

Physician to be honored for historic decision on thalidomide

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It was a straightforward assignment for a newcomer to the Food and Drug Administration, such a simple task that Frances Oldham Kelsey was given a cubbyhole of an office and the bare basics to get it done: review an application from a drug company to market a new sedative called Kevadon.

The drug was already widely used in Britain, Germany and about 20 other countries and it was a lucrative success for its manufacturer, the William S. Merrell Co., which was eager to get it into medicine cabinets in the United States.

At the time, in 1960, Americans were dazzled by vaccines, antibiotics and the vast array of new discoveries defining modern life.

But Kelsey, a physician and a pharmacologist, questioned the safety of Kevadon, the brand name for thalidomide, and refused approval. "It just came with so many extravagant claims that I didn't believe," Kelsey, now 96, said Monday in an interview at her Bethesda home.

The drug company pushed back and started an intense campaign, repeatedly calling and meeting with Kelsey and her superiors, including the FDA commissioner.

Kelsey was steadfast, and her resistance became the stuff of legend when it turned out that thalidomide caused severe birth defects in thousands of babies born in Europe and elsewhere. The drug had been prescribed for women to help them sleep or manage morning sickness. The babies often had malformed arms or legs or extra appendages.

As a young researcher at the University of Chicago, Kelsey had been concerned about the dangers that drugs can have on fetuses, and she held that in mind as she handled the thalidomide case.

Kelsey was celebrated as a heroine, and President John F. Kennedy gave her the highest civilian honor, making her the second woman to receive it. She wore a new dress from Garfinckel's for the occasion, she said.

To mark the 50th anniversary of Kelsey's action, FDA Commissioner Margaret A. Hamburg will present her with the first Kelsey Award on Wednesday, an honor that will be given regularly to an FDA employee to "celebrate courage and scientific decision-making."

The thalidomide case transformed the way Americans think about medicine, said Morton Mintz, a former Washington Post reporter who broke the story of Kelsey and thalidomide in 1962. Images of deformed babies underscored the dangers of drugs, and the need for careful scientific vetting by regulators, he said.

"Until that point, people used to think that science, technology and the drug industry could bring only progress," Mintz said. "People used to think new is necessarily better. But Kelsey nurtured a healthy skepticism in the public and the news media."

The United States was not entirely spared in the thalidomide tragedy. Merrell gave the drug to more than 1,000 U.S. physicians to distribute to 20,000 patients as part of an "investigational" trial. In many cases, the patients were not informed they were participating in an experiment. An estimated 40 babies in the United States were born with deformities as a result.

The scandal prompted Congress to amend the drug law in 1962 to impose strict limits on the testing and distribution of new medication. The regulations required that drugs had to be proved safe and effective, and that patients had to give

informed consent to participate in clinical trials. It also required that the manufacturer report any adverse reactions to the FDA.

After the law was changed, the FDA created a division of new drugs and made Kelsey the director of scientific investigations. Her principal responsibility for the rest of her career in the agency was directing drug testing.

Kelsey was moved from a prefabricated building from World War I that had been erected on the Mall to a new campus in Maryland.

The FDA used her story and image as a recruiting tool, said John P. Swann, a historian at the agency, pointing to a recruiting poster that featured Kelsey's image and the moniker "Drug Detective."

"Most civil servants toil in anonymity," he said. "Here is this woman, almost a Peter Gunn figure, decorated by one of the most beloved presidents. She inspired not just a lot of people to come to the FDA but to realize what a contribution a single person could make."

Kelsey retired from the FDA in 2005 at age 90 but not before recording two oral histories for the agency's archives. "There's just a lot of love around here for her," Swann said.

Despite tougher legislation, critics, consumer groups and public interest organizations say the FDA remains under constant pressure from the companies it regulates.

Last year, the agency took the unusual step of announcing that it was reevaluating its approval of a knee-surgery device after an internal review found that its staff may have been swayed by political pressure. Also last year, a federal court ruled that the FDA bowed to political pressure when it limited access to the emergency contraceptive called Plan B to women older than 18.

Today, Kelsey spends her time playing bridge, watching birds at the feeders on her windowsills and completing crossword puzzles in ink. Her days are punctuated by a glass of sherry at 11 a.m. and an old-fashioned cocktail at 5 p.m.

But 50 years later, the details of her decision and the complex drug names roll off her tongue easily. And on Wednesday, she will return to visit the agency where she made history.

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