

THALIDOMIDE: The Impact On The Practitioner

Ethics of marketing a teratogen

"Presentation I gave at the Utah Medical Conference. This was the intended presentation, but as usual, I addressed other issues deemed significant to the Association at the conference over and above this abstract."

-- Randolph Warren, January 30th, 1999

Allow me to begin with my respect and appreciation for the organizers of this conference — not only is it timely, but from our perspective, mandatory, and should occur all through the United States ... therefore, I commend all of you attending. I wish there were more of you, as we believe that the forecasted increased use of thalidomide will soon be a reality.

Now, I will focus directly on the subject at hand, due to the brief amount of time allocated, yet I alert you on behalf of all thalidomide survivors that we have much more to say on this whole subject and have many opinions regarding all aspects of the return of thalidomide ...or the fact that it never disappeared.

To us, to have "ethics" and "thalidomide" in the same sentence is an oxymoron with emphasis on the moronic syllables of that word.

Please forgive this written presentation, I am usually an "off the cuff man" with passion and humor, but time restrictions necessitate that I ensure that some major points are at least touched on ... Normally, an interesting word, I would be bringing a human face to thalidomide, I would describe our concerns and our daily experiences ... but today the humanity will come from my attendance as a living, breathing thalidomider, here in the flesh, and I will cut to the chase, still born out of our experiences.

I wish to deal with the whole subject in two parts —

First is the title of the day, Thalidomide: Impact on the Practitioner.

From our perspective, we wish to turn this around and challenge it by re-titling this segment the impact of Practitioners on thalidomide victims.

Our history, and even today, is one of thalidomiders being let down by practitioners. This began at the beginning, in the initial identification and diagnosis of thalidomiders as persons born disabled as a consequence of the drug thalidomide. This history is a murky one, with fully 10 - 20% of persons identified as thalidomiders by practitioners (usually working as agents for drug companies in lawsuits) being misdiagnosed. Let us evidence the whole discussion last year of 2nd generation thalidomiders ... it is our humble, yet firm opinion that thalidomide is not mutagenic ... and we have information that persons identified as having thalidomide-like (with the emphasis on like) malformations giving birth to children with like malformations have been misdiagnosed and should be re-classified with other genetic disorders.

To undo this damage means profound issues for those individuals who have invested years of identity and self-esteem into believing they knew what caused their disabilities.

Today we are confronted, mostly from the United States, with many disabled individuals who claim a

doctor did a visual call on them and said they were thalidomiders based on their unilateral limb malformation bearing some resemblance to traditional thalidomide victims.

To begin with, thalidomiders around the world believe that bi-lateral malformations of limbs, most particularly displaying phocomelic tendencies to some degree, are the correct identification of thalidomide victims. We have never understood unilateral malformations, or that happenstance implication, to be valid.

Many times the persons contacting us are also 10, 20, and even 30 years older than the drug's creation.

Why is this happening? We feel that it is a lack of information about the drug, and the victims as a whole ... after all, we are not even listed in the Medical Reference Book SMITH'S RECOGNIZABLE PATTERNS OF HUMAN MALFORMATIONS (5th Edition).

With the return of thalidomide, this is a priority issue with us, should practitioners be confronted with yet another generation ... the responsibility is yours to seek that information before making "snap decisions" that become imprinted on families.

Moreover, it is unconscionable that a tragedy the proportions of thalidomide is neglected and pushed aside by the medical establishment.

We find this ironic as we have long been the curiosities and guinea pigs of the medical profession due to the rarity of our condition in North America. As well, this is due to the rarity of the solutions to our problems. My finger transposition seems to generate great excitement as I was one of the first in Canada, to the point where my doctors have often tried to treat head colds with extensive investigation of my hands.

We have war stories in our group of persons with upper bilateral phocomelia going to emergency rooms with broken legs, and having their arms extensively treated and discussed. Eventually, I am happy to report, the legs did get treated.

In a new world, with thalidomide licensed once again, we must be sure that we are not only attributing birth defects to the drug, but also that we are attributing the correct birth defects to the drug.

These facts do not give us much heart in practitioners right to prescribe off label ... not every practitioner is at the same level of sophistication and understanding as this esteemed body. We have even fielded calls from physicians convinced that this time around it is a new and improved version of thalidomide with the side effects weeded out.

We believe that in the case of thalidomide, and all teratogens, that off label rights should not apply ... thalidomide prescription, in our opinion should be driven by indications that have undergone appropriate scrutiny and clinical studies. We disagree with the possibility that thalidomide may be prescribed with only anecdotal or media presented evidence.

I have just spent much time in apparently criticizing the medical establishment, who slapped us into artificial limbs to look like everyone else and to be more acceptable to society's vision of a body, often causing the deteriorations we are experiencing today and certainly self-esteem issues but let me now redeem myself.

Many of us do owe our very lives and independence to the creativity of physicians ... and in general, we hold practitioners in high regard, and even though we don't always appreciate the news we are given, we choose not to shoot all reporters.

In order for the Celgene STEPS system to work, physicians are an integral part of the equation, not only in offering or facilitating patient education, but also in ensuring that the patient truly understands.

If thalidomide is truly again a "wonder" drug, then we must, together, also view it as Pandora's Box, never to be fully opened ... Thalidomide must be a drug of last resort ... thalidomide must make a temporary return ... to be replaced with safe analogues.

We believe that all licensed teratogens should be under constant review, and that resources should be fully dedicated to their eradication and safe replacement. Teratogens should be, must be, licensed differently, and temporarily.

Don't kid yourselves, no system is foolproof, there will be thalidomide foetal exposures, and some of the women will have their children ... witness Accutane.

Abortion, each woman's choice from our perspective, is not your safety net ... the objective is that there be no foetal exposures. A foetal exposure resulting in abortion, is not a cause for a deep sigh of relief ... it is yet another death as a result of thalidomide.

As confident as we can be, we are in the STEPS Program, with some exceptions.

Obviously the more times thalidomide is prescribed, the more likely an accident will happen.

We are disappointed that the medical community felt upset that prescribing practitioners might be forced into workshops co-hosted by thalidomiders before being given permission to enter this system ... we failed in that request ... and we pray that this failure doesn't come back to haunt us. That is why this forum is so important to us ... we, thalidomide victims, have a lot to teach you ... and yes, you could well learn from us.

I will go back now to the core of our position which is relevant to the topic.

We will never accept a world with thalidomide in it, however, we cannot deny this drug from those who may benefit with a markedly better quality of life or even longer lives.

We are here to specifically address the issue from a "thalidomide baby" perspective ... but we are also equally concerned that all side effects be revealed ... and we resent the watered down language surrounding "nerve damage" side effects ... they exist for some ... know that ... recognize the symptoms ... then choose with your patients, the lesser of two evils ... Each patient must make a "RISK AWARE CHOICE" and must be effectively and clearly given the information to make that choice.

Remember us ... be aware of what you are giving ... and with every prescription ask: Does the benefit truly outweigh the risk?

Do not let history repeat itself.

Thank you.