

Table 31.1 Manufacture of Elixir Sulfanilamide by S.E. Massengill Co

Component	Quantity
Sulfanilamide	58.5 pounds
Elixir flavor	1 gallon
Raspberry extract	1 pint
Saccharin soluble	1 pound
Amaranth solution	1.5 pints
Caramel	2 fluid ounces
Diethylene glycol	60 gallons
Water q.s.	80 gallons

argued for the passage of the Federal Food, Drug and Cosmetic Act of 1938. Mr. Larrick received an undergraduate degree in Ohio, and in 1923 became a food inspector in Cincinnati, Ohio. At a later time, Mr. Larrick served as the Commissioner of the FDA, that is, in the years 1954–1965 (8).

But at the time of the Federal Food, Drug and Cosmetic Act of 1938, the FDA Commissioner was Walter G. Campbell. Mr. Campbell received a law degree from the University of Louisville in 1905, where he helped enforce Kentucky's food and drug laws. Campbell was selected by Harvey Wiley to be chief inspector at the FDA, where he enforced inspections of whiskey, milk, eggs, vinegar, oysters, and medicines marketed by charlatans, that is, "patent medicines" (9). Campbell, FDA Commissioner from 1921 to 1924 and 1927 to 1944, was to the Federal Food, Drug and Cosmetic Act of 1938 what Harvey Wiley was to the 1906 Act.

In 1960, thalidomide was characterized as a new sedative that "produces no toxic effects when administered orally to animals in massive doses," and that was found to have "no deleterious side effects and does not affect the heart, respiration or autonomic nervous system" (10). However, in 1961, the drug was implicated in an epidemic of congenital malformations (11). Pregnant women who took thalidomide to relieve morning sickness delivered babies without arms or legs, some blind, and some mentally retarded. There were about 8,000 such deformed births (12).

The requirement for efficacy for regulatory approval was motivated, in part, by the thalidomide tragedy. In 1962, partially as a result of the thalidomide disaster, Congress amended the 1938 Act to strengthen FDA control over new drugs. The amendments

⁸ Editorial. Personal profile: George P. Larrick. *J Agric Food Chem.* 1956;6:572 (one page only).

⁹ Hickmann MA. *The Food and Drug Administration.* Hauppauge, NY: Nova Science Publishers; 2003.

¹⁰ Somers GF. Pharmacological properties of thalidomide (alpha-phthalimido glutarimide), a new sedative hypnotic drug. *Br J Pharmacol Chemother.* 1960;15:111–116.

¹¹ Diggle GE. Thalidomide: 40 years on. *Int J Clin Pract.* 2001;55:627–631.

¹² Nelson RJ. Regulation of investigational new drugs: "giant step for the sick and dying"? *Georgetown Law J.* 1988;77:463.