

While limited in its scope, this first attempt to ensure the safety of drugs had far reaching consequences for the pharmaceuticals industry, as it established the foundation upon which the Food and Drug Administration (FDA) would eventually be built. “Dangerous” drugs such as cocaine, heroin, alcohol, and morphine could no longer be used as secret ingredients in medicines, although they could still be included as long as they were accurately labeled. In addition, the U.S. Pharmacopeia¹²⁴ and the National Formulary¹²⁵ were put in place as the authorities for drug composition and formulation. More importantly, however, the new law provided the Bureau of Chemistry in the U.S. Department of Agriculture, the authority to establish a group of federal inspectors to enforce the laws. These inspectors were empowered to seize and destroy material found to be in violation of the new law (at the company’s expense) and provide publication of all violations that occurred. Although direct financial penalties were modest, the prospect of negative publicity and physical loss of manufactured materials became a major tool in enforcing drug regulations.

The Elixir of Sulfanilamide Disaster of 1937¹²⁶

Although the Pure Food and Drug Act of 1906 set the stage for further improvements in the regulation of the pharmaceuticals industry, the law was far from adequate. The law provided no guidance or requirements for the safety of drugs brought to market. As is often the case, a disaster of some type would be required before this would change. Thus, in 1937, the S. E. Massengill Company began marketing a new formulation for the antibiotic sulfanilamide under the name Elixir of Sulfanilamide. Sulfanilamide had been successfully employed for the treatment of streptococcal infections when provided in the form of a tablet or powder, but a liquid formulation was not available. After receiving requests from field sale agents, the company’s head of chemistry and pharmacy, Harold Watkins, created a new formulation in response to this request. The new product contained three key ingredients, sulfanilamide, raspberry flavoring, and diethylene glycol (Figure 2.24). After tests for flavor, appearance, and fragrance were deemed acceptable, the new product

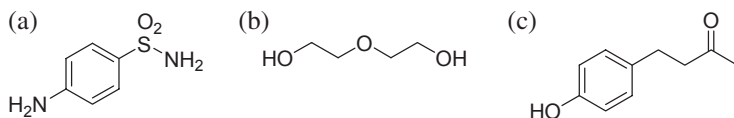


FIGURE 2.24 Elixir of Sulfanilamide marketed by S. E. Massengill contained (a) sulfanilamide, (b) diethylene glycol, and (c) Raspberry flavoring.