AIMS For a better birth...

Obituary of Frances Oldham Kelsey, 1914-2015

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By Marein Schmitthenner, doula and AIMS volunteer

Frances Oldham Kelsey was a Canadian-American pharmacologist and physician. As a reviewer for the U.S. Food and Drug Administration (FDA), she saved thousands of babies from thalidomide by refusing to authorise the drug for the U.S. market due to safety concerns. Her stance led to much tougher drug testing and new laws regulating pharmaceuticals.



Frances Oldham was born on Vancouver Island in British Columbia on 24 July 1914, the daughter of Frank and Katherine Stuart Oldham. She had an unusual career for a woman at the time – she earned a master's degree in science in 1935 and a PhD in pharmacology in 1938. By 1942, she was studying possible cures for malaria at the University of Chicago. This led her to become increasingly interested in drugs that pass from mother to fetus through the placenta.

She got married in 1943 and she and her husband had two daughters. She continued her studies and received a medical degree from the University of Chicago in 1950.

After working as an editorial associate for the American Medical Association Journal, teaching pharmacology and practicing general medicine, in 1960 she accepted a job with the FDA, evaluating applications for licenses to market new drugs.

The pharmaceutical company Merrell's application to licence thalidomide, a sedative that had been developed in Europe and was widely sold there since 1957, was one of the first cases Frances dealt with in her new job. Although the company claimed the drug was safely giving people deep, natural sleep and doctors had already been prescribing it to pregnant women in other parts of the world to suppress

nausea, Frances found the safety evidence to be insufficient. She withheld approval and asked for more data on toxicity from controlled studies. A battle lasting months with Merrell ensued, during which time Frances was called 'stubborn' and 'unreasonable', but, luckily for thousands of American babies, she did not give in. About a year later, reports started to flood in from Europe and Africa about horrendous side effects and babies born with terrible malformations of their limbs. Merrell withdrew its application and the drug never made it onto the American market.

Dr. Kelsey's strength of character and courage are all the more amazing considering the laws on the safety of pharmaceuticals were not rigorously enforced at the time. She could have done what everyone else at the FDA was doing, with approval often being routine, but Dr. Kelsey was a very intelligent woman and not easily fooled. She acted according to strict scientific and ethical principles and according to her own strong morals, and she was not afraid to speak up for what she believed in.

The Kennedy administration used the Thalidomide tragedy to pass stronger drug regulations, and the 1962 law required tighter proof of safety and effectiveness of new drugs, disclosure of side effects and the swift removal of unsafe drugs from the market.

Dr. Kelsey moved on to head up the Division of Scientific Investigations of the FDA, which ensured the scientific integrity of the data on which the agency's decisions on drugs were based.

Her contributions have been widely recognized through Presidential and other awards. In 2000, she was inducted into the National Women's Hall of Fame.

Francis Oldham Kelsey died on 7 August 2015 in her daughter's home in London, Ontario, Canada.