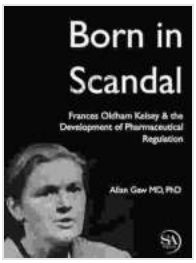
Frances Oldham Kelsey: The Development of Pharmaceutical Regulation



Born in Scandal: Frances Oldham Kelsey & the Development of Pharmaceutical Regulation

4.5 out of 5

Language	: English
File size	: 1935 KB
Text-to-Speech	: Enabled
Enhanced typesetting	: Enabled
Print length	: 48 pages
Lending	: Enabled
Screen Reader	: Supported

Frances Oldham Kelsey was a Canadian-born American pharmacologist who played a pivotal role in the development of pharmaceutical regulation in the United States. She is best known for her work on the drug thalidomide, which was found to cause birth defects. Kelsey's actions prevented thalidomide from being marketed in the United States, and she is credited with saving the lives of thousands of children.

Kelsey was born in Cobourg, Ontario, Canada, on July 24, 1914. She earned her bachelor's degree in pharmacy from the University of Toronto in 1936 and her master's degree in pharmacology from the University of Chicago in 1938. After graduating, she worked as a research pharmacologist at the University of Rochester for several years.

In 1960, Kelsey joined the Food and Drug Administration (FDA) as a medical officer. She was assigned to review the application for thalidomide, a new drug that was being developed by the German pharmaceutical company Grünenthal. Thalidomide was being marketed in Europe as a safe and effective treatment for morning sickness.

Kelsey was not convinced that thalidomide was safe. She noted that the drug had not been adequately tested in humans, and she was concerned about its potential side effects. She also raised concerns about the lack of information about the drug's effects on pregnant women.

Despite pressure from Grünenthal and the FDA, Kelsey refused to approve thalidomide for marketing in the United States. Her decision was based on her belief that the drug was not safe and that it could cause serious harm to pregnant women.

Kelsey's decision was vindicated in 1961, when it was discovered that thalidomide caused birth defects. The drug was responsible for over 10,000 birth defects in Europe, including many cases of phocomelia, a condition in which babies are born with missing or deformed limbs.

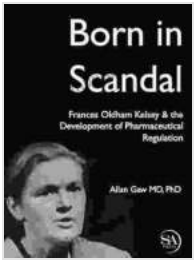
Kelsey's actions prevented thalidomide from being marketed in the United States, and she is credited with saving the lives of thousands of children. Her decision also led to a major overhaul of the FDA's drug approval process. The FDA now requires that all new drugs be adequately tested in humans before they can be marketed.

Kelsey's work has had a lasting impact on the development of pharmaceutical regulation. She is considered to be one of the most

influential figures in the history of the FDA, and her legacy continues to inspire others to work for the protection of public health.

Additional Resources

- Frances Oldham Kelsey - FDA
- Frances Oldham Kelsey and the Thalidomide Disaster: A Case Study in the Regulation of New Drugs - NCBI
- The Woman Who Saved Thousands of Babies From Thalidomide - The Atlantic



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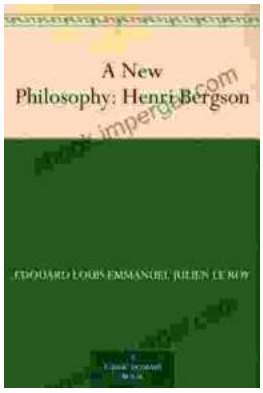

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