

A Bitter Pill to Swallow: Dr. Kelsey's Triumph Hides an American Tragedy

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Process Paper

I am fascinated by medicine and wanted a topic that exposed a tragedy that forever changed the way we practice medicine. While exploring possibilities, I found an article about Dr. Frances Kelsey and her work with thalidomide at the Food and Drug Administration. Learning about the horrifying thalidomide tragedy in Germany, I was astounded by Dr. Kelsey's heroism and the idea that she was the reason America avoided a similar fate. Later, I realized this was not the whole story. While it is important to illustrate how thalidomide transformed clinical trials and U.S. drug approval, I feel my duty is to be a voice for affected children and their families.

I began by reading about clinical trials in America. As I continued, interviews became my most valuable sources, including in-person meetings with Christine Kelsey, Dr. Kelsey's daughter, and thalidomide survivor Gwen Riechmann. Ms. Kelsey shared her memories, her mother's insight on Merrell's thalidomide application, and six scrapbooks full of newspaper clippings. She gave me a White House ceremony program, a book by Martin Mintz, who broke the American thalidomide story, and more. Gwen Riechmann gave me private access to settlement papers between Merrell, Dr. Nulsen, and her parents during our Cincinnati interview. This interview changed the focus of my project. I realized I was neglecting the real tragedy, the American survivors, so I also conducted interviews with other thalidomide survivors. My final interview was by email with my cousin, Andrew Fuller. At first, it seemed impossible that I would be able to talk to him. He had distanced himself from his family for 40 years. Because of my work, not only was I able to interview him about thalidomide, but I reconnected him with his sisters. Finally, I toured Mary Free Bed Prosthetics Clinic, and was loaned a 1960s-era prosthetic leg for my exhibit.

I chose an exhibit because I wanted the devastating images of thalidomide-affected children to remain in focus. Doctors called them monsters and sometimes suggested infanticide. Displaying their photos invites viewers to empathize with the victims. My exhibit is designed like a bottle of thalidomide, which could have been found in the office of any American physician.

The story of thalidomide in the United States has layers of both tragedy and triumph. Conventional wisdom that only European children suffered the effects of this toxic drug, and that Dr. Kelsey saved the U.S. from its impact, is not accurate. Her triumph hid the tragedy of our broken drug approval system. Because of the reckless nature of the secretive, unregulated clinical trials, American mothers unknowingly exposed their babies to a debilitating drug. Out of this hidden tragedy, however, came positive changes that made drug trials stricter and safer. The real triumph came with the addition of the 1962 Kefauver-Harris Amendments to the 1938 Food, Drug, and Cosmetic Act. These amendments continue protecting Americans from immoral drug trials even today. Still, the tragedy remains, as almost none of the victims have been compensated or recognized by our government.

Annotated Bibliography

Primary Sources

Interviews

Blue, Ruth. E-mail interview. 25 Mar. 2019.

I reached out to Dr. Ruth Blue because she is the secretary of the Thalidomide Society in Great Britain and because she worked with Dr. Anne Borsay on the thalidomide oral histories, which I utilized on my board. This interview was also a great resource for my project because she gave me information about the oral histories she conducted and the childhoods of the people affected. Most importantly, she told me that none of the people affected in Great Britain have received compensation from Grunenthal for their struggles.

Calora, Jose. E-mail interview. 20 Apr. 2019.

This was one of the interviews I conducted with a person affected by thalidomide, Jose Calora, a member of the American Thalidomide Society. This interview helped me understand the pain these people experience on a day to day basis. Jose went into detail about the scoliosis problems he has because of thalidomide, which his mother took without knowing she was in a clinical trial.

Cronin, Eileen. E-mail interview. 15 Feb. 2019.

This interview was crucial for my project. Dr. Cronin helped me better understand the struggles she went through as a person affected by thalidomide. Not only that, but she went into detail about the drug's history in America, mostly focusing on the clinical trials and the lying of Richardson-Merrell.

---. Telephone interview. 30 Jan. 2019.

This interview with Dr. Cronin was incredibly helpful for my project. Although its direction was unstructured, she still gave me a lot of information regarding the American news coverage of thalidomide, including how many journalists contributed to the gross system of lies by not keeping up with their requirements in the U.S. newspaper Code of Ethics. Also during her interview, she talked about Dr. Frances Kelsey's impact on the number of American children born with deformities while declining Merrell's application.

Fenton, Vickie. Interview. 24 Mar. 2019.

I chose to contact Vickie Fenton because she is a family member of mine with a direct relationship to thalidomide. Vickie's mother was suspected of having used thalidomide during her pregnancy because of her brother, Andrew's, deformities. After reviewing the photos that Vickie let me look at, I could see that Andrew's limb difference was similar to children born with

phocomelia-related deformities. Even though his mother never confirmed that she took the drug, because he was born with a limb deformity during that time, it is possible that she did. This interview was also crucial because it helped me better understand my family's thoughts about Andrew.

Fuller, Andrew. E-mail interview. 30 May 2019.

I reached out and interviewed Andrew Fuller because he is an affected family member of mine. When I interviewed his sister, Vickie Fenton, I walked out of there thinking he had had it easier than most survivors I interviewed. After finally being able to talk to him about his life story, I realize how wrong my previous thought was. His story, although similar to many others regarding infanticide and tearing his family apart, is unique. Being able to read about everything this drug did to my family was an unforgettable experience. Andrew shared many things throughout our interview that he has not talked about for 40 years. I feel as though it is my duty to share his story.

Kelsey, Christine. Interview. 29 Mar. 2019.

This interview was by far my most valuable interview. Christine Kelsey is the daughter of Dr. Frances Kelsey, the heroine of my project. She was twelve years old when her mom was fighting Merrell, and she remembered the times. My mom drove me for twelve hours just to go to Ontario so I could conduct the interview in person, and it was worth it. Not only did Ms. Kelsey give me great information regarding how the media portrayed Dr. Kelsey to fit into the standards for women, but she gave me great information about her mother's contribution to the Kefauver-Harris Amendments. Another reason why this interview was crucial for my project is that Christine Kelsey gave me access to six scrapbooks full of newspapers for my project and let me keep a copy of Dr. Kelsey's awards pamphlet from the John F. Kennedy presentation, both of these being great help with primary sources.

Riechmann, Gwen. Interview. 5 Apr. 2019.

Gwen Riechmann was one of the few American thalidomide survivors to receive compensation from Merrell. I realized this when I compared the list of people affected who were willing to be interviewed from Carolyn Sampson to a *New York Times* article about the lawsuits. During spring break, I went to Cincinnati, Ohio to Ms. Riechmann's house to conduct an interview. This not only changed my thinking about my topic, but also gave me multiple primary source documents from the settlement. Being able to sit down with someone who has four deformed limbs because her mom took one pill, and just hearing what she went through, was beneficial for writing a new script.

Sampson, Carolyn. E-mail interview. 1 June 2019.

I emailed Carolyn Sampson because she is the founder of the U.S. Thalidomide Survivors Group. She originally helped me with my project by giving me the contact information for JoJo Calora, Gwen Riechmann, and more. I wanted to hear her story, as she was affected by

thalidomide, too. During the interview, she gave me great information regarding why she felt she needed to start a group, how her mom got thalidomide, and the failure of the news companies to report accurately about people with disabilities.

Documents

"Categories of Damages." Gwen Riechmann Collection, Cincinnati, 1964. Manuscript.

This was one of the primary documents Gwen Riechmann let me photograph. This specific one categorizes damages to Mrs. Riechmann that George Riechmann sued Merrell over. I thought this would be a great primary source to put on the section of my exhibit about the Riechmann settlement because you won't be able to find this paper anywhere online, only through the Riechmann family.

Food and Drug Administration. *Thalidomide : Important Patient Information*. Food and Drug Administration.

This pamphlet is very useful for my project because it shows a physical example of what the FDA was doing to regulate thalidomide. Not only that, but the pamphlet has explicit guidelines for taking thalidomide, which gave me a better perspective on how the prescribing of it to patients changed.

Ohio State, Legislature, Assembly, Ohio Department of Health. *Certificate of Live Birth*. 23 May 1962.

Another document Gwen Riechmann let me look at, her May 23, 1962, Ohio birth certificate, helped me make my point. On my board, I have a newspaper article from July 25, 1962, where Dr. Nulsen states that he never delivered any deformed babies, but to have evidence against him that he did was huge for my project.

Ministry of Health. *Reports on Public Health and Medical Subjects*. London, Her Majesty's Stationery Office, 1964.

This source helped me understand the scandal and its effects in Great Britain, and I was able to grasp the country's problems with the drug. Not only that, but this source also provided some effective pictures for my display.

Program for Presentation of The President's Award. The White House, 1962.

This is an original program from Dr. Kelsey's award ceremony, which I was given while interviewing her daughter. During the interview, Christine Kelsey went into detail about the reason why her mom's name was not on the front page of the program with everyone else's names. It intrigued me that the reason was that Dr. Kelsey was a last minute insert to the ceremony, because of the *Washington Post* article that was published. I use this program in my exhibit.

Richardson-Merrell. Letter to Jeanne S. Riechmann and George C. Riechmann. 27 Sept. 1968, Gwen Riechmann.

This was another document I accessed through Gwen Riechmann during my in-person interview with her. This one was one of her legal settlement papers with Merrell. I included this on my board because Gwen is one of the only survivors to ever be compensated for her struggles.

---. Letter to Jeanne S. Riechmann and George C. Riechmann. 30 Sept. 1968, Gwen Riechmann.

This was the other document from the Riechmann settlement that I gained access to. I wanted to include this one because it describes their agreement with Dr. Ray Nulsen.

Lecture/Tour

Brenner, Alex. "Mary Free Bed Orthotics and Prosthetics." Mary Free Bed, 19 Apr. 2019, Grand Rapids, MI. Lecture.

Alex Brenner originally helped me with my exhibit by giving me a prosthetic leg from the 1960s. I contacted him a second time about a possible tour at Mary Free Bed's orthotic and prosthetic center, and he agreed. Seeing what American prosthetics were available in the 1960s gave me a clearer understanding of the pain it caused the patients. Alex also explained how today's prosthetics have advanced but how they still follow the basic structure from the 1960s.

Oral Histories

Kelsey, Frances Oldham. "Autobiographical Reflections." PDF file.

This was one of my most valuable sources. This oral history report by Dr. Frances Kelsey helped me grasp what she was thinking during the time of the Kevadon application and why she responded as she did. It included why she thought Merrell submitted such a poor application and why she thought Merrell knew about the peripheral neuritis accusations, even though they claimed they did not. Overall, this source gave me a chance to look at my project through the perspective of someone who was involved.

"Thalidomide Lives: birth stories." *Sound Cloud*, uploaded by Dr. Ruth Blue et al., 2015, soundcloud.com/wellcomelibrary/sets/thalidomide-an-oral-history. Accessed 15 Apr. 2019.

This was one of the most informative oral histories I utilized because of the people's recollections from a young age. They told their birth stories based on what their parents had told them. Hearing how many of their doctors told the mother that killing the baby would be easier gave me a better idea of the doctors' horror and the mothers' anguish.

"Thalidomide Lives: drug companies." *Sound Cloud*, uploaded by Dr. Ruth Blue et al., 2015, soundcloud.com/wellcomelibrary/sets/thalidomide-an-oral-history. Accessed 15 Apr. 2019.

This oral history report was very helpful because it talked about how drug companies would have children affected by thalidomide perform different daily tasks. Their ability to complete these tasks determined what amount of compensation they would receive. In general, this oral history report gave me great information regarding the proceedings of drug companies.

"Thalidomide Lives: mothers' guilt." *Sound Cloud*, uploaded by Dr. Ruth Blue et al., 2015, soundcloud.com/wellcomelibrary/sets/thalidomide-an-oral-history. Accessed 15 Apr. 2019.

This report was emotionally difficult to listen to because of the people affected and what they were talking about surrounding their mothers' guilt. Many, if not all, said that even if you say that the birth defects were the government's or the drug companies' fault, their mothers would not have believed it because they were the ones who swallowed the pills.

"Thalidomide Lives: parenthood." *Sound Cloud*, uploaded by Dr. Ruth Blue et al., 2015, soundcloud.com/wellcomelibrary/sets/thalidomide-an-oral-history. Accessed 15 Apr. 2019.

I chose to use this oral history because I was curious about what it was like raising the affected children. When I saw this one and how it gave the perspective of the parents, I knew I had to utilize to it. Hearing how it affected their daily schedules worrying about their child's well-being, and the procedures some children needed, was very helpful for my exhibit.

"Thalidomide Lives: prejudice." *Sound Cloud*, uploaded by Dr. Ruth Blue et al., 2015, soundcloud.com/wellcomelibrary/sets/thalidomide-an-oral-history. Accessed 15 Apr. 2019.

I listened to this oral history because I wanted to learn more about the preconceived notions people had against thalidomide survivors. In the video, a lot of the people affected that were interviewed told about how other kids would point, stare, laugh, and more about their deformities. I also wanted to use this one because every survivor's story is different.

Books

Sjöström, Henning, and Robert Nilsson. *Thalidomide and the Power of the Drug Companies*. Penguin Books, 1972.

This source was especially useful because it gave me credible information about Richardson-Merrell and Chemie Grunenthal's impact on the FDA, from improper testing to the conflict between Richardson-Merrell and Dr. Kelsey. More specifically, it talked about the lack of information during Richardson-Merrell's approval process. The book pointed out how this tragedy reformed the American drug approval process by making it more strict.

Articles

Associated Press. "Drug That Hurt Babies Used in U.S." *The Indianapolis News*, 19 July 1962.

This newspaper was helpful because it provided me with information about Merrell contacting the doctors about the drug's toxic effects. It also gave me more knowledge about data on birth defects in Germany.

---. "Senators Call Dr. Kelsey." *The Evening Star*, 6 Aug. 1962.

I chose to use this article because it was about Dr. Kelsey testifying for the approval of the Kefauver-Harris Amendments. It was very useful because it explained Senator Kefauver's and Dr. Kelsey's specific contributions to the new drug regulations.

"A Baby Tragedy In Europe; How U.S. Escaped It." *The National Observer* [New Orleans], 30 July 1962.

This newspaper gave me great information about the evidence that was revealed about thalidomide. I also chose to use this article because of the data it had about the number of children born with defects and what countries they are from.

Burns, John F. "German Drug Maker Apologizes to Victims of Thalidomide." *The New York Times*, © 2019 The New York Times Company, 1 Sept. 2012, www.nytimes.com/2012/09/02/world/europe/grunenthal-group-apologizes-to-thalidomide-victims.html. Accessed 7 Mar. 2019.

I used this article to access a copy of the speech that Harald Stock gave apologizing on behalf of Grunenthal to the victims of their drug. The victims did not like the apology. They thought it was a scripted apology and in no way a sincere apology for their suffering.

"Development & Approval Process (Drugs)." *U.S. Food & Drug Administration*, U.S. Department of Health and Human Services, 13 June 2018, www.fda.gov/drugs/developmentapprovalprocess/default.htm. Accessed 1 Dec. 2018.

I used this website to understand the present-day drug approval process. I decided to use this article for my project because although it surrounds thalidomide and past FDA and drug company drug testing, I thought that reading about the present day would help me later on with looking at the progress. In the article, they talked not only about the FDA's process, but also

about drug development designations and how that can affect the time when a drug is put on the market.

"The Drug that left a Trail of Heartbreak." *LIFE*, vol. 53, no. 6, 10 Aug. 1962.

This source was definitely of benefit to me because of its valuable information regarding the conflict between Dr. Frances Kelsey and Richardson-Merrell. It included her reactions to the inadequate data they gave to her and what events developed from that. The magazine also gave me great details about the withdrawal of Merrell's application for their drug and the withdrawal of the drug globally. This article additionally gave me a few quotes to use for my exhibit, three photos of Sherri Finkbine, and a photo of the men of Merrell.

Hunter, Marjorie. "U.S. Finds 67 More Doctors With Supplies of Thalidomide." *The New York Times*, 4 Aug. 1962. *The New York Times*, timesmachine.nytimes.com/timesmachine/1962/08/04/83499801.html?action=click&contentCollection=Archives&module=LedeAsset®ion=ArchiveBody&pgtype=article&pageNumber=20. Accessed 14 Apr. 2019.

I used this article because it has a lot of information regarding Anthony J. Celebrezze and the "pill by pill" search for thalidomide around the U.S. The article also had great information about the link to Army wives and the drug, which helped me to better understand that part of the story.

---. "U.S. Tightening Testing of Drugs on Human Beings." *New York Times*, 10 Aug. 1962.

This newspaper was by far my most helpful because of its information about the triumph part of my project. It gave great details about the specific parts of the Kefauver-Harris Amendments and how these laws changed the process of drug approval as a result of the tragedy. Not only that, but the article also talked about Anthony J. Celebrezze, the Secretary of the Department of Health, Education, and Welfare, and his contribution to the triumph.

Landauer, Jerry. "Dr. Kelsey Fears That Thousands Have Taken Defect-Causing Drug." *The Washington Post*, 28 July 1962.

This was one of the most informative primary newspapers I had access to because it was about how Dr. Kelsey and George P. Larrick, the commissioner of the FDA at the time, dealt with Merrell and the taking away of thalidomide from physicians. The article also included how both Dr. Kelsey and Mr. Larrick talked publicly about the physicians and the amount of pills they were distributing.

Libman Block, Jean. "Dr. Kelsey's Stubborn Triumph." *Good Housekeeping*, Nov. 1962.

I used this magazine article to better understand how Dr. Kelsey was portrayed by the media, through pictures and articles. This one, in particular, was useful because it not only

described the thalidomide saga from her perspective, but also how she was treated by male representatives from Merrell.

Lyons, Richard L. "Survey Shows U.S. Doctors Gave Sedative to 207 Pregnant Women." *Washington Post*, 8 Aug. 1962.

This article was incredibly useful because it gave me data about women who took thalidomide in the United States compared to the number of Americans who took it in general. It was also useful because it talked about how Anthony J. Celebrezze, the Secretary of Health, Education, and Welfare, reported on the FDA surveys and concluded that 207 pregnant women in the U.S. had taken thalidomide.

"Medicine: Nation Checks Its Cabinets For Peril in a Pill." *Sunday News*, 29 July 1962.

I used this source to better understand how the media covered the FDA's response to the distribution of pills by Merrell. The article talked about how the FDA ordered a national "pill by pill" check to find out who had taken thalidomide and where the drugs were to that day.

Mintz, Morton. "'Heroine' of FDA Keeps Bad Drug Off Market." *The Washington Post*, 15 July 1962.

I chose to use this article because it was the first to be published in the U.S. about Dr. Kelsey's FDA work with thalidomide. All of the data had been leaked from Senator Kefauver's office and was given to the *Washington Post*. The article, in general, was very useful because of its information about Merrell's rat tests.

"Mrs. Finkbine Undergoes Abortion in Sweden." *The New York Times*, 19 Aug. 1962. *The New York Times*, timesmachine.nytimes.com/timesmachine/1962/08/19/90573225.html?pageNumber=69. Accessed 14 Apr. 2019.

This was one of the articles I chose to use from the *New York Times* archives because it had information regarding Mrs. Finkbine's abortion. I also used this article because it talked about the differences between Arizona's abortion laws and those in Sweden.

"No Drug Deformities Found in U.S. Tests." *The Evening Star* [Washington D.C.], 7 Aug. 1962.

This source was useful because it was about Mr. Celebrezze revealing the data from the FDA surveys about the number of pregnant women the drug was distributed to. I also utilized this article because of its information about the Kefauver hearings and the people who were involved.

Nulsen, R. O. "Trial of thalidomide in insomnia associated with the third trimester." *The American Journal of Obstetrics and Gynecology*, 19 June 1961.

This is the letter that was written by a Merrell representative who forged Dr. Ray Nulsen's signature, was sent out to American physicians encouraging them to support the drug getting on America's pharmaceutical market.

O'Connor, Edward F. "Dr. Kelsey to Receive Presidential Award." *Washington Post*, 10 Aug. 1962, sec. 2.

I used this source because it helped me better understand what Dr. Kelsey received before the ceremony, and what she said to the media. I also used this source because it had a part where Dr. Kelsey talked about how much financial support each of the children with phocomelia would need.

---. "Mrs. Finkbine to Seek Abortion in Sweden." *Washington Post*, 10 Aug. 1962, sec. 1.

This article helped me better understand the probability of Sherri Finkbine having a child with birth defects. The article also talked about her going to Sweden in hopes of them allowing her an abortion, and the public's reaction.

"Senators Settle for mild drug controls; Kefauver bill is toned down." *Co-Op Newsletter*, 25 July 1962.

I used this source because it helped me better understand the difference between the two proposed bills to make drug testing stricter. It shows how the Kefauver bill succeeded the Eastland-Dirksen bill. Not only that, but this article listed the specific parts of the approved Kefauver bill.

Spencer, Steven M. "The Untold Story of the Thalidomide Babies." *The Saturday Evening Post*, 20 Oct. 1962.

This is was one of the two magazines I used from the 1960s to see how the thalidomide tragedy was portrayed to American citizens. This magazine, in general, gave me great photos and quotes for my board and details about how the mothers reacted to their deformed babies.

"2 Suits Over Thalidomide Seek \$4.1 Million in Ohio." *The New York Times*, 16 Dec. 1964. *The New York Times*, timesmachine.nytimes.com/timesmachine/1964/12/16/100018698.html?action=click&contentCollection=Archives&module=LedeAsset®ion=ArchiveBody&pgtype=article&pageNumber=3. Accessed 21 Apr. 2019.

This article was the one that made me realize I needed to reach out to Gwen Riechmann for an interview. I connected this article with the list of survivors namesCarolynn Sampson gave me, which made me realize that Gwen's family was one of the only ones to ever sue. This article, in general, was helpful because it gave me the details of how much the two families were suing for.

Vindicator Washington Correspondent. "Found Drug to Be Safe Late in Pregnancy." PDF file, 25 July 1962.

I used this source as evidence to back up my analysis that Dr. Nulsen lied about delivering deformed babies and about thalidomide's effects. The article was published in late July after he had delivered three deformed babies just months before. Not only that, but this article gave me a quote to use in my project when talking about Dr. Nulsen.

Photos

A 3-year-old girl uses power-driven artificial arms fitted to her in 1965 by Dr. Ernst Marquardt of the University of Heidelberg in Germany. Tulsa World.

I thought this was a great photo for my project because the child getting fitted for the prosthetic looks very confused as it's being put on. That demonstrates how the victims, especially at a younger age, never fully understood what was happening to them.

Andrew Fuller and his mother, Dorothea. 1968, Vickie Fenton.

This was one of the photos I got from Vickie Fenton when I met to have an interview with her. I chose to use this photo because of the way Mrs. Fuller looks when she is holding her son. On my board, I have a quote by Andrew about his mother's mental state after his birth. He said she was committed to a mental hospital and was treated using electroshock therapy. The quote also says that he felt he caused it, and I thought her forced smile in this photo said it all.

Associated Press. *Dr. Kelsey reshaped American drug safety rules.* The New York Times.

I used this photo to show what the heroine of the thalidomide saga looked like. I chose this specific one because she looked very serious, and that's how she acted throughout the entire process of Merrell's Kevadon application.

Corbis. *Housewife Ironing Shirt Looking at Camera.* Magnolia box, www.magnoliabox.com/products/1950s-smiling-woman-housewife-ironing-shirt-looking-at-camera-42-45532342. Accessed 21 Apr. 2019.

I was browsing for photos of homemakers to put next to my section about the 1950s and setting the times. I thought this one was perfect because of her forced smile and exhausted eyes while working.

The defendants Mückter (right) and Dr. Sievers with their lawyers Schmitz, Waldowski and Damassiotis in front of the headquarters of Grünenthal Chemie in Stolberg. Brown History: The Contergan Inventor, Spiegel Online Photo Gallery.

During the downfall of thalidomide, people affected by the drug in Germany sued Grunenthal, the makers of the drug. I chose this photo because it shows the Grunenthal representatives leaving the courtroom after their trial. I also chose this photo because of the facial expression of Heinrich Mückter, the man who invented thalidomide.

Distillers. *Distaval thalidomide advertisement*. 1961. *Bonker Institute*, www.bonkersinstitute.org/medshow/thalidomide.html. Accessed 21 Apr. 2019.

Another one of the photos I put next to my section about the 1950s was this ad for Distaval (the name for thalidomide in Great Britain), reassuring people of its safety. I thought that showing people how drug companies advertised it would be beneficial for my project.

Dpa. *Contergan Scandal, Trial expert Lenz*. Getty Images.

I chose this photo for my project because it is of Dr. Widukind Lenz, one of the men credited with linking thalidomide to the increase of phocomelia-related birth defects. I wanted this on my board so the readers would have a visual aid to go with the paragraph.

Eileen Cronin - Author, Therapist, Thalidomider. "No Limits," Thalidomide Story.

I chose to use this photo of Dr. Eileen Cronin for my exhibit because my conclusion is based on what she said to me during an interview.

FDA. *A seized bottle of Kevadon (thalidomide)*. U.S. National Library of Medicine.

This photo shows that the design I chose for my exhibit this year was a scaled version of a bottle of Kevadon (thalidomide).

Frances Kelsey Speaking to Senate. Getty Images.

This photo was of Dr. Frances Kelsey speaking to the Senate during the hearings that Sen. Estes Kefauver conducted to question the conflict of interest between the doctors and the drug companies. She also was suggesting to add the Kefauver-Harris Amendments to the 1938 Food, Drug, and Cosmetic Act. I thought having this next to the section about the 1962 Kefauver-Harris Amendments would be a good idea.

Fuller, Harlan. *Andrew Fuller, thalidomide survivor*. 1963, Vickie Fenton.

I was shown this photo of my affected family member Andrew from his sister, Vickie Fenton, during my interview with her. I thought having a photo on my board of someone with a personal connection to me would be valuable.

John Kennedy Presenting Award. Getty Images.

I used this photo, much like the other one of JFK and Dr. Frances Kelsey, because it shows how they thought they avoided the thalidomide saga. The public believed that, too. I used it as well because of her being presented the award.

The LIFE Picture Collection. *Frances O. Kelsey*. Getty Images, www.gettyimages.com/photos/dr.-frances-kelsey?family=editorial&phrase=dr.%20frances%20kelsey&recency=anydate&sort=best&page=1&suppressfamilycorrection=true#license. Accessed 21 Apr. 2019.

I used this photo of Dr. Kelsey working on new drug data to put next to my section about her and Merrell's Kevadon application. I also used this photo because of the serious expression on her face while she was working.

McCombe, Leonard. *Child crippled by drug Thalidomide is learning to dress herself at Heidelberg Orthopedic Clinic*. The LIFE Picture Collection, Getty Images.

Immediately after I found this photo, I knew I had to use it on my exhibit because it is superior to the others. It shows how the girl suffered from phocomelia but was also learning to adapt. I put this photo right next to my thesis, so that people's eyes are immediately drawn to it.

Obstetrician William McBride who discovered risk of thalidomide to unborn babies. The Weekend Australian.

In part of my information on my exhibit, I tell about Dr. William McBride being commonly known for linking thalidomide to phocomelia, and I thought this photo was a great fit for that, especially because he's holding a baby.

Phillipa Bradbourne, a Thalidomide baby born without arms. 1963. ATI, allthatsinteresting.com/thalidomide-babies. Accessed 22 Apr. 2019.

I used this photo to show how people affected by thalidomide had to relearn daily activities. In this one, a young girl plays with her toy, but it is noticeable that she uses her feet like hands, since she does not have arms.

Richardson-Merrell. *Photo of Gwen Riechmann for Merrell Settlement*. 1968, Gwen Riechmann.

I chose to use this photo because Merrell took it four years after the lawsuit started. I thought it would be beneficial to have photos of Gwen Riechmann as a child.

Riechmann, Jeanne. *Gwen Crawling*. 1963, Gwen Riechmann.

I used this photo because it was the first one Merrell took before they settled the lawsuit with Mr. and Mrs. Riechmann. I included it because I wanted to have a variety of images of Gwen as a child.

Rowe, Abbie. *President Kennedy Signs Drug Legislation*. 10 Oct. 1962, Christine Kelsey.

I got access to this photo of the signing of the Kefauver-Harris Amendments when I was at Christine Kelsey's home in London, Ontario. I value this one over other options because it came straight from the White House when they took it at the ceremony.

Senator Estes Kefauver. 11 May 1952, *The Denver Post*.

I used this photo to show what Senator Estes Kefauver looked like when I was describing his work with the drug conflict of interest trials and the 1962 Kefauver-Harris Amendments.

Sherri Finkbine Holding Thalidomide Pills. Getty Images, www.gettyimages.com/photos/thalidomide-babies?family=editorial&phrase=thalidomide%20babies&sort=best&page=1&recency=anydate&suppressfamilycorrection=true#license. Accessed 25 Apr. 2019.

I chose to use this photo for my board because I wanted an image of thalidomide pills to go next to my section about the government doing a pill-by-pill search after thalidomide's harmful effects were discovered. I also used this one because Sherri Finkbine is holding the pills.

Sherry, Andrew, and Vickie Fuller. 1965, Vickie Fenton.

This photo is of my cousin Andrew and his two sisters. I wanted to use it on my board to show people viewing my exhibit how happy the siblings were when they were little. I also chose to use it because I have a quote by Andrew talking about how he felt like he was more of a burden than a brother to his sisters, and I thought this photo would be powerful to put next to that.

Tate, Susan. *Gwen Riechmann*. 5 Apr. 2019.

This is a photo that my mother took of Gwen Riechmann and me while I was at her house interviewing her. I cropped myself out of the photo because I wanted the viewer's focus to be on Ms. Riechmann. In the U.S. Thalidomide Survivors group photo, I have on my board of their spring meetup, most people would not be able to pick Gwen out because she was not wheelchair-bound as a child, so I put this photo on my board to help people find her in the group picture and show what she looks like now.

Thalidomide. *Onco'Zine*, Sunvalley Communication, LLC, oncozine.com/reversal-of-fortune-how-a-vilified-drug-became-a-life-saving-agent-in-the-war-against-cancer/. Accessed 22 Apr. 2019.

I used this photo of Contergan (thalidomide) for my exhibit because I needed a photo for my section about the 1950s. I liked this specific one because it had the Grunenthal logo on it.

Thalidomide Survivors lifelong search for the truth. *U.S. Thalidomide Survivors*, www.usthalidomide.org/us-thalidomide-survivors/our-story. Accessed 22 Apr. 2019.

I used this photo to show diversity within the thalidomide survivors. I had yet to find a photo of a survivor who was Hispanic or African American, so when I ran across this photo, I knew I needed it for my exhibit.

U.S. Thalidomide Survivors. 2018. *U.S. Thalidomide Survivors*, www.usthalidomide.org/. Accessed 20 Apr. 2019.

As soon as I saw this photo, I knew it was the perfect one to place next to my conclusion. My whole exhibit is based around telling the survivors' stories, and I knew that to have a photo of a couple of American survivors during their 2018 meetup was important.

Wayman, Stan. *A baby born with stunted arms because his mother took thalidomide during her pregnancy*. *Getty Images*, www.gettyimages.com/photos/thalidomide-babies?family=editorial&phrase=thalidomide%20babies&sort=best&page=1&recency=anydate&suppressfamilycorrection=true#licensing. Accessed 22 Apr. 2019.

I chose to use this photo of a boy reading because my exhibit was lacking diversity. I thought this photo would also go well with my section about thalidomide's harmful effects being unveiled to the public.

Wearing her new pneumatic arms for the first time, Christiane Allary clutches a toy dog at a Heidelberg clinic. After modifications, the arms will be covered with plastic shells. The Untold Story of the Thalidomide Babies, *The Saturday Evening Post*.

I wanted to use this photo on my exhibit because of the look on Christiane's face while her prosthetic was being adjusted. I also thought it would be an amazing example of a chest prosthetic from the 1960s, since I wasn't able to get one of these from the Mary Free Bed Clinic.

Secondary Sources

Books

A History of the FDA and Drug Regulation in the United States.

www.fda.gov/downloads/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandingover-the-countermedicines/ucm093550.pdf. Accessed 11 Feb. 2019.

This PDF of the history of the FDA and the regulations it has created was very helpful considering it's from the FDA website. I used this to find deeper information regarding the 1938 Food, Drug, and Cosmetic Act and the 1962 Kefauver-Harris Amendments. Some of the information I found dealt with the historical background of events that inspired these amendments.

The Insight Team of "The Sunday Times" of London. *Suffer the Children: The Story of Thalidomide*. The Viking Press, 1979.

This book was one of the most helpful secondary sources for my project because of its informational data and statistics about the thalidomide children and their homes. Not only that, but this book went into great detail about the process of the drug and rat tests that took place that were never released because of their toxic effects. Also, this book gave me a couple of great quotes for my project.

Junod, Suzanne White. "FDA and Clinical Drug Trials: A Short History." PDF file.

I used this source because I wanted to know more about the history of the clinical trials and specific details about how they were reshaped after certain tragedies. Not only that, but this source elaborated on the hearings Estes Kefauver had before the 1962 Amendments, and how they brought attention to the inadequate clinical trials in America. The article also explained how America did not even start having clinical trials until the public stopped associating them with medical malpractice.

Stephans, Trent, and Rock Brynner. *Dark Remedy*. New York, Basic Books, 2001.

This was my most useful secondary source book because it gave me great information about the drug's introduction in Germany and its effects in America. For instance, the company had remarkable data from its toxicity tests, making the drug superior to all other compounds. This book also talked about how Grunenthal had released a sedative before thalidomide that caused deafness, proving Grunenthal had a pattern of releasing drugs that were not tested properly.

The Sunday Times. *The Thalidomide Children and the Law*. Andre Deutsch, 1973.

This book gave me a general overview of the history of Distaval in Britain and its effects. Including how when the tragedy was first discovered, it was the subject of intense national concern, which later resulted in families having to fight for compensation. It also gave me some direct quotes for my display.

Teff, Harvey, and Colin Munro. *THALIDOMIDE: the legal aftermath*. Westmead, Saxon House, 1976.

I used this more specifically for the section about the American legal aftermath. The book focused on the state's commitment to liability with prescription drugs, specifically using Richardson-Merrell's Kevadon tragedy in the U.S. as the prime example. Finally, I used this source to learn more about the Kefauver-Harris Amendments that gave the FDA more power, and the history of the 1938 Food Drug and Cosmetic Act.

Documentaries

No Limits: The Thalidomide Saga. 2016. Directed by John Zaritsky, produced by Anne Pick.

I initially watched this film to learn more about the history and impact of Grunenthal and its victims, but as it turned out, the majority of the film focused on the individual stories of ruined childhoods. I learned the victims' personal stories and got a better understanding of the bigger picture of the pharmaceutical industry that thalidomide impacted. Not only that, but the film highlighted people's activism towards this issue and how far Grunenthal went to cover up its lies, including, having an ex-employee hide information from the court.

Thalidomide, A Wonder Drug. BBC.

I used this source to get basic knowledge about my topic. This documentary not only gave me great quotes describing details of the rat tests, but it also gave me information dealing with how thalidomide made a comeback, going from a toxic sedative that caused babies to be born with cases as severe as phocomelia, to a vital drug for patients with severe cases of leprosy and patients with multiple myelomas.

Articles

Arfons, Lisa M., et al. "The Rise, Fall and Subsequent Triumph of Thalidomide: Lessons Learned in Drug Development." *U.S. National Library of Medicine*, National Center for Biotechnology Information, 2 Oct. 2011, www.ncbi.nlm.nih.gov/pmc/articles/PMC3573415/ . Accessed 23 Nov. 2018.

Being able to read about how thalidomide has become a treatment for multiple myeloma and leprosy helped me improve my understanding of how this treatment has progressed. Bear in mind that during the 1950s and 1960s, thalidomide was commonly used as a sedative and to prevent morning sickness, which led to severe birth defects.

Bernstein, Adam, and Patricia Sullivan. "Frances Oldham Kelsey, FDA scientist who kept thalidomide off U.S. market, dies at 101." *The Washington Post*, 7 Aug. 2015, www.washingtonpost.com/national/health-science/frances-oldham-kelsey-heroiner-of-thalidomide-tragedy-dies-at-101/2015/08/07/ae57335e-c5da-11df-94e1-c5afa35a9e59_story.html?noredirect=on&utm_term=.8be35991f029 . Accessed 14 Nov. 2018.

I used this article to understand the triumph part of my project better, especially with the Food and Drug Administration and how the regulation system surrounding New Drug Applications was changed. It also talked about the federal law that was passed because of thalidomide.

Cronin, Eileen, and Michele Botwin Raphael. "Born Without Arms or Legs: The Secret Legacy of Thalidomide." *Huffington Post*, 8 Dec. 2014, www.huffingtonpost.com/eileen-cronin/thalidomide_b_5669839.html. Accessed 2 Feb. 2019.

I found this article after my phone interview with Dr. Cronin. It helped me understand more about Richardson-Merrell's impact in the United States, including the specific details regarding the number of pills distributed around the country to doctors.

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This article was written by Dr. Cronin and is one part of the series about Merrell and the United States. Specifically, it has information about the 1,267 American physicians that Merrell distributed Kevadon to and the corresponding data about the 20,000 Americans that were given it. Furthermore, it tells how a Merrell executive published a paper in the *American Journal of Obstetrics and Gynecology* under Cincinnati obstetrician, Dr. Nulsen's name. This paper was trying to get thalidomide into the hands of more obstetricians around the U.S.

---. "Part II: When Mad Men Met a Sedative — False Hype, Fake Numbers and Untold Birth Defects." *Huffington Post*, 26 Nov. 2014, www.huffingtonpost.com/eileen-cronin/part-ii-when-mad-men-met-_b_5763378.html?1411752662. Accessed 7 Feb. 2019.

This source was a follow up to "Part One" of this series. It filled in some specific details that were not included in the first article, as well as information regarding Dr. Nulsen and the babies he delivered because of the pill.

"The Death and Afterlife of Thalidomide." *The New York Times*, 23 Sept. 2013, www.nytimes.com/2013/09/23/booming/the-death-and-afterlife-of-thalidomide.html. Accessed 11 Feb. 2019.

This documentary on thalidomide's history in America was of much use for my project for many reasons. One is that it gave me great quotes for my exhibit, including one from President John F. Kennedy and another from Rock Brynner, the Author of *Dark Remedy*, who was interviewed for the documentary. This source also gave me information dealing with the use

of the drug now, and how it had to be approved by a group of victims before it could be allowed again on the market for leprosy and multiple myeloma. Even now, it is the most restricted drug on the United States market, proving we have learned our lesson.

Hoffmann, Roald. *The Same and Not The Same*. PDF file, Columbia UP, 1995.

I used a chapter out of this PDF about Dr. Nulsen's trial where he admitted he did not write the article promoting thalidomide. I have a section on my board where I talk about all of the lies that surrounded Dr. Ray Nulsen about thalidomide, and I thought to have a document proving he lied about the article would be great evidence for proving my point.

Kaplan, William. "This is Dr. Frances Kelsey's story." *The Globe and Mail*, London, 11 May 2017, www.theglobeandmail.com/news/national/one-canadian-doctor-kept-thalidomides-harm-from-america/article34961202/. Accessed 25 Nov. 2018.

This source was especially helpful because the author wrote it based on an interview he conducted with Dr. Frances Kelsey. Before he shared the information about Dr. Kelsey, he went into a short history of thalidomide and how it was marketed. The interview part of the article not only gave me many quotes from Dr. Kelsey, but also talked about the struggles she went through while voting down thalidomide. One issue was the sexism she experienced from Merrell's representatives.

"Kefauver-Harris Amendments Revolutionized Drug Development." *U.S. Food and Drug Administration*, 10 Sept. 2018, www.fda.gov/ForConsumers/ConsumerUpdates/ucm322856.htm. Accessed 11 Feb. 2019.

I used this article to understand what Sen. Kefauver's ideas were for the hearings he led in the late 1950s, dealing with the topic of conflict of interest between the doctors and the drug companies. This source also talked about the results of the Kefauver-Harris amendments and how they revolutionized the process of clinical trials to the point where we still use the same system today.

McFadden, Robert D. "Frances Oldham Kelsey, Who Saved U.S. Babies From Thalidomide, Dies at 101." *The New York Times*, 7 Aug. 2015, www.nytimes.com/2015/08/08/science/frances-oldham-kelsey-fda-doctor-who-exposed-danger-of-thalidomide-dies-at-101.html . Accessed 14 Nov. 2018.

This article talks about Kevadon, Merrell's name for thalidomide, and how Merrell attempted to sell it, including the company providing over 1,000 doctors with samples because it was legal during the 1950s - 1960s to do so, even before the FDA approved the drug for sale.

Because of this, America still had thalidomide children born, even though Kevadon was not legal, unlike how other countries who experienced the thalidomide tragedy had legalized it. Finally, the article mentions how, because of the thalidomide tragedy, a federal law was passed to give the FDA more control over drug companies and having them provide more information about their drug.

McNeill, Leila. "The Woman Who Stood Between America and a Generation of 'Thalidomide Babies'." *Smithsonian.com*, 8 May 2017, www.smithsonianmag.com/science-nature/woman-who-stood-between-america-and-epidemic-birth-defects-180963165/. Accessed 25 Nov. 2018.

This article focused on how countries discovered the birth defects connected to thalidomide and a side effect for adults taking it, peripheral neuritis. When it talked about the peripheral neuritis side effect, it mentioned that in a December 1960 issue of the *British Medical Journal*, multiple adults came forward saying that they were experiencing painful tingling, which doctors knew was inflammation of the peripheral nerves. This led some to wonder, if it affects the arms of fully-developed people, what would be the effect on the unborn? Finally, the article mentioned that during November of 1961, physicians in Germany and Australia found out that mothers who took thalidomide during early pregnancy had infants with birth defects.

"Milestones in U.S. Food and Drug Law History." *U.S. Food and Drug Administration*, 1 Feb. 2018, www.fda.gov/aboutfda/history/forgshistory/evolvingpowers/ucm2007256.htm. Accessed 11 Feb. 2019.

This source, similar to the PDF I used to learn about the timeline of FDA Acts and Amendments, had a great deal of information. Unlike the other source, this one went into further detail about what the FDA would have been doing at the time of these acts.

Raza, Azra. "Rx: Thalidomide And Cancer." *3 Quarks Daily*, 3 Apr. 2006, www.3quarksdaily.com/3quarksdaily/2006/04/rx_thalidomide_.html. Accessed 20 Apr. 2019.

This was an interview of Rock Brynner, the author of *Dark Remedy*, that was transferred into an article. I used it for reading what Brynner had to say about thalidomide and for a couple quotes for my board.

Tantibanchachai, Chanapa. "US Regulatory Response to Thalidomide (1950-2000)." *The Embryo Project Encyclopedia*, Arizona Board of Regents, 1 Apr. 2014, embryo.asu.edu/pages/us-regulatory-response-thalidomide-1950-2000. Accessed 11 Feb. 2019.

This was the first source I used to learn about the quick changes made after the thalidomide saga that had long-lasting effects on America's pharmaceutical market. I also used this article because of its information about the doctors who made some of the first observations linking thalidomide to peripheral neuritis and birth defects.

Williams, Roger. "The Nazis and Thalidomide: The Worst Drug Scandal of All Time."
Newsweek, 10 Sept. 2012,
www.newsweek.com/nazis-and-thalidomide-worst-drug-scandal-all-time-64655.
Accessed 5 Dec. 2018.

While reading this, I learned a great deal of information about Grünenthal and how they hired convicted Nazis, one of which was Heinrich Mückter, who is credited with the making of thalidomide. Mückter worked on possible anti-typhus vaccines during World War II, which he would test on prisoners, leading to him being responsible for hundreds of deaths. The Polish government wanted to put him on trial after the war. Instead, he was offered a new life working with Grünenthal, where he later developed thalidomide.