

OVERVIEW

Some 27 years ago, a group of 125 special babies were born in Canada. They exhibited severe birth defects which resulted from fetal damage caused by the drug thalidomide.

Today, the survivors are courageous young men and women with some extraordinary (and very costly) needs, far greater than those of ordinary Canadians.

They face 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 written by the thalidomide victims themselves. (The research papers are presented in Appendix A of this Report.)

In addition to these problems, some of them have had to cope with public attitudes, ranging from curiosity to downright rejection. They are not bitter, but they would have every right to be. The federal government, which sanctioned the use of the drug that created such havoc among them, does not even know their names! They are entitled to the highest respect, as well as some tangible form of restitution: the disabilities they bear today occurred because of a failure of our public service and the legislation it administers.

Some of these people have succeeded in their lives and will continue to succeed, despite the cruel handicaps. Others are barely surviving. The significant issue, however, is that they are the victims of a classic mistake over which neither they nor their families had any control.

In the early 1960s, Canadians were well aware of the thalidomide tragedy, and public indignation ran high. Notwithstanding, there still remains an unresolved issue: the issue of compensation for those who suffered the consequences of this drug.

Ironically, thalidomide victims are remembered because of the scope of the tragedy. Until now, however, very little has been done to bring to the attention of the Canadian public the problems these people face in their years of early maturity.

Insofar as the Thalidomide Task Force has been able to determine, the Canadian government has never tried to assess responsibility for this disaster. This task was not within the mandate of the two committees created by the federal government in the immediate wake of the disaster.

One committee was formed at government request by the Royal College of Physicians and Surgeons of Canada. Its purpose was “to examine critically and objectively our present procedures for dealing with new drugs, the requirements of the regulations and other matters that, in the opinion of the committee, are relative to the issue.”

The terms of reference were limited to an examination of procedures and regulations and, although such terms did include a broader scope in the words “any other matters that, in the opinion of the committee, are relative to the issue” there was no mandate to determine any matters of incompetence or dereliction of duty.

The second committee appointed by the government was entitled: Expert Committee on Rehabilitation of Congenital Malformations Associated with Thalidomide. As its name implies, this committee dealt specifically with the medical and rehabilitation problems.

It is perhaps understandable that, in the light of the national feeling of outrage which was exhibited in this country following the revelations concerning thalidomide, there would have been a reluctance to deal with the cause. Such cause may have led to the involvement of individuals whose careers or reputations could have been placed in jeopardy.

The fact remains, however, that something went very wrong in Canada. Although the disaster was on an international scale, preventative measures in the United States were sufficient to avoid calamitous results, even though the same firm (Merrell) owned the distribution rights in both countries. Where, then, does the fault lie in our country and with whom?

Possibly the failure to investigate the specifics would not be of such importance, except that the surviving thalidomide victims in Canada are now paying the price. It seems reasonable to assume that if an attempt had been made when the catastrophe was ‘front-page news’

to determine why it had occurred and who (if anyone) was responsible, the issue of compensation for the victims might have been more clearly defined. This seems particularly so, inasmuch as the federal government allowed the drug on the market.

If the person or persons directly responsible were government officials, there is provision under law which protects them from personal liability. This should have made it easier for the government of the day to institute an inquiry, bearing in mind that if such investigation revealed error on the part of the government employees, the question of financial compensation for the victims would not have been a personal matter, but would have developed directly upon the employer - in this case, the federal government.

It is germane to this issue that there was legislation on the statutes which, if properly acted upon, could have prevented this sad occurrence.

It is possible to call to mind parallel situations where flawed performance did occur; and indemnification was provided by the federal government.

The failure of government inspectors to enforce safety standards in regard to insulation materials installed in a public structure provides an excellent example in this context. The situation arose in the early 1980s when the government recognized its error in certifying the safety of the urea-formaldehyde foam insulation (UFFI). The government established a compensatory program by acknowledging the error made by the Central Mortgage and Housing Corporation (CMHC) in certifying the use of UFFI and set up a funding program

to indemnify all homeowners who had used it in their homes. The parallel is interesting in that the government, through a national agency (CMHC), had actually approved the usage of a substance which led to the problems encountered by homeowners, problems related not only to their health but to the marketability of their properties.

If such investigation techniques had been carried out in respect of thalidomide, and failure to protect the public had been established on the part of the federal government and/or its servants, the question of compensation would certainly have been raised 25 years ago. Where there is fault, there is responsibility. Where there is responsibility, it follows that financial compensation must be a consideration.

The manufacturers of this drug must bear some liability. This question has been vigorously pursued through the courts for many years. Further attempts are now being made to convince the drug companies of their responsibility, notwithstanding the legal obstacles created by the settlement of earlier claims and the stricture of the relevant statutes of limitations.

A significant factor has been revealed in recent years which has considerable bearing on further attempts to obtain monies for damage claims against the U.S. manufacturer.

The William S. Merrell Company, a division of Richardson-Merrell, was well aware of the toxic properties of thalidomide - under the trade name Kevadon - within weeks of applying to have the drug licensed in Canada.

Merrell tried for more than a year to get the drug approved in the United States by the Food and Drug Administration (FDA). Company officials applied vigorous pressure to have Kevadon approved by the FDA, without success.

During the same period, Merrell carried on a furious marketing pitch in the Canadian market. At no time was any discernible effort made on the part of the U.S. company to reveal the adverse effects of the drug, which were well known to the company in Germany that had developed the drug and to at least some Merrell executives. If indeed Merrell carried on an active sales campaign in Canada, despite the knowledge of the drug's dangers, it would have to be seen as **a very black mark** against a large pharmaceutical firm.

It should be stated that some representatives of the legal profession carried out a herculean task on behalf of Canadian thalidomide victims.

Most of the members of this Task Force have been aware, for a number of years, of the brilliant legal work done on behalf of Canadian victims. The firm of Spangenberg, Shibley, Traci, Lancione of Cleveland, Ohio, and attorney Arthur Raynes of Philadelphia, Pennsylvania, assisted by Canadian lawyers including Pierre Marois of Montreal and Lloyd Perry of Toronto, took on an almost impossible challenge in pursuing claims against the U.S. manufacturer.

They faced many difficulties: language differences, geographic distances, the statute of

limitations, and matters of jurisdiction and jurisprudence. In addition, the highly talented but small legal force supporting the Canadians was up against a phalanx of top-flight personal injury law firms that had been hired by Merrell.

The settlements obtained for the Canadian thalidomide clients were far beyond expectations. Having said this, it is obvious that the amounts nevertheless bear little semblance to the needs of the thalidomide group today.

There is a reasonable case to be made to have these settlements reviewed by the company that later took over the assets of Merrell. The Task Force has accepted this as an additional challenge. More information on the appeal to the drug manufacturers is provided below in the section on legal settlements.

Notwithstanding any additional claims against the manufacturer, the federal government must shoulder some obligation for compensation. Firstly, the obvious laxity in Canadian government legislation permitted the U.S. manufacturer to distribute its brand of thalidomide (Kevadon) to members of the medical profession in Canada who were known as “clinical investigators” without any check whatsoever by the federal government in regard to the safety or other properties of the drug.

Secondly, the federal government licensed the drug under legislation designed to protect the public from the very occurrence (drug-induced damage) which is responsible for the additional needs of these thalidomide victims. The obligation of the federal government is

the main issue being addressed in this report.

The Canadian government does not know the names of thalidomide victims in this country nor has it ever provided compensation to them. Provision now by the government for compensation would not, however, establish a precedent.

In Japan, the government provided \$18 million in compensation in a payment shared by Dai-Nippon, a pharmaceutical company. The Japanese government has also continued to administer an active program on behalf of Japanese thalidomide victims, and had followed their progress over the years. A Japanese expert reported on these victims during an international conference on children with limb deficiencies held August 27 - September 2, 1988, in Heidelberg, West Germany. (Mitsuhiro Kida's article, "A Quarter Century of Thalidomide Embryopathy," appears in Appendix B.)

(According to Thalidomide and the Power of the Drug Companies by Henning Sjorstrom and Robert Nilsson [Penguin 1972], some "leading Japanese are now faced with civil law suits for taking no measures to force withdrawal of thalidomide from the market for a year or more after being informed both of Dr. Lenz's revelations and of the withdrawal of the drug from other countries." Dr. Widukind Lenz - head of the children's clinic at Hamburg University in Hamburg, West Germany - is acknowledged as the first medical practitioner to publish warnings about the teratogenic danger of thalidomide.)

In Germany, the government paid, in the form of damages to thalidomide children, a sum

of between \$13.5 million and \$27 million. This was matched by a payment from Gruenenthal, the German manufacturer, of \$31 million.

Settlements, modest by today's standards, have been received by some Canadian thalidomide victims from Merrell. A similar sharing, from the Canadian government, is sought to meet the demonstrated needs of those damaged by this fateful drug.

In the United Kingdom, a substantial settlement was made by Distillers Company (Biochemicals) Limited, the U.K. company that produced thalidomide under licence. Funds were paid from Distillers into a private trust for administration on behalf of thalidomide victims.

A similar arrangement was made in Germany under which Chemie Gruenenthal, the German manufacturer of the drug, made a settlement which is administered by a trust agency, with government control. It is noteworthy that the settlement was agreed to on the understanding that the German government would not proceed with criminal charges against Gruenenthal officers.

The drug thalidomide was apparently licensed for use in Canada solely on the basis of assurances from the U.S. manufacturer regarding its safety. Thalidomide, primarily a sedative, was developed by Gruenenthal. This German company licensed The William S. Merrell Company to manufacture thalidomide in the United states for distribution in North America.

It would appear that the Canadian government, which has jurisdiction to certify the use of new drugs, carried out no tests of its own. Moreover, a review of the documentation provided by the Department of National Health and Welfare (DNHW) indicates that departmental officials must have been aware that the drug caused peripheral neuritis in adults, even before authority was granted for its use on prescription in Canada.

The drug came on the market in Germany in 1957, some four years before applications were made to license it in Canada, thus providing ample time to determine whether reports existed regarding its safety. Apparently the Canadian authorities made no attempt to inquire!

There is evidence to indicate, moreover, that Canadian officials failed to withdraw the drug in this country for a period of more than three months **after** its use had been banned in Germany, England and Australia. Further, subsequent to the drug's withdrawal in Canada, the senior official responsible for licensing in Canada still issued a statement suggesting that the drug could be reinstated.

All other considerations aside, we have here in Canada a very small group of courageous young men and women - many of them of above-average intelligence - who have paid, and will continue to pay, the penalty for someone's mistake.

The government of Canada was involved in this grievous error. Surely it is reasonable that this country, with its quite considerable resources, can set aside a reasonable

compensation payment to make up in some small measure for this obligation.

In an era in which the government accepts the necessity of providing funds for various causes, it is remarkable - and should be emphasized - that these outstanding young Canadians have, themselves, **asked for nothing**. It is our desire as a Task Force, however, to bring to the attention of all concerned the pitiful story of what happened to them. Many of the Task Force members were involved in the tragedy from the outset. We have first-hand knowledge of the details as they unfolded then; we can provide accurate data as to the problems of these people in today's society.

(It may be of interest that the very first gathering of these Canadian thalidomide victims took place in Ottawa, August 2-4, 1988. Their courage was inspiring, their spirit and determination was heroic; but their physical loss was heartbreaking to observe, and their needs were devastatingly obvious.)

We are firmly of the opinion that Canadians as a whole will generously applaud any reasonable effort by the Canadian government to provide remedial assistance. Obviously, money alone can never make up for what has happened to this group of disabled people. It will, however, help!

HISTORICAL OBSERVATIONS

Some may ask why it has taken all of this time to prepare a request to the federal government for compensation. Such request should have had more appeal immediately following the births of the thalidomide victims when thalidomide was an international issue.

The history of the thalidomide victims provides part of the explanation.

1961 to 1971: During this period there was a great deal of effort being put forward in two areas: possible surgical improvement of their limbs and prosthetic research in the event that artificial limbs could be developed. When the children were very young, a few realized that compensation would be an issue.

1971 to 1982: During this period there was the major problem of adjustment of teenagers to family, social and school environments. Also, efforts were made to pursue legal avenues in regard to liability of the manufacturer. This was time consuming, particularly inasmuch as these matters would not be dealt with in Canadian courts of law.

1982 to the Present: Only during this period would the financial problems of the thalidomide victims, now young adults, become fully realized - that is, when the victims reached the age of majority. The first attempt to investigate the possibility of compensation by reason of responsibility of the federal government was, we believe, initiated by

The War Amputations of Canada in 1982. These attempts were reinstated as a result of media controversies of 1987, which provided the springboard to bring into action the Thalidomide Task Force.

Publication bans arising from the legal battles which raged both in England and Germany were major factors in the delay in making public the problems associated with thalidomide.

Thalidomide first came on the German market in Germany in 1957 under the trade name Contergan. The first reports, in any strength, of physical damage caused by the drug were made in 1958; and they made a link with peripheral neuritis, a serious form of nerve damage. The manufacturer, Gruenenthal, immediately went on the offensive. The company even hired private detectives to track down and attempt to embarrass those doctors who were complaining about Contergan. In short, the company took the posture of denying that Contergan was in any way a damaging drug.

In October of 1960, at the International Meeting of Pediatrics in Kassell, Germany, two doctors presented cases of children born with horrible malformations. This gave Gruenenthal some cause for concern but the company continued its defensive tactics, fearing a lawsuit (which eventually did develop).

Certainly, from that point in time, any information from German sources regarding the damaging effects of thalidomide was suppressed.

In the United Kingdom, the situation was even worse, from the point of view of obtaining information about the side-effects of the drug. The United Kingdom distributor, Distillers Company (Biochemicals) Limited (DCBL), marketed thalidomide under the name of Distaval. Company officials should have been aware of the drug's contra-indications, but little information was released.

The British media were faced with legal injunctions that prevented them from reporting on the legal proceedings which went on for many, many years in the British courts before appropriate settlements were made.

Hence, as in Germany, the opportunity of obtaining any data concerning the damaging effects of thalidomide were essentially blocked.

In retrospect, this should have acted to the advantage of the Canadian government. Although there was little public knowledge, information to the effect that the drug was causing untold damage to unborn children was being widely circulated in the medical and pharmaceutical fields. Although there was ample data available to the medical and pharmaceutical professions throughout the Western world, very little of this information was being made available to the public or the media in Canada. The result was, of course, what amounted to a 'blackout' of information in the print and electronic media in Canada. Ostensibly, if this information had been made public, there would have been a strong movement to determine who or what was to blame for allowing this drug to become available to Canadian users.

Concerning delays in regard to claims for compensation, the authors of Suffer the Children: The Story of Thalidomide (published in 1979) stated:

Secrecy cast a long shadow in the thalidomide affair, first over the discovery of what went wrong, medically and logically, and then over publication of the truth. Much of the story in this book has lain for 15 years under veils of legal censorship. It is a story about a cover-up as well as about a drug disaster. It is less a scientific horror tale - though that element is present - than a parable about the predicament of the individual who is asked to pay a price for progress.

The drug thalidomide, under various trade names, was available in many countries. In respect of compensation, however, the position of the Canadian victims was, and is, unique.

In Germany, the government launched an action against the developer, Chemie Gruenthal. In Great Britain, parents of the thalidomide victims organized themselves into groups and were in a position to sue the manufacturer, DCBL.

In Belgium, Sweden and Japan, pharmaceutical firms had obtained franchises from Gruenthal in Germany to manufacture and market the drug; hence, the victims could sue the drug companies in their own countries.

Apparently most of the tablets taken by mothers in Canada had been manufactured under the control of the United States licensee. This resulted in the situation where, from a practical stance, lawsuits had to be launched in U.S. courts.

This presented a classic case where there might have been grounds for the Canadian

government to sue the U.S. manufacturer, on behalf of Canadian victims. This scenario makes even more sense in the light of the insistence by the Canadian government that the responsibility for the safety of a drug rests with the manufacturer. Be that as it may, the Canadian government took no action to assist Canadians seeking legal recourse in the United States.

As they enter young adulthood, the Canadian victims of thalidomide stand alone. Some did receive compensation from the pharmaceutical company but the entire picture of these settlements is much like a patchwork quilt.

In some instances, no payments were received at all. In others, the amounts, although possibly considered as adequate at the time, are pitifully small once the effect of inflation is taken into account.

There may have been other settlements which could still be considered as reasonable, but the full story will never be known: the pharmaceutical company insisted that the recipients must never reveal the details.

As will be discussed later in this report, the Task Force believes that there may still be grounds for Canadian victims to obtain further settlements from the drug company. Notwithstanding, it can be expected that any new settlements (which would have to be provided on a voluntary basis due to the statute of limitations) would scarcely begin to cover the needs of those so seriously damaged by this drug.

Because of the unique situation in which the Canadian victims find themselves, and because of all of the factors which seem to indicate failure on the part of those whose job it was to prevent the importation of this drug, there is the strongest possible argument for partial compensation from the government of Canada.

LEGAL SETTLEMENTS

Some members of the public have the erroneous perception that the victims of thalidomide were paid sizeable financial settlements from the drug companies as a result of court actions. In preparing this report, the Task force has surveyed more than 75% of the thalidomide survivors in Canada.

There are few cases where, by today's standards, it could be stated that the legal settlements were sufficient to meet the current and future needs of the victims. It would seem that this is one of those instances where one or two very large settlements in the U.S. courts served to create a general impression which is far, far from the truth. (For example, a case in the United States involved a girl in Los Angeles whose mother had taken thalidomide before any application had been made to have the drug licensed in that country. Samples had apparently been distributed to the mother's doctor. When a settlement was reached in the case, the media reported it was for close to \$2 million.)

In Canada, those who would attempt to unearth the details of thalidomide settlements encounter severe difficulties. In most instances, the settlement were made on the understanding that the thalidomide families would not reveal any details about them, including the amounts. There were a number of strategic reasons for this edict on the part of the drug company. Firstly, apparently some cases had been settled very early for much smaller amounts than those in later settlements. Secondly, in that the U.S. drug company

had distributed more than 6.4 million thalidomide tablets in Canada, there must have been a very real fear that information concerning settlements would lead to further applications to the court.

Be that as it may, a review of the media coverage of the day does seem to indicate that the general impression was given that some very large amounts of money had been paid to the thalidomide families. The truth of the matter is two-fold.

Firstly, on the average, the amounts have to be described as moderate by the standards of those days. Secondly, litigants, and the lawyers representing them, were attempting to devise what is known as an annuity contract to cover future care costs during the period when the inflation rate was less than two per cent. In most cases where provision was made for indexing, it was totally unrealistic, given the fact that within a few years we were into double-digit inflation in Canada.

Secondly, our files contain a number of cases where the settlements were woefully insufficient; or non-existent!

A third factor affecting court settlements is that, in some instances, the terms of the trustees were such that by the time the thalidomide children reached the age of majority, the settlements had all but depleted. This was largely due to:

1. The significant demands on the trust funds in order to meet the serious needs of the thalidomide children during their earlier years;

2. The ravages of inflation and the costs of living.

In summary, then, there are very few, if any, of the surviving thalidomide children who do not have extraordinary needs, far beyond the capability of any legal settlements, whatever they may have been.

Moreover, in order to protect government and other donors who may wish to contribute funds to the Thalidomide Victims Foundation of Canada, its officers have established a grant policy based on need. This should certainly guarantee that compensation paid from the government of Canada, in response to this appeal on behalf of those who suffered damage from thalidomide, will be used only where their needs are well documented, and justifiable.

As an adjunct to the Task Force's research on this matter, we retained the services of the Thomson, Rogers law firm in the city of Toronto and more specifically Mr. Ken Howie, Q.C., the senior partner and one of the leading personal injury lawyers in Canada, to make an assessment as to the type of court award that a thalidomide victim would receive in today's courts in the event the damages were being adjudged pursuant to current legal standards. (The Thomson, Rogers study can be found in Appendix C of the Report.)

His findings have resulted in some rather startling conclusions vis-a-vis the adequacy of the settlements struck in the 1960s and early 1970s for the children.

As a matter of background, the Thomson, Rogers study makes clear that the Supreme Court of Canada in deciding three now famous cases (the Trilogy in 1978), set up a damage standard which has since been followed by courts throughout Canada and which dramatically changed the assessment of these types of court awards.

As was stated in the Trilogy decisions by the current Chief Justice and then the Honourable Mr. Justice Dickson:

If the Plaintiff has to pay for expensive medical or nursing attention, then this cost should be borne by the Defendant. These costs are “losses” to the Plaintiff, in the sense that they are expenses which he would not have had to incur but for the accident. The amount of the award under these heads of damages should not be influenced by the depth of the Defendant’s pocket or by sympathy for the position of either party. Nor should arguments over the social costs of the award be controlling at this point. The first and controlling principle is that the victim must be compensated for his loss. (Dominion Law Reports, pp 643-5. S.C.R.)

The Thomson, Rogers study points out that the major effect that the Trilogy cases had was to ensure an appropriate quantification of damages awarded in personal injury disaster cases. The main premise was that if logical assessment technique was used across Canada, the cases across the country might be compared for reasonableness and fairness of the award.

The Supreme Court of Canada left very little doubt that the economic loss incurred by the thalidomide victims, for example, would not have been subject to any limitations for reasons of public policy. The principle to be applied is simply this: in fairness to the victim, monies are to be awarded for continued preservation of health, entitlement for future lost income, and their various needs for medical rehabilitation and care costs. This principle represents

the standard that the thalidomide victim would have had applied to this case in the event the claim had been adjudicated in the current context.

In effect, the Supreme Court of Canada Trilogy cases lead to the conclusion that the thalidomide victim would have had the right to a standard of living equal to a non-disabled person. Therefore, in the event the courts were to deal with a thalidomide case today, the court would actually work out the entire program for a lifetime as to the specific needs of the thalidomide victim and then seek out the evidence required to establish what those needs are in actuality. As a matter of practice, the types of damages to be awarded in the normal assessment as noted by the Supreme Court of Canada in order to quantify the non-pecuniary and pecuniary losses are as follows:

- a) General damage - non-pecuniary (pain and suffering);
- b) Lost income past and present;
- c) Future loss of income;
- d) The capital costs of equipment, or services for various personal and family expenses up to the time of assessment;
- e) Family claims - for the care, comfort, and companionship, either lost by the family or the extra care that the family must provide to the thalidomide victim;
- f) Interest on the above amounts since the date of the injury to the time of assessment;
- g) Future care cost, i.e. prosthetic limbs, nursing, (if there is evidence for the needs for nurses or attendants), companionship, etc.;
- h) Management fees; and
- i) Gross-up for income tax.

The Thomson, Rogers study continues by examining the issues of employability, the impact on the immediate family and the precise calculations employed by the Canadian courts in establishing the quantum for future care costs and future loss of income.

It is interesting to note that the Thomson, Rogers study concludes by providing two examples of how a Canadian court would assess a thalidomide victim's case today.

In the first example, the study assumes a case dealing with a young male thalidomide victim, 24 years of age, who has suffered birth defects leaving him with two deformed upper limbs necessitating the use of two myo-electric prosthetic arms. There is no cognitive disability and other than the above-noted, he is perfectly "normal". The young man has a family, a father now 40 years of age and a sister 22 years of age. The young man's mother died three years ago. The disability revolves around his not being able to use his arms and his dependency upon others to help circumvent that problem.

The Thomson, Rogers assessment of this young man's claim, which is calculated precisely in the study, reflects a court award of \$1,694,885. (It is to be noted that this award has not been increased for the gross-up due to income tax consequences.)

The second example is more complicated. In this case, the thalidomide victim, now approximately 25 years of age, is suffering from severe physical and cognitive deficits so that he is totally dependent upon his family to care for him. In addition, in the event that the thalidomide victim is better off being cared for at home rather than an institution, home care

will be the standard long-term cost the court will approve. The Thomson, Rogers study concludes in this particular case that the damage award would be \$6,008,360. (Again, it is to be noted that this figure has not been increased for income tax.)

The Task Force would wish to emphasize that these illustrations in the Thomson, Rogers study are cited not as a basis of our current claim for compensation, but as an indication of the significant distinction in the approach of the Canadian courts in the present context as compared to the time frame when the greater majority of thalidomide victims' cases were concluded with the pharmaceutical companies.

In this regard, it is also of significance to note that the thalidomide victims are **presently** confronted with the future care costs, loss of income, and other losses described in the Thomson, Rogers study, given the nature of their individual disabilities and incapacities.

In attempting to determine a further basis for future care costs, the Task Force also used the standards of the Canadian Pension Commission for veterans. On quadruple amputation or paraplegia, the figures, per annum, would be as follows:

Single Rate	\$15,525.00
Spouse	3,881.28
First child	2,018.28
Second child	1,474.80
Attendance Allowance (maximum)	10,273.08
Exceptional Incapacity Allowance (maximum)	8,218.56
Veterans Independence Program - Home Care	5,074.00
Adult Residential Care	71.08
Ambulatory Health Care	589.99
Transportation	708.00
Personal Comforts	<u>117.99</u>

TOTAL

\$47,952.06

Note: Such amounts are tax free; in addition, allowances would be available for home adaptation up to \$2,950 or nursing home care at \$71.08 per day.

CANADIAN MANUFACTURER

It is known that Frank W. Horner Limited of Montreal sought and was granted a licence to distribute a brand of thalidomide called Talimol. Our research has indicated that slightly more than 900,000 tablets were distributed by Horner. Horner manufactured the tablets from the raw material shipped to them by Merrell.

In discussions with lawyers who handled the claims on behalf of Canadian victims, we have been advised that legal proceedings were taken, on behalf of such Canadians, only in U.S. courts against The William S. Merrell Company.

It would appear that no claims were made against Horner; nor were any settlements paid. We are continuing our research in this area.

In view, however, of the accurate information regarding the large number of tablets produced and distributed by Horner, it seems likely that some of the thalidomide damage in Canada was, in fact, the result of the Talimol brand of thalidomide.

This Task Force intends, as its work continues, to approach Horner to determine whether that company would be prepared, on a voluntary basis, to provide funding which would be available to the victims through the Thalidomide Victims Association of Canada, and the Foundation being established by the Association.

PROFILE: THALIDOMIDE CASES

The standard description of the thalidomide-damaged person envisages loss of all four limbs, loss of two limbs or loss of digits (fingers and toes).

The damage done by thalidomide, however, depends very largely upon the time, during pregnancy, when the mother used the drug. As a result, in many instances the fetus was born with severe damage other than limb defects. Hearing loss and damage to the external ear were common. Extensive disabilities were found, in many, to exist in the gastrointestinal system, the genital-urinary system, and the heart. There was, as well, evidence of paralysis of the face or underdevelopment of the tongue and some effect, generally, on the motor system.

Many of the disabilities, other than missing limbs, are of the 'hidden' variety or, to use another term in the area of compensation, 'not obvious to the eye of the untrained observer.' Such disabilities are, notwithstanding, serious and in many instances are life threatening, possibly to a greater extent than missing limbs.

Our research documents contain instances where the thalidomide child had to undergo as many as 40 or 50 surgical operations required to improve cosmesis and/or achieve function. It is of more than casual interest to know that, in most cases, the success achieved was only minimal, which in reality met the expectations of the surgeons themselves.

(Donald Traci, the lawyer in Cleveland, Ohio, who handled many of the Canadian legal claims against Merrell, the manufacturer, stated publicly that in some of the cases he was handling, the thalidomide child was not expected to live.)

Thalidomide is a drug which came on the market in Germany in the late 1950s. The bulk of the Canadian children were born in 1961 and 1962. They are today entering young adulthood. There are two factors which are of very considerable concern regarding the long-term effects.

Firstly, no one knows for certain whether damage which may have been done to the internal organs will manifest itself in later life, representing a threat in the area of an acquired disease or loss of function of vital organs which may interfere with or terminate life. Current reports do indicate, however, some loss of life expectancy.

Secondly, little or nothing is known about the sequelae of those who have lived, in the early part of their lives, having to contend with physical effects of the malformations, that is to say: twisted spines; unusual and prolonged use of crutches, prostheses or wheelchairs; undue pressure upon vital organs such as the heart and lungs to sustain bodily function; or mental defects. Reports from Germany do indicate some thalidomide victims are now experiencing a decrease in normal function.

These, and many other possible later effects, are the cause of very grave concern among the people in this group.

UNITED STATES AND CANADA: A COMPARISON

It is significant, in the study of the use of thalidomide in Canada, to draw a parallel with the United States. In essence, the protection for the consumer is the same; that is, both governments have legislation designed to prevent the sale and use of hazardous pharmaceutical products.

Concerning thalidomide, it is understood that the North American rights of manufacture were granted to The William S. Merrell Company, a U.S. company.

Merrell applied on September 12th, 1960 to the Food and Drug Administration (FDA) in Washington, D.C. for a licence to market its brand of thalidomide - Kevadon - in the United States. The application from Merrell to market Kevadon in Canada was submitted under date of September 8, 1960.

Our research indicates that both applications were supported by the same data. Some of it was furnished by Gruenenthal of Germany, the drug's inventor; some was based on Merrell's experience.

The Canadian Department of National Health and Welfare (DNHW) issued the compliance order permitting availability of the drug, on prescription, under date of November 22, 1960.

The application to the FDA was submitted to Dr. Frances Kelsey, a medical doctor with a

Ph.D. in pharmacology who, incidentally, was a Canadian. In contrast to the quick and favourable response in Canada, when Dr. Kelsey wrote to Merrell on November 10, 1960 her letter raised a number of serious questions, as follows:

1. The animal studies were not reported in sufficient detail, and the study on the absorption of the drug in rats was not supported by evidence.
2. The company had failed to report the clinical studies in full detail. In addition, an insufficient number of cases had been studied. Kelsey also observed that many of the 3,156 cases cited were in foreign literature reports and “in many instances the reports do not represent detailed studies to determine the safety of the drug.”
3. Chronic toxicity data were incomplete, leading to the obvious conclusion that “no evaluation can be made of the safety of the drug when used for a prolonged period of time.”
4. The application contained rather limited information about the drug’s stability.
5. Side effects were passed over lightly. “The impression is left that the single ‘hangover’ frequently observed by Lasagna was due to over dosage, yet in double blind studies this investigator was unable to elicit a therapeutic response with lower doses.”
6. There was no data to support the claim advanced in a report by one Dr. Ray Nulsen that expectant mothers suffering from nocturia (excessive passing of urine in the night) had no difficulty arising or returning to sleep after taking thalidomide.

Also, the U.S. Food and Drug Administration prepared an analysis of the application by Frances Kelsey’s husband, F.E. Kelsey, a pharmacologist who also worked for the Food

and Drug Administration.

This analysis was critical of Merrell and, in fact, accused the company of unacceptable ignorance of what was scientifically legitimate. The analysis stated: “The section entitled ‘chemical comparison of thalidomide and glutethimide’ is an interesting collection of meaningless, pseudo-scientific jargon, apparently intended to impress chemically unsophisticated readers. The selection of one chemical difference between two compounds as the ‘most important chemical difference’ is absurd. What is the most important difference between an apple and an orange?”

F.E. Kelsey commented on the company’s submissions on absorption studies as follows:

...the experimental procedure used is either undescribed or inadequate. The data are completely meaningless as presented.

On May 5, 1961 Dr. Frances Kelsey wrote to Merrell as follows:

In our opinion the application as it now stands is entirely inadequate to establish the safety of the Kevadon tablets under the proposed labeling. In particular the application does not include complete reports of adequate animal studies nor sufficiently extensive, complete and adequate clinical studies to permit an evaluation of the toxic effects of the drug which have been manifested by reports of cases of peripheral neuritis. On the present evidence we cannot regard Kevadon tablets as safe in the sense that its usefulness as a sedative hypnotic outweighs the toxic effects indicated by cases of peripheral neuritis. Detailed case reports with adequate follow-up studies will be required to determine whether the condition is reversible....We have taken appropriate note of your contention that it has not been proved that Kevadon tablets actually cause peripheral neuritis, and the fact that the labeling of the drug proposed in your letter of March 29th, 1961, fails to make a frank disclosure that the drug has been found to cause peripheral neuritis. In the consideration of an application for a new drug, the burden of proof that the drug causes side effects does not lie with this Administration. The burden of proof that the drug is safe - which must include adequate studies

of all the manifestations of toxicity which medical or clinical experience suggests - lies with the applicant. In this connection we are much concerned that apparently evidence with respect to the occurrence of peripheral neuritis in England was known to you but not forthrightly disclosed in the application.
[Underlining is ours.]

The differences in approach taken by the U.S. and Canadian regulatory authorities is of critical importance in this claim against the Canadian government.

The U.S. authorities did not conduct any additional testing. It can be safely assumed that their refusal to approve the Merrell application was based entirely upon their skeptical opinion of the data provided by Merrell and/or of reports about which there was wide knowledge in the medical and pharmaceutical fields.

The major point here, however, concerns the responsibility of the applicant (drug company) to furnish the burden of proof that the drug is safe. Both the U.S. and Canadian officials accept this as an overriding principle.

Using what appears to be the same set of rules and the same premise that the responsibility was the applicant's to prove that a drug is safe, the experience in the United States and Canada was widely divergent! Sadly, in the Canadian situation, the results were much different, as well!

As we have seen, the U.S. officials exerted the authority to deny the application for marketing on the grounds that the drug company had not furnished the necessary evidence regarding safety of the drug.

Conversely, the Canadian authorities, who had access to the same data, apparently concluded that the company had satisfied the criteria regarding the safety of its drug; and the marketing licence for Canada was approved.

The obvious conclusion is that a comparison of the manner in which U.S. and Canadian authorities acted, in regard to the Merrell application, is rather conclusive proof that the decision affecting consumers in Canada was flawed.

Further study of the developments in the Food and Drug Administration in the United States indicate, quite clearly, that the original data concerning peripheral neuritis symptoms in adults should have been taken as a warning that the drug could have a teratogenic effect on the fetus.

Dr. Kelsey stated, in writing, that before proceeding with the application, she would need evidence that thalidomide would be safe to take during pregnancy and indicated “this was based on peripheral neuritis symptoms in adults.”

Thalidomide was never authorized for use in the United States. Some limited clinical use was made in that country by so-called ‘qualified investigators’ prior to the application for licensing. Fortunately, only a very few damaged children resulted; all were compensated by the drug company.

There have been reports suggesting there was an element of luck and/or bureaucratic

delay involved in Dr. Frances Kelsey's refusal to issue a permit. The truth of the matter appears to be that criticisms of thalidomide by Dr. Kelsey and her husband were based on valid, scientific deductions, as we have set out herein.

It is of interest that the president of the United States conferred the Presidential Medal on Dr. Frances Kelsey, for her performance, the result of which thalidomide was NOT licensed for sale in the United States. Compared to this, it should be noted that the official of the Canadian FDD, who had the same responsibility in regard to the evaluation of thalidomide, was not reprimanded or any way censured for his performance, the result of which more than 100 Canadian children were severely damaged.

It is accepted, of course, that a government official may be commended for properly performing his or her duty; conversely, when a civil servant fails to carry out the duty of his or her office, it hardly seems reasonable that the lack of performance is **not** noted. The difference between the U.S. government action to withhold, and the Canadian government's action to ignore, quite probably harmed the Canadian victims' chances, in the short-term, of receiving some remuneration from the Canadian government.

BASIC PREMISE OF CLAIM AGAINST THE GOVERNMENT

The essence of this proposition is that the federal government must bear some responsibility for compensation of thalidomide victims. The Food and Drug legislation allowed thalidomide to be used on an experimental basis simply by sending notification to the Canadian authorities. The legislation at that time placed an onus on the Food and Drug Directorate (FDD) to give official approval before a pharmaceutical product could be marketed in Canada, on a general basis; it did not, however, regulate the distribution of “samples.” (See the section which examines the ‘human guinea pig’ element.)

It is our submission, therefore, that physicians who prescribed this drug and patients (pregnant women) who ingested it were acting on the assumption that reasonable precaution had been taken by federal government officials to ensure that the drug would not harm an unborn child.

The existence of protective legislation should be regarded as a form of ‘insurance,’ and where the protection proves to be inadequate, the government, as the ‘insurer,’ has the responsibility for at least partial compensation for damages arising out of use of an authorized medication.

Officers of such department did in fact issue written permission for thalidomide to be used in Canada. The test of the validity of this proposition is evident in the fact that, under the legislation it administers, the Department withdrew the permission with the result that the

drug could no longer be prescribed or dispensed in this country.

The claim for compensation against the federal government hinges on the fact that the legislation and regulations arising therefrom provide that the FDD of the DNHW is responsible to ensure that it has been furnished with “**adequate**” reports from a pharmaceutical company before approving an application for licensing of a drug to be marketed in Canada.

The evidence is clear that the officers of the federal government failed to obtain reports which would meet the test of “**adequate.**” As a direct result, thalidomide damage was done to the unborn children of pregnant women who ingested the drug.

PROTECTION OF THE PUBLIC

It is generally accepted that the purpose of legislation for control of pharmaceutical products is to ensure that the government is providing reasonable protection for its people, in regard to medications which might otherwise cause physical or other impairment.

In certifying thalidomide for use in Canada, the FDD accepted the data from the U.S. manufacturer. In the absence of reports which would guarantee the safety of the drug (and obviously this was the case), the FDD took upon itself to assume a risk; a situation which the Canadian consumer had every right **not** to accept, in that the responsibility of the government was to protect the public.

Where, however, the risk has serious consequences for a group of individuals, there lies a responsibility for compensation to them, by or on behalf of the risk takers.

HUMAN GUINEA PIG ELEMENT

Most Canadians would undoubtedly be surprised to know that under the Food and Drug legislation which existed in the early 1960s, a foreign manufacturer could distribute a new drug in Canada on an experimental basis, simply by notifying the federal authorities. Such drugs were sent in the mail or were delivered to members of the medical profession (known as clinical investigators) by drug company representatives called 'detailers.'

This meant that, in the case of thalidomide, the product manufactured by Merrell (under the trade name Kevadon) was available to Canadians without any investigation by federal authorities.

This use of an experimental drug on what might be termed 'human guinea pigs' required only that an application for a new drug follow through official channels.

As a result, the thalidomide drug was being distributed to Canadian physicians for trial use, without any supervision of the federal government. In many instances the patients were not even aware the drug was of an experimental nature; or that they were part of the experiment.

Some Canadian mothers may have had access to thalidomide under this method, as many as 15 months before the Canadian government was aware that thalidomide was being administered through Canadian physicians (except that Merrell was required to file a

notification that they had placed the drug with Canadian physicians for clinical investigation).

The amazing and disturbing fact is that this procedure was acceptable to Canadian officials who had the mandate to protect the public from hazardous drugs. The procedure allowed for extremely active marketing by drug company representatives, without the specific knowledge of the FDD.

The regulations respecting new drugs distributed in Canada for clinical investigation may still permit such use, provided the recipients are 'qualified investigators.' This is an area which should be the subject of further examination.

LICENSING OF THALIDOMIDE

The following outline of the actions taken concerning thalidomide by the Food and Drug Directorate (FDD) of the Department of National Health and Welfare is based on documents produced by the Minister of National Health and Welfare (DNHW) in accordance with a request from a Member of Parliament (Mr. Stanley Knowles). The authenticity of the documents was established by the Clerk of the House of Commons in a certification dated May 30, 1973.

In a letter dated November 22, 1960 addressed to Merrell and signed by the Director of the FDD, permission was granted for the use in Canada of Kevadon tablets (thalidomide). The letter states:

I am pleased to enclose a new drug clearance form for KEVADON TABLETS.

In a further letter dated November 28, 1960, the Director advised Merrell as follows:

...it is the recommendation of the Prescription Drug Sub-committee of the Canadian Drug Advisory Committee that KEVADON should be added to Schedule F of the Food and Drugs Act.

This meant, effectively, that Kevadon could be used and sold in Canada on prescription from a qualified medical practitioner.

The permission was granted in accordance with a request from Merrell in a letter to the Director dated June 23, 1959. This letter was in the form of advice to the Department that a drug, identified by code MRD-32 (and believed to be thalidomide), was being distributed

in Canada for experimental use by 'qualified investigators'; and that, as the letter states:

As soon as possible, a New Drug Submission will be submitted to the Department, requesting approval to sell this product.

In reply to this advice, the Director notified Merrell, in a letter dated June 25, 1959 as follows:

This information complies with the requirements of Section C.01.302(a). No objection will be taken to the importation or distribution of this drug under the terms of Section C.01.302. [N.B. This section of the Act authorizes use of a drug on an investigational basis.]

The procedure in Canada is that a foreign manufacturer may issue samples to 'qualified investigators' if he informs the FDD. This is a prerequisite to licensing which is the subject of a formal application. It is to be noted, however, that the federal government must issue authority for the experimental use of a new drug. Hence, the 'qualified investigators' (medical doctors) had what amounted to the 'green light' from the federal government to issue samples of thalidomide to pregnant women. The authorization was granted in **two days!**

Apparently, there was no requirement for the drug company to furnish any data to the Canadian FDD other than what might be termed 'brief details' together with a notice that it was being made available under a system which would indicate controlled use.

A description of how this system, known as 'detailing,' operated was set out in a letter dated July 26, 1962 from Dr. James Edward McArthur of Noranda, Quebec and addressed to the DNHW in Ottawa. We quote from this letter as follows:

We certainly would not want to have any of this bloody drug in our possession, or anywhere, if we could help it.

When the drug traveller came in with this wonder-drug he had it, of course, propped up to the sky as to its values and advantages, etc. I told him that doctors should try new drugs on themselves before giving them to patients. I took 2 or 3 in a single pill dose, probably a couple of nights apart. Anyhow after taking the second one, or perhaps the third one, I felt very dizzy, nauseated, etc., and I had enough evidence that I should not recommend it to any of my patients. I thereupon wrote the Company doctor. (Horner) He wrote saying that I should have taken a smaller dose than a single tablet. I could have told him that his traveller advised me to take one, and if one was not enough, to repeat up to two or three tablets, that there was no danger. Anyhow I was not convinced by what the Company doctor told me so I sent back some of the samples that we received. It seems strange to me that some of these damn drugs were allowed into the Country and were allowed to be used on poor helpless pregnant women. I have seen one baby born here with the deformities described in Germany and in our country too; the sight would make a person weep!

What surprises me too is, that the United States of America had the knowledge or the intuition, or some good sense, not to accept this drug into their Country when we, in Canada, apparently were gullible enough to give it full swing. Now some poor people are paying for this.

The application from the pharmaceutical company for formal licensing was made on the standard government form under date of September 23, 1960. This standard form required a pharmaceutical company to provide in a statement:

- the amounts of all ingredients
- details of its method of manufacture necessary to evaluate its safety
- details of reports of tests made to establish the safety of the drug [Underlining is ours.]
- a draft of the proposed label
- a sample of the drug

Departmental regulations placed an onus on the FDD to ensure that the drug company furnish information "adequate" to determine the drug's safety.

It is assumed from the data required in connection with the submission that the Department was satisfied with the information on Kevadon provided by the pharmaceutical company, as to its safety.

There was, in our view, an inherent requirement upon the Department to grant permission for the use of the drug only if the Department is satisfied with the data provided by the pharmaceutical company. Presumably this was the case!

A further application for permission to distribute the drug was made by Frank W. Horner Limited of Montreal, Quebec in regard to Talimol, a brand of thalidomide. The application was dated September 15, 1961. The correspondence appears to indicate that, in making the application, Horner had obtained permission from Merrell in Cincinnati to make reference to the data provided by that company.

Horner was advised in a letter dated October 11, 1961 from the Director that its drug submission for Talimol tablets (thalidomide) had been approved. The accompanying form letter stated:

This drug may be sold in Canada subject to the other terms and conditions relevant to the sale of such drug as set forth in the Food and Drugs Act and Regulations. [N.B. Such regulations are, to all intents and purposes, in the form of standard procedures.]

It is of interest that the data provided by Horner on Talimol contained the following information:

...has a wide range of application as a bedtime hypnotic or daytime sedative in general practice, pediatrics, obstetrics, geriatrics, psychiatry, etc. As well as pre- and post-operatively. [Underlining is ours.]

Horner data contained a further reference to use of thalidomide for pregnant women quoting a research report concerning its use on 81 pregnant patients, with no ill effects. The report referred to another study of 370 patients and includes the statement that such study “corroborated the absence of deleterious effect on the babies. If thalidomide did pass the placental barrier, it did not influence respiration of the baby.”

Merrell, in its report titled Sequence of Events, stated that on September 8, 1960 it had submitted data on animal and clinical findings to the FDD (Canada) and in the United States to the Food and Drug Administration. (A duplicate of the Merrell report appears in Appendix D-1.)

In a report prepared by the FDD and titled Chronology re Thalidomide (duplicated in Appendix D-2), the following statement is made:

October 5: New drug submission re Kevadon (Thalidomide) received from Wm. S. Merrell Company by Food and Drug Directorate. Submission consisted of some 500 pages of material indicating recommended use for “symptomatic treatment of insomnia.”

Presumably the same information was submitted by Merrell to both U.S. and Canadian officials. As has been stated earlier, the U.S. officials refused to grant the licence for thalidomide whereas the Canadian officials did. This must be seen as a criticism regarding neglect on the part of the Canadian officials.

The lack of communication of Canadian authorities with American authorities is scarcely believable given the notoriety and publicity that was attached to the thalidomide marketing campaign. This failure of the Canadian Drug Directorate to establish a reasonable inter-relationship with the U.S. authority is unacceptable as a matter of administrative practice. The Canadian officials were apparently prepared to rely on the alleged German and British approval of the drug and yet were unaware of, or ignored information regarding, the refusal of American authorities to sanction an identical drug application.

This factor is an important consideration in assessing the responsibility of the Canadian government for compensation to the victims. Details of the U.S. rejection of thalidomide have been discussed elsewhere in this report, under the heading UNITED STATES AND CANADA: A COMPARISON.

FAILURE OF THE DEPARTMENT TO ACT IN RESPONSE TO EARLY CONTRA-INDICATIONS CONCERNING THE SAFETY OF THE DRUG

On March 24, 1961, The William S. Merrell Company wrote to the Director of the FDD with reference to “several reports in the form of letters to the editor of the British Medical Journal concerning possible peripheral neuritis induced by continuous administration of thalidomide in some patients.” The Merrell letter stated the company’s conclusions on the matter, as follows:

The symptoms occur in a very small percent of patients on continuous thalidomide therapy....

On the basis of our investigations, we are convinced the problem is not a serious one but we do feel that the physician should be made aware of the problem so that he might discontinue therapy if symptoms should appear.

The letter then stated that the company proposed to add information to its introductory literature to the effect:

Pins and needles of the fingers and toes, parasthesia and muscle cramps have been reported in a small percent of patients receiving thalidomide continuously for three to six months. Immediate withdrawal of the drug is recommended since this has resulted in prompt reversal of symptoms.

The Director of the FDD, in a letter dated April 06, 1961 acknowledged receipt of Merrell’s letter, noting that it was the company’s intention to add a warning statement.

Our research appears to confirm that this was the first revelation to Canadian officials regarding dangerous side-effects of the drug. No mention was made of its contra-indications in pregnancy. The DNHW took no action to issue a precautionary warning to persons or institutions in Canada who were prescribing and dispensing the drug.

An earlier article in the British Medical Journal, published on January 10, 1958 dealt with experiments carried out by two distinguished medical researchers in Britain: James Murdoch, senior registrar in the Department of Therapeutics at Edinburgh University; and G.D. Campbell, research fellow at The Royal Infirmary, Edinburgh.

Their experiments indicated that normal functioning of the thyroid gland might be inhibited by thalidomide in doses of 100-200 mg. As such, their research might have revealed a clue about the possible hazards of thalidomide for pregnant women and their unborn children.

In this regard, criticism of the British manufacturers of thalidomide - in Suffer the Children (page 57) - also applies to the U.S. drug manufacturers and Canadian government regulators.

Anyone interested in the worries expressed by some scientists in the 1950s - that there was "increasing evidence that the unborn child can be injured by agents well tolerated by the mother" - might well have gone on to notice that endocrine (and particularly thyroid) upsets appeared to be associated with human birth defects.

This is just one more instance of material published in a respected, widely circulated medical journal that might well have provided an indication as early as January 1958 that thalidomide could cause severe damage to the fetus of a pregnant woman.

POSSIBLE CONGENITAL MALFORMATIONS

On December 7, 1961, Frank W. Horner Limited advised the Director of the FDD of a circular letter sent to “all Canadian physicians, hospital pharmacists and drug stores....”

The circular letter stated:

We have just received sketchy information from abroad on the occurrence of congenital malformations in the offspring of some mothers who had been taking thalidomide early in pregnancy.

The letter indicated that there would be a thorough investigation of the matter and stated further:

In the meantime we are taking this precautionary step of advising that the drug should not be used in pregnant patients or in pre-menopausal women who may become pregnant.

Under date of December 08, 1961, The William S. Merrell Company advised the Director that it had issued warning letters to the Canadian medical profession on Kevadon.

The warning letter issued by Merrell dated December 05, 1961 was headed DRUG WARNING - KEVADON. The letter stated:

We have received information from abroad on the occurrence of congenital malformations of a few mothers who had taken thalidomide (marketed in Canada as Kevadon) early in their pregnancies. It is impossible at this time to determine whether, in fact, there is any causal relationship...

Kevadon should not be administered to pregnant women nor to pre-menopausal women who may become pregnant.

There is no indication in the correspondence that any representative of the Canadian government acknowledged or commented upon receipt of any information from either Horner or Merrell regarding the possible side effects of the drug if used by pregnant women.

In a further letter to the Director dated December 15, 1961, Merrell provided what is called "an interim report." The letter stated, in part:

We have heard that Distillers of London is putting the product back on the market for hospital use next week.

Experiments by Gruenenthal with pregnant rats receiving 100 mg/kg daily of thalidomide are in progress. A fair number of offspring already delivered have had no malformations. [N.B. Later testing revealed that although birth defects were minimal, the number of offspring was considerably less than normal, where thalidomide was administered.]

The letter stated further that Merrell had been advised that a panel of 12 experts appointed by the German government concluded that "a definite association of the drug with malformations has not been established."

A letter from Horner dated December 19, 1961 stated:

...the situation is still very unclear and we are far from convinced that thalidomide is implicated in these malformations.

A further report from Horner dated December 19, 1961, a copy of which is included in DNHW files, stated that Gruenenthal in Germany had "no choice but to take the product off the market until the question had been resolved."

This report indicated that the British manufacturer in London, Distillers Company (Biochemicals) Limited had also taken the product off the market:

Distillers were not convinced either that there was a real association between the drug and the condition, but they were most anxious to avoid the press furor that had occurred in Germany.

It should be noted that the information conveyed to the Canadian government had apparently contained sufficient evidence regarding the potential hazard of the drug to prevent permission for its use in the United States. Under the Canadian legislation, the DNHW had authority to withdraw use of the drug but failed to do so, or for that matter, to issue any precautionary warnings to the professionals in Canada who were prescribing and administering it.

An examination of such documentation as was made public indicates that Chemie Gruenthal was not convinced that there was an association between thalidomide and limb defects in newly born infants. There is, however, other data that seems to suggest it!

Because of Gruenthal's position in respect to legal proceedings, it is not likely that the company officials would have done other than continue to deny such relationship. Certainly, research now indicates that this company was well aware of the teratogenic effect of its drug at the time of, and in fact, well before its withdrawal from the market in Germany.

The drug thalidomide, marketed in Great Britain under the name of Distaval, was withdrawn for use in that country on December 02, 1961.

Despite withdrawal of the drug in Germany on November 27, 1961, in Australia on November 29, 1961 and in Great Britain on December 02, 1961, the **FDD's official notification of withdrawal of the drug in Canada was not until March 02, 1962.**

Representatives of the DNHW stated, before parliamentary committees, that they had insufficient staff and investigative facilities to conduct a proper evaluation of thalidomide.

In judging the legitimacy of this statement, it should be remembered that thalidomide was not 'just another drug' for which a foreign manufacturer was seeking permission for distribution in Canada.

On the contrary, thalidomide had been the subject of worldwide attention. It had been hailed as a significant breakthrough: a new hypnotic which was non-toxic and incapable of causing death by overdose.

This Task Force believes that the hyperbole which accompanied the introduction of this drug should have been sufficient to warrant the closest possible examination by Canadian authorities before authorizing its use in this country.

Much has been said, in establishing the defensive posture of the Canadian government, to the effect that the responsibility for the safety of a product rests with the manufacturer.

In the case of thalidomide, it is assumed that the manufacturer did, in fact, provide

information to government officers relative to the drug's effectiveness and its safety.

Our research has indicated that, to some extent, this information would have originated with Gruenthal, the German firm that invented thalidomide. A careful scrutiny of the data emanating from Gruenthal would have indicated that the research reports on which it was basing its promotional material were not from entirely independent evaluators. In fact, they had been obtained from doctors who had used the drug in their practices, but who were - at the same time - in the employ of Gruenthal.

It should be observed that at no time did the FDD investigate the objectivity of the information which was provided by the drug manufacturer; nor did it examine the credibility of the sources cited in the information provided to the FDD by the manufacturer.

It is clear today, beyond a shadow of a doubt, that no independent testing of thalidomide had been done by or for the pharmaceutical firm which was responsible for its development.

STATISTICAL CLASSIFICATION

The Chief of the Child and Maternal Health Division of Health and Welfare (DNHW) presented a report on the "Canadian Thalidomide Experience: at the 1963 annual meeting of the Canadian Medical Association. The report, which was also published in the Canadian Medical Association Journal (November 1963), set out four criteria that had been used in selecting the medical cases for its analysis:

1. A clinical syndrome which indicates the presence of deformities of a long bone of the limb described as ectromelia, dysmelia, micromelia, amelia, peromelia, phocomelia and hemimelia; also malformation of the external ear and auditory meatus, with, in some cases, paralysis of the side of the face; also anomalies involving the gastro-intestinal tract, the genital-urinary system and the heart.
2. Confirmed intake of thalidomide.
3. Evidence that the drug had been ingested at about the estimated time of conception or within 12 weeks of the date of the last menstrual period.
4. Evidence that the drug had been obtained from a Canadian source.

The report also categorized the severity of the malformations seen in those cases that had met the initial selection criteria, describing the grades of severity as follows:

- 1) Least Severe - Simple defects or combinations of the following: Minor defects of one or two limbs; defect of one or two limbs but not complete absence of a part....Abnormal or hypoplastic external ear or ears but not absence. Facial palsy. Correctable atresia or stenosis of gastro-intestinal tract....

- II) Intermediate - Varying combinations and degrees of malformations not classifiable in grades I or III.
- III) Most Severe - Malformations of two or more limbs - for example, shortening, major defect or absence. Any single limb or ear malformation with associated internal malformation - cardiac, gastro-intestinal or renal. Any uncorrectable internal malformation or malformations regardless of degree of limb malformations - such as severe cardiac malformation or multiple defects incompatible with life.

According to statistical data obtained at the time by DNHW, 115 children, including three sets of twins, were born in Canada in 1961 and 1962 with congenital malformations associated with the use of thalidomide by their mothers in early pregnancy.

Of these 115, only 74 were reported to be alive in November 1963. (The report estimated that many of those with internal anomalies had failed to survive.)

Statistics furnished by Merrell indicate that a total of 6,423,795 Kevadon tablets were distributed in Canada, either directly to doctors acting as 'qualified investigators' or through hospitals, clinics and pharmacies.

The federal government report, particularly in regard to statistics, cannot be considered totally reliable. The following qualification was given in the report:

There may be a group of affected children in which the intake of the drug could not be confirmed, and by the same token there may be cases attributable to thalidomide, which would have occurred regardless of the intake of the drug.

The report highlighted "the serious inadequacy of information on the rate of incidence of congenital malformations generally" and concluded that "better methods of obtaining such

...data on a systematic basis must be developed, and fairly urgently.”

The report, as stated therein, would necessarily have some flaws, as indicated by the following statement:

The method whereby the information for this study was obtained might be considered rather cumbersome, but in the atmosphere which prevailed at the same time the study was undertaken, it was the only practical one.

The report stated also:

It is gratifying such complete information was made available to the department in a sensitive area of this sort.

The records analyzed by the author of the report were provided by Canadian physicians. In this regard, it was noted that the report’s “completeness and accuracy are dependent on the reporting of physicians in practice even through it may add to the paper burden they already carry.”

Most of the members of this Task Force have been involved for many years in the thalidomide situation. It is our view that, although the statistical data provided by the DNHW in 1963 was most useful, it cannot be relied upon completely for two reasons:

1. Reports from physicians were necessarily incomplete. Some doctors were provided with samples of the drugs and asked by the pharmaceutical firms to perform the function of ‘investigators.’ This did not mean that they would keep adequate records; moreover, it is understandable that many of them did not want to volunteer information for fear of law suits or possible criticism, particularly from families and patients.

2. It is understandable that some mothers who gave birth to children with thalidomide-type malformations may not have wanted to admit that they took the drug and/or may not have been sure that they did. Some of them **did not want to know**, and were content to consider that the births were an act of God. Certainly no one could blame them in this regard.

The reliability of statistics on thalidomide victims has been questioned in other quarters as well. In a letter to the Director of the FDD dated May 15, 1962, Horner is critical of a scientific paper published in a German medical journal. The author of the paper was involved in attempting to determine the relationship between thalidomide and malformations. The Horner letter states, in part:

This latest publication...can be criticized in that it depends on the physicians' or mothers' memory as to whether or not thalidomide was taken at any time during pregnancy....[M]emory is notoriously unreliable in this respect.

In support of this argument, the Horner letter makes reference to the work of Dr. A.L. Speirs, a doctor from Scotland who had recently had an article on thalidomide published in Lancet, a journal of the British Medical Association.

Dr. Speirs had questioned 10 mothers of malformed babies concerning the drug they had taken. He also questioned their doctors. He obtained "vague or negative answers." Refusing to accept these replies, he had the prescription records searched. Eight of the ten mothers had been taking Distaval (thalidomide) "and a ninth might have been."

The Task Force cites this statistical data to indicate the difficulties which might develop in the present context if the classifications established by the DNHW were to be used; that is, the description of the clinical syndromes; confirmed intake of thalidomide during the vulnerable period of conception; and confirmation that the drug had been obtained from a Canadian source.

It is specifically for this reason that the payment of benefits to individual persons with thalidomide-like damage should be left to the discretion of the Thalidomide Victims Association of Canada, which is described elsewhere in this Report.

It is obvious that, in deciding which persons can benefit, the Association officers may not always make the correct decision, but their adjudication would be relatively free from criticism; also, as thalidomide victims themselves, they would presumably be in an advantageous position to make judgments based on observations and other details which would be available to them from individuals applying for assistance.

(Recent reports from Great Britain and Germany indicate some dissatisfaction among thalidomide victims regarding administration of their trust funds by appointed officials. A fund administered by the thalidomide-affected persons themselves would lessen the chances of similar criticisms in Canada.)

The Task Force was surprised to learn, at the outset of its research, that there was no accurate list of thalidomide victims in Canada. Accordingly, we wrote to agencies and

clinics which were known to have been involved in providing treatment and after-care for those damaged. Through these sources, we did obtain some data.

It was necessary, however, to place notices in newspapers throughout Canada and we have now identified more than 100 persons who can be considered as having disabilities for which thalidomide is a probable cause.

Most of these individuals were born between 1961 and 1963. However, there are some exceptions. There is one case, for example, where thalidomide samples in an aunt's medicine cabinet found their way several years later to the victim's mother. The circumstances were explained to us in confidence by the latter.

She had been experiencing nausea during the early stages of pregnancy and complained of this to her sister. The sister in turn remembered that, during her own pregnancy several years before, a physician had given her some sample pills... and she still had a few left. Grateful for the relief, the woman we spoke with took "a number of them."

It turns out that the woman's sister had been much further along in her pregnancy when she took the pills; her child suffered no ill effects and so she had no cause to suspect the potency of the pills in that fateful, partly used bottle.

Incidentally, it is a moot question as to whether the government's responsibility ended when it withdrew the drug! Obviously, the aggrieved young mother mentioned above had taken

them in good faith, and it is not reasonable to assume that every person who received samples of the drug would necessarily have seen the warnings issued by the drug companies or the government.

This particular case history is instructive in a number of ways. For one, it illustrates in the extreme the dangers associated with a drug of this nature when it is widely distributed. Secondly, it also suggests some of the difficulties that may be involved in determining whether thalidomide accounts for an individual's deformities.

To be sure, there are many instances on record where the date of a prescription or other such details of timing can be used to reliably identify an affected individuals as a thalidomide victim. The above case shows, however, that it would be cruel and, indeed, senseless in this regard to look at the dates the drug was on the market as an exclusive criterion.

There must clearly be some measure of flexibility built into any system we might use in deciding whether a deformity is due to thalidomide. The Task Force believes that leaving the ultimate decision to the Thalidomide Victims Association of Canada is the only practical solution.

The Task Force is convinced that, in the very least, the number of surviving thalidomide victims whose mothers took the drug, obtained from Canadian sources, is higher than the

figure of 74 which was given in the DNHW report of 1963.

**FAILURE OF THE DEPARTMENT TO ACT IN REGARD TO
REPORTS OF BIRTH DEFECTS**

The policy of the DNHW is outlined in a letter dated February 15, 1962, from the Director of the FDD to Dr. D.R. Gunn, Director of Clinical Research at The Ontario Hospital:

When the news about the possible connection between thalidomide and congenital malformations in newborn babies was brought to our Department, we met with the representatives of Frank Horner and the Wm. S. Merrell Company and advised them that we would agree to their proposed warning restricting the use of Thalidomide in pregnant females or females in the age group for that condition.

To date we have not heard any further word on the results of their investigation and we are not prepared to take any further action until we have seen the results of a complete study. I sympathize with the position taken by the Food and Drug Administration in Washington, D.C. but, since we have cleared the drug in this country and since we have reason to believe that this is a useful sedative hypnotic, we feel that the stand we have taken is adequate for the time being. [Underlining is ours.]

Some Canadian physicians were sufficiently alarmed by the apparent links between thalidomide and congenital malformations in newborns to contact the FDD in writing. In a letter dated February 27, 1962, Dr. A. Gordon Hewitson of Pointe Claire, Quebec urges the Director of the FDD to act swiftly to withdraw thalidomide from the Canadian market:

This drug as you are well aware has been removed from the market in Great Britain and was never licensed for use in the United States.

The firm marketing the drug in Canada sent out a warning notice to doctors in December and a follow-up notice was distributed last week. This hardly seems enough for such a hazardous drug; certainly it should be removed forthwith from further use.

Dr. Allan Ross, Physician-In-Chief of the Montreal Children's Hospital, also voiced his

concerns about the drug in correspondence with the Director of the FDD. Dr. Ross's letter of March 01, 1962 states:

I am afraid that there can be little doubt with the accumulating literature on the subject, of which I know you are well aware, that there is more than a casual relationship between this drug and the occurrence of serious abnormalities in newborn infants. I would appreciate having some information on what the attitude of the Food and Drug Division is in regards to the drug's continued availability in Canada....

According to our information, the first indications of any action on the part of DNHW to withdraw the drug came on March 02, 1962. The Director of the FDD responded to Dr. Hewitson's query:

We have decided to ask the two companies concerned to withdraw thalidomide from the Canadian market until such time as its connection with congenital abnormalities in newborn children can be proved or disproved.

On the same day, the Director wrote a letter to Horner, which produced thalidomide under the brand name Talimol, to inform the company of this decision:

We have decided to ask you to withdraw your product TALIMOL from the Canadian market until such time as we can be certain of its possible association or lack of association with congenital deformities in newborn children.

More than a month later, the Director issued what appears to be a form letter to physicians in Canada concerning thalidomide. Dated April 10, 1962, this letter states in part:

The problem unfortunately does not begin and end with thalidomide. The regulations under the Food and Drugs Act make it the responsibility of the manufacturer to supply accurate and detailed data and information to establish the safety of a new drug for the purposes and under the conditions of use recommended by him. While every effort is made under the part of the Directorate to ensure that adequate experimental tests and clinical trials have been conducted by pharmaceutical manufacturers to ensure that a new drug is safe for use for the purpose recommended, the Food and Drug Directorate has been very much concerned about the undesirable reactions

that have occurred after some new drugs have been on the market and used for some time.

This letter appears to establish, beyond question, that the procedure in the FDD of DNHW was to rely on “accurate and detailed data and information to establish the safety of a new drug....”

It should be noted, accordingly, that DNHW had the responsibility to ensure that it had obtained such “accurate and detailed data and information.” By inference, therefore, the Department must have been satisfied, in regard to thalidomide, that the data provided by the manufacturer indicated that such drug was safe for use by pregnant women.

It is suggested that the Department cannot divest itself of the responsibility to ensure that the data concerning a new drug is of sufficient accuracy and detail to ensure that its use is safe; otherwise, the protection of the people of Canada would rely entirely upon the word of pharmaceutical companies.

In short, the officials of the Canadian government charged with the responsibility of administration of the Food and Drug legislation must necessarily act as a buffer between the drug companies and the public. In this respect, there lies a responsibility to ensure that the information being provided by the drug company does in fact, and in so far as may be possible, provide some guarantee of the safety of the drug.

In carrying out its mandate in this area of public trust, some responsibility must be accepted

by the Department, if the information proves to be lacking in respect of a drug's safety.

It may be argued that this is an area in which uncertainty can occur. When, however, an error is committed, and there is physical damage, the possibility of mistake does not absolve the body charged with the authority to regulate. Accordingly, even though permission to market the drug was granted in error, the government still has some responsibility for indemnification.

A letter sent from the Director of the FDD to Dr. Ian Rusted of St. John's, Newfoundland contains significant information on the thalidomide issue. Dated April 17, 1962, the letter states in part:

On December 1, 1961 after having received information from the manufacturers of the possibility that thalidomide could cause malformations in the human fetus, the manufacturers were requested to send out warning letters....

Our review of the file indicates that the request was not issued by the Department; warning letters were issued voluntarily by the drug companies. This is, however, of minimal importance. The letter to Dr. Rusted continues:

On March 2, 1962, having received further information to support the previous report, we told both manufacturers to withdraw the drug from the Canadian market.

This letter contains an interesting statement concerning the policies followed by the Department:

As to new drugs in general, the responsibility for carrying out tests for safety

is placed on the manufacturer. The Directorate demands that they submit all the evidence on the safety and controls of the drug before they market any new drug in Canada. The information submitted for this drug included tests carried out on at least three thousand individuals by many specialists in their particular line but no information was available prior to November, 1961 that the drug had the property of producing phocomelia [limb deficiency].

It should be noted that there were in fact published reports, at least in Europe, concerning the dangers inherent in the use of thalidomide for pregnant women prior to November 1961.

The Director's letter to Dr. Rusted continues:

It is felt that the responsibility for the safety of the drug is properly placed on those who manufacture and market a product and that the responsibility of the Food and Drug Directorate is only to make sure that the tests carried out by the manufacturers are reasonable and suitable for the purposes intended....[Underlining is ours].

We suggest that this statement is at the heart of the matter. That is to say, the letter signed by the Director indicates that FDD does in fact have the responsibility "to make sure that the tests carried out by the manufacturers are reasonable and suitable."

There is no hard evidence to suggest that the data provided by the manufacturers concerning such tests provided sufficient indication to permit safe use of the drug in Canada. It is possible to state the simple fact that, no matter what data was provided to the department, the horrifying results of the use of this drug indicate stark and irrefutable proof that the tests must not have been, to cite the language of the Departmental letter, "reasonable and suitable for the purposes intended."

The Rokeah Pharmaceutical Association in Toronto wrote to the Director of the FDD under date of August 28, 1962 as follows:

We are writing to express our concern over what we feel can only be described as your Department being very lax in its responsibility with regard to thalidomide.

A letter sent by [the Director] states that your Department was informed of the possibility of malformed births due to the drug in November 1961 yet it was not until March of 1962, nearly four months later that it was ordered to be withdrawn from the market. Certainly it appears to us that November of 1961, when the first reports appeared and you were informed of them, was the time to act to either withdraw the drug, or at least to prevent further marketing of it pending investigation into the reports.

Our investigation indicates that the Director answered this letter on September 4, 1962 stating:

Existing regulations do not authorize us to prohibit the sale of a drug in Canada.

So far as we have been able to determine, this preposterous statement by the Director of the FDD has not received the public exposure that it deserves. It defies the imagination to understand how a Canadian government department, which has the authority to license the use of a drug, does not (as the Director states) have the authority to "prohibit the sale of a drug in Canada."

THE DEPARTMENTAL POSITION SUBSEQUENT TO WITHDRAWAL

It is perhaps of some significance that, even after withdrawal of the drug, the Director appeared to be of the opinion that the evidence concerning the causal relationship between the use of thalidomide and birth malformations was not conclusive.

It was stated in a letter from the Director to Dr. Harry Brown of Westhill, Ontario, dated April 27, 1962:

I think if the medical profession would take a stand, such as you have taken, that there is every possibility that thalidomide could indeed be reinstated on the Canadian market and to this end I would encourage you to strongly urge your colleagues to express themselves to us on this question.

In conclusion, I feel certain that if the majority of Canadian physicians want to have this drug, it will make a strong case for its reinstatement. [Underlining is ours].

RESPONSIBILITY OF THE LEGISLATORS

Cognizance is taken of the fact that DNHW officials were acting under the provisions of the Food and Drugs Act. If the mandate on the part of federal government officials to prevent the use in Canada of an unsafe drug was not clearly stated in the legislation, it can then be said that the government itself (separate and apart from its civil servants must bear some responsibility).

This point comes to the fore when we examine what happened after the thalidomide tragedy. That is to say, the federal government wasted little time in strengthening the legislation to put further safeguards in place: Bill C-3, an Act to amend the Food and Drugs Act, was passed by the House of Commons December 4, 1962. This may well be taken as an admission that the legislation itself may have been flawed to the extent the thalidomide tragedy occurred.

In such respect, it is our submission that this indicates another probable area of justification for compensation.

It should be noted that, in moving Second Reading of Bill C-3, the Minister made prominent reference to the need to ensure that stronger protective legislation existed, in order to prevent tragedies such as that which occurred with the use of thalidomide.

In fact, it seems appropriate to interpret the Minister's remarks in introducing the legislation for Second Reading as an indication that such new legislation was prompted specifically by what had transpired in the granting of permission to market thalidomide in Canada. He made what he called "a somewhat extended statement" and explained that he felt "justified in doing so because of the circumstances which have led the government to put forward these proposals." Then he continues: "I am referring, of course, to our experience with the drug thalidomide..."

Some of the comments made in the House of Commons on October 26, 1962, during Second Reading of the Bill, are cited herein. Each speaker is identified by name. We have added underlining to emphasize certain passages.

THE HONOURABLE J. WALDO MONTEITH, MINISTER OF NATIONAL HEALTH AND WELFARE:

First, we must introduce such legislation as may serve to minimize the risks involved in the introduction of new drugs, to protect the people of Canada to the greatest extent possible....

The second responsibility of government, as I see it, is to maintain a staff competent to administer this Food and Drug legislation...to provide adequate technical advice, to conduct analyses and tests of drugs, to do research directed to the improvement of our testing capability, and to carry out field inspections with a view to enforcement of regulations under the Act....

[Bill C-3] embodies three changes in our Food and Drugs Act: 1) it provides authority to impose additional controls on the distribution of drug samples; 2) it authorizes the prohibition of the sale of a drug; and 3) it emphasizes that new drugs require special consideration....

I come now to the second portion of Bill C-3 which provides for the prohibition of the sale of any drug listed under Schedule H of the Food and Drugs Act. The purpose here is to put beyond any shadow of doubt the authority to prohibit the sale of a drug should this prove necessary....

Turning now to the third item...[Bill C-3] provides authority to make special

regulations relative to new drugs. While we have had authority in the legislation to make regulations in this field, the recent experience with thalidomide has, I believe, served to focus attention on this particular area.

MR. H.C. HARLEY, MEMBER FOR HALTON:

The tragic circumstances are well known. As can be seen, the drug was first suspected of causing abnormalities in December, 1961. However, it was not withdrawn from the market [in Canada] until March 2, 1962, an interval of three months. This is the area in which the government's responsibility must lie....

This drug was withdrawn from the market in Germany, where it was first made, on November 26, 1961. It was withdrawn from the market in England on December 2, 1961. It was withdrawn from the market in Canada, on March 2, 1962. Here, we note that the country which first used the drug withdrew it from the market on November 26, 1961. Where were our communications, the communications between those companies, one in Germany and one in Canada, to warn us of these dangers?...[There were] more than three months of wasted time during which it might have been the source of further suffering and anguish to parents of these babies....

At the present time, no clinical testing is carried out by this body [the Food and Drug Directorate], and a decision in this regard is one which will have to be made in future. At least, the Department should play a more active part in the testing of new drugs.

MR. GUY MARCOUX, MEMBER FOR QUEBEC-MONTMORENCY:

...At the present time, the people of Canada rely on the Department of National Health and Welfare because they believe that inside that Department there are all the technical services needed to ensure the rational use of drugs and forbid their use if they are dangerous. Therefore, the population relies entirely on a government system that has proved ineffective.

MR. STANLEY KNOWLES, MEMBER FOR WINNIPEG NORTH CENTRE:

...I have already indicated that if there was blame, if there was negligence in this story, it is largely because we have not provided enough people to work in this important field. But I must say that in my view there is blame that this federal government must bear for the tragedy.

...I know that one of the arguments the minister puts up is that the Act at that time or as it still exists did not provide the kind of authority to withdraw this

drug from the market that it will have after Bill No. C-3 has passed. But, Mr. Speaker, it seems to me that the action that was taken by the government in April, 1962 of withdrawing the drug from the market, is an action that could have been taken in December, 1961. There was no change in the statutory provision in that period of time. It was only because in the meantime so much publicity has been attached to this subject that the government could not delay action any longer.

...Many Canadians regretted very strongly the first statements that were made by or attributed to the Minister of National Health and Welfare (Mr. Monteith) when it became apparent that a number of Canadian babies would be born deformed because their mothers had taken thalidomide. I refer to the minister's first reported statements to the effect that if there were such deformed babies their care and the extra cost connected with looking after them would not in any sense be a federal responsibility. As the minister knows, these statements were protested very strongly by a number of us who are now members of this house. They were protested editorially right across the country. Perhaps this is another indication of the advantages of a free society such as ours because, as a result of these protests, within a few days the minister was making a different type of statement. He was doing it in the time honoured way. He was denying he had said what he was reported to have said a few days before, and was indicating something would be done....

I suggest that when we are talking about financial aid to assist the victims of thalidomide we should think not only of the babies themselves and of the years ahead of them to childhood and adulthood, but we must also think what this has done to parents in some cases....

The point I make, Mr. Speaker, is that financial assistance may be necessary not only for the children themselves but for the parents and families who have been through this tragic experience. I am sure that all Canadians will want the government, in the name of the Canadian people, to assume its full responsibility for these people.

I had one letter from a person...who expressed concern about asking the government to pay the extra costs for these thalidomide babies..I said to him something to this effect....if that mistake were in any sense the responsibility of government, we could all, including me, pay for it as taxpayers, probably for a few cents each....

...I think we must also recognize the responsibility of the drug companies in a tragedy such as this.

This Task Force would wish to direct attention to the fact that when the Food and Drugs Act was under amendment in October 1962 some members of the House were raising the

question of compensation.

A thorough research of the statements by the then Minister of HNW would appear to indicate, without fear of contradiction, that the government was prepared to consider the question of compensation, together with other questions raised in connection with thalidomide such as the need to ensure that the screening process was a balanced one; a process which would allow Canadians access to new drugs which were of proven beneficial value but would serve to protect the public from harmful effects. As the Minister said:

...On the one side, are the drug's advantages; and on the other, its risks. There is always the problem of balancing these two factors.

...Our aim must be to reduce these risks to the greatest extent possible, to minimize the dangers so that the balance will be strongly on the side of promoting health, and not of compounding suffering.

This Task Force notes, and repeats, that the government's action in strengthening the Food and Drugs Act, as a direct result of the thalidomide tragedy, must stand as an indication that the legislation which was in effect at the time that the marketing of thalidomide in Canada was approved, may not have been sufficient for the purposes of preventing such tragedy.

NEW LEGISLATION

It is pertinent to matters outlined in this submission that, as a direct result of the thalidomide disaster, the government amended the legislation to provide stricter controls. The Food and Drugs Act was amended in 1962 following which the former regulations were revoked.

A comparison of the old and new regulations makes it abundantly clear that the government was of the opinion that the former regulations were not sufficiently stringent, nor adequately detailed, to combat the type of situation created by the thalidomide travesty. The mandate to protect the public was, however, fully evident in the former legislation. The amendments merely clarified the intent.

The following five points respecting the new legislation are of interest.

Firstly, the definition of a “new drug” was significantly extended and substantially tightened, for the purposes of the Act and the FDD, to mean:

A drug that contains or consists of a substance, whether as an active or inactive, carrier, coating, excipient, menstrum or other component, that has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug.

The definition continues in parallel language to cover other types of applications dealing with “New Drugs.”

Secondly, the new regulations provide that:

No person shall sell or advertise for sale a new drug unless the Minister has issued a notice of compliance to that manufacturer of the new drug in respect of that new drug submission pursuant to Section C.08.004....

Further in subsection (2) the new regulations provided substantially greater detail than the former regulations. Most importantly they extended the requirements for tests pertaining to the safety of a new drug and also pursuant to sub paragraph (K) indicated that the new drug submission must include a statement “...of all the representations to be made for the promotion of the new drug respecting...the contra-indications and side effects of the new drug.”

Thirdly, it is to be noted that “...the Minister shall, within one hundred and twenty days after filing of a new drug submission or a supplement thereto: issue either a notice of compliance or a notice of non-compliance.

In comparison to the old regulations the time for review was extended from two months to effectively four months; presumably this indicated that the legislators were of the opinion that a more cautious approach was required in dealing with drug applications.

Fourthly, the powers of the Minister to suspend a notice of compliance in respect of a new drug submission was significantly expanded and the grounds or criteria for such suspension were substantially widened in order to allow the Minister to act in appropriate circumstances.

Fifthly, a heavy onus was placed on the manufacturer of the drug to provide and establish records containing “full information” respecting:

- (a) animal or clinical experience, studies, investigations and tests conducted by the manufacturer or reported to him by any person concerning that new drug;
- (b) reports from the scientific literature or the bibliography therefrom that are available to him concerning that new drug;
- (c) experience, investigations, studies and tests involving the chemical or physical properties or any other properties of that new drug....

The amendment goes on to describe the fact that no manufacturer shall sell a new drug unless he has, with respect to all his previous sales of that drug, furnished to the Director full records.

In summary, there can be little doubt that the thalidomide tragedy was the triggering factor in the enactment of these new regulations as evidenced by the language of the regulations and the statements made by the government of the day in the House of Commons.

Bill C-3, an Act to amend the Food and Drugs Act, was passed by Parliament in early December 1962, and received Royal Assent in late December 1962.

From the material we have reviewed, the two objectives of the Bill and the Supplementary Regulations were as follows:

1. To minimize the risks involved in the introduction of new drugs.

2. To maintain a staff competent to administer the Food and Drug legislation including powers to conduct analysis and testing of new drugs.

In the parliamentary debates of October 16, 1962, it was revealed by the government that only five or six people were employed in the FDD to determine the safety of 200 or more new drugs in each year.

Comments were made that many of these submissions covered 500 or more pages and that this created an appalling situation vis-a-vis evaluating the safety of new drugs. It would appear in this area that the government was negligent in providing such a limited staff with restrictive resources to review these new drug applications.

A significant amendment to the Act itself was the addition of a section to prohibit the actual sale of thalidomide (1962-63, C.15, S.2).

It is fair to say, notwithstanding, that even under the old legislation, the Department failed to scrutinize appropriately and apply the standards established under the regulations in place at the time of the thalidomide drug application.

To wit: Under the old regulation, no person was allowed to sell a new drug unless a submission had been filed that included:

Details of its method of manufacture where necessary to evaluate its safety; detailed reports of tests made to establish the safety of the drug; and particulars of tests applied to control the potency, purity, and safety of the drug....[Underlining is ours.]

Although there was not the detail and stringency evidenced in the new regulations passed in October 1963, the old regulations certainly did contain enough substance to allow the Department to review new drug applications and to evaluate the essential element of safety.

A fair assessment of the situation concerning the legislation and/or the regulations would be this: either the legislation or the interpretation thereof was woefully weak in regard to the lack of prevention where a drug company wanted to use doctors as 'qualified investigators' prior to the application for licensing.

In fact, an interpretation of the legislation as it existed at the time that thalidomide was first introduced to Canada as an experimental drug would indicate that a pharmaceutical manufacturer in the United States could place his product with Canadian doctors, and the only authority required would be to notify the DNHW. This would seem to indicate that the legislation did not provide sufficient protection in regard to new drugs prior to an official application for certification.

The legislation, however, did provide for regulations which were sufficient to ensure that a pharmaceutical manufacturer would have to provide adequate data regarding the safety of the drug, before it could actually be sold or marketed on prescription.

It seems justifiable to suggest, therefore, that in the case of thalidomide, **both** the legislation and the interpretation and administration (i.e. the regulations) failed: first in allowing the drug to get to pregnant women through physicians who were asked to investigate its properties; and second in regard to the full-scale marketing of the drug which should have been more carefully controlled by the administrators of the legislation.

SEQUENCE OF EVENTS

Thalidomide in Canada: What steps were taken by the companies and the government, in what order, and on what dates? The U.S. drug manufacturer and the Department of National Health and Welfare (DNHW) each prepared chronological summaries that answer these questions, in point form. (Both documents are duplicated in Appendix D of this Report.) Merrell's Sequence of Events was included in a company report dated August 16, 1962. The DNHW Chronology re Thalidomide was distributed to participants at a federal-provincial conference held August 16, 1962 to discuss the Canadian victims of thalidomide.

It may be significant to note a discrepancy. In the report by the pharmaceutical company, there is an entry under date of December 1, 1961 as follows:

Merrell scientists arrived in Ottawa to report what we knew to the Canadian Food and Drug Directorate and to review a warning letter which Merrell proposed to send to Canadian physicians.

This is not consistent with the statement, to which reference has been made earlier, by the official of the Canadian FDD, to the effect that the warning letters by the drug company were sent out on direction of the Canadian department.

It is noted, as well, that the Merrell report states under date of September 8, 1960:

Merrell submitted data on animal and clinical findings to the Food and Drug Directorate and in the U.S. to the Food and Drug Administration. These findings covered more than a year and a half of testing by Merrell.

Considerable importance must be attached to this statement! If, indeed, Merrell did provide

data on “animal and clinical findings, the questions must be raised concerning the interpretation given to them by the Canadian FDD.

It is suggested that the chronology prepared by the DNHW could be self-serving, in that apparently great care was taken in its preparation to avoid indicating any responsibility on the part of the federal government.

ADMISSIONS OF RESPONSIBILITY

A Federal-Provincial conference was held in Ottawa at the instigation of the federal government on Friday, August 17, 1962. Officially titled the Federal-Provincial Conference on Congenital Malformations Associated with Thalidomide, it was attended by representatives of the federal DNHW and all provincial health ministries.

The proposition placed before this meeting by the Minister of NHW was an offer to share, on a 50-50 basis with the provinces:

1. The cost of assessment for each individual case which would include medical , psycho-social and economic features; also essential transportation.
2. Surgery, medical care, prosthetic devices and rehabilitation therapy and training.
3. Hospitalization.
4. Maintenance costs and related welfare services for programs which are considered essential to the welfare of the children, under certain circumstances, the cost of home, foster home or institutional care and maintenance.

The significant factor in this: The federal government offered assistance, but only on a shared basis with the provinces. This ignores the fact that the drug thalidomide was marketed in Canada on the basis of a permit issued by the federal government, which has the primary responsibility of protecting the public from unsafe pharmaceutical products imported into Canada.

It is understandable that the provinces would neither wish, nor in fact have authority, to become involved in the issue of compensation. The provinces had no licensing powers which could have kept the drug from entering Canada. That responsibility, by law, has always been accepted as one coming under federal jurisdiction.

It is hardly reasonable to expect that the provinces should become involved in compensation where disablement could be traced directly to ingestion by pregnant mothers of a pharmaceutical product which was being marketed in Canada with the specific authorization of the federal government; considering that such government exercises the sole right to prohibit the use of, or withdraw from use, any drug it judges to be a hazard to health.

It would appear from our research that no action evolved in regard to cost sharing of compensation, although it is known that assistance was available from the federal government and some provincial governments in regard to the medical aspects.

There is no indication that any form of indemnification to the victims was made available; this despite the federal government's suggestion that its assistance would extend to "related welfare services to programs which are considered essential to the welfare of the children."

The Minister of NHW issued a statement at the end of the day-long meeting. The statement concluded:

It is the earnest and sincere hope of the Dominion Government that through full discussion, we may develop at least the beginnings of a broad and comprehensive efforts to assist those who have been caught in one of those tragic by-ways of that medical and scientific program which has been of such great benefit to Canadians and to people throughout the world.

RESPONSIBILITY OF THE FEDERAL GOVERNMENT IN RELATIONS TO THE PROVINCES

As has been pointed out elsewhere in this Report, the federal government convened a special meeting with provincial representatives at which time it offered to pay on-half of the costs of treatment and rehabilitation for thalidomide children.

There could be no clearer indication that the federal government was prepared to accept some blame in the thalidomide disaster, bearing in mind that - under the federal-provincial division of powers - medical treatment and rehabilitation are considered to be matters of provincial jurisdiction.

The very fact that the Minister of NHW, speaking on behalf of the federal government, was prepared to arrange for expenditure of federal funds in an area which normally would be considered as coming within provincial mandate, can be given a clear interpretation: The federal government was admitting some responsibility in the matter.

THE SPECIAL COMMITTEE ON NEW DRUGS

A Special Committee appointed by the Royal College of Physicians and Surgeons of Canada at the request of the Minister of National Health and Welfare examined the thalidomide tragedy. The report of the three-member committee was dated December 1962, submitted to the Minister January 18, 1963, and tabled in the House of Commons January 24, 1963.

When the chairman of this Royal College Committee appeared before the House of Commons Special Committee on Food and Drugs on February 5, 1963, he stated:

...It is perfectly obvious to us as a committee that the Food and Drug Directorate [FDD] is working under conditions that, to say the least, are infinitely more difficult that it can cope with, with its present staff.

The inference can be drawn from this comment that the effectiveness of the FDD, may well have been jeopardized by lack of staff, in attempting to carry out its mandate to protect the public. While this may be taken as a vindication of sorts for the FDD, it might well amount to additional evidence concerning responsibility of the government for the thalidomide tragedy. **Also, the complaints regarding the lack of staff do not appear to have been made prior to the thalidomide misfortune.**

The chairman of the Royal College Committee commented on a further recommendation of his committee that the government establish a Standing Drug Committee:

...when I say that if this Committee (the proposed Standing Drug Committee) is going to do any good it will require the same kind of effort that the three of us have put into this report and all that has gone before it.

It can be fairly stated that in making the recommendation concerning the Standing Drug Committee, the Royal College Committee **had come to the conclusion that the existing procedures within the Food and Drug Directorate were inadequate to carry out its mandate.**

In its report, the Royal College Committee made reference to the responsibility of the FDD and, in particular, quoted excerpts from “Protecting the Consumer in the Field of Food and Drugs.” This was a paper presented by the Director of the FDD to The Consumers Association of Canada Conference in a meeting at Queen’s University in Kingston, Ontario on June 21, 1962. Some of the quoted passages follow:

The Food and Drugs Act is a consumer’s act intended to protect the consumer from health hazards....

Up to the present, at least, it has been considered that all necessary precautions have been taken for the safety of the public. If an acceptable new drug submission has been made, the drug meets the standard, if properly labeled and packaged and is required to be sold on prescription only (which means it can be legally sold to a patient on a doctor’s order) and if doctors are made aware of the dangers of the drug.

When one considers the amount of work and complexities involved, the administration and enforcement of the Food and Drugs Act can be frightening to contemplate.

...keeping informed of the significant advances in the world literature (medical and scientific) that influence our work is a monumental (yes, a colossal) task. How are we going to keep up with it is a problem we are now studying. Some sort of literature review and information retrieval section seems to be necessary.

Food and Drug is not a benevolent, all powerful, all pervasive protector that acts as a personal, immediate guardian in respect to every mouthful of food and drink you take or every pill you swallow. It is a “police-organization” set up to “police” a great number and variety of products and industries for the

purpose of bringing about compliance with the terms of the Food and Drugs Act, the Proprietary or Patent Medicine Act and the Narcotic Control Act. The essential purpose of our policing is to make the manufacturers and dealers live up to these laws. [Underlining is ours.]

In commenting upon the concepts extracted from the paper produced by the Director of the FDD, the Royal College Committee stated:

Before forming an opinion on the suitability of these concepts and the present procedures for dealing with new drugs, it is appropriate to consider the interests of the various parties concerned.

First and foremost it is in the interest of the public, perhaps represented best by the patient who receives a new drug with the expectation he may receive benefit from it. His concern (although perhaps not expressed) is with his safety and with the benefit he expects to receive.

Nevertheless, the story of the past successes does not alter the basic principle, that the public has a prime interest in the safety of new drugs, in their effectiveness, and in the way in which they are introduced. [Underlining is ours.]

This Task Force believes that in respect of the developments which led to the licensing of the drug thalidomide, there is a legitimate question. Did, in fact, those responsible for ensuring that the manufacturer live up to the letter of the law “police” (their word) the manufacturers in regard to compliance with the Food and Drugs Act, to the extent that the public was protected?

Our research shows what appears to have been a recurring tendency on the part of the spokesman for the Department of National Health and Welfare (DNHW) to state that the manufacturer must accept responsibility for his product. If this is an accurate statement,

it must necessarily lead to another question. What then was (and is) the function (and the responsibility) of DNHW when, despite its efforts to “police” the product and the industry which produced it, the thalidomide tragedy occurred?

Obviously, DNHW’s apparatus to carry out its “police” function failed, and the result was physical damage to unborn children as in the case of thalidomide. Therefore the government cannot escape its duty to make some financial provision to compensate for the results inflicted upon individuals by that damage.

The report of the Royal College Committee was critical of the method of carrying out the procedures within the FDD respecting licensing of new drugs, in the following terms:

In the opinion of the committee the procedures of the Department are sound, but, due to a lack of personnel and increasing volume of work, the present staff is inadequate to meet the demands placed upon it. [Underlining is ours.]

Concerning the Food and Drugs Act and Regulations, the Committee noted what it called, a “fundamental difficulty”:

The Food and Drugs Act is intended to protect the consumer from hazards to health, and from fraud and deception arising out of the sale of drugs. Certain things may be prohibited but authorization or approval of others cannot be given.

This imposes definite problems in controlling the manufacture of drugs, new or old.

The Royal College Committee made a number of recommendations including:

1. The staff of the Food and Drug Directorate be increased.
2. Adequate clinical trials be conducted in Canada before a new drug is released for sale in this country.

The Committee's report stated that the ultimate effectiveness and safety of a new drug can be determined only by its use by a body of practitioners over a sufficiently long period of time to enable qualified persons to make such an evaluation from accumulated data.

The Committee recommended, therefore, that after a notice of compliance (licence) had been issued, greater controls than at present be exercised to ensure that the drug was dispensed by prescription only; that the manufacturer be required to report toxic reactions promptly; and that practitioners report adverse reactions either directly or through appropriate local organizations.

The report of the Committee contains a number of observations and recommendations which appear to indicate that either the manner in which the DNHW mandate was being carried out, and/or the legislation under which the FDD operated, were deficient.

The report of this Task Force is not the vehicle through which these observations and recommendations should be examined. Our objective is, quite simply, to point out that such observations and recommendations were made in regard to the FDD mandate to protect the public; and it would not be stretching a point to make the finding that, had the

protective legislation functioned in the manner in which Canadians might expect it to, the thalidomide tragedy would not have occurred! While the Royal College Committee report was written with the degree of professional decorum which might be expected, it is nonetheless a serious condemnation of the FDD!

It may be noted that, in its report, the special Royal College Committee stated:

The Act and regulations, as interpreted currently, appear to have been efficacious and satisfactory.

This statement does not, in any way, mitigate the failure of DNHW officials but is presumably a statement to the effect only that the Act and regulations as they were interpreted by those handling the thalidomide application were apparently, as the report says, “efficacious and satisfactory.”

This recommendation would have to be viewed, in retrospect, having regard for the fact that following the thalidomide disaster the government did, in fact, amend the legislation.

**EXPERT COMMITTEE ON REHABILITATION OF CONGENITAL MALFORMATIONS
ASSOCIATED WITH THALIDOMIDE**

The federal government was instrumental in establishing also what was known as “An Expert Committee on the Rehabilitation of Congenital Malformations Associated with Thalidomide.” This committee included experts in the fields of genetics, physical medicine, orthopedic surgery, psychiatry, pediatrics, plastic surgery and medical social work.

The frame of reference of the committee included the “procedures and techniques necessary for the rehabilitation of these children.”

We have reviewed the findings of this expert committee. It can be assumed that compensation was not considered!

FAILURE TO INSTITUTE FORMAL INQUIRY

It seems incomprehensible that, in the light of the formidable exposure in the media of the thalidomide disaster, and in view, also, of the public interest in the matter, no formal inquiry was launched to determine where fault might lie - if indeed there was fault!

The public generally and the media may well have shared a perception of the situation in the early 1960s that was misleading! A review of media reports at the time does seem to indicate that the government was taking steps to carry out an investigation to identify the cause of the thalidomide tragedy and to draw some conclusions as to why, despite government control of therapeutic drugs, the tragedy occurred. Such inquiry, if it had been made, might well have determined whether there were specific persons who could be held accountable.

Unfortunately, the so-called 'investigation' acted as an effective smoke-screen. It served to give the impression that an effort was being made to uncover the reasons for the tragedy. Unfortunately, the 'investigators' were denied the necessary mandate to establish culpability, if it existed.

As indicated earlier in this report, the government did, in fact, establish two committees, namely:

1. The Special Committee on New Drugs appointed, at the request of the government, by The Royal College of Physicians and Surgeons of Canada.
2. The Expert Committee on Rehabilitation of Congenital Malformations Associated with Thalidomide.

An examination of the terms of reference of these committees indicates, however, that the committees were empowered neither to attempt to determine the cause of the disaster nor to name any person or persons who may have been responsible. The Royal College Committee was to examine into procedures, and to make recommendations which might conceivably avoid a repetition of the disaster. The task of the second committee, as its title implies, was to devise rehabilitation methods to meet the requirements of the thalidomide group.

The conclusion might easily be reached that, in limiting the terms of reference of these committees by specifically omitting an instruction to conduct an investigation as to probable cause, a deliberate (and perhaps adroit) attempt was made to deflect criticism of the government.

If this is so, the reasons are understandable, and could be set out under two classifications:

1. **Insulation of the public servants**: It is a truism of Canadian politics that where public servants fail to perform, and such failure has catastrophic results which become a public issue, invariably the accusations are directed at their political masters.

Therefore, in respect of the thalidomide situation, any government-inspired inquiry which placed the blame upon persons under the employ of the federal government would ostensibly have resulted in censure of the government of the day; this, despite the fact that the lack of performance may have been on the part of the civil service rather than the elected officers.

2. **Public confidence**: Another reason why the government may have wanted to avoid an investigation as to cause is one in which its motives would certainly have been commendable.

We refer to the distinct possibility that a probe which unearthed the fact that a foreign drug became available in Canada, despite the government mandate to evaluate such drugs as to safety, might well have served to undermine confidence in government controls. Accordingly, use of prescription drugs in Canada might have come under unfair and unjustifiable suspicion.

This Report is not intended as an attack upon the government or any of its servants. An attempt is being made, however, to establish the basis of a claim for compensation and,

in this regard, there is a compulsion to express an opinion concerning what appears to have been a lack of performance within the DNHW.

Was their incompetence? The drug was licensed at a time when departmental officials should have known that literature published in other countries reflected unfavorably upon thalidomide. As well, improper conclusions may have been drawn by the FDD in regard to the prior experience following from earlier use of the drug in other countries: particularly Germany and Great Britain.

There is room to speculate that the Canadian officials made the assumption that, if there were any serious side effects from the use of the drug, they would have shown up in those countries where it had achieved the status of a useful tool in treating certain medical conditions. A close examination would undoubtedly have revealed that there certainly were some reservations being expressed publicly in these other countries regarding its contraindications.

Was there negligence? A sensitive examination of the documentation in this report is perhaps sufficient to allow one to make his or her own judgment in this respect. It is certainly evident, for example, that there was a lack of communication with other governments; the most obvious case being the failure to determine the basis upon which the U.S. agency banned the drug!

The Task Force considers it more reasonable to look at the performance of DNHW officials

from the point of view of attitude. The actions of Canadian government officials might represent a classic example of doing the wrong thing for the right reasons; undeniably, they felt that the drug would be of benefit to the Canadian population. Hence, they may have sanctioned the use of the drug in Canada based on the desire to make it available to alleviate suffering. In so doing, they may well have failed to carry out a sufficiently careful examination of the application from the U.S. drug company. This attitude (of wanting to bring a benefit to Canadians) might explain, as well, the failure to ban the drug until some three months had elapsed following its withdrawal in other countries where it had been in general use.

This same attitude would possibly explain why, on April 27, 1962 - nearly two full months after the drug had been withdrawn in Canada - a departmental official wrote a letter in which he stated: "...there is every possibility that thalidomide could indeed be reinstated."

On reflection, regardless of the reasons for the failure of its officials, it is undeniable that the Canadian government, perhaps deliberately, took no action to institute an investigation.

The parliamentary committee lacked the powers of investigation. The establishment of two committees composed of persons outside of the government, with terms of reference which

contained no specific direction to investigate cause, directed public attention into the areas of prevention and rehabilitation. The appointment of such committees appeared also to give the impression that the government was taking steps to enquire into the reasons for the disaster. Such was not the case!

These acts, overt or otherwise, avoided what might have amounted to a political scandal. This is not of concern today. It is important to realize, however, that there was a huge ground swell of sympathy for the thalidomide children and their families. This ground swell could well have turned to anger. It did not!

The reason? The actions of government resulted in attention being focused on the victim's immediate needs, including the possibility of providing an artificial means of function (prostheses) and attempts to harness medical and rehabilitation expertise.

The government was seen as doing something constructive. Hence, the public outrage which might have resulted in compensation for the victims failed to materialize! As a second consequence, the government side-stepped any public reproach concerning its failure to keep the drug off the market.

It seems reasonable to conclude that, had all of the facts come out when the fate of the thalidomide children was very much of an issue before the public, there would have been a demand for government assistance for the parents and their children, in regard to both legal claims and direct indemnification for the victims.

THALIDOMIDE PARENTS

The drug thalidomide caused indescribable mental anguish for the parents of children who were disfigured or otherwise damaged by its ravaging effects. This report does not make a plea for compensation for them, although there would be quite reasonable justification for doing so. Indeed, current compensatory legislation in Canada recognizes this form of parental award in the context of enlightened family law legislation with reference to the impact that personal injury or disability can have in relation to claims of other family members.

It is necessary and fully warranted in any claim on behalf of the children, however, to recognize that, in some cases, the psychological consequences experienced by the mothers and fathers had the unfortunate result of creating additional hardships for the thalidomide victims.

Many parents did cope and should be commended accordingly. Notwithstanding, statistical evidence in our surveys indicates that the rate of divorce and separation among thalidomide parents was significantly higher than the norm. There were, as well, a sizeable number of desertions, particularly where there were a large number of other children or where the financial circumstances of the family presented very real hardships.

One case recorded in our research seems fairly typical. The natural mother developed severe psychological stress, despite her best efforts, and this made it very difficult for her to fulfil the requirements of mothering her thalidomide child. In other cases, the effect upon the father was equally damaging from the point of view of the child's upbringing.

Some parents, mothers particularly, were plagued with feelings of guilt, in that they had taken the drug: feelings which, incidentally, were unjustified, in that they had every reason to believe that the drug was safe.

In many cases, mothers neither asked for nor took the drug voluntarily, in the broad sense. For example: There are many cases on record where attending physicians, in good conscience, suggested the use of the drug and provided it free of charge as a sample. Some mothers were asked to try the drug, without being told that it was **experimental**.

In at least one case (and there is reason to believe that there were more), the mother was in fact "given" the drug as night-time medication while hospitalized, not knowing the purpose but being led to believe that it was an ordinary sleeping pill, in common use.

It is not possible, either, to discount the grief which must have been felt by the parents. In some instances, accusations were levelled, usually at the mother, for taking a drug believed to be beneficial in relieving the pain and discomfort of childbearing.

It is of no small concern that, even now, dissemination of information to the effect that the drug was made available through an error of government or was the subject of **high-pressure** marketing can serve to **alleviate** feelings of self-blame.

Financial assistance in the way of compensation from the government to the offspring would provide even greater comfort; it would also provide an additional measure of relief for these long-suffering people, as it would be a tangible expression of the fact that a serious mistake had been made in allowing the use of the drug.

Such compensation, quite apart from its benefit to the thalidomide victim, would go a very long way towards relieving the mental stress among those mothers who have had to bear the burden of guilt all these years, not knowing that faulty judgment in regard to an evaluation of thalidomide on the part of those who regulate the use of drugs in Canada, was possibly to blame.

Finally: The significance of the effect upon parents in regard to increasing the seriousness of the disability should not be lost sight of. It is a very real factor. The anxiety of the parents affected their ability to provide effective parental care. This served to exacerbate the effects of the disability itself and, indeed, should be another dimension in assessing the matter of compensation for the victims.

SPECIAL PARLIAMENTARY COMMITTEE
ON FOOD AND DRUGS

In his statement before a Special Parliamentary Committee on Food and Drugs of the House of Commons (see Minutes of Proceedings and Evidence, No. 2, Tuesday, January 29, 1963), the Minister of National Health and Welfare, the Honourable J. Waldo Monteith, stated:

The apparent effects of thalidomide will be with us through the lives of every man in this room, as its victims grow into the world.

It is our job to ensure that these victims are cared for in the best possible manner, that their needs are met to the fullest extent we can devise and to ensure, as much as is possible, that a similar tragedy will never occur again. [Underlining is ours.]

Concerning the policies of the department, the Minister stated:

Canadians must be allowed to enjoy all the benefits of scientific discovery - and there have been many in recent years - but they must also be protected.

When the risks cannot be avoided, they must be reduced as much as possible to the point where the balance will be on the side of promoting health and not compounding suffering....

Our aim is also safety when we require that a manufacturer take every precaution possible in introducing a new drug.

There must be quality control, exhaustive animal and clinical testing and the provision of detailed information to the medical profession.

It is also the responsibility of the government to maintain a staff competent to administer the food and drug legislation.

The job of this staff is to provide adequate technical advice, conduct analyses and tests of drugs, do research and carry out field inspections....

Our firm conviction is that we must insist a manufacturer accept full responsibility for something he puts his name on and sells to the general public.

Any softening of this conviction could result in the weakening of one of the

principal elements of our control program for the protection of the public.

This does not mean our responsibility is lessened or that we are relying on the companies to do everything.

Our job is to see - to insist - that the companies do their job and, from time to time, to check on their work, and to carry on sufficient research and investigation in our own establishment to be able to not only check the work of the manufacturer, but to form a well-based opinion on the quality of the work being done with a special eye open to possible dangers to the consumer.

Under the present system, manufacturers are required to submit detailed reports on the development and testing of drugs - tracing this process through laboratory and clinical stages. Our experts can - and do - detect shortcomings by scrutinizing these reports. Then they require supplementary information...

In other words, every possible care now is taken to ensure that Canadians are protected. And the system now used appears to be working. [Underlining is ours.]

Concerning the offer of federal assistance, the Minister stated:

Last August [1962], I announced to the provinces that the government stood ready to share the cost of rehabilitation of thalidomide victims. Since then, a number of fact-finding groups have been working to add to federal and provincial knowledge of the problems in this sphere. The Expert Committee on Habilitation reported last week, and copies were tabled in the House.

Asked whether the Department has the legal authority to approve or bar drugs for public use, the Minister stated:

Yes, we believe it does; by putting the drugs under Schedule H we prohibit the distribution, the sale, and so on of a drug. We can do this by order in council.

Concerning the assistance program proposed by the federal government, the Minister was

asked:

Does the assistance program you have outlined...include all deformed children?

The Minister replied:

No, it includes only those definitely tied in with thalidomide.

This parliamentary committee met in January 1963, some seven months after the Canadian government had withdrawn the drug from the market. It would appear, however, from a careful analysis of the comments of the Minister, that **he was stating a policy which had been in force at the time that thalidomide was licensed.**

The report of this Committee contains what appears to be a significant finding. (See page 6 of the letter to the Task Force chairman from the Minister of National Health and Welfare dated May 13, 1988. A copy of the letter is in Appendix E.) The statement is as follows:

The Committee feels that the legislation of Canada and its administrators, along with the drug manufacturers, druggists and doctors all played a significant part in keeping Canada relatively free of drug catastrophes such as evidenced in Europe and to a smaller extent in Canada, after the use of thalidomide. [Underlining is ours.]

Inasmuch as this statement was contained in an explanatory letter written by the Minister of National Health and Welfare under date of May 13, 1988, it may have been intended to indicate that the parliamentary committee was in fact vindicating the department in regard to thalidomide. It will be noted, however, that the committee's conclusion deals with the situation following the thalidomide tragedy.

The other conclusions of the Special Parliamentary Committee on Food and Drugs do not

appear to deal with the question of fault.

EVIDENCE OF THE FOOD AND DRUG DIRECTORATE

The comments of the Director of the Food and Drug Directorate (FDD) before the Parliamentary Committee raise some concerns as to whether the policy of the Department was being carried out effectively, in regard to the drug thalidomide. The Director stated:

Perhaps I ought to say here that all new drug submissions that come in are not always satisfactory. I would say that more than half of them are sent back with a request for additional information. Certainly more than half.

It seems of special significance that the Director told the committee that more than half of new drug submissions were judged to be unsatisfactory. This leads to an interesting question: If the FDD's investigation policy was **that** strict, how, then, was the thalidomide application judged to be acceptable? The FDD certainly sought no additional information from the applicant (Merrell). The Director stated further:

We do not do clinical testing...This is the responsibility of the manufacturer. If we do not like the manufacturer's clinical test we tell the manufacturer or hold up the drug application which forces the manufacturer to do further work in this regard.

The point must be raised here that no such action was taken in regard to the thalidomide application!

ANIMAL TESTING

The Canadian government's investigation with thalidomide begs an important question: Was there sufficient scientific knowledge, including the possible results of animal testing, available at the time that thalidomide was licensed for use in Canada, to have prevented such licence being issued?

This question was the subject of considerable debate during the Parliamentary Committee hearings. A review of the proceedings of such hearings failed to detect a clear answer. It should be noted, however, that in scientific literature there is considerable evidence to indicate that such knowledge was available, if the FDD wished to use it.

The internationally known teratologist, Professor Walter Landauer, was asked to comment on the question, during the thalidomide trials in Sweden, as follows:

Were any methods available in 1959 by which the teratogenic properties of thalidomide could have been demonstrated?

Professor Landauer replied as follows:

The answer emphatically must be in the affirmative. All animals which are currently in use for testing the teratogenicity of thalidomide and other drugs have for long been commonly employed by pharmacologists, nutrition specialists, endocrinologists, general physiologists, developmental geneticists and others.

This evidence was supported further by Professor John D. Thiersch, Director of the Institute of Biological Research and professor of clinical pharmacology at the University of Seattle, who stated, in answer to the same question:

The methods available to examine fetal abnormalities of fetuses did not differ in the years from earlier methods.

Professor Thiersch then went on to describe such methods and states:

...however this technique was also well established by the time thalidomide came onto the market.

**POSITION OF THE MINISTER OF NATIONAL HEALTH
AND WELFARE (MAY 1988)**

In a letter addressed to the Chairman of this Task Force, the Honourable Jake Epp - as Minister of National Health and Welfare - makes the following statement:

The Food and Drugs Act at the time of the thalidomide crisis and as it is now in Canada and other countries such as the United States required that those selling drugs establish the safety of their products. [A duplicate of the Minister's letter - which is dated May 13, 1988 - is provided in Appendix E.]

The interpretation with which the Minister appears to agree is that the regulations to the Food and Drugs Act provide that no person shall sell a new drug which "is not generally recognized ...as safe for the use which it is proposed or recommended."

The Minister's letter explained further that, under the regulations, any application to the Department concerning a new drug must provide:

A description of the drug...a statement of the amounts of all ingredients...details of its method and manufacture...[and] particulars of tests applied to control potency, purity, and the safety of the drug... [Underlining is ours.]

In his letter, the Minister provided information as to actions taken within the Department in the following terms:

In seeking and disseminating information, the Department interacted directly and indirectly with many individuals and organizations of international, national and provincial stature, in addition to the pharmaceutical firms implicated in selling thalidomide in this country.

Our Task Force appreciated the position of the present Minister, and is grateful for his cooperation in providing detailed information descriptive of the situation that developed in Canada in respect to the use of thalidomide.

In response to some of the Minister's statements, it is of importance to stress, in support of this claim for compensation, that:

- The William S. Merrell Company of Cincinnati, Ohio filed application to market thalidomide, in the form of a "new drug submission" under date of September 23, 1960.
- The Food and Drug Directorate notified the manufacturer by way of a "notice of compliance" that the thalidomide drug could be marketed in Canada, such notice having been issued under date of November 22, 1960.
- The United States Food and Drug Administration (FDA) had delayed issuing its compliance in accordance with a similar "new drug submission" for thalidomide. The FDA action was based, as we understand it, upon suspicion concerning the safety of the drug, following published reports in Europe regarding its harmful effects. (Thalidomide never was marketed in the United States, as is well known.)
- The assumption has usually been that such reports contained information sufficient to prevent the drug from being marketed in the United States. The same reports were available to Canadian authorities. This gives rise to the suggestion that the information in such reports was ignored by the FDD.

There was a responsibility on the part of Canadian officials to take such data into account before issuing its compliance order. **The appropriate officials may not have done so!**

The letter from the Minister could be interpreted to indicate that the position of the federal government was (and still is) that the responsibility for the safety of a new drug lies with the manufacturer.

With respect, we suggest this premise is open to challenge!

Surely the overriding principle in this regard is that the appropriate government officials must be satisfied that the manufacturer has taken suitable precautions to ensure the safety of a drug.

The intent and purpose of the Food and Drugs Act obviously implies a requirement that the federal government must adopt procedures which would represent effective guarantees regarding safe use of a drug.

The government cannot absolve itself of the responsibility for the ultimate protection of the public by relying exclusively on data provided by a manufacturer.

If no additional testing is done by the government, its mandate under the legislation to ensure the safety of a new drug could be discharged **only** if the government were satisfied that the report from the pharmaceutical firm were adequate to permit effective decision-making regarding the application for licensing.

It is of interest to examine the situation involving foreign drugs if there were no federal presence in the form of the FDD with powers to determine whether such drug may be marketed in Canada. In other words, what would be the position of health care professionals and the public if the safety of the drug rested entirely with the manufacturer?

In the absence of such federal presence, the physician and pharmacist would necessarily rely on the marketing information and other data provided by the pharmaceutical firm or its agents.

The consumer, in the case of a prescription drug, would have no written material upon which to judge its safety unless he/she specifically requested the opportunity of seeing data which might be in the possession of the physician or the pharmacist.

It is one thing for the federal government to insist that the manufacturer guarantee the safety of a drug. However, where legislation exists to regulate the question of whether a drug is licensed, the ultimate responsibility must assuredly rest with the legislators and/or the administrators of that legislation.

In his letter of May 13, 1988, Minister states that:

...the first case of phocomelia was reported to the FDD in a letter dated February 27, 1962.

The Task Force has noted that **three months earlier**, under date of November 27, 1961, the original manufacturer (Chemie Gruenenthal of Germany) wrote to the Drug Commission of the German Medical Association stating:

Because press reports have undermined the basis of a scientific discussion, we have decided to withdraw Contergan from the market immediately. [Contergan was the trade name for thalidomide marketed by Gruenenthal.]

This information was in the public domain. Why, then, did our FDD officials remain ignorant of it; or take no action if they knew of it?

It seems likely that the FDD relied on the fact that the drug thalidomide had been in use in West Germany for several years with no reported ill effects, a fact stressed by the U.S. manufacturer. Thalidomide was also on the market in Great Britain and Australia.

If indeed this is the case, then surely it would be incumbent upon the FDD to monitor the experience in Germany and other countries to determine the status of the drug in those jurisdictions. The fact that the Canadian authorities delayed three months after the drug was withdrawn in Germany, the United Kingdom and Australia is totally unacceptable given these circumstances.

WORLD HEALTH ORGANIZATION

In noting the Minister's statement to the effect that Canadian government policy is to insist that the manufacturer is responsible for the safety of its drug, such is contrary to a resolution passed on May 24, 1962 by the Fifteenth World Health Assembly, quoted hereunder:

...that it should be the responsibility of national health authorities to ensure that the pharmaceutical preparations available to the medical profession are therapeutically efficient and that their potential dangers are fully recognized.

It would appear, from the above resolution, that the World Health Organization considers that the "national health authorities" of a nation are responsible, in the final analysis, for the potential dangers of a therapeutic drug.

PUBLIC/MEDIA REACTION

The reaction reported in the media at the time that information first became known concerning thalidomide damage in Canada was exceedingly critical of the federal government. We quote from an editorial by radio station CKGM on April 15, 1962:

Now the Federal Department of Health has shown itself delinquent in another drug called thalidomide, which was developed in Germany and used as a sedative for pregnant women.

It has been on sale now for exactly a year in Canada on prescription. The U.S. has not allowed public sale of the drug but has restricted its use to researchers only. Some 3000 cases of malformation in newborn children have since been reported in West Germany. Last December two U.S. companies reported to Ottawa that the drug was dangerous. On February 23rd, the Director of the Food and Drug Directorate in Ottawa discounted this report, but on March 2nd, he ordered the drug withdrawn.

At the end of March three babies whose mothers had used thalidomide were born without arms and legs. Doctors warn there will be more.

Our Food and Drug Directorate is gravely negligent here. They were warned but did not listen. Who knows how many human tragedies will result from it? [Underlining is ours.]

TIME magazine ran a major article in its February 23, 1962 issue advising that the manufacturer had taken the drug off the market in Germany, and noting that **it was still being marketed in Canada!**

These are by no means isolated instances. They represent the attitude of much of the media. (Our files are available for examination, if necessary.)

DEFENSIVE ATTITUDES

The Task Force has had access presumably to all of the correspondence initiated by both the drug companies and the Department of National Health and Welfare in regard to thalidomide.

It is perhaps understandable, but there is a very strong sense of what might be seen as the 'defensive attitude' in most if not all of it.

As the feelings of alarm and terror grew with each new revelation of the horrifying damage caused by the drug, the tendency to avoid censure was apparent. The pharmaceutical firms had reason to fear the consequences, in terms of legal claims. Officials of the Canadian government exhibited extreme caution, or even wariness, lest the legislators or civil servants might have to accept blame for allowing the drug on the market in this country.

Admittedly, there were bleated attempts on the part of both the drug companies and the Canadian government to exercise a form of damage control by issuing warnings and attempting to retrieve supplies of thalidomide.

The correspondence which we have viewed (and we have reason to believe that it is fairly complete) is, however, singularly silent in regard to who or what might have been responsible for the tragedy. In fact, as late as mid-1962, the pharmaceutical firms in three countries (West Germany, the United Kingdom and the United States) were still suggesting that thalidomide may not have been the proven agent which had caused the birth defects.

We offer the foregoing in the sense of editorial comment. It is an opinion which this Task Force has formed, based on its somewhat intense study of the entire matter. The significance of the comments of the manufacturers and the Canadian government is, simply, that they portray an attempt to deny any sense of responsibility for the tragedy!

HUMAN RIGHTS

Human rights legislation is founded on the principle that such rights cannot be denied or violated by an act of government.

The United Nations Declaration of the Rights of the Child specifically obliges national governments to recognize that a child, by reason of his physical and mental immaturity, needs special safeguards and care, including appropriate legal protection, before, as well as after, birth.

It can be concluded that the Canadian government failed to protect the interests of the thalidomide children as declared in the aforementioned international declaration.

It is interesting, in the context of the U.N. declaration, to view the damage caused to a number of persons in Canada by the drug thalidomide, the use of which was authorized in this country by government decree.

Thalidomide was distributed for trial purposes, with implied consent of the Canadian government, and was later authorized as a prescription drug, with consent of such government. It follows that the physical and mental damage to the victims might be interpreted as a denial of the human rights of such thalidomide damaged persons. The government failed to provide for them the protection which it ought to have provided in that its servants allowed the drug to be used in this country.

Presumably it is not necessary, in this report, to deal with the rights of the fetus, although at the time that damage occurred the thalidomide survivors were, indeed, being carried in the wombs of their mothers.

It is perhaps sufficient to recognize that the damage which occurred by reason of ingestion of this drug by the mother became known at the time of birth; and was, in most cases, readily apparent for all to see.

It is interesting to conjecture as to how this violation of human rights would be viewed by both the provincial and national human rights bodies in Canada.

Furthermore, it should not be overlooked that the Human Rights Commission of the United Nations might well have an interest in this matter, in the same way as such commission is currently considering whether acts of the Canadian government have indeed deprived other segments of our population of their human rights, including Native Indians and war veterans who were prisoners of war of nations which, during World War II, were hostile to Canada.

The author of this report and other members of the Task Force have had recent contact with what might be termed the 'human rights community' and, in fact, have been party to deliberations of the Human Rights Commission.

It is of interest to note that procedures now exist under which non-governmental organizations can gain status before the United Nations. Such have the right to seek the issuance of a DECLARATION through the human rights mechanisms of the United Nations.

Such declaration could state that a national government should bear the financial responsibility for the violation of individual human rights which results in disability or incapacity and which is caused by the harmful effects of a drug that has been licensed or certified by such government. The implication, of course, is that the human rights of the Canadian thalidomide victims were violated by the Department of National Health and Welfare, in failing to prevent the importation and use of thalidomide in Canada. A declaration of this nature might well serve as a form of subtle direction to the Canadian government that compensation should be paid.

Indeed, the United Nations adopted a Declaration of the Rights of the Child as proclaimed by the General Assembly of the U.N. on the 20th of November, 1959 (Resolution 1386 [xiv]). Not only is the date 1959 of significance with regard to the thalidomide tragedy, but in addition the language of the declaration is extremely supportive. The following principles contained in the Declaration should noted:

- i. The child by reason of his physical and mental immaturity, needs special safeguards and care, including appropriate legal protection, before as well as after birth.
- ii. The need for special safeguards has been stated in the Geneva Declaration

of the Rights of the Child of 1924, and recognized in the Universal Declaration of Human Rights and in the statutes of specialized agencies and international organizations concerned with the welfare of children.

- iii. The child who is physically, mentally or socially handicapped shall be given the special treatment, education and care required by his particular condition.
- iv. The child shall enjoy special protection, and shall be given opportunities and facilities, by law and by other means, to enable him to develop physically, mentally, morally, spiritually and socially in a healthy and normal manner in conditions of freedom and dignity. In the enactment of laws for this purpose, the best interests of the child shall be the paramount consideration.
- v. The child shall be entitled to grow and develop in health; to this end, special care and protection shall be provided both to him and to his mother, including adequate pre-natal and post-natal care.
- vi. The Declaration requires that national governments et al recognize these rights and strive for their observance by legislative and other measures progressively taken in accordance with the principles contained in the Declaration.

Hopefully, it would not be necessary to bring the matter of compensation for thalidomide victims in Canada to the human rights agencies.

If, however, there is no other alternative, it is certainly justified that the rights of this fine group of young men and women - who are today paying the penalty for an act of the Canadian government, which permitted the use of a dangerous drug in Canada - be pursued until all avenues have been exhausted.

In this regard, it may be of interest that there are a number of non-governmental

organizations in the human rights community which would probably have a direct interest in such matter, including the International Committee of Health Professionals.

In this report, the issue of human rights is raised because the thalidomide persons are deserving of full consideration of every aspect of the tragedy of which they are the victims.

In the general sense, the remedying of a wrong, in today's world, is often a judgmental decision involving, on one hand, the person (or persons) whose human rights have been violated and, on the other, the government which may have been responsible for the violation.

It is obvious that, in those countries which have a law intended to protect the consumer, its peoples are justified in expecting that their rights have been violated if the government fails to provide the protection consistent with the law.

Accordingly, thalidomide victims in Canada may well have a strong case for violation of their human rights. This aspect of their claim must be placed for consideration before the Government of Canada as an additional reason for compensation. In the case in point, the Canadian government may well be both the protector and the violator.

CURRENT NEEDS OF THALIDOMIDE GROUP

In the early 1960s, when thalidomide was the lead story in the print and broadcast media, there was a wave of public horror and indignation concerning the damage which had been done to these small babies.

At that time, only a handful of people were attempting to assess their future. It is not difficult to understand why they met with little success. Immediate concerns were prosthetic restoration (if possible), surgical improvement, cosmesis and the possible psychological effect on the family. Those who had been dealing with the social and economic problems faced by the seriously disabled in society attempted to express their concerns. Their pleas were either ignored or over-shadowed by the immediacy (and sensationalism) which attracted the interest of the public.

This is understandable, particularly in that only a very few people had the experience necessary to project the situation these babies would face when they reached the years of early maturity. Time passed: Now these needs are apparent, for all to see.

Independence: This is very high on the priority list, in assessing the requirement for funds. Surely none would deny the thalidomide victim the right, as a young adult, to live his or her life with the same freedom and self-sufficiency enjoyed by Canadians generally, subject of course to certain undeniable limitations dictated by their disabilities.

For the thalidomide group, self-reliance in the work place and at home translates into very significant additional cost. They certainly, however, have the right to as much independence as they can attain. Compensation from the federal government, having regard to the manner in which this drug became available to Canadians, is a legitimate proposition.

Parental Support: The cost in terms of dollars of the loss of enjoyment of life, the sacrifice and the mental anguish for the **parents** of thalidomide children is almost too great to comprehend.

That, however, is not an issue for discussion in this report. What must be considered is the situation which the thalidomide group has already faced, and will continue to face in increasing numbers: the situation which occurs when such parental support is no longer available.

With the passage of time, the ability of parents to cope with the needs of the thalidomide-damaged person is seriously diminished and will continue to diminish to the point where it is non-existent.

When that time comes (and it is already here for some), the thalidomide group will require a type of care available at a cost far beyond the amount which will be available from normal salaries and/or the relatively meagre legal settlements.

Transition Plans: The Task Force, in its studies, has been made aware of the need to make an immediate start upon the development of what might be termed 'transitional programs for those thalidomide victims who have been reared within the confines of their own families.

None of these victims should have to face the prospect of institutionalization. In order that such may be avoided, however, planning must be put into effect which will allow them to function autonomously. Such planning would encompass some form of employment (including home-bound or sheltered workshops where necessary), transportation, housing, the provision of attendance and/or aids-for-daily-living - cost which, incidentally, is far beyond hope of even the most generous financial settlement received through the courts.

Transportation: Most Canadians take transportation for granted. For the thalidomide victim, this often means specially adapted automobiles; wheelchairs with electronic control; an attendant when travelling and many other specific items.

From a humanitarian viewpoint, it is necessary to add the tremendous physical effort required on the part of the disabled person.

The point being made here is that, for the average Canadian, transportation to and from work for recreation and maintenance of contacts with family and friends is in itself a large item of expenditure. For the thalidomide person, one can multiply the cost figure by a factor of 10, at the very least.

Home Environment: Our surveys, and others which have been done and which are readily available, indicate the cost of adapting the home environment averages out (in 1988 dollars) to between \$10,000 and \$12,000. Some of the adaptations include ramps, railings, special bathroom and kitchen accessories, elevating device, and special diets.

Recreation: Surely no one would deny the thalidomide victim the right to the maximum recreation possible, within the limits of his or her disability.

This might best be explained by an example: J.N. gained extreme pleasure from operating his own boat. He earns sufficient income. He purchased the boat. Consider the added cost for him: specially constructed mechanical escalator to get down to water level; a permanent lifting device to get him out of his wheelchair and into the boat; and, finally, controls and safety devices tailored specifically for this needs. Before anyone gets the idea that his is a luxury, it should be considered that it is his only means of recreation, when weather permits. (J.N.'s story is representative and indicates where special expenditures would be useful.)

Education and Training: Because of their disabilities, many of the thalidomide victims were unable to complete secondary education. In other cases, due to absences from school to deal with physical needs and for hospitalization, the attainment of basic high school education was delayed by three or four years.

With the computer age, great possibilities were opening up for many of this group. By the same token, universities, in many instances, have converted to wheelchair access and, for other reasons, are more easily available for attendance by the heavily disabled.

Our studies indicate, however, that for a rather large number of thalidomide victims, the crucial years are upon them and an all-out effort is required if they are to benefit from post-secondary school education.

Such accelerated programs are costly and can include relocation, housing needs in new communities, transportation facilities to and from the institutes of higher learning and possibly other costs including attendants, specially-made clothing and other needs which would be necessary to allow them to concentrate upon the attainment of college or university qualifications.

In this regard it should be appreciated that, because of their **physical loss**, there is the realization that they must develop their potential and make use of mental skills.

(Our research has indicated that what training was taken by the thalidomide group is, in many instances, out of date as it did not include instruction in regard to computers. This has resulted in a rather incongruous situation, in that the computer field does, indeed, offer some very real advantages for persons with the types of disabilities exhibited in those who were damaged by thalidomide.

The cost and other elements of establishing training for heavily disabled persons in the computer field are well known to The War Amputations of Canada. Six years ago, we established what is known as The War Amps Super Sheltered Workshop, in which we were able to move a number of disabled persons who were employed on the assembly lines in our Key Tag Service into computer-oriented positions. This was done through an intensive on-the-job training regimen supported by classroom modes. In fact, the cost of establishing the special Super Sheltered Workshop facility was in excess of \$250,000 and the ongoing cost of training approximately 12 persons a year is a further \$200,000 a year. Part of this is recovered in that the trainees are able to make a contribution to computer operations of the Key Tag Service. This is mentioned so that this Report can furnish some actual data relative to the cost of training or retraining these individuals.)

General: For further details regarding the special needs of the thalidomide group, please refer to the research reports in appendix A.

CONCLUSION

This Report sets forth the jurisdiction of the Government of Canada to carry out its mandate to ensure that harmful drugs are not distributed or licensed for use or sale within the borders of Canada.

It appears beyond question that there was overriding federal government responsibility. Had the Food and Drug Directorate properly exercised its authority, there is a strong probability that thalidomide would not have been available in Canada.

As stated earlier in this submission, if the drug reached pregnant mothers through an error on the part of either the legislators and/or the administrators, this does not lessen the responsibility of the federal government.

There is, therefore, a strong case to be made that the Government of Canada should, and must, provide compensation to the victims of thalidomide.

It is clear, of course, that the thalidomide victims in Canada have no claim in law against the Canadian government.

Moral considerations in the thalidomide situation, however, do seem to be called for! The reference to moral is in the sense of the distinction between right and wrong. It is of no

consequence as to whether the wrongs done against the thalidomide victims were due to human error, omissions in the legislation, faults in the procedures and/or the manner in which such were being carried out.

The claim on moral grounds is concerned with the principles of rules of conduct. In the general sense, a moral certainty rests upon convincing grounds of probability as to whether an action which caused damage was **morally** correct. If not, in the case of a government, there lies a responsibility to assist in alleviating costs which can properly be attributed to failure where there has been deviation from the broad principle governing moral duties.

The Task Force is cognizant of the problems which may be created, if compensation for the victims is seen as indemnification for some flawed action, whether (as has been stated earlier) such was due to personal conduct or defects in the act or regulations.

Should this be a concern, it is suggested that the thalidomide victim receive consideration on **humanitarian** grounds!

There is the possibility that the federal government can provide acceptable reasons, as to the manner in which this hazardous product became available to Canadians. Also, arguments could be put forward which may be seen as relieving the federal government of liability.

Notwithstanding, the thalidomide victims represent a very fine group of young Canadian

men and women who have been left severely handicapped by the ravages of an evil drug. It has been seen as the objective of this Task Force, therefore, to make public all of the factors which have served to put the thalidomide victims in the position in which they find themselves.

If the claim on their behalf cannot be accepted as valid on any other premise, then the suggestion is put forward that the **humanitarian** aspects are certainly sufficient to warrant some form of reparation for the injured parties.

PROPOSED FORMULA FOR COMPENSATION

Under the aegis of this Task Force, administrative arrangements have been made to establish THE THALIDOMIDE VICTIMS ASSOCIATION OF CANADA. This Association has been granted Letters Patent under the provisions of the Canada Corporations Act, Part II as a federal non-profit corporation under the Department of Consumer and Corporate Affairs. The officers of the Association are all thalidomide **victims** (their word).

(A copy of the Letters Patent and other documentation relating to the incorporation of this Association is included in Appendix F.)

We have identified and are in contact with 109 individuals who appear to qualify as having suffered from the effects of thalidomide. Such persons have been or will, if they so desire, be enrolled as members of the Thalidomide Victims Association of Canada.

The Task Force was fortunate to have the services as consultant of Randolph Warren of London, Ontario who is a thalidomide victim. In addition, the Task Force has enlisted the assistance of regional representatives (all thalidomide victims), including:

GAVIN BAMBER, North Vancouver, British Columbia
JAMES BRESHAHAN, Kingston, Ontario
ALVIN LAW, Regina Saskatchewan
PAUL MURPHY, Winnipeg Manitoba
CHERYL WOOD, Calgary, Alberta

The Task Force, and the thalidomide victims, have wrestled with methodology of payment. It is recognized that considerable difficulty could be encountered if the federal government had to accept the obligation of attempting to assess the damage in each individual case, using a formula for compensation based on the degree of disability (or any other concept such as loss of earning power). Some problem could occur, also in identifying bona fide thalidomide victims.

With the approval of the Thalidomide Victims Association, it is therefore proposed that compensation from the federal government should be in the form of a cash grant to the Association.

To facilitate this, again with the approval of the Thalidomide Victims Association, this Task Force has made the necessary administrative arrangements to establish a Foundation which would accept responsibility to administer benefits from such grant from the federal government. The Foundation, registered as The Thalidomide Victims Foundation of Canada would, under its Charter, be able to receive funds from other sources, to be used for the purposes of the Foundation.

(A copy of the Letters Patent for this Foundation is included in Appendix G along with other documentation relating to the incorporation of the Foundation.)

With regard to the Government of Canada, the establishment of the Thalidomide Victims Association, and of the Foundation to be administered under its control, presumably would provide an acceptable and attractive method under which funds from the federal government could be administered.

The Foundation officers would accept responsibility in identifying the actual thalidomide victims, and assessing their needs.

The requirement on the part of the federal government would be to determine that the Foundation is established in such a manner as to ensure proper distribution of funds which may be forthcoming from the federal government.

It is the proposal of the Task Force that the amount of such grant should be open to negotiation, involving the government, our Task Force and the Thalidomide Victims Association of Canada.

It may be practical for the federal government to advance a sum of money in the form of 'start-up' funds for the Foundation, with the proviso that additional funds could be made available if and when the Association can submit proof that:

1. The funds already advanced have been expended in a reasonable and proper manner.
2. There is a demonstrable need for additional funding.

THALIDOMIDE FOUNDATION

Special emphasis is placed upon the need to establish a Foundation which can inspire confidence in the public, the government and others concerned, in regard to the capability of administering funds, in trust.

In this regard, the Thalidomide Victims Foundation of Canada - which has been established under the provisions of federal government legislation - will provide that:

1. All financial transactions of the Foundation will be subject to the scrutiny of an established audit firm. The Foundation has appointed the firm of Coopers & Lybrand as its auditors.
2. The expenditures will, of necessity, have to meet the rigid standards required by federal government regulation in regard to expenditures of charitable institution and/or a foundation operating under the non-profit corporation legislation; that is, under the regulations and guidelines of the federal Department of Consumer and Corporate Affairs and the Department of National Revenue.

The Foundation will, in reality, be operated by the thalidomide victims themselves. This will ensure that their special knowledge will be available in assessing who will benefit, and that the need is genuine.

Moreover, at the insistence of the officers of the Thalidomide Victims Association of Canada, the directors of the Foundation will always include a number of prominent persons who are not, themselves, thalidomide victims but who have the capability of inspiring public confidence.

The first Board of Directors includes Dr. Gustave Gingras, one of Canada's most respected physicians; Brian Forbes, a prominent member of the legal profession; Lloyd Perry, another prominent lawyer and formerly official guardian for the Province of Ontario; and H. Clifford Chadderton, Chief Executive Officer of The War Amputations of Canada and the founder of The Thalidomide Victims Association of Canada.

The intent of those who established the Foundation was to ensure that it would instil, in the minds of the public, both stability and credibility. These, together with necessity of operating under the stringent guidance of the government's own legislation, give the assurance that the administration of funds entrusted to the Foundation would eliminate, or at least minimize, the possibility of impropriety, faulty management or misrepresentation.

The principles for the guidance of the Foundation in respect of expenditures for or on behalf of thalidomide victims include:

1. Reasonable depletion of the capital funds together with interest would be acceptable; this to avoid any tendency to hoard capital to meet future needs which may never occur.

2. All applications would be in writing, on prescribed forms.
3. All applications would be properly supported by data that would allow effective adjudication.
4. A regular report on expenditures would be notified to all members of the Thalidomide Victims Association of Canada.
5. Donor's requests for additional funding would be based upon acceptable records which would indicate the manner in which expenditures had been made.

COMPENSATION FOR FUTURE INCIDENTS

(A “No-Fault” Insurance Plan)

There appears to be general agreement, world-wide, that the authoritative report on the thalidomide tragedy is Suffer the Children: The Story of Thalidomide, written by the Insight Team of the Sunday Times of London and first published in 1979.

In attempting to draw reasonable and acceptable conclusions, the Insight Team suggested that by the end of the 1970s, despite the thalidomide disaster of the early 1960s, very little had occurred in the way of progress in the matter of compensation for drug-related personal injury. In the Viking Press imprint of the book (page 241), the authors state:

People injured by drugs are still almost universally in the same position as the thalidomide families: they are at the mercy of antiquated legal systems that assume they have the money, knowledge, and mental fortitude to fight for compensation....

[Many countries] have made prominent national efforts to stiffen the scrutiny of new drugs, and the World Health Organization is pooling information from twenty-two member states on adverse effects. But drug monitoring is scientifically still at a relatively primitive stage.

It is not the intent of this Task Force to deal with shortcomings in regard to legal remedies available to victims who may suffer physical damage from the ingestion of pharmaceutical products.

Our main thrust has been in the area of what might be termed the moral responsibility of government (specifically the Canadian government). It is obvious that, in this particular area, a government finds itself in the position of what has been termed a ‘balancing act.’

On one hand, the health authorities at government level must attempt to ensure that their people have access to the advantages of drug therapy from the standpoint of care and treatment of medical problems. Conversely, the government of Canada, like most other governments, has a mandate to provide the ultimate protection from the physical damage which might be caused by drugs.

Many of the members of this Task Force have had considerable experience in the combined fields of medicine, and the applicability of the law in regard to pharmacology.

The thalidomide disaster cries out for a solution in regard to compensation for its victims! A formula must be devised under which the Government of Canada can provide for the special needs of the Canadian victims.

An analysis of the problems they have encountered raises some serious questions which go beyond the requirement to assist the 1960-62 group disabled by thalidomide. Indeed a government grant such as that being sought in this Report would establish a precedent - and one which is long overdue. At the same time, compensation for future incidents should be considered.

Government officials charged with the responsibility of granting permission for the use of new drugs should be able to function, knowing that there is always an element of danger.

Such administrators should be able to perform their duties without having to live with the possibility that legitimate error might cause physical damage, for which compensation would have to be sought through the courts.

Accordingly, it would appear that the provision which now exists on the statutes of West Germany has much to commend it. We refer to a government-funded scheme which provides compensation where, despite the most effective controls possible, an individual suffers physical damage from an experimental drug.

It is recognized universally that, in certain instances, the effects of a new drug can only be determined on the basis of its usage by humans, over an extended period. There is, therefore, always the possibility of unavoidable error. If it is accepted that the search for effective new medication must continue, the very least that a government could do would be to enact a form of no-fault insurance which would compensate persons who, despite the best precautions, become victims of progress in this area.

It should be noted that current media reports indicate that Canadian authorities are being criticized for what is called the drug-lag. They are being accused of unnecessarily delaying new drug approvals. Presumably, the proposed no-fault insurance would make it somewhat easier for the drug-control mechanism to operate.

REVIEW

In concluding this section of the Report, it may be as well to recount the thalidomide story. In 1956, a new hypnotic called Contergan was introduced in West Germany by a company called Chemie Gruenthal. The phenomenal success of the drug was attributed to its high degree of safety.

The German company commenced to seek licensing in the international market and was successful in most countries, the most notable exception being the United States.

The drug quickly came into general use to control nausea among pregnant women and it is no over-exaggeration to say that the use of the drug was widespread throughout the western world.

It has now been established that in West Germany, where the drug had been available firstly over the counter as a hypnotic and latterly as the standard treatment for morning sickness, fragmentary reports were in circulation as early as 1959 concerning its teratogenic effect; that is that it could cause incredible malformations in children whose mothers had taken the drug.

A somewhat sinister chapter of the story then followed with the drug company failing to reveal the disastrous results being reported to it. As drug companies in many other countries had obtained the franchise, it seems that there was an obligation on the German

company to sound a warning, but apparently this was not done.

Also, in Great Britain, as was later proved in legal proceedings, at least one researcher working for the company producing the drug in that country had attempted to convince his superiors that the drug was not safe.

When the final statistics were in, it was estimated that more than 8,000 'thalidomide' children were born in Europe, South America, Australia, Japan, the United States (relatively few) and Canada. Many of these babies had missing or stunted limbs, or suffered from deafness, visual problems, heart defects, spinal abnormalities and urinary-tract complications.

Much of what took place in regard to accusations against the original developer and those companies which manufactured the drug on licence has never been revealed. It remains, notwithstanding, as the very worst example of what happens when a drug proves to be capable of creating untold damage; and where, at the same time, that drug is the subject of energetic and modern marketing techniques.

A FINAL WORD

Thalidomide was a violent drug - there is no question of that! The pharmaceutical company which developed it, according to the recorded history of the thalidomide disaster, may not have acted in good faith.

At least, those who have made an impartial study of the thalidomide tragedy seem to support the theory that thalidomide was widely promoted as a wonder drug. Accordingly, much of the damage which resulted from its use can be attributed specifically to high pressure marketing techniques, designed to ensure that the product was available to the public with the least possible delay.

There was, obviously, some demand for a new hypnotic with no side effects and little or no toxicity, on which, if taken as an overdose (on purpose or accidentally), would not cause death. Conversely, there is irrefutable evidence that, at least in the case of some of the pharmaceutical firms, their officers either were not interested in pursuing investigational methods which would have tested the safety of the drug or, even worse, actually suppressed evidence of its side effects.

Their motives? The reputation of the company? Profits for the owners or shareholders? (Some directors of the German company which developed thalidomide were with criminal offenses!)

The important issue here is not what pharmaceutical companies did, but what they may have failed to do. It is obvious that a commercial firm manufacturing pharmaceutical products must subject itself to government control; hence, in the final analysis, the responsibility lies with a government to protect its people.

Where the government fails to do so, and compensable injury and physical impairment results, the disabled person has a valid claim for compensation against his or her government.

The thalidomide disaster resulted in indemnity payments from some governments. The government of Japan shared in a payment of \$18 million. West Germany paid out upwards of \$27 million. This Task Force is asking, on behalf of the thalidomide victims of Canada, that reasonable compensation be paid to the victims by the Canadian government.

In doing so, we are looking beyond the needs of this particular group of fine young Canadians. It seems obvious that, in regard to indemnifying the victims, the Canadian government itself has gotten off scot-free! This, despite the obvious fact that a serious error occurred in a matter in which the federal government has a jurisdictional mandate to attempt to prevent such error.

It is suggested therefore, that the payment of monies to this group now might **well act as a deterrent in regard to future problems of this nature**

Accordingly, at stake here is not only the immediate needs of the thalidomide group. It is reasonable to suggest that the payment of such indemnity might represent, for those responsible for the administration of the legislation which protects one and all, an incentive to ensure they carry out this mandate with utmost care. Moreover, if they need additional staff, equipment or other requirements to do their job, there is an obligation on them to say so - in the strongest possible manner!

SUPPORT DOCUMENTATION

Volume II of this Report comprises the appendices. Appendix A includes the following reports prepared by Randolph Warren, Research Consultant to the Thalidomide Task Force:

- Overall Needs Report
- Report on Sexuality and Its Implications
- Insurance Report
- Recreation Report
- The Future Outlook

These reports are, beyond question, the most significant exposition of the impact of the drug thalidomide upon those who were directly affected by it. It is our belief that if those whose responsibility it will be to adjudicate on this proposal were to understand fully what the thalidomide victims are saying, then the claim for compensation **could not fail!**

Other supporting documentation comprises Appendix B to Appendix G:

- “A Quarter-Century of Thalidomide Embryopathy”
- Thomson, Rogers study
- Sequence of events (prepared by Merrell)
- Chronology re thalidomide (prepared by DNHW)
- Letter of May 13, 1988 from the Honourable Jake Epp, Minister of National Health and Welfare
- Documentation relating to the incorporation of The Thalidomide Victims Association

- of Canada
- Documentation relating to the incorporation of The Thalidomide Victims Foundation of Canada

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Chairman
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