

= Frances Oldham Kelsey =

Frances Kathleen Oldham Kelsey , CM ( July 24 , 1914 ? August 7 , 2015 ) was a Canadian pharmacologist and physician . As a reviewer for the U.S. Food and Drug Administration ( FDA ) , she refused to authorize thalidomide for market because she had concerns about the drug 's safety . Her concerns proved to be justified when it was shown that thalidomide caused serious birth defects . Kelsey 's career intersected with the passage of laws strengthening FDA oversight of pharmaceuticals . Kelsey was the second woman to be awarded the President 's Award for Distinguished Federal Civilian Service by President John F. Kennedy .

= = Birth and education = =

Born in Shawnigan Lake on Vancouver Island , British Columbia , Kelsey was graduated by St. Margaret 's School high school at age 15 , and attended Victoria College , British Columbia ( 1930 ? 1931 ) in Victoria , British Columbia ( now University of Victoria ) . She then enrolled at McGill University to study pharmacology . At McGill , she received both a B.Sc. ( 1934 ) and a M.Sc. ( 1935 ) in pharmacology , and " on [ a ] professor 's urging , wrote to EMK Geiling , M.D. , a noted researcher [ who ] was starting up a new pharmacology department at the University of Chicago , asking for a position doing graduate work " . Geiling presumed that Frances was a man and offered her the position . Kelsey accepted and began working for Geiling in 1936 .

During her second year , Geiling was retained by the FDA to research unusual deaths related to elixir sulfanilamide , a sulfonamide medicine . Kelsey assisted on this research project , which showed that the 107 deaths were caused by the use of diethylene glycol as a solvent . The next year , the United States Congress passed the Federal Food , Drug , and Cosmetic Act of 1938 . That same year she completed her studies and received a Ph.D. in pharmacology at the University of Chicago . Working with Geiling led to her interest in teratogens , drugs that cause congenital malformations .

= = Early career and marriage = =

Upon completing her Ph.D. , Kelsey joined the University of Chicago faculty . In 1942 , like many other pharmacologists , Kelsey was looking for a synthetic cure for malaria . As a result of these studies , Kelsey learned that some drugs are able to pass through the placental barrier . While there she also met fellow faculty member Dr. Fremont Ellis Kelsey , whom she married in 1943 .

While on the faculty at the University of Chicago , Kelsey was awarded her M.D. during 1950 . She supplemented her teaching with work as an editorial associate for the American Medical Association Journal for two years . Kelsey left the University of Chicago in 1954 , decided to take a position teaching pharmacology at the University of South Dakota , and moved with her husband and two daughters to Vermillion , South Dakota , where she taught until 1957 .

She became a dual @-@ citizen of Canada and the United States in the 1950s in order to continue practicing medicine in the U.S. , but retained strong ties to Canada where she continued to visit her siblings regularly until late in life .

= = Work at the FDA and thalidomide = =

In 1960 , Kelsey was hired by the FDA in Washington , D.C. At that time , she " was one of only seven full @-@ time and four young part @-@ time physicians reviewing drugs " for the FDA . One of her first assignments at the FDA was to review an application by Richardson Merrell for the drug thalidomide ( under the tradename Kevadon ) as a tranquilizer and painkiller with specific indications to prescribe the drug to pregnant women for morning sickness . Even though it had already been approved in Canada and more than 20 European and African countries , she withheld approval for the drug and requested further studies . Despite pressure from thalidomide 's manufacturer , Kelsey persisted in requesting additional information to explain an English study that documented a

nervous system side effect .

Kelsey 's insistence that the drug should be fully tested prior to approval was vindicated when the births of deformed infants in Europe were linked to thalidomide ingestion by their mothers during pregnancy . Researchers discovered that the thalidomide crossed the placental barrier and caused serious birth defects . She was hailed on the front page of The Washington Post as a heroine for averting a similar tragedy in the U.S. Morton Mintz , author of The Washington Post article , said " [ Kelsey ] prevented ? the birth of hundreds or indeed thousands of armless and legless children . " Kelsey insisted that her assistants , Oyam Jiro and Lee Geismar , as well as her FDA superiors who backed her strong stance , deserved credit as well . The narrative of Dr. Kelsey 's persistence , however , was used to help pass rigorous drug approval regulation in 1962 .

After Morton Mintz broke the story in July 1962 , there was a substantial public outcry . The Kefauver Harris Amendment was passed unanimously by Congress in October 1962 to strengthen drug regulation . Companies were required to demonstrate the efficacy of new drugs , report adverse reactions to the FDA , and request consent from patients participating in clinical studies . The drug testing reforms required " stricter limits on the testing and distribution of new drugs " to avoid similar problems . The amendments , for the first time , also recognized that " effectiveness [ should be ] required to be established prior to marketing . " The new laws were not without controversy .

As a result of her blocking American approval of thalidomide , Kelsey was awarded the President 's Award for Distinguished Federal Civilian Service by President John F. Kennedy , becoming the second woman to receive that award . British Pathé released a film of Kennedy acknowledging Kelsey in a speech . After receiving the award , Kelsey continued her work at the FDA . There she played a key role in shaping and enforcing the 1962 amendments . She also became responsible for directing the surveillance of drug testing at the FDA .

Kelsey retired from the FDA in 2005 , at age 90 , after 45 years of service . In 2010 the FDA named the Kelsey Award for her , to be awarded annually to an FDA employee .

= = Later life and death = =

Kelsey continued to work for the FDA while being recognised for her earlier work . She was still working at the FDA 's Center for Drug Evaluation and Research in 1995 and was appointed deputy for scientific and medical affairs . In 1994 , the Frances Kelsey Secondary School in Mill Bay , British Columbia was named in her honour . She retired in 2005 .

In 2010 , the FDA presented Kelsey with the first Drug Safety Excellence Award and named the annual award after her , announcing that it would be given to one FDA staff member annually . In announcing the awards , Center Director Steven K. Galson said ? I am very pleased to have established the Dr. Frances O. Kelsey Drug Safety Excellence Award and to recognize the first recipients for their outstanding accomplishments in this important aspect of drug regulation . ?

Kelsey turned 100 in July 2014 , and shortly thereafter , in the fall of 2014 , she moved from Washington , D.C. , to live with her daughter in London , Ontario . In June 2015 , when she was named to the Order of Canada , Mercédes Benegbi , a thalidomide victim and the head of the Thalidomide Victims Association of Canada , praised Dr. Kelsey for showing strength and courage by refusing to bend to pressure from drug company officials , and said ? To us , she was always our heroine , even if what she did was in another country . ?

Kelsey died in London , Ontario , on August 7 , 2015 at the age of 101 , less than 24 hours after Ontario 's Lieutenant @-@ Governor , Elizabeth Dowdeswell , visited her home to present her with the insignia of Member of the Order of Canada for her role against thalidomide .

= = Legacy and awards = =

1962 ? President 's Award for Distinguished Federal Civilian Service

1963 ? Gold Key Award from University of Chicago , Medical and Biological Sciences Alumni Association

2000 ? Inducted into the National Women 's Hall of Fame

2001 ? Named a Virtual Mentor for the American Medical Association

2006 ? Foremother Award from the National Research Center for Women & Families

2010 ? Recipient of the first Dr. Frances O. Kelsey Award for Excellence and Courage in Protecting Public Health given out by the FDA

2012 ? Honorary doctor of science degree from Vancouver Island University

2015 ? Named to the Order of Canada