

# Frances Oldham Kelsey: Nevertheless, She Persisted

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Eight years ago, when I was touring New Zealand, I walked into a travel agency and was greeted politely by the middle-aged receptionist. With her short, flipper-like arms, the woman pointed me towards a desk containing the touring pamphlets that I had requested.

The receptionist, as my Kiwi friend told me later, was “a thalidomide baby”.

Most people of a certain age remember the notorious sedative thalidomide, which in the late 1950s and early 1960s was given for morning sickness to thousands of pregnant women in Europe, Britain, Canada, the Middle East, and elsewhere.

The drug was never approved for use in the United States. And thus, the tragedy of thalidomide babies -- born with severely deformed limbs and other major birth defects -- was averted in America. For this, we can thank one person, and one person only: a young medical officer at the U.S. Food and Drug Administration (FDA) by the name of Frances Oldham Kelsey.

Dr. Kelsey died in 2015 at the age of 101. As we celebrate Women’s History Month, she is one of my favorite heroines.

Dr. Kelsey was new to the FDA post -- responsible for reviewing requests to license new drugs -- in September 1960 when the application to market thalidomide landed on her desk. Since the drug had “already been sold to pregnant women in Europe,” recounted her obituary in The New York Times, “the application seemed routine, ready for the rubber stamp.”

The former family doctor and teacher in South Dakota, however, saw some data on the drug’s safety that troubled her. She requested more information from the drug’s manufacturer, the William S. Merrell Company of Cincinnati.

The company “stood to make millions and was anxious to get moving,” according to The Times. “It had tons of [the drug] in warehouses, ready for marketing, and 1,000 American doctors had already been given samples for ‘investigational’

research. The company supplied more data, but also mounted a campaign to pressure Dr. Kelsey. Letters, calls and visits from Merrell executives ensued. She was called a fussy, stubborn, unreasonable bureaucrat.”

But Dr. Kelsey would not be hurried. She persisted.

The doctor did her own research and discovered that the drug hadn't even been tested on pregnant animals. She told Merrell that the drug might affect the limbs of fetuses. The company called her evidence “inconclusive.”

Six months later, “European reports indicated that the drug was linked to an epidemic of phocomelia, a rare but monstrous malformation of limbs in newborns.” Merrell withdrew its application.

No one knows, said The Times, “how many babies were affected by thalidomide, but estimates range into the tens of thousands in Europe alone. Many were born without arms or legs, some with no limbs or with withered appendages protruding directly from the trunk. Some had no external ears or deformities of the eyes, the esophagus, or intestinal tracts.”

In response to the public uproar that followed, in 1962 Congress passed the Kefauver-Harris amendments to the Federal Food, Drug and Cosmetic Act, requiring manufacturers to prove that a drug was not only safe but also effective. The new law also required full disclosure of side effects and generic names, and quick removal of unsafe drugs from the market.

The 1962 legislation ensured that “the best drugs and treatments rose to the top, not simply those that were most heavily marketed,” says Dr. Margaret Hamburg, who served as FDA Commissioner under President Obama.

President Trump last week nominated Dr. Scott Gottlieb, a conservative health policy expert with extensive ties to the pharmaceutical industry, as his new FDA Commissioner. Gottlieb has served on the boards of several drug companies, and received more than \$400,000 in payments from Big Pharma companies between 2013 and 2015, according to a federal database.

Mr. Trump has said he wants to slash regulations and speed up drug approvals by the agency. I'm sure that Dr. Kelsey, who went on to have a distinguished 45-year career with the FDA and who, in 2000, was inducted into the National Women's Hall of Fame, would counsel the new administration to tread carefully here.

We should remember the thalidomide babies, and thank Dr. Kelsey that  
“nevertheless, she persisted.”

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