Thalidomide in America

Posted by Steve Berman on Nov. 2, 2011

On September 18, 1962, a baby boy was born in the small town of Brownfield, Texas. Immediately after he was born, doctors noted that the boy had serious and disfiguring birth defects. He was missing his right leg, including his foot. He had no fingers on his right hand and his right arm ended above the elbow.

The baby, named Philip Yeatts, has lived his life without the use of his right leg or hand. He persevered and grew into a strong-willed and determined man. In fact, he became a professional racecar driver, using a specially modified car to win a championship in the U.S. Legends Series in 2008.

Its tempting to end Philips' story there, and honor his courage and determination to overcome his disability. But there is much more to this story. We believe that Philip was not simply victim of poor luck. We think that his birth defects were a preventable tragedy, side effects from a dangerous drug called thalidomide.

Those of us who were alive in the early 1960s remember the tragedy caused by thalidomide. The drug was widely available in Europe, given to pregnant women to ease morning sickness. We now know that the drug caused debilitating birth defects, resulting in thousands of infant deaths and shocking deformations throughout Europe and elsewhere around the world. The pictures Americans saw of thalidomide babies shocked the nation's collective consciousness, infants with what appeared to be flippers where arms should be, among other severe malformations.

Yet, at the same time the tragedy seemed so far away. The FDA never approved the drug here, so it was never widely used in the U.S., or so we were told. Later, Billy Joel's song "We Didn't Start the Fire," would juxtapose the European tragedy, "children of thalidomide," with a much more American tragedy, "Starkweather homicide."

The belief that America avoided the thalidomide tragedy has persisted for nearly 50 years now, but we believe we have discovered evidence that casts doubt on the story. Newly uncovered and translated documents, combined with new medical advances that help us to better understand how thalidomide works, suggests that there may be many victims in the United States that were never identified.

Even worse, our research has uncovered evidence that the thalidomide tragedy was foreseeable and preventable, but due to the greed of a number of drug companies, safety risks were overlooked and covered up.

The origins of thalidomide take us back to post-war Europe, specifically to the early 1950s in Germany. In 1953-54, German pharmaceutical company Chemie Grunenthal synthesized thalidomide for the first time, and subsequently received a German patent to begin producing

and distributing the drug. Grunenthal originally considered the drug a panacea, or at least marketed it as such, claiming it could cure everything from the common cold to premature ejaculation.

New documents suggest that on Christmas Day 1956, an earless baby was born to the wife of a Grunenthal employee who had taken thalidomide during pregnancy. Yet, instead of slowing down development and running more tests, the company continued to push ahead. A mere 10 months later, in October 1956, the drug was released for commercial, over-the-counter sale in Germany.

In 1956, the company entered into an agreement with U.S. pharmaceutical company Smith Kline and French (SKF) to begin domestic testing of thalidomide on animals and humans, including pregnant women.

By August 1958, a pregnant woman participating in the SKF trial delivered a malformed baby. Unlike Grunenthal, who decided to move ahead with the drug, SKF declined to market it in the U.S. However, from what we have seen, the company never let the public know about its test results. The failure to disclose test results is no trivial matter; it is possible that if SKF had sounded an alarm bell early, the distribution of thalidomide in the United State and elsewhere might have been slowed, and less people would have been exposed to the drug.

Having failed to convince SKF to distribute the drug, Grunenthal signed a U.S. distribution agreement for thalidomide with the William S. Merrell Company. Merrell began human trials simultaneous with animal trials in February 1959, and expanded the trials to include pregnant women in May 1959, all while conceding that it had no access to any human clinical safety data.

We believe that sometime during 1959, Grunenthal destroyed its testing data. In September 1960, Merrell submitted a New Drug Application (NDA) with the FDA for commercial sale of thalidomide, which Merrell named Kevadon. The proposed label in the application specified that the drug was intended for use by pregnant women.

One month later, Merrell began its “Kevadon Hospital Program,” a series of large-scale “clinical trials” that we believe were nothing more than a marketing effort to pave the way for expected sales of the drug in the United States. Merrell kept disorganized and occasionally nonexistent records of who, where and when Kevadon was distributed and even informed doctors that they did not need to keep records of the “studies” either. Again, the drug was recommended for use treating morning sickness in pregnant women.

As part of this trial, we believe that more than 2.5 million doses of the drug were given to more than 20,000 patients. While those trials ran, the FDA’s Dr. Frances Kelsey repeatedly denied Merrell’s application to sell thalidomide, deeming its testing to be incomplete. She encouraged testing on pregnant animals.

Then, the truth about the drug began to come out. In July 1961, Australian Dr. William McBride suspected that thalidomide was responsible for recent birth-defect cases and contacted Distillers, the Australian distributor and licensee of thalidomide.

On November 26, 1961, German newspaper *Welt am Sonntag*, published an article revealing physician suspicions that thalidomide was causing malformations in babies. Grunenthal pulled the drug in Germany, but continued to dispute claims that thalidomide was responsible for the defects. Merrell did not pull its NDA, did not recall the drug and only alerted about 10 percent of its clinical investigators of the danger.

Sometime during the first three months of 1962, Jerry Sue Yeatts of Brownfield, Texas, began suffering from violent morning sickness and went to her physician, Dr. Noah Stone, for help. He prescribed a drug for her illness but did not tell her the name. He also performed at least one sonogram but did not share the results with her. Multiple babies born to Dr. Stone during this time period suffered from birth defects and several died.

On March 8, 1962, Merrell finally pulled its NDA. Like Grunenthal, Merrell contested the claim that thalidomide can cause birth defects and sent letters to doctors disputing the evidence against thalidomide.

In June 1962, Merrell's Director of Medical Research Dr. Carl Bunde testified before Congress that thalidomide was never sold in the U.S., leaving out the fact that 2.5 million doses had been distributed to 20,000 people by 1,200 doctors.

Two months later, SKF President Walter Munns was also called before Congress, where he claimed that SKF's clinical trial participants had not given birth to any babies with birth defects, a claim that we believe newly uncovered documents prove was a blatant lie intended to cover up SKF's guilt.

On September 18, 1962, Phillip "Hook" Yeatts was born to Jerry Sue in Brownfield, Texas. He is one victim, we believe, of a silent epidemic that occurred in the United States during the early 1960s as a result of widespread distribution of thalidomide through a marketing program thinly disguised as a clinical trial.

Yeatts was overlooked as a possible victim of thalidomide not only because SKF and Merrell temporarily succeeded, we believe, in covering up the extent to which the drug was distributed in the U.S., but also because new medical advances have changed our understanding of thalidomide victims.

Yeatts' deformities are mainly unilateral, affecting only the right side of his body. When thalidomide was first being studied and its horrific side effects being assessed, it was thought to be primarily a neurological drug that caused only bilateral injuries – those affecting both sides of the body. Through some very innovative new cancer research, it is now believed by many doctors that the drug's mechanisms are actually vascular, enabling it to cause unilateral injuries

as well. In the original judgment of thalidomide's damage, anyone with a unilateral injury like Yeatts' was summarily discounted as a victim.

Yeatts, along with 12 similarly affected plaintiffs, is part of a new lawsuit we have filed in Philadelphia. At trial, we will show that new documents prove that Grunenthal, SKF and Merrell were criminally negligent, ignoring the hazards of thalidomide and keeping the public in the dark.

The worst element of this entire situation is only now coming to light – the fact that hundreds or thousands of people who have struggled with birth defects their entire lives were originally told that they were just unlucky, when in fact they were victims of a senseless, preventable tragedy.

As Billy Joel might have said, we may not have started the fire, but the least we can do is care for those burnt by the flames.