TVAC's Position On The Return Of Thalidomide

Living In A World with THALIDOMIDE: A New Reality

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July 17, 1998

"We will never accept a world with thalidomide in it."

THALIDOMIDE was licensed for use in the United States on July 16, 1998. Although expected to happen, the Thalidomide Victims Association of Canada (TVAC) remains sombre about this event. The reality is that we anticipate a domino-effect around the world, with other countries likely to follow the example of the United States.

Thalidomiders (as we call ourselves) feel compelled to remind the world of the tragedy of the late fifties and early sixties when 10,000 - 12,000 babies were born needlessly disabled as a result of negligence and greed. We remind the world that no one will ever have a full accounting of those children who were never born or died in the first three days of life. We remind the world of dreams shattered and mothers, families and friends forever scarred by the "wonder drug" of the past, now returned to use. Only by remembering those lost and harmed can we hope to prevent history from repeating itself.

In a world that turned its back on thalidomiders and our needs, we ask the question, is society ready for another generation of persons born disabled as a consequence of the drug thalidomide? Who will step up to the plate and take responsibility for the needs of these children...and who should???

We of the Thalidomide Victims Association of Canada **will never accept a world with thalidomide in it**. We demand that resources and energies aggressively be applied to the development of analogues to replace thalidomide -- analogues with the benefits but without the horrific side effects! The return of thalidomide must remain a temporary reality with the goal of replacing it being the priority.

TVAC has been **forced** to prefer licensing of thalidomide due to the rampant unmonitored availability of the drug through Buyer's Clubs and the fact that it may be useful in combating devastating diseases and disabilities. Thalidomiders now expect, with the licensing of the drug, that authorities close down Buyer's Clubs that handle the drug and make all efforts to stop all illegal smuggling. We have never supported the return or rehabilitation of the drug thalidomide, but we are dealing with it.

Our Association made a determination that never again would thalidomide devastate and control our lives --- we would control it... and for that reason we proactively chose to become part of the process, ensuring the safety of the public.

We have aggressively consulted with all associated with the return of thalidomide to remind them of the dangerous properties of the drug. We have lobbied for changes in educational materials and packaging to be sure that patients and physicians know the severity and reality of all side effects (not only the teratogenic properties, but the irreversible nerve damage issues as well.) We lobbied for a picture of a thalidomide baby to be included on the package. We lobbied for the drug to always be called "Thalidomide", no matter the brand/trade name. We reviewed and offered input into the system proposed by the drug company to prevent foetal exposure.

It was determined in September 1997 by an Advisory FDA Committee that the risks associated with the drug thalidomide were outweighed by the benefits. This statement alone however acknowledges that

there are risks! Apparently, these are "acceptable risks."

It is the view of the Thalidomide Victims Association of Canada that babies will be born disabled. No system is foolproof. If these children are born as "acceptable risks", we must ensure that these children are treated with the respect they deserve for their sacrifice in helping so many others. These children must be ensured a full quality of life and they must not be punished.

When a child is born... there will be outcries... there will be blame... there will be confusion! We must not lose the best interests of the child in this scenario. We must prepare today to meet the needs of these children. A percentage of the profits of every prescription of thalidomide must be set aside to meet that purpose in an independent trust. Adult thalidomiders (our Association) must be involved in this process to protect and advocate for these children. This is the most responsible solution --- this is the right thing to do! This must be done now! TVAC remains ready to assist in the mechanics of this necessity.

When a child is born, everyone will hide... and insurance agents and lawyers will create a climate of diversion. Everyone will hide except for the Thalidomide Victims Association of Canada. In the fifties and sixties no one helped families and they were taken advantage of. This will not happen again, we will be there. No child born disabled because of thalidomide, today or tomorrow, will be isolated again.

Any foetal exposure, resulting in a live birth or not, must demand speedy and intensive investigation and review of the system. Thalidomiders will be watching and must be involved in the investigation, as observers, to ensure no cover-ups.

Do we sound insecure and suspicious... we are... we are living it!

We have serious concerns that must be addressed. Foremost of these is the issue of off-label prescription of thalidomide. It occurs to us that this is an archaic process that must be changed in the case of all teratogenic drugs --- not just thalidomide.

Teratogenic drugs must only be used for conditions proven to be legitimate through clinical trials. It should be the condition that drives the prescription and not the discretion of many doctors with varied experience. Teratogenic drugs must be drugs of last resort! Thalidomide must be a drug of last resort.

The system developed for the return of thalidomide is complex. Thalidomide is now the most regulated drug in American history. But what of other teratogenic drugs which have flaws in their systems resulting in death and disability of innocent babies. The need for a new foetal exposure prevention system for thalidomide already shows that there are holes in systems that exist for other drugs. We feel all drugs with the potential for causing birth defects must be reviewed, and the holes in their systems must be plugged.

Although the Thalidomide Victims Association of Canada was consulted in the process of licensing, and was given unprecedented access to all materials associated with the return of this devastating and dangerous drug, there were battles lost that thalidomiders felt would add to the safety protocols undertaken.

- Every patient being prescribed thalidomide must complete a questionnaire/survey form designed to identify potential foetal exposure. We feel that this survey form is incomplete and should have also included formats to identify any and all other side effects that may be experienced by patients.

- Male patients are only required to complete the survey from every three months. We feel that as with women, men should be required to complete this survey every 30 days.
- At every opportunity the association has expressed the concerns that all doctors who may be prescribers of thalidomide should attend a workshop co-conducted by thalidomiders as part of a certification process to be allowed to prescribe. We believe that doctors of varied experience must receive this firsthand exposure to thalidomiders and the devastation of the drug to make them wary enough to make thalidomide a drug of last resort and not first choice.

We do not believe that any women who is pregnant would knowingly harm their foetus... any incident that will occur with thalidomide will be a result of a horrible accident or unforeseen failure in the system... and will not be an excuse to destroy and blame a mother.

Is society ready for more thalidomiders --- the answer is no! Witness the experience of Canadian thalidomiders and our association! We struggle for our very financial survival. We are the only group in North America organised specifically to meet the needs of thalidomiders and **we have no secure funding to operate!** We are forced to beg for every dollar and must always wonder whether we will exist in three months.

We must not assume that the world knows of thalidomide and the tragedy of 40 years ago. Two generations have grown up without firsthand knowledge of the devastation.

The Thalidomide Victims Association of Canada must exists, financially secure, to meet the needs of current thalidomide survivors and future thalidomide victims, and to educate and protect the public. Whenever thalidomide is represented, by drug companies or others, thalidomiders must be there to complete the narrative and to educate.

The thalidomide history is unique and ironic. No longer do we have an "assumption of safety" regarding new drugs, safety must be proven before licensing. The very reputation of the FDA was built on preventing a thalidomider tragedy in the United States in 1961, and now they have approved this drug under the strictest regulation ever. As a result of the thalidomide tragedy, society now knows that the foetus is vulnerable in the womb. Drug company officials (Celgene) and thalidomide survivors (TVAC) worked together towards a common goal putting aside fears and distrust.

We of the Thalidomide Victims Association of Canada will be ever vigilant! As long as thalidomide remains a presence in this world, thalidomiders will be the watchdogs. By virtue of our existence as survivors, we have that right!