Senator Royal S. Copeland, a physician and former New York City health commissioner, worked to reform the old statute, and argued (3):

> *A law which permits the continued manufacture and sale of utterly worthless remedies for cancer, tuberculosis, diabetes, and other maladies considered incurable by such means, is certainly defective. Because their manufacturers cannot be shown to know that their products are worthless creates a legal situation which is unbearable. That actually poisonous cosmetics and injurious slenderizing compounds can be distributed without interference from the Federal Government is positively indecent.*

b. Federal Food, Drug and Cosmetic Act of 1938

Efforts to reform the 1906 law produced the Federal Food, Drug and Cosmetic Act of 1938 (4). Passage of this new law was motivated, in part, by the fact that in 1937, 105 people died after ingesting a drug marketed as "Elixir Sulfanilamide," where the deaths resulted from the excipient, ethylene glycol. The Elixir Sulfanilamide disaster of 1937 occurred shortly after the introduction of sulfanilamide, the first sulfa antimicrobial drug. Under the existing drug regulations, premarketing toxicity testing was not required. Elixir Sulfanilamide was manufactured and sold by the S.E. Massengill Company of Bristol, Tennessee. About 240 gallons were manufactured. Since the Federal Food and Drugs Act contains no provision against dangerous drugs, seizures had to be based on a charge that the word "elixir" implies an alcoholic solution, whereas this product was a diethylene glycol solution. Had the product been called a "solution," rather than an "elixir," no charge of violating the law could have been brought (5).

The elixir was manufactured as shown in Table 31.1 (6). No tests had been made to determine the toxicity of the separate ingredients or of the finished product.

The Federal Food, Drug and Cosmetic Act of 1938 created a new drug approval process under which the FDA had 60 days to reject a new drug application. After 60 days, if the FDA had not acted, the drug was automatically approved. Under this law, the FDA had the option of requiring drug sponsors to provide evidence of safety before marketing the drug. But the 1938 law did not require evidence of efficacy (7).

In 1937, George P. Larrick led a team of FDA inspectors in tracking down Elixir Sulfanilamide and, in effect, served as the "point man" for gathering evidence that

[3] 78 Congressional Record 4,572 (March 15, 1934), reprinted in Dunn C. FEDERAL FOOD, DRUG, AND COSMETIC ACT 88 (1938).

[4] Merrill RA. Regulation of drugs and devices: an evolution. *Health Aff (Millwood)*. 1994;13:47–69.

[5] Report of the United States Secretary of Agriculture. Elixir sulfanilamide-Massengill. *California and Western Medicine*. 48:68–70.

[6] Report of the United States Secretary of Agriculture. Elixir sulfanilamide-Massengill. *California and Western Medicine*. 48:68–70.

[7] Nelson RJ. Regulation of investigational new drugs: "giant step for the sick and dying"? *Georgetown Law J*. 1988;77:463.