

Dr. Frances Kelsey and the Thalidomide Outbreak

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Historical paper

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What was originally marketed as a sedative, turned out to be a dangerous pill for a fetus, as well as being the reason for death for thousands of deceased fetuses, as well as causing more to be born with birth defects. It should be noted that Thalidomide was a sedative produced in Germany by a company named Grünenthal and sold by the company Merrell, around the world. Furthermore “The drug was popular in Germany, and sold over the counter (without a prescription) as a sleeping tablet, sedative, and tranquilizer—for both adults and, in liquid form, for children. (An American pediatrician called it ‘West Germany’s babysitter.’)”¹. Undoubtedly Merrell sent an application to the FDA to sell Thalidomide in the US; their case was given to Dr. Frances Kelsey (Oldham), the newest member of the FDA in 1960 as an easy start to her job. But in the process of her work the news started reporting (some) newborns with birth defects, one baby was born with no arms at all, and it just had little toes where its feet should even be. Subsequently, the baby had no eyes, because the nerves did not develop in the eyes, and it had no ears as well...they couldn’t tell the gender of the baby because its genitalia were all mixed up as well ² (see Appendix I). Indeed What was viewed as an easy head start to her position in the FDA turned out to be a complicated battle that would save multiple lives and change history. During her fight to keep Thalidomide out of the US (prescription) drug market, Dr. Frances Kelsey became a symbol for women to take action and have integrity. First and foremost she prevented the death of multiple babies caused by Thalidomide. Furthermore, her discovery pushed the Kefauver-Harris Drug Amendment to be passed, which extended the FDA’s authority. In Addition to this Dr. Frances Kelsey developed to become a woman with a legacy to remember.

¹ Thalidomide: The American experience

² Mikey Argy - Thalidomide Survivor Interview | Lorraine

“Three scientists were needed to approve a new drug – a chemist, a pharmacologist, and a medical officer. In the case of thalidomide, these scientists were Lee Geismar (chemist), Jiro Oyama (pharmacologist), and Dr. Frances Kelsey (medical officer). Her role was to review the safety and efficacy of the drug. All three scientists found problems with the application to approve thalidomide;”³ not to mention that Merrell put thalidomide through some animal studies to supplement what it believed was the “basic research” already done in German. “Among the concern of Dr. Frances Kelsey concerns was the lack of data indicating whether the drug could cross the placenta, which provides nourishment to a developing fetus.”⁴ without hesitation Dr. Frances Kelsey took facts before the theories of Merrell and prevented this tragedy from reaching the US. By resisting the pressure put on her by Merelle, Dr. Frances Kelsey prevented this particular Drug form being distributed (commercially) in this country⁵. Not to mention, Dr. Frances Kelsey made an exceptional decision of ignoring Merrell, even though they were a compelling company. “she refuse to be hurried into approving an application for marketing a new drug. It should be noted that she regarded its safety as unproven, despite considerable data arguing that it was ultra safe.”⁶ Along with one of those claims stating that Thalidomide was suicide-proof “the development of thalidomide seemed to have been a breakthrough, largely because it was ‘suicide-proof.’(One man was reported to have swallowed 140 pills, slept for several days and awaked with merely a bad hangover.)”⁷

³ Frances Kelsey- Famous Scientists

⁴ THE THALIDOMIDE TRAGEDY: LESSONS FOR DRUG SAFETY AND REGULATION

⁵ Press Conference, 1 August 1962

⁶ 'Heroine' of FDA Keeps Bad Drug Off Market

⁷ Thalidomide: the American experience

Evidently Dr. Frances Kelsey made sure that her work was elegant and that all statements wouldn't put the lives of Americans in jeopardy. Furthermost Dr. Frances Kelsey stood up for what she believed in, keeping compelling companies like Merrell from bringing tragedy to families in the US. In doing so Dr. Frances Kelsey saved the lives of future generations by keeping Thalidomide from reaching the next generation. With her probing analysis of Merrell's application and her insistence on scientific rigor, Dr. Frances Kelsey ensured that the effects in the United States were far more limited.⁸

Andrea Tones from Ted-Ed said, "Dr. Frances Kelsey's life-saving work was almost prevented by the gender biases of the 1930's"⁹ As a woman starting out with her career, Dr. Frances Kelsey was underestimated because she was able to do the work that was demanded from her from the beginning. "I went to school quite early, with my brother, who was two years older, and I kept up with him."¹⁰ said Dr. Frances Kelsey Even at such a young age she was already showing signs of responsibility and self-care as much as her older brother. Particularly when she was put in the school it might have been difficult for her since she was younger than her brother, but she ended up doing an exquisite job. In that event starting early meant finishing high school early at the blossoming age of 15.¹¹ In particular the normal age of graduating high school is 18, but Dr. Frances Kelsey took advantage of her head start and finished early, "proving that women can compete at top academic institutions"¹². Regardless of the fact that Dr. Frances Kelsey has accomplished her education early, When Dr. Frances Kelsey Oldham applied

⁸ The Public's Quiet Savior From Harmful Medicines

⁹ How one scientist averted a national health crisis - Andrea Tone

¹⁰ Alumna and Hero: An Interview with Dr. Frances Oldham Kelsey

¹¹ How one scientist averted a national health crisis - Andrea Tone

¹² National Women's Hall OF Fame- Dr. Frances Kelsey Oldham

to the University of Chicago she received letter starting with a “Mr. Oldham”, with a misconception of her name being a masculine name. Dr. Frances Kelsey later joked about saying “that had her name been Elizabeth of Marie Jane her career might have ended there”¹³. But as much as she joked about this misconception Dr. Frances Kelsey had to tragically say this “When a woman took a job in those days, she was made to feel as if she was depriving a man of the ability to support his wife and child.” “But my professor said: ‘Don’t be stupid. Accept the job, sign your name and put “Miss” in brackets afterward.’ ”¹⁴

For her hard work and courage of keeping Thalidomide out of the US, “Dr. Frances Kelsey was listed as one of top 10 admired woman in America in 1963”¹⁵ (mostly for her action and her bravery) this would have pushed her actions furthermore of proving that girls can compete at the top of the academic institution. Dr. Frances Kelsey also received the President's Award for Distinguished Federal Civilian Service on August 7th, 1962 (see Appendix 2),¹⁶ she was the second woman to receive this award – the highest award the government gives to civilians¹⁷. This was truly a favorable broadcast considering that she was a symbol (for woman to take actions and have integrity). For her vigilance, Dr. Frances Kelsey received numerous honors and awards. She was also called to testify before Congress on legislation to strengthen drug safety oversight. This would change the forthcoming considering that Merrell's test were not compatible with the regulation of the FDA.

¹³ How one scientist averted a national health crisis - Andrea Tone

¹⁴ The Public's Quiet Savior From Harmful Medicines

¹⁵ Dan Carpenter on "Reputation and Power at the FDA"

¹⁶ Distinguished Federal Civilian Service, 7 August 1962

¹⁷ National Women's Hall OF Fame- Dr. Frances Kelsey Oldham

A speech by president John F. Kennedy, says “I am pleased to approve this bill (see Appendix 3), which is designed to provide safer and more effective drugs to the American consumer...Fortunately, prior to the revelation of the dangers posed by drugs like thalidomide, the foundation for legislative action on drugs had been laid down.”¹⁸ “Moreover, Dr. Frances Kelsey helped write the rules that now govern nearly every clinical trial in the industrialized world, and was the first official to oversee them.”¹⁹ Also most of the clinical trials of Merrell were fraud and possibly lethal. “In 1959 Merrell started sending thalidomide to doctors for tests on humans...the doctor did not have to tell patients the drug was experimental. Merrell shipped about 2.5 million thalidomide pills to more than a thousand American doctors, who gave some of the pills to about 20,000 patients, including many women of childbearing age”²⁰. By refusing to accept this drug not only did she stop it from reaching the US’s (prescription) drug market, she shined the spotlight on the FDA’s flaws. “Which helped the Kefauver-Harris Amendments of 1962 update the Food, Drug, and Cosmetic Act of 1938 (FDCA) to abolish the 60-day time limit for FDA reviews and require animal testing before human trials can begin, among other measures. It also added efficacy to safety as a criterion for approval.”²¹

President John F. Kennedy in a press conference said this after the thalidomide outbreak, about the 1962 amendment. “In the terrible association between the drug and these very severe birth defects the havoc wrought by this led to the 1962 amendments of the law.”²² Dr. Frances Kelsey was a huge inspiration and symbol that her integrity helped rewrite the FDA, making sure that the only drugs that get passed through the FDA are the ones who will help the US society,

¹⁸ REMARKS ON SIGNING DRUG REFORM BILL, 10 OCTOBER 1962

¹⁹ The Public’s Quiet Savior From Harmful Medicines

²⁰ Thalidomide: the American experience

²¹ Bureaucracy Can Save Lives – The Legacy of Dr. Frances Kelsey

²² UVic Legacy Awards - Dr. Frances Oldham Kelsey -- Alumni Legacy Award

and prevent other mislabeled drugs like Thalidomide from ever reaching the US. “She became director of the agency’s Office of Scientific Investigations, and in a distinguished 45-year career with the FDA helped rewrite the nation’s medical-testing regulations, strengthening protections for people and against medical conflicts of interest. The rules have been adopted worldwide.”²³

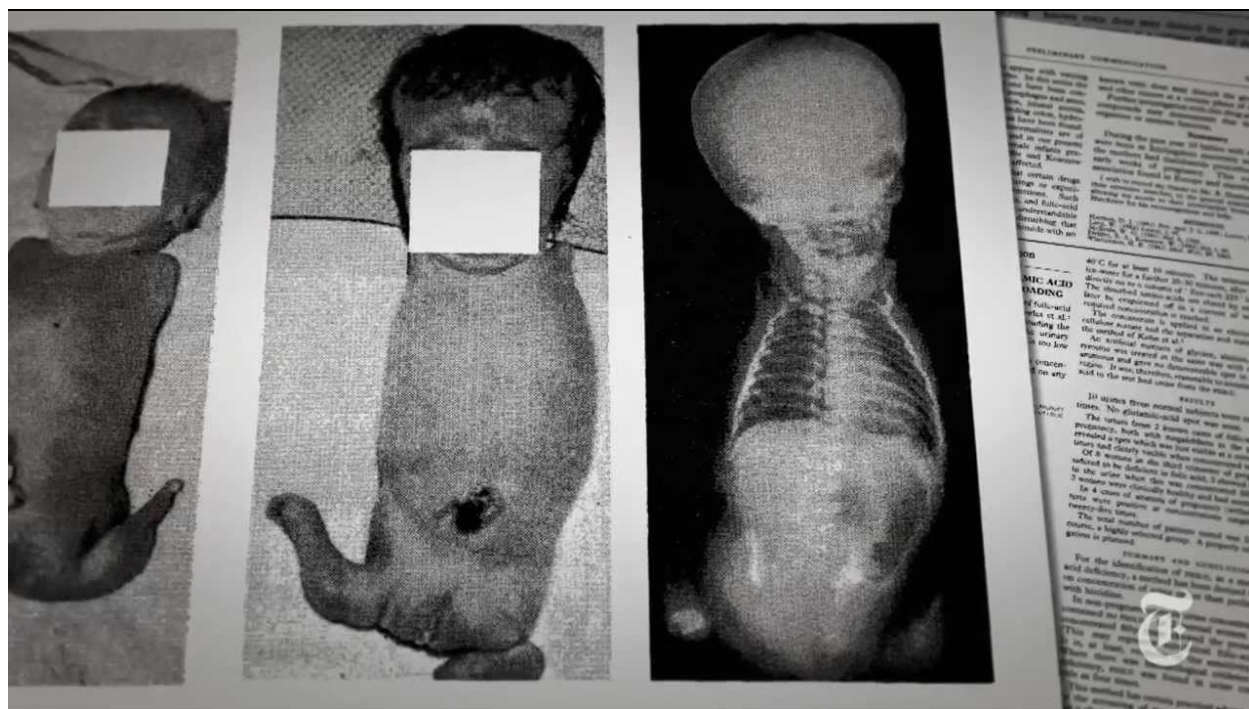
Dr. Frances Kelsey strengthens the safety medically and her work was such a huge inspiration that her impact became worldwide. Her work might have just saved people from thalidomide but in doing so she saved the lives of future generations from drug crisis. “Kefauver-Harris Drug Amendments passed to ensure drug efficacy and greater drug safety. For the first time, drug manufacturers are required to prove to FDA the effectiveness of their products before marketing them.”²⁴ Her work was replicated into a law that makes sure that facts came before theories, the law also reflected the integrity that she showed in her work.

It is with courage and integrity that Dr. Frances Kelsey was able to hold back from the pressures of Merrell. During her fight to keep Thalidomide out of the US Dr. Frances Kelsey became a symbol for women to take action and do what is right. She prevented the death many of children and birth defects caused by Thalidomide; her discovery pushed the Kefauver-Harris Drug Amendments to be passed, which extended the FDA’s authority. As a working woman, Dr. Frances Kelsey was underestimated and was looked over, but in response, Dr. Frances Kelsey became the spotlight of the world. She proved to the U.S. government that short cuts on pharmaceutical testing can be dangerous, and can cause lots of damage.

²³ Frances Oldham Kelsey, Who Saved U.S. Babies From Thalidomide, Dies at 101

²⁴ Promoting Safe and Effective Drugs for 100 Years

Appendix I



This picture shows babies victim of the thalidomide effects on babies in a newspaper in the NYT video.

The shadows of the thalidomide tragedy

Appendix II



This picture shows Dr. Frances Kelsey Oldham being presented with the Distinguished Federal Civilian Service in 7 August 1962, JFK library.

AR7400-L. President John F. Kennedy Presents President's Award for Distinguished Federal Civilian Service to Dr. Frances Oldham Kelsey

Appendix III



This picture shows President John.F Kennedy offering a pen to DR. Frances Kelsey after he signed them for her to sign in 1962, JFK library.

BILL SIGNING - S. 1552 PUBLIC LAW 87-781, DRUG INDUSTRY ACT OF 1962, 9:45 AM

Annotated Bibliography

Primary sources

Kennedy, John Fitzgerald. "Remarks on Signing Drug Reform Bill, 10 October 1962." JFK Library, 10 Oct. 1962.

He also talks about the steps being done to prevent event like this from happening in the future. I used this information to prove the fact that things in the FDA will change after the thalidomide outbreak, and that Dr. Frances Kelsey was a huge influence in the change.

"Mikey Argy - Thalidomide Survivor Interview | Lorraine." Performance by Mikey Argy, *Mikey Argy - Thalidomide Survivor Interview | Lorraine*, Lorraine, 22 Mar. 2006, www.youtube.com/watch?v=LnD_MHgr820.

In this interview by Lorraine, Mikey argy (a thalidomide survivor) talks about how thalidomide affects the victims and the family of victims. She also talks about a thalidomide victim that she saw on TV. This information helped me Realize that thalidomide would have affect more people that just the victims and would have hurt many people.

"PRESS CONFERENCE, 1 AUGUST 1962." Performance by John Fitzgerald Kennedy, *PRESS CONFERENCE, 1 AUGUST 1962*, 1 Aug. 1962, www.jfklibrary.org/asset-viewer/archives/JFKWHA/1962/JFKWHA-116/JFKWHA-116.

In This recording President John F. Kennedy thanks Dr. Frances Kelsey for keeping thalidomide out of the US. I used this piece of evidence to argue that Dr. Frances Kelsey was the one who kept thalidomide out of the US.

"UVic Legacy Awards - Dr. Frances Oldham Kelsey – Alumni Legacy Award." *UVic Legacy Awards - Dr. Frances Oldham Kelsey – Alumni Legacy Award*, UVIC, 9 Dec. 2010, www.youtube.com/watch?v=eVSVkO2btdg.

In this interview of Dr. Frances Kelsey by the university of victoria, she talks about how she was concerned for the safety that thalidomide had on pregnancy. She also talks about how the thalidomide outbreak lead to the 1962 drug amendment. Used this Evidence to prove that Dr. Frances Kelsey had a roll in the change of laws that occured in the FDA that would later save lives by preventing other outbreaks from happening due to the stronger cautions taken.

Secondary sources

"Dan Carpenter on 'Reputation and Power at the FDA.'" Performance by Dan Carpenter, *Dan Carpenter on "Reputation and Power at the FDA"*, 16 Dec. 2010, www.youtube.com/watch?v=OhtHf3JhXOw.

This video talks about the book *Reputation and Power*, and goes over the main ideas of the book, but especially about Dr. Frances Kelsey. I used this to prove that what she did had to be huge for her to be the top most admired woman in 1963.

"Frances Kelsey." Famous Scientists. famous-scientists.org. 25 Apr. 2017. Web. 2/21/2019
<www.famousscientists.org/frances-kelsey/>.

This article talks about the life of Dr. Frances Kelsey, her beginning and her education. It also talks about how she played a huge role in keeping thalidomide out of the US. I used this article to give credit to the other people who were aware of the side effects of thalidomide and shared it with the world so that Dr. Frances Kelsey had more evidence to prove that thalidomide was dangerous.

"Frances Kelsey Oldham." *Woman Hall of Fame*, www.womenofthehall.org/inductee/frances-oldham-kelsey/.

This article claims that Dr. Frances Kelsey proved that women can compete at top academic institutions. I used this claim to support the fact that she started school early with her older brother, and finished early, so she must have been at the top of the academic institution. I also used this article to argue that she was the second woman to ever receive the Distinguished Federal Civilian Service, 7 August 1962, so what she did must have been brave.

Fintel, Bara, et al. "THE THALIDOMIDE TRAGEDY: LESSONS FOR DRUG SAFETY AND REGULATION." *Helix*, 28 July 2009, helix.northwestern.edu/article/thalidomide-tragedy-lessons-drug-safety-and-regulation.

This article talks about how thalidomide started out in Germany, and how Dr. Frances Kelsey prevented it from reaching the US because of its unproven facts and statements. I used this to argue that Dr. Frances Kelsey cared and was concerned about the effects that thalidomide had on babies with her past experiments.

GENG, Veronica. "Thalidomide: the American Experience." *Thalidomide: the American Experience*, 29 Apr. 1973, www.nytimes.com/1973/04/29/archives/thalidomide-the-american-experience.html.

I used this article to find evidence on why Dr. Frances Kelsey declined the application of Thalidomide.

HARRIS, "The Public's Quiet Savior From Harmful Medicines." *The New York Times* , 13 Sept. 2010, www.nytimes.com/2010/09/14/health/14kelsey.html.

This article talks about how Dr. Frances Kelsey prevented thalidomide from reaching the US, it also talks about how she changed the FDA. I used this to prove that Dr. Frances Kelsey was vigilant with her work, and watched out for unproven statement that might have been said about thalidomide by Merelle. I used this to prove that there was a gender bias against her, even in a professional workplace. I also used this to prove that she changed the FDA after the thalidomide outbreak. .

Mintz, Morton. "Heroine of FDA Keeps Bad Drug off Market." *Washington Post* , Jan. 1962, www.washingtonpost.com/wp-srv/washtech/longterm/thalidomide/keystories/071598drug.htm?noredirect=on.

This article talks about the process of Dr. Frances Kelsey keeping thalidomide out of the US. It also talks about her heroism, stubbornness and her strength. I used this evidence to prove that she was very clear on what was safe and not for the fetus.

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.

This article talks about the legacy of Dr. Frances Kelsey oldham, and the impact she made on the world, It also talks about her heroism in keeping thalidomide out of the US.

Tone, Andrea, director. *How One Scientist Averted a National Health Crisis - Andrea Tone. How One Scientist Averted a National Health Crisis - Andrea Tone*, 7 June 2018, www.youtube.com/watch?v=4wIBCoxuOJ0.

This TED-Ed video talks about the legacy of Dr. Frances Kelsey, it also talks about her time in the FDA. I used this to prove that there was gender biases in her time at the FDA and before that. I also used this to argue that since Dr. Frances Kelsey started school early she would finish early.

Watts, Geoff. "Frances Oldham Kelsey." *The Lancet*, 3 Oct. 2015, [www.thelancet.com/journals/lancet/article/PIIS0140-6736\(15\)00339-6/fulltext#articleInformation](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)00339-6/fulltext#articleInformation).

This article talks about the life of Dr. Frances Kelsey's life, and her education. It also talks about the other people required to keep thalidomide out the US. I used this to argue that Dr. FRances kelsey was strong and was able to hold back from the pressure of Merrell, and that in doing so she saved the US.

Process paper

My Project is about Dr. Frances Kelsey and how she was stepping stone in history for woman. I choose this topic because it was about a woman who was brave and stood up for what she believed in, no matter what people said about her. Dr. Frances Kelsey was a woman who changed the US, even though there were wrong things done to her and I wanted to learn about how she overcome those obstacles. She was also a great hero that wasn't recognized as often now as she was when the when people found out what she did for them, so I thought if I learned something about her I could teach others what she did.

My research wasn't too hard to do, but I had to learn a lot about her early life so I Had some information about her, and so I can get comfortable telling her story. Finding primary sources was quite hard because I had to know the exact type of information in order to look for it. That was sometimes hard because I didn't know what type of information I needed and just wanted to read through papers and look for random ones. Most websites offered a lot of pieces of information about her and that was good to start with. But as the project got deeper, I found myself going back out the same sources for different parts because they were the most trusted that kept coming up. The videos I watched were mostly interviews with Dr. Frances Kelsey, and I mostly learned about her background and her victories.

I choose to write a paper about Dr. Frances Kelsey because I felt that her story was long and couldn't fit in a poster. A documentary would also just be of pictures of her, and there aren't that many available to the public's view. I also wanted to write a paper because the rules of NHD about the papers were styles that I have not experienced yet and wanted to learn something new about writing.

Dr. Frances Kelsey Oldham and thalidomide outbreak fits into the NHD theme Triumph and Tragedy very well. This story is about a woman who triumphantly save millions of american babies, helps change the us, and women's history. But during these times there was a lot of tragic gender biases toward her, and especially because she was a woman working a man's job. Even though the triumph surpasses the tragety, Dr. Frances Kelsey's story is about strength integrity and courage and not about the tragedy of the gender biases.