Elixirs, Diluents, and the Passage of the 1938 Federal Food, Drug and Cosmetic Act

Abstract

The Elixir Sulfanilamide disaster of 1937 was one of the most consequential mass poisonings of the 20th century. This tragedy occurred shortly after the introduction of sulfanilamide, the first sulfa antimicrobial drug, when diethylene glycol was used as the diluent in the formulation of a liquid preparation of sulfanilamide known as Elixir Sulfanilamide. One hundred five patients died from its therapeutic use. Under the existing drug regulations, premarketing toxicity testing was not required. In reaction to this calamity, the U.S. Congress passed the 1938 Federal Food, Drug and Cosmetic Act, which required proof of safety before the release of a new drug. The 1938 law changed the drug focus of the Food and Drug Administration from that of a policing agency primarily concerned with the confiscation of adulterated drugs to a regulatory agency increasingly involved with overseeing the evaluation of new drugs. The Elixir Sulfanilamide tragedy, its effect on drug regulations, and the history of other diethylene glycol and diluent mass poisonings are discussed.