could be brought to market. The New Drug Application (NDA) process had been born.

The new laws were not without flaws, however, as applications for marketing approval would be automatically approved if the FDA did not act within a set period of time. In addition, companies were not required under the new law to demonstrate that their products were effective. These issues would be addressed in later legislative and regulatory proceedings, but for all intents and purposes, the Food, Drug, and Cosmetic Act of 1938 established the framework of the modern drug approval system.[127]

The Thalidomide Story[128]

The commercialization and subsequent withdrawal from market of Thalidomide is perhaps one of the most compelling and tragic events in the history of drug discovery and development. Originally prepared in 1954 by scientists at Chemie Grünenthal GmbH, a German pharmaceutical company, Thalidomide was studied clinically soon after it was patented. By July of 1956, safety studies on animals had demonstrated that it was nearly impossible to achieve a lethal dose of the drug, so it was licensed for sale as an over-the-counter sleep aid in Germany and most of Europe. Use among pregnant woman increased significantly when it was discovered that Thalidomide was also useful as an antiemetic for the suppression of morning sickness, and the drug was marketed under as many as 37 different names worldwide.

Unfortunately, Thalidomide turned out to be far more dangerous than expected. While animal safety studies did indicate a lack of acute toxicity, other safety issues were not studied, especially those related to the effects of a drug on a developing fetus. The prevailing theory on fetal development during the 1950s was that the placenta provided perfect protection to a developing fetus, protecting it from any drugs or toxic material ingested by the mother. As such, few, if any, studies were performed to determine the safety of new drugs during pregnancy. If such testing had been done, Thalidomide would probably have never made it out of the labs at Chemie Grünenthal GmbH. In the absence of such testing, Thalidomide was used by thousands of pregnant women across the globe, but by 1959 questions began to arise about the true safety of the drug. In 1960, reports of peripheral neuropathy after long term usage began to appear in England, although the manufacturer continued to insist that the drug was safe. Frances Oldham Kelsey, an FDA physician assigned to review the Thalidomide New Drug Application, refused to provide marketing approval, however, insisting that additional safety studies were necessary before Thalidomide could be approved in the United States.