US Thalidomide Survivors

usthalidomide.org

"[US thalidomide survivors] now know their bodies are the ground on which the country built its legal safeguards. They hope the country will help them in return."

– Jennifer Vanderbes,
WONDER DRUG:
the Secret History of
Thalidomide in America
and Its Hidden Victims

Since 1962, the Food & Drug Administration has publicly declared that only 9 American babies were harmed by thalidomide distributed via mid-century clinical trials in the United States. And since 1962, the agency has known this number is false.

US Thalidomide SURVIVORS

US Thalidomide Survivors, formed in 2018, represents approximately one hundred disabled Americans born between 1957 and 1964 whose mothers likely took American-made thalidomide during pregnancy and who were misled by the US government's decades-long campaign of misinformation.

Our birth injuries were caused by thalidomide distributed in the United States. Many of us have tried to pursue legal action against the responsible drug companies, but our efforts were stalled by the statute of limitations.

The quest for independence and dignity

Our birth injuries have ampified the aging process for all of us. After years of compensating for short limbs, or no limbs, the bodies of survivors are breaking down. Chronic pain and degenerative skeletal and spinal conditions are common. American thalidomide survivors fear early institutionalization due to inability to perform personal care tasks, in order to keep up with care needs most cannot afford.

Thalidomide survivors in eight countries receive financial support from the company that produced and sold thalidomide and additional support from their national government.

The US Government failed to hold the manufacturers of the sample pills distributed in this country accountable to assist its victims and also has not provided government assistance.

Thalidomide survivors in five additional countries that did not hold the manufacturer accountable receive financial support from the national government.

Help us right the wrong

The previously hidden victims of thalidomide in America and our millions of supporters worldwide call for the U.S. Congress to immediately establish a fund to provide financial support comparable to that received by survivors in Canada in 2018. Using the model established by Canadian leaders will quickly right the wrong caused by the 60-year system-wide national cover up, and allow us, the survivors, to live the remainder of our lives with dignity and independence.

Read *WONDER DRUG;* watch our short film

The facts of the American thalidomide scandal are laid out in Jennifer Vanderbes's *WONDER DRUG: the Secret History of Thalidomide in America and Its Hidden Victims* (Random House, 2023).

In addition, you can hear fears for the future from us, the survivors ourselves. Scan the QR code below to view a 15-minute film that captures our words, our struggle, and our request for your help.

Scan the code below to watch *Thalidomide in the USA: Seeking a Life of Dignity and Independence.*

https://www.youtube.com/watch?v=dO_LrVZ9wS0

Seeking US Congress assistance for American thalidomide survivors

Recognition from the US Government that the US did not escape the thalidomide tragedy of the late 50s and early 60s; and that there were more thalidomide babies born in the United States than the original 6 reported by the US FDA.

Establishment of an American Thalidomide Survivors Support Program (ATSSP) to register and confirm American thalidomide survivors and provide a support package for the aging American thalidomide survivors to live the remainder of their lives with dignity and independence.

Establishment of a panel of medico-legal experts similar to what is being done in Canada to develop a probability-based medical assessment process to determine if individuals are thalidomide survivors, employing techniques utilized in other international thalidomide survivor programs

Make the probability-based medical assessment process freely available to Americans who believe that they are thalidomide survivors. Allow all candidates to undergo the assessment to determine if they are eligible for the American Thalidomide Survivor Support package.

Provide a support package to meet the needs of confirmed American thalidomide survivors to live the remainder of their lives with dignity and independence.

- a one-time tax-free immediate assistance grant for each confirmed American thalidomide survivor
- a yearly tax-free support grant adjusted for inflation for each confirmed American thalidomide survivor

Provide access to an annual Extraordinary Medical Assistance Fund (EMAF) to help cover the cost of extraordinary daily living and health support costs of confirmed American thalidomide survivors such as specialized surgeries and home or vehicle adaptations.

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US Thalidomide Survivors is a registered 501(c)(3) organization, ID # 83-2200144

Thalidomide in the USA: a summary

- The drug thalidomide, created in Germany, used worldwide in the late 50's and early 60's, was billed as a sedative without risk of overdose
- One of the drug's purported benefits was alleviating morning sickness.
- In September of 1960, the Cincinnati-based William S. Merrell Company submitted an FDA application to sell the drug in the U.S. telling the FDA it was running 37 clinical trials in humans.
- FDA Medical Reviewer Frances Kelsey withheld approval of the drug, demanding safety evidence, including proof that thalidomide was safe during pregnancy.
- In late 1961, German health authorities learned that thalidomide was linked to severe birth defects - babies were often missing limbs - and the drug was withdrawn from the German market. American drug firms testing the drug were alerted, but the Merrell Company waited four months to withdraw its FDA application and over six months to attempt to ensure doctors who had received the drug were no longer handing it out.
- The FDA learned that five subsidiary companies of Richardson-Merrell distributed the unapproved drug to over 1,200 American physicians for undocumented "clinical trials," with those doctors distributing doses to other doctors. Smith, Kline & French also tested the drug in humans. Between 1956-1962, approximately 5 million doses were distributed, usually without patients' knowledge that this was an experimental drug.
- The U.S. Department of Justice declined the FDA's request to prosecute Merrell, citing only one victim of American thalidomide. The FDA, however, had documented nine victims, and knew there were likely more, though this information was not made public.
- Because women were never told what drug they had been given and the long-standing public assertion thalidomide was never "sold" in the U.S., most American victims were unaware of the cause of their birth defects for decades.
- U.S. thalidomide victims began finding each other in 2016 through social media. Approximately 100-200 American survivors currently struggle to manage the physical ramifications of their congenital defects.

Vanderbes, Jennifer. *Wonder Drug: The Secret History of Thalidomide in America and Its Hidden Victims.* New York, Random House, 2023.

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Assistance for Canadian thalidomide survivors

A blueprint for a US assistance program

What Canadian thalidomide survivors received in 2019

An initial lump sum, tax-free payment of $250,000 for survivors confirmed under the new Canadian Thalidomide Survivors Support Program (CTSSP). Survivors already recognized under the former TSCP received a top up payment of $125,000 to equalize the ex-gratia amount payable to all survivors under the two programs.

Ongoing annual tax-free payments to thalidomide survivors indexed at 2% per year for life; the annual amount can be up to $100,000 based on the severity of an individual's thalidomide injuries.

Access to an annual Extraordinary Medical Assistance Fund (EMAF) to help cover the costs of extraordinary health support costs of Thalidomide Survivors with needs such as specialized surgeries and home or vehicle adaptations that are not otherwise provided in provincial/territorial healthcare plans.

An increase to the EMAF to $1 M per year, indexed at 2% per year, to account for an anticipated greater number of confirmed survivors.

Annual ongoing support payments will continue uninterrupted for the Confirmed Thalidomide Survivor's lifetime.

How are survivors determined eligible?

Canadian Thalidomide Survivors Support Program (CTSSP) uses a three-step probability-based medical assessment process summarized below. Applicants must meet the preliminary screening requirements established at the first step in order to move onto the next steps.

1. Preliminary Screening:
    - The date of birth of the person in Canada falls within the period beginning on December 3, 1957 and ending on December 21, 1967;
    - The person's date of birth or any other information available is consistent with maternal ingestion of thalidomide in the first trimester of pregnancy and;
    - The nature of the person's congenital malformations is consistent with known characteristics of congenital malformations linked to thalidomide.

continued on reverse

CTSSP Canada, Canadian Thalidomide Survivors Support Program
https://www.canada.ca/en/health-canada/services/canadian-thalidomide-survivors-support-program.html

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2. Application of a diagnostic algorithm for thalidomide embryopathy:

The algorithm will harness the best available international science in understanding the patterns of thalidomide embryopathy, and will yield a probability based result. It is not a definitive medical test. Regardless of the result, applicants will move to the last step.

3. Recommendation by medical-legal committee:

A medical-legal committee, established by Epiq, will consider the totality of the information related to the application and any other evidence that it considers to be relevant. This could include genetic test results and medical exams it may requisition, to inform its recommendation to the third party administrator that an individual is eligible for support under the Program.

This program is intended to help meet the lifetime needs of Canadian thalidomide survivors.

It is being delivered by Epiq Class Action Services Canada (also known as Epiq), an independent third-party service provider.

(Contact Epiq by phone: 1-877-507-7706; or e-mail: info@tsspcanada.ca)

Epiq is responsible for:

- delivering ongoing support payments
- managing the Extraordinary Medical Assistance Fund (EMAF); this fund will pay for specialized surgery, home and vehicle adjustments to accommodate survivor disabilities and some ongoing health support costs such as chiropractic care, physical therapy and attendant care
- assessing and re-assessing the health status of thalidomide survivors
- determining the eligibility of people who identify themselves as survivors of thalidomide

CTSSP Canada, Canadian Thalidomide Survivors Support Program
https://www.canada.ca/en/health-canada/services/canadian-thalidomide-survivors-support-program.html

Assistance for Australian thalidomide survivors

A blueprint for a US assistance program

What Australian thalidomide survivors received in 2019

An initial lump sum, tax-free payment of between $75,000 to $500,000 for survivors and an annual tax-free payment of between $5,000 and $60,000 scaled according to the level of disability of registered in and confirmed by the Australian Thalidomide Survivors Support Program (ATSSP) .

Access to an annual Extraordinary Assistance Fund (HCAF) to help cover the out-of-pocket health care costs associated with thalidomide-related injuries. These may include costs health products and consumables, out-of-pocket pharmaceutical and health services costs, and health related travel and transport costs.

Access to an annual Extraordinary Assistance Fund (EAF) to help cover the costs of goods and services to assist with actvities of daily living impacted as a likely result of thalidomide-related injuries. costs of Thalidomide Survivors with needs such as self-care activities, personal aids and appliances, assistive technology, vehicle modifications, home modifications, and other thalidomide-related daily living costs.

Annual ongoing support payments will continue uninterrupted for the Confirmed Thalidomide Survivor's lifetime.

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How are survivors determined eligible?

Registered thalidomide survivors are people who were recognised through either the:

- 2010 Diageo ex gratia scheme
- class action approved by the Victorian Supreme Court in 2014

Or those who successfully participated in the program's eligibility assessment process.

An eligibility assessment process was undertaken to identify previously unrecognised Australian thalidomide survivors. This process was open for applications from 1 November 2020 to 1 May 2022 and has now closed.

ATSSP Australian Thalidomide Survivors Support Program
https://www.health.gov.au/our-work/australian-thalidomide-survivors-support-program

According to
WONDER DRUG: The Secret History of Thalidomide in America and Its Hidden Victims
by Jennifer Vanderbes (Random House, 2023):

1. The Commissioner of the FDA, George Larrick, blatantly misled a Congressional committee in 1962 by declaring that the William S. Merrell Company, the drug firm which had distributed thalidomide, had "proceeded with reasonable diligence" in alerting doctors to the drug's dangers. His false statement led to the media widely declaring that the drug firm in question had been "exonerated."

2. In August 1962, President John F. Kennedy erroneously told the American public that "every doctor, every hospital, every nurse" had been "notified" of the situation -- also false. Only the day before this statement had government inspectors even begun to probe the distribution of thalidomide within the country, and the lead FDA investigator would soon determine that "many doctors gave the drug to other doctors who were not investigators and those doctors in turn gave other doctors the drug...the distribution pattern became very, very large and difficult to follow up."

3. In 1963, the FDA asked the Justice Department to bring criminal charges against the drug manufacturer. By that point, the agency was certain that at least nine babies were directly harmed by thalidomide handed out in sham "trials." Even that was an undercount; the agency, according to records detailed in WONDER DRUG, knew of many babies born with phocomelia likely passed along from trial doctors.

4. The US Justice Department told the FDA it would not bring charges because only one child in the United States had been harmed. Records show the FDA was irate that their estimate had been arbitrarily whittled down to near-zero. But the DOJ closed the case. The failure of the US government to bring the recommended criminal charges against William S. Merrell significantly hindered the ability of children harmed by the drug to later bring civil cases.

5. The FDA never acknowledged that the drug had spread widely beyond the listed trial doctors, and for years the agency refused to acknowledge injured babies if the mother's doctor had not been an official trial doctor, falsely suggesting the baby's injuries could not stem from thalidomide.

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Just a few of the US thalidomide survivors we have found.

Reviews of
WONDER DRUG: The Secret History of Thalidomide in America and Its Hidden Victims
by Jennifer Vanderbes (Random House, 2023):

Washington Post June 23. 2023 Parri Klass review of *WONDER DRUG:*
https://www.washingtonpost.com/books/2023/06/23/wonder-drug-book-thalidomide/

NPR Book of the Day July 5, 2023 Interview with Jennifer Vanderbes about *WONDER DRUG:*
https://www.npr.org/2023/06/28/1184933355/wonder-drug-traces-the-dark-history-of-thalidomide-and-the-birth-defects-it-caus

Harvard Public Health July 17. 2023 Richard J. Tofel review of *WONDER DRUG:*
https://harvardpublichealth.org/reviews/thalidomide-the-untold-american-story-in-wonder-drug/

Ralph Nader Radio Hour: July 29, 2023 Interview with Jennifer Vanderbes about *WONDER DRUG:*
https://www.ralphnaderradiohour.com/p/wonder-drug#details

Ralph Nader Radio Hour on YouTube:
July 29, 2023 Interview with Jennifer Vanderbes about *WONDER DRUG:*
https://youtu.be/kACE-4-HSeg?feature=shared

The Globe and Mail Geoff Spink Review of *WONDER DRUG:*
https://www.theglobeandmail.com/arts/books/reviews/article-wonder-drug-book-thalidomide/

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