The Story of Thalidomide: A New Chapter in Drug Regulation

Senior Division

Group Website

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The medical industry and its origins have always been an interest of ours. When the Thalidomide Tragedy appeared in our research of mid century medications, the emphasis it put on honesty between government and consumers was especially intriguing, as well as its irreversible impact on the world. Prior to our research, the intricacies of drug testing processes were a mystery to us. We did not know the tragedy that had to occur in order to develop such strict drug testing laws. The Thalidomide tragedy was a turning point for toxicity testing protocols in the United States and the rest of the world. The malformations in thousands of children led to the construction of the Kefauver-Harris amendment that forced safer drugs and a more observant FDA, it also made the importance of toxicology known to governments around the world.

We analyzed countless newspaper articles, magazines, and advertisements from the 1950s, and utilized these sources to build our evidence. We also read many sources in the Gale in Context database and the National Library of Medicine, where we found photos and historical text that was crucial to building a strong understanding of the time period as a whole. Some of our most valuable sources were newspapers. The interviews and photos we uncovered provided primary sources for us to incorporate. One of the newspapers included an interview conducted with Frances Kelsey, a key figure in our project. The interview shed light on how her involvement affected citizens of the United States, and created a more personal view of the tragedy.

Our research was organized by a collection of quotes that shaped each section of our website. For each page, we found quotes with the central ideas we wanted to include, and used

our collection of images and information to build strong support around them. We finalized the structure and color scheme before transitioning to formatting. After familiarizing ourselves with the software, we were able to start formatting our text and media. Formatting was time consuming, and it took a lot of patience to learn the software. In the end we focussed on our individual strengths, one of us focussed on media and formatting, while the other researched information and incorporated it into the project.

The Thalidomide Tragedy marked a critical turning point in history because it not only created stricter drug regulation and testing in the United States. but also in the rest of the world. The systematic protocols implemented by the U.S. government were established to protect the safety of consumers. The tragedies' irreversible effects on thousands of victims around the world emphasized the frequently overlooked field of medicine: toxicology. Understanding how harmful substances can affect the human body and environment is crucial when developing new medications. Victims of the Thalidomide Tragedy are still alive to this day, and face the consequences of the influential pharmaceutical companies and government's actions. The story can not be left in the past, as its influence is still felt greatly in our current society today.

Annotated Bibliography

Primary Sources

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This website contains photos of thalidomide in various forms. We used these photos to provide an illustration of the historical event and time period.

"FDA Will Now Watch All Test Drugs." *Evening Star* [Washington D.C.], 27 Jan. 1963, p. A-8. *Library of Congress*,

chroniclingamerica.loc.gov/lccn/sn83045462/1963-01-27/ed-1/seq-8/#date1=1953&inde x=4&rows=20&words=amendments+drug&searchType=basic&sequence=0&state=&dat e2=1963&proxtext=Amendments+and+drug&y=13&x=23&dateFilterType=yearRange& page=1\.

This was a newspaper from 1963, it contains an interview conducted with FDA menber Dr. Frances Kelsey. We quoted this newspaper.

Frances Kelsey Works with her Major Professor, E. M. K. Geiling, in the Department of

Pharmacology at the University of Chicago, around the late 1930s. Food and Drug

Administration,

www.fda.gov/about-fda/fda-history-exhibits/frances-oldham-kelsey-medical-reviewer-fa mous-averting-public-health-tragedy. Accessed 3 Feb. 2024.

This source is an image of Dr. Frances Kelsey working with a professor at Univercity of Chicago. It was used to show Kelsey's notability because of her research and degree.

"The History of the Thalidomide Tragedy." *Grunenthal*, edited by Grunenthal, www.thalidomide-tragedy.com/en/the-history-of-the-thalidomide-tragedy. Accessed 5 Feb. 2024.

This source is a website made by Grunenthal, the original manufacturer of
Thalidomide. It explains Grunenthals history and role in the Thalidomide
Tragedy. We used photos for primary sources, quotes, and different perpectives of history.

Kelsey, Frances. Interview. Conducted by Noltan Nash. *CBC News: The National*, 1962, www.youtube.com/watch?v=ykeREfe1Jpc.

This source is an interview of Frances Kelsey in 1962, after her sparing the U.S. from the devestation of the Thalidomide tragedy. We used this interview in "A Bitter Pill" to explain Kelseys view and role in drug legislation.

Kevadon. *Thalidomide Victims Association of Canada*, thalidomide.ca/en/the-canadian-tragedy/.

Accessed 6 Feb. 2024.

This source is a picture of an original Kevadon pill bottle sold in Canada. We placed it in the causes section to show the product that would have been sold in the U.S. if the FDA hadn't refused it.

Navajo Times. [volume] (Window Rock, Ariz.), 29 Aug. 1962. Chronicling America: Historic American Newspapers. Lib. of Congress.

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This source is a newspaper published in 1962 about Thalidomide and it's effects around the world. We quoted this newspaper.

The 1960s Medicine and Health: Headline Makers. Gale in Context: High School,
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=a0e553e5. Accessed 5 Jan. 2024.

This source provided photos of major figures in the Thalidomide tragedy including Frances Oldham Kelsey.

The Nome Nugget. [volume] (Nome, Alaska), 01 Aug. 1962. Chronicling America: Historic American Newspapers. Lib. of Congress.

<https://chroniclingamerica.loc.gov/lccn/sn84020662/1962-08-01/ed-1/seq-4/>
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President Kennedy Confers on Frances Kelsey the President's Award for Distinguished Federal Civilian Service in 1962. Food and Drug Administration,

www.fda.gov/about-fda/fda-history-exhibits/frances-oldham-kelsey-medical-reviewer-fa mous-averting-public-health-tragedy. Accessed 3 Feb. 2024.

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"The Shadow of the Thalidomide Tragedy | Retro Report | the New York Times." *Youtube*, New York Times, www.youtube.com/watch?v=41n3mDoVbvk. Accessed 6 Feb. 2024.

This video provides history of thalidomdide and interviews of thalidomide victims. We used a clip from this source.

"Thalidomide: Grunenthal Responds." *The Guardian (London, England)*, 15 Nov. 2014, p. 28. *Gale in Context: High School*,

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Includes Grunenthal taking responsability for Thalidomide and the company's response to event. We used quotes and photos.

"Thalidomide Victims Get Apology from Makers after Half a Century." *The Guardian (London, England)*, 1 Sept. 2012, p. 4. *Gale in Context: High School*,

link.gale.com/apps/doc/A301353771/SUIC?u=mnkdelshs&sid=bookmark-SUIC&xid=0a 67692a. Accessed 5 Jan. 2024.

Newspaper that provides information on Grunenthal's apology to Thalidomide victims, and response to tragedy. We used this for perspective on biases in the companies past.

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Thomas, Katie, editor. *The Unseen Survivors of Thalidomide Want to Be Heard*. New York Times, 23 Mar. 2020,

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Ultrasound Image of Baby with Deformity. *Collaborative for Health and Environment*, www.healthandenvironment.org/environmental-health/health-diseases-and-disabilities/bir th-defects-research-and-resources. Accessed 6 Feb. 2024.

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United States, Congress, Senate. Kefauver-Harris Amendment. Gale, 19 July 1962. *Gale in Context: High School*,

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Wellcome collection. *Safe Sedation 'Distaval'*. *Thalidomide, a Bitter Pill*, Wellcome Collection, wellcomecollection.org/articles/YIBmoBAAACgA1TRE. Accessed 4 Feb. 2024.

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The WM. S. Merrell Company. Letter to American Doctors who participated in trial. 21 Feb. 1962. *The New York Times*,

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The W.M. S. Merrell Company. Letter to American Doctors who participated in trial. 21 Feb. 1962. *The New York Times*,

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This source is a letter written by Richardson Merrell company to American doctors who participated in the experimental trials of Thalidomide. The company had applied to sell Thalidomide in the U.S. and were denied. This letter details their denial of side effects that the drugs were proven to cause.

Secondary Sources

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link.gale.com/apps/doc/A86858893/SUIC?u=mnkdelshs&sid=bookmark-SUIC&xid=4ff aed76. Accessed 5 Jan. 2024.

This website provided insight into real life families affected by Thalidomide. It tells the story of Mr. and Mrs. Moriarty, who's baby was born without arms, and were advised to give the baby up to the government, as at the time there was a

great stigma around deformed baby's. We used this source for our overall understanding of the background to this historical event.

After 60 years, Scientists Uncover How Thalidomide Produced Birth Defects. Dana-Farber Cancer Institute, 1 Aug. 2018,

www.dana-farber.org/newsroom/news-releases/2018/after-60-years-scientists-uncover-ho w-thalidomide-produced-birth-defects#:~:text=The%20degradation%20of%20SALL4%2 0interferes,a%20treatment%20for%20morning%20sickness. Accessed 26 Feb. 2024.

This website goes into specific detail on how the chemical thalidomide affects the body. It explains how thalidomide causes congenital malformations by interfering with the cell protein SALL4. We used this website to better understand the science behind it.

AIHP

aihp.org/remembering-pharmacys-past-looking-back-at-pharmacy-and-the-kefauver-hearings/. Accessed 5 Feb. 2024.

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General overview of effects, aftermath, and key figures in thalidomide tragedy.

We used it for our background knowledge.

"Contamination Ruling: Thalidomide: 'Wonder Drug' Left Babies with Deformed Limbs." *The Guardian (London, England)*, 30 July 2009, p. 5. *Gale in Context: High School*, link.gale.com/apps/doc/A204677574/SUIC?u=mnkdelshs&sid=bookmark-SUIC&xid=05 87b7ad. Accessed 4 Jan. 2024.

This website provided history of thalidomide and what the medication could be used to treat. This was an important source for our our causes background section.

Elash, Anita. "Thalidomide Is Back; A Horror Drug from the '60s May Find New Uses."

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"Frances Oldham Kelsey." *World of Health*, Gale, 2006. *Gale in Context: High School*, link.gale.com/apps/doc/K2191100206/SUIC?u=mnkdelshs&sid=bookmark-SUIC&xid=6 d05cdb4. Accessed 5 Jan. 2024.

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Kim, James H, and Anthony R Scialli. "Thalidomide: The Tragedy of Birth Defects and the Effective Treatment of Disease." *Toxicological Sciences: An Official Journal of the Society of Toxicology* vol. 122,1 (2011): 1-6. doi:10.1093/toxsci/kfr088

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This source is a video providing history and effects of Thalidomide. Also interview of victim of Thalidomide. We used it for better understanding of history.

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Provided information about history of Thalidomide, why it wasn't approved in the U.S. and what the side effects were. We used this for information on our main turning point and the effect that the FDA had in denying Thalidomide.

"Thalidomide: Timeline of a Scandal; It Has Taken Half a Century for the Victims of Birth

Defect Pregnancy Drug Thalidomide to Receive an Apology from Its German Inventors." *The Telegraph Online*, 1 Sept. 2012. *Gale in Context: High School*,

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Timeline of events directly before and after Thalidomide. Helped us understand key events and when they occured.

"Unlocking a Mystery of Thalidomide." *NewsRx Health*, 25 May 2014. *Gale in Context: High School*,

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Use of Topical Tazarotene for the Treatment of Acne Vulgaris in Pregnancy: A Literature Review.

Journal of Clinical and Aesthetic Dermatology, 1 Sept. 2020,

jcadonline.com/topical-tazarotene-in-pregnancy-review/. Accessed 26 Feb. 2024.

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Explains aftermath of Thalidomide and how regulations were put in place in U.S. Used this to understand long term impact.