



# A Brief History of the FDA

Founded to protect consumers from adulterated and misbranded food and drugs, the agency's role is now supported by approximately 9,100 people.

BY STEPHEN DAILY, NEWS EDITOR

The history of the US Food and Drug Administration traces back to a single chemist in the US Department of Agriculture in 1862. Today, the agency has a budget near \$4 billion, 20 district offices, 150 field offices and laboratories, and a staff of approximately 9,100 employees. Its jurisdiction encompasses most food products (other than meat and poultry); human and animal drugs; therapeutic agents of biological origin; medical devices; radiation-emitting products for consumer, medical, and occupational use; cosmetics; and animal feed. The agency oversees items accounting for 25 cents of every dollar spent by consumers.

## SHAPING THE FDA

John P. Swann, PhD, a historian in the FDA History Office and author of the book *Academic Scientists and the Pharmaceutical Industry: Cooperative Research in Twentieth-Century America* spoke with *Cataract & Refractive Surgery Today* about the history of the agency and the influences that shaped its function.

What began as the Division of Chemistry became the Bureau of Chemistry after July 1901, but the modern era of the FDA dates to the 1906 passage of the Federal Food and Drugs Act, known by many as the most important date in the history of the agency. The act added regulatory functions to the agency's scientific mission.

From 1879 to 1906, there were numerous attempts to pass laws concerning the regulation of domestically produced foods, and eventually drugs, Dr. Swann said. "In those 25 years, there were maybe 100 bills that were considered. There were people across the country who were interested in seeking more protection, because let's face it, the marketplace for food and drugs was let the buyer beware," he said.

On June 30, 1906, President Theodore Roosevelt signed the Food and Drugs Act, known as the Wiley Act, a reference to chemist Harvey Washington

"Misbranding was a source of considerable controversy in the regulation of drugs, and the bureau lost a lot of egregious cases."

— John P. Swann, PhD

Wiley, MD. Called the father of the FDA, Dr. Wiley demonstrated his concern about chemical preservatives in foods by calling them adulterants. The act, which the Bureau of Chemistry was charged with administering, prohibited the adulteration and misbranding of foods and drugs.

"[The law] basically said you couldn't add hazardous materials to food or conceal problems with food," Dr. Swann said.

Although the act did not establish standards for food, it did enforce the labeling of ingredients. The food or drug label could not be false or misleading, and the presence and amount of 11 dangerous ingredients, including alcohol, heroin, and cocaine, had to be listed.

## EMPHASIS ON MEDICINES

After Dr. Wiley's resignation in 1912, the bureau devoted more effort to drug regulation, with some emphasis on patent medicines. Misbranding was a source of considerable controversy in the regulation of drugs, and the bureau lost a lot of egregious cases. Proving fraudulence was difficult, Dr. Swann explained, but the seizure of misbranded and adulterated drugs increased substantially in the 1920s and 1930s.

The Wiley act set into motion the initial steps of the regulatory oversight that the FDA is charged with enforcing today, but it fell short in many areas. A new generation of journalists and consumer protection organiza-

tions aided in pushing a reluctant Congress to sponsor a bill that would replace the old law. Among the needed changes were legally mandated quality and identity standards for food, prohibitions against false therapeutic claims for drugs, coverage of cosmetics and medical devices, clarification of the FDA's right to conduct factory inspections, and control of product advertising.

The FDA itself demonstrated the need for change by assembling a collection of products that exemplified the shortcomings in the 1906 law. These exhibits included a radium-containing tonic that sentenced users to a slow and painful death, an eyelash dye that blinded many women, and an inhaler that was falsely promised to cure tuberculosis and other pulmonary diseases. A reporter dubbed the exhibit *The American Chamber of Horrors*.

"By and large, things like cosmetics and devices were not included [in the 1906 Food and Drugs Act], and there were no standards for food and drugs," Dr. Swann said. "There were some provisions for select labeling, basic standards, but anyone could put anything on the market as long as it was accurately labeled."

The worst example of the consequences of making false claims on labels came in 1937, when a Tennessee drug company marketed a form of the new sulfa wonder drug that would appeal to pediatric patients, Elixir Sulfanilamide. The solvent in the untested product was a highly toxic chemical analogue of antifreeze. It killed more than 100 people, many of them children. The public outcry reshaped the drug provisions of the new law and propelled the bill through Congress. The Food, Drug, and Cosmetic Act was signed by President Franklin Delano Roosevelt on June 25, 1938. It brought cosmetics and medical devices under the agency's control and required that drugs be labeled with adequate directions for their safe use. The law also mandated the premarket approval of all new drugs.

"Companies thereafter would have to submit to the FDA evidence that the product was safe before it could go on the market," Dr. Swann said. "Although it's been amended many times, it's the law we still operate under."

## INCREASED CONTROL OVER CHEMICALS AND DEVICES

Following hearings in the early 1950s, a series of laws addressing pesticide residues (1954), food additives (1958), and color additives (1960) gave the FDA much tighter control over the growing list of chemicals entering the food supply, thus putting the onus on manufacturers to establish their safety.

From the 1940s to the 1960s, the abuse of amphetamines and barbiturates required more regulatory effort by the FDA than all other drug problems combined. In

1962, the Kefauver-Harris Amendments were passed. They mandated efficacy as well as safety before a drug could be marketed, required the FDA to assess the efficacy of all drugs introduced since 1938, instituted stricter agency control over drug trials, and transferred from the Federal Trade Commission to the FDA the regulation of prescription drug advertising.

In the 1960s and 1970s, the medical device industry grew tremendously, Dr. Swann said. This prompted the FDA to pass amendments that mandated the reporting of adverse reactions to medical devices and postmarket monitoring of implants and other devices that pose a serious health risk. The amendments also gave the FDA the authority to recall medical devices.

"There was a realization that not all devices were the same, and so with the amendments in 1976, we see not only a requirement for premarket approval for medical devices, but also different categories of devices," Dr. Swann said.

In the 1970s, the FDA began protecting people against unnecessary exposure to radiation from electronics. In May 1980, the agency was transferred from the Department of Health, Education, and Welfare to the Department of Health and Human Services, the FDA's current home. In 1984, the FDA passed an act that expedites the availability of less-costly generic drugs by permitting the agency to approve applications to market generic versions of brand name drugs without repeating the research done to prove them safe and effective.

In 1990, Congress passed the Nutrition Labeling and Education Act, which completely reformulated the way food product labels convey basic nutritional information. During the past decade, several laws were passed that focus on clarifying the nutritional and safety information on food labels, including the listing of trans fats and allergens. The agency has also launched initiatives to increase public awareness of the adverse effects of tobacco products.

## CONCLUSION

Dr. Swann said the evolving focus and responsibilities of the FDA are a product of several influences, with the main emphasis always on public safety.

"Our charter exists within the laws that Congress charges us to uphold, and those have changed constantly over time," he said. "Not only laws but also executive orders have changed the way we do some things. The charter exists in the US statutes." ■

*John P. Swann, PhD, is a historian in the FDA History Office. Dr. Swann may be reached at (301) 796-8953; john.swann@fda.hhs.gov.*