

THALIDOMIDE Related Web Sites

Look at many of the following web sites and determine if YOU would have given approval for the drug thalidomide in 1962. Have reasons for your opinions.

Terms to be familiar with: efficacy, teratogenic, MER/32, LD₅₀

Thalidomide Task Force – Fact Sheet

<http://www.waramps.ca/news/thalid/89-02-14a.html>

The Many Faces of Thalidomide

<http://www.thalidomide.ca/english/faces.html>

Center for Drug Evaluation and Research – History

<http://www.fda.gov/cder/about/history/indexs.htm> (people)

<http://www.fda.gov/cder/about/history/indexs.htm#T> (subject)

http://www.the-scientist.com/asp/Registration/login.asp?redir=http://www.the-scientist.com/yr2001/jan/lewis_p1_010122.html

Background

<http://www.arachnoiditis.co.uk/parisian-6.htm>

Quackwatch

<http://www.quackwatch.org/13Hx/MM/19.html>

<http://health.yahoo.com/health/drugs/k.html>

Minds On Science – Web Course on the Art of Teaching Science

http://scied.gsu.edu/Hassard/mos/mos_ch1.PDF

Calls for Reform

http://www.rsna.org/REG/research/officersdev/fda_rad/reform.html

Vivisection

<http://vivisection-absurd.org.uk/thalid.html>

Frances Kelsey

http://collections.ic.gc.ca/heirloom_series/volume6/218-219.htm

The Mighty Oak Was Once a Little Nut

<http://www.thevisionpaper.com/articles/2000/Oct252000/editorial.htm>

Corrections

<http://keithlynch.net/cryonet/15/06.html>

Chemical Repository

http://ntp-server.niehs.nih.gov/htdocs/Chem_H&S/NTP_Chem5/Radian50-35-1.html

Thalidomide

http://www.library.duq.edu/eresources/clinref/datasets/patch_f/html/chapter/mono/hf123330.htm

History

<http://www.sisp2.net/~waynerod/thalidomide/HTML/history.htm>

<http://www.pharmacology2000.com/General/Introduction/Introobj1a.htm>

The Nature of Science

<http://scied.gsu.edu/Hassard/mos/1.6.html>



A more recent example of courage is the case involving Dr. [Frances Oldham Kelsey](#). In a book entitled, *Women of Courage*, Frances Kelsey is referred to as "the doctor who said no." After earning a Ph.D. in pharmacology (an infant field of science at the time she earned her degree), and then a medical degree from the University of Chicago, she moved with her husband and two children to Washington, and took a job with the Food and Drug Administration (FDA) in Washington. Her job was to evaluate applications for licenses to market new drugs. In the Fall of 1960, shortly after she arrived at the FDA, the William S. Merrell Company applied for a license to market a new drug called [Kevadon](#). Kevadon was a sleeping pill. It had been used all over the world, was very effective in relieving pregnant women from morning sickness, and was very profitable. Truman describes how Frances Kelsey showed great courage as a scientist in the case of Kevadon:

'While Merrell's application was being reviewed by Kelsey at the FDA, they were distributing two thousand kilograms of the drug. At the time this was a legal practice as long as the drug company labeled the drug "experimental." Merrell, in their advertising and marketing materials, informed their salespeople that they had firmly established the safety, dosage and usefulness of the drug by both foreign and U.S. laboratory clinical studies. They had not.

At the FDA, Merrell's application was being reviewed. Dr. Kelsey and her research team were not satisfied with the information Merrell provided as part of their application. For example, the drug when administered to animals showed no sign of toxicity but did not make the animals sleepy. The drug was being distributed to humans as a sleeping pill. Two days before the 60 day approval period was up, Dr. Kelsey told the Merrell Company that their application was not approved and would have to submit further information.

This initial rejection (November 10, 1960) of Merrell's application to distribute the drug was followed by a series of episodes between Dr. Kelsey and the Merrell Company. There were attempts by the Merrell Company to go over Kelsey's head and in so doing try to embarrass her in front of her superiors. This did not work. Merrell even supplied research reports supposedly documenting the safety of the drug. Upon investigation it was discovered that the researcher's name that appeared on the report did not even write it. And Merrell threatened Kelsey with a law suit saying that one of her letters to them was libelous. Through all this Kelsey stood firm and boldly held her ground. It culminated with the banning of the drug in December 1961 when thalidomide had been traced to an outbreak of deformities in new born babies by the thousands in Europe. Then in 1963, the American public was stunned when they read stories and saw the horrible pictures in their newspapers that one gallant woman doctor had stood between them and a repetition of this disaster in the United States. On August 7, 1963 President Kennedy present Dr. Kelsey the Distinguished Federal Civilian Service Medal. Kennedy applauded Dr. Kelsey's work saying she had defended the hopes that all of us have for our children. The courageous behavior of Frances Kelsey also lead to an increase in the FDA's staff and a change in the laws regulating the distribution and sale of drugs to humans" (Truman, 1978)

Two Books on the Subject:

Suffer the Children: The Story of Thalidomide

The Insight Team of "The Sunday Times" of London

The Viking Press; New York, 1979

Fine, Ralph Adam, The Great Drug Deception Stein and day, New York, 1972
(outstanding book to give a chronological narrative of what happened)