Frances Oldham Kelsey trained as a pharmacologist at McGill University, Montreal and completed her PhD and MD at the University of Chicago where she became interested in drugs that cause birth defects.

In 1960 Kelsey began working at the US Food and Drug Administration (FDA). During her first month of employment, Kelsey received an application from the pharmaceutical company Richardson Merrell to begin mass-marketing the drug thalidomide in the United States. The drug had already been sold to pregnant women in Europe, Africa, Australia and Canada to prevent morning sickness. Kelsey was not convinced the drug was safe, and repeatedly denied the company’s request to market the drug, citing the insufficient availability of clinical trials to establish risks. The company complained to Kelsey’s bosses, calling her a petty, fussy, and stubborn bureaucrat.

Kelsey’s stand was vindicated in 1961 when reports from Europe began appearing, linking thalidomide to numbing in the arms and legs, and then to malformation of foetal limbs. The Australian researcher William McBride had also written a letter to The Lancet drawing attention to the link between the drug and birth defects. Studies eventually revealed that more than 10,000 children worldwide had birth defects linked to the drug and it was finally withdrawn from sale.

Kelsey was hailed a hero and the case was used by the Kennedy Administration to pass stronger drug regulations. She received the President’s Award for Distinguished Federal Civilian Service in 1962 from John F. Kennedy, and in 2000 was inducted into the National Women’s Hall of Fame.