careers, housing, transportation, insurance, daily living, socialization, sexuality and recreation. In short, their entire lives have been affected.

All of these issues are addressed in research reports which have been written by the thalidomide victims themselves (These reports are included in the appendix to the Task Force Report.) It is the view of the Task Force that it is indeed unfortunate that until now very little has been done to bring to the attention of the public the problems faced by the thalidomide group in their years of early maturity.

### ASSUMPTION RE SAFETY

The physicians who prescribed thalidomide, the pharmacists who dispensed it and the patients who ingested it were entitled to the assumption that reasonable precautions had been taken by the appropriate federal government officials to ensure that the drug would not harm an unborn child.

## **MANDATE OF FEDERAL GOVERNMENT**

The mandate of the federal government under the Food and Drug Act is to protect the public; and to this extent the legislation, and any regulations arising therefrom, places the onus upon the government to prevent, insofar as that may be possible, the sale and use of hazardous drugs.

## **GOVERNMENT RATIONALE**

It would appear to have been (and may still be) the position of the federal government in regard to thalidomide that responsibility for the safety of the new drug lies with the manufacturer.

The fallacy in this argument is that the appropriate government officials must be satisfied as to whether a pharmaceutical firm has given information concerning adequate safeguards against the harmful effects of a drug.

## **HUMAN GUINEA PIG ELEMENT**

Under Canadian law, drugs of an experimental nature could be delivered to members of the medical profession, classified as 'clinical investigators' without restrictions, so long as an application for a 'new drug' license followed within a reasonable period of time. As a result, the thalidomide manufacturer in the United States was able to distribute to Canadian physicians, for trial use, their thalidomide-based drug Kevadon. No check was required. There was, as well, no requirement for the physician to maintain records of follow-up. Some Canadian mothers had access to thalidomide, under this method of distribution, as much as three months before the Canadian government was even aware that thalidomide was being administered to Canadians. This procedure was apparently acceptable to those Canadian officials who had the mandate to protect the public from hazardous drugs. It also allowed for active marketing of Kevadon by drug company representatives.

## **GOVERNMENT SCREENING PROCESS (LICENSING)**

There is an implied requirement that the federal government institute an effective screening process as a pre-requisite to the licensing of a new drug. This process failed tragically in the licensing of thalidomide for use in Canada.

New drug applications were approved, allowing both a U.S. company (MERRELL) and a Canadian pharmaceutical firm (HORNER), to manufacture the thalidomide under licence from the original developer in Germany.

The standard government form required a pharmaceutical company to provide details of the method and manufacture "necessary to evaluate its safety" and details of reports of tests made "to establish the safety of the drug."

This Task Force concluded that such details must necessarily have been inadequate for the purposes of evaluating the consequences of use of this drug.

### **FAILURE TO ACT ON EARLY CONTRA-INDICATIONS**

After licensing, the federal government failed to act in response to early evidence of thalidomide's side effects described as "possible peripheral neuritis."

### **FAILURE TO WITHDRAW**

Further, although the drug was withdrawn from the market in Germany and Great Britain in December 1961, the drug was not withdrawn by the Canadian government until three months later.

### **REINSTATEMENT PROPOSAL**

Even after withdrawal of the drug, the Director of Canada's Food and Drug Directorate suggested in writing that "there is every possibility that thalidomide could indeed be reinstated on the Canadian market . . ."

### **COMMENT ON LEGISLATION**

The Food and Drug Act itself may have been deficient, evidenced by the fact that within a few months of the withdrawal of the drug, the federal government introduced a bill to strengthen the legislation. This may well be an indication that the administrators should not share the full responsibility. The deficiency in the government legislation may have been in part responsible for the tragedy.

### **POSITION: CURRENT MINISTER**

The position of the current Minister of National Health and Welfare is that the legislation "required that those selling drugs establish the safety of their products."

### **U.S. PROHIBITION**

The Food and Drug Administration of the United States refused to approve thalidomide. Officials of the Food and Drug Directorate in Canada had access to the same information upon which U.S. officials based their decision to deny approval for the use of the drug in the United States.

### **THALIDOMIDE VICTIMS ASSOCIATION**

The Thalidomide Task Force worked closely with thalidomide victims in Canada, assisting them to establish an Association and a Foundation: the Thalidomide Victims Association of Canada, and the Thalidomide Victims Foundation of Canada.

### **COMPENSATION FORMULA**

The proposed formula for compensation, as endorsed by the Thalidomide Victims Association of Canada, provides that an attempt be made to negotiate the payment to the above Foundation from the federal government; and that the Thalidomide Victims Association accept responsibility to administer such funds in a manner considered equitable and fair to its members.

The federal government should make an initial payment. If and when the Thalidomide Victims Association can produce satisfactory proof that the funds have been properly administered, additional payments could be made by the government to meet current and future needs of the thalidomide victims.

### **HISTORICAL PERSPECTIVE**

Thalidomide victims are remembered, because of the notoriety surrounding the tragedy. Very little

has been done to bring to the attention of the public the problems faced by the group in their years of early maturity.

### **STATISTICS**

Statistical data provided by the Child and Maternal Health Division of the Department of National Health and Welfare in a report published in November 1963 stated that 115 children had been born in Canada in 1961 and 1962 with congenital malformations associated with thalidomide. At that date, only 74 were reported to have survived. These numbers are not reliable. Our Task Force has identified 109 victims.

### **GOVERNMENT-SPONSORED COMMITTEES**

The federal government instituted two separate committees, one appointed by the Royal College of Physicians and Surgeons of Canada and the other an independent committee of specialists to deal with medical rehabilitation. There was no official investigation to determine whether the government bore a share of the responsibility for the tragedy and/or to determine why the drug was marketed in Canada by the same U.S. company which was refused a permit to market the drug in the United States. The media and the public appeared to have concluded that probable cause for the disaster was being investigated. It is suggested that had a public determination been made, when thalidomide was 'front-page news,' financial responsibility of the federal government would have been apparent at that time.

### **RESPONSIBILITY: GOVERNMENT vs MANUFACTURER**

Canadian officials suggest that the manufacturer is solely responsible for the safety of the drug which, if true, would leave no role for the Canadian government to carry out independent evaluations.

The federal government has also made reference to the legal responsibility of the manufacturer. Claims had to be dealt with in U.S. courts, which complicated the matter of legal proceedings. Moreover, in view of the fact that preventive legislation did exist in Canadian statutes, the responsibility for compensation cannot be wholly accepted by the foreign manufacturer.

### **NEED FOR PERMANENT COMPENSATION PLAN**

he present situation in Canada is seriously flawed in regard to potential victims of further errors concerning authorization for pharmaceutical products. Departmental officials who must rule on new drug applications have the obligation to ensure that Canadians can participate in the benefits of new drug discoveries; on the other hand they face the terrifying alternative that they could be authorizing a drug which has severe medical side effects.

So that such officials could properly carry out their work, striking a balance between the benefits and the possible undesirable consequences, the government should initiate legislation – based on what might be termed the "no-fault insurance principle" – to provide compensation where it can be established that a victim has been harmed by the ingestion of an approved 'new drug'.

### **MORAL RESPONSIBILITY**

The establishment of moral responsibility does not necessarily imply liability; the essence of moral judgment is that it is either right or wrong. In the case of thalidomide, it was wrong and the reasons need not be examined. It should be sufficient to accept that the government had the responsibility to protect the public. Its failure to do so makes a strong argument for compensation.

### **HUMANITARIAN GROUND**

The initial government response appears to be that the claim for assistance is not acceptable on grounds of either legal or moral responsibility. If this position is maintained, there is ample evidence concerning the effect of the damage caused by thalidomide to warrant government assistance on humanitarian grounds.

### **HUMAN RIGHTS**

It is the position of the Task Force that a reasonable case can be made that the government's failure to protect the interests of the children damaged by the drug thalidomide would constitute a violation of the human rights of these children.

Reference has been made in the Task Force Report to the jurisdiction of the Human Rights Commission and the Human Rights Committee of the United Nations and the substantive relevance of the Universal Declaration of Human Rights and the Declaration of the Rights of the Child proclaimed by the General Assembly of the United Nations on the 20th of November, 1959.

## SIGNIFICANT DATES

1953 - Chemie Gruenenthal synthesized thalidomide.

1957 - Thalidomide was placed in commercial use in West Germany.

1959 - January - The William S. Merrell Company of Cincinnati, Ohio commenced development of thalidomide under brand name Kevadon.

1959 - June 23 - Merrell advised the Food and Drug Directorate of Canada's Department of National Health and Welfare that samples of Kevadon were being shipped to "qualified investigators" in Canada for clinical investigation.

1959 - June 25 - The Director of the Food and Drug Directorate acknowledged receipt of the Merrell letter.

1960 - September 8 - Merrell submitted data concerning Kevadon to the Food and Drug Directorate (Canada). Merrell submitted these data to the Food and Drug Administration (United States) four days later.

1960 - November 22 - Merrell received a notice of compliance from the Canadian Food and Drug Directorate, authorizing the drug to be marketed on a prescription basis in Canada.

1960 - December - Articles appeared in a British medical journal warning that thalidomide was a possible cause of peripheral neuritis, a severe form of nerve damage.

1961 - April 1 - Merrell began marketing thalidomide for prescription sale in Canada under the brand name Kevadon.

1961 - November 27 - Chemie Gruenenthal took the drug off the market in West Germany.

1961 - November 30 - Merrell revealed the possibility that congenital malformations could be attributed to thalidomide.

1961 - December 2 - Distillers Company (Biochemicals) Limited took the drug off the market in the United Kingdom.

1961 - December 5 - Merrell mailed a letter to all Canadian doctors containing a warning that

thalidomide was contra-indicated for pregnant women.

1962 - February 21 - Merrell sent a further follow-up warning to Canadian doctors.

1962 - March 2 - The Canadian Food and Drug Directorate advised that thalidomide should be removed from the market in Canada.

1962 - April 21 - A letter from the Director of Food and Drug Directorate suggested the possibility that thalidomide could be reinstated.

1962 - December 4 - Canada's Food and Drugs Act was amended.