Because the government's first regulator of food products and patent medicines, Harvey Washington Wiley, lacked the statutory authority needed to impose the controls he believed necessary for the public's welfare, he established his indelible imprint on Congress and the people by sheer force of will. Yet, when he wielded that power in the early decades of the twentieth century, he often collided with the federal judiciary. The original pure food and drug law was flawed by its ambivalent language. The FDA lacked the authority to restrict lead arsenate, a recognized human toxin, from fruit sprays, for example. Not even the Supreme Court could add the words necessary to provide the "Wiley Law" with its missing clout.

Soon after his election in 1932, President Franklin Delano Roosevelt recognized the need to rewrite the original statute and add some teeth. A much stronger bill was introduced in 1933 by New York State Senator Royal Copeland, a physician and past commissioner of health for his state, but its fate was five long years of legislative inertia and indecision. Suddenly, in 1937, the bill received an unexpected but critical boost following the shock of more than one hundred tragic deaths attributed to a commercial drug product.

**Sulfanilamides**

The sulfanilamides were derived from an entirely new compound with unprecedented power to cure bacterial infections. The potency of these drugs had been increasing throughout the 1920s and 30s. News of the miracle cure reached Eleanor Roosevelt whose son, Franklin Jr., was near death because a throat infection had entered his bloodstream. Prontosil, the first commercial sulfa preparation, effected a dramatic recovery that newspapers contrasted with the streptococcal death of President Calvin Coolidge's son ten years earlier.

No requirement existed in that day for advanced testing of new drugs. Licenses to distribute the new sulfa compounds were issued to several manufacturers, among them the S. E. Massengill Company of Bristol, Tennessee. In October, 1937, Massengill announced "A New Sulfanilamide" in elixir format that was "entirely suitable for children." Left out of the announcement was the fact that an obscure solvent, diethylene glycol, had been used to dissolve the sulfa powder. Its bitter taste was diminished by addition of saccharin, caramel, and raspberry extract. Initial testing for clarity, stability, and flavor to the tongue hadn't required professional tasters to actually swallow the preparation.
The company's pharmacist, Harold Watkins, suffered a momentary lapse of chemical awareness by confusing glycerols with glycols, the former being well-known for safe human consumption and the latter being used for cooling aircraft engines and stabilizing dynamite. Diethylene glycol knew no biologic use because it was highly toxic to every living tissue. For this fatal error, the Massengill Company's erstwhile chemist would relieve his personal torment by committing suicide.

**AMA, Not Just FDA, Vital in Responding**

Although the FDA has since claimed the lion's share of credit for responding to Watkin's error, it was the American Medical Association (AMA) Council on Pharmacy and Chemistry that took immediate decisive action after receiving initial word of tragedy following consumption of the elixir. The AMA had long maintained its drug council in the absence of effective government regulation of drugs. Practicing physicians throughout the nation were in the habit of contacting the AMA whenever they needed information about a drug's benefits or ill effects.

Two telegrams dispatched from Tulsa, Oklahoma to AMA headquarters in Chicago alerted council members to six sudden and unexplained deaths following ingestion of Elixir Sulfanilamide Massengill. While telegrams were sent asking Massengill for a list of components, the AMA's chemist soon identified the solvent and confirmed by animal testing that it was lethal, especially to children who were the liquid suspension's target consumers. Morris Fishbein, editor of the *Journal of the American Medical Association*, halted the printing presses so that his next issue could include a full accounting of the tragedy for the nation's physicians. No one could recall a similar drug catastrophe or a faster response on the part of any professional or governmental agency.

Meanwhile, the FDA's response was to dispatch its inspectors first to Tulsa where they reviewed autopsy reports confirming acute kidney degeneration, and then to Bristol, Tennessee where they found Sam Massengill in a state of shock and denial. The entire fate of his company was in jeopardy. Not yet willing to accept blame, he assured FDA inspectors that every shipment of the product in question had already been recalled, that his employees were working around the clock sending telegrams and telephoning their clients, and that retrieval of the product would surely avoid further tragedy.

**Changes in Washington**

In Washington, Senator Copeland lost no time bringing news of the elixir sulfanilamide disaster to the attention of Congress. Resolutions were immediately passed calling for a full accounting of the tragedy. Secretary of Agriculture Henry Wallace came to the Hill to reassure Congress that because of the quick action of the FDA, 228 of the 240 gallons produced and distributed had been seized and destroyed. In the end, 107 deaths from ingestion of the poisonous elixir were recorded, most of them children, since streptococcus infects the young more than it does adults or the elderly. It was estimated that if all 240 gallons had been dispensed and consumed, there might have been as many as 4,000 deaths.

Secretary Wallace was correct; the FDA had acted responsibly and as quickly as any government agency could, but so had the Tulsa Medical Society, the American Medical Association, Ruben E. Donnelly Publishers, the S. E. Massengill Company, Western Union, Bell Telephone, and many
local public health departments. It was as unusual then as it is today for a government official to willingly share credit with the private sector for responsibilities believed to lie within the domain of a federal agency.

In the long run, the true impact of the elixir sulfanilamide tragedy was genuine empowerment of the FDA via passage of the Copeland Bill. Letters to President Roosevelt began arriving from the mothers of young victims in Oklahoma and nearby states. Women's organizations rallied in support of passing the strongest possible legislation. The Food, Drug, and Cosmetic Act of 1938 gave the FDA virtually unrestricted control over the release of new drugs. Penalties were increased, and the agency received a new weapon: use of the court injunction. For every new drug brought to market, the law restricted any marketing or interstate commerce until FDA officials were convinced the product was safe for use as directed.

Efforts to further expand the power of government to control foods, drugs, cosmetics, and medical devices would continue, however, with each legislative advance preceded by some galvanizing public incident.

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