The History of the Food and Drug Administration

Introduction

One of the oldest protection agencies in the US federal government, the Food and Drug Administration’s modern regulatory functions began with the pass of the 1906 Pure Food and Drugs Act, a law that was a quarter-century in the making. Before then, the federal government utilized chemical analysis to monitor the safety of products, specifically agricultural products throughout the US; this was a responsibility that was inherited by the Department of Agriculture in 1863 and later by the current FDA. Since its beginning in the early 19th century, the FDA has authored and passed economic, political, social, and legal amendments and bills in the US. Examining the history of the FDA and these changes demonstrate the evolving role that the FDA has played in promoting general safety and health of the public, as well as illustrating the history of how the US evaluates current regulatory affairs and challenges.

Since 1848: The Very Beginning

Operating since 1848, the Food and Drug Administration, or the FDA, is the oldest protection agency in the United States. The federal government has utilized chemical analysis to monitor the safety of consumer goods, specifically, agriculture products, which was a responsibility inherited by a single chemist in the Department of Agriculture in 1862 (A Brief History of the FDA, 2021). From 1862 to 1906, there were multiple attempts to pass laws concerning the regulation of foods and drugs that were products in the US. Dr. Swann, the author of Academic Scientists and the Pharmaceutical Industry, mentioned that over 100 bills were considered in Congress, but none of the bills reached majority. Citizens of the US wanted and were seeking more protection for produced drugs and food. What started as the Division of Chemistry quickly became the Bureau of Chemistry after 1901. In 1906, which is known by many as the most important date in the history of the FDA, there was a passage of the Federal Food
and Drugs Act, known as Wiley Act, by President Theodore Roosevelt. The Wiley Act is a common reference to chemist Harvey Washington Wiley, the single chemist that inherited the Department of Agriculture in 1862. The Wiley Act prohibited the misbranding and contamination of produced foods and drugs, which said the producers and manufacturers of food and drugs could not add any hazardous chemicals or materials to conceal problems; the Bureau of Chemistry was responsible for administrating and enforcing the Wiley Act Office of the Commissioner (Office of the Commissioner, 2021b). This Act might not have established standards for food, but it did enforce labeling ingredients on the packaging. The label on the packaging had to list 11 ingredients, which include alcohol, cocaine, and heroin. The label for food and drug products could not be false or misleading, which was a start.

After Doctor Harvey Washington Wiley retired in 1912, the Bureau of Chemistry devoted more effort to the regulation of drugs, with emphasis on medicines. Misbranding of product labeling was the first step, but the Bureau continued with medicine and agents. Misbranding of drugs was a source of controversy when it came to the regulation of drugs, and the Bureau of Chemistry lost a lot of court cases. Proving misbranding and contamination of drugs was extremely difficult, but the confiscation of misbranded drugs substantially increased in the 1920s and 1930s. While the Wiley Act set the stage for regulatory oversight that is currently being enforced today by the FDA, it fell short for cosmetics and devices (Office of the Commissioner, 2021a).

Journalists and organizations influenced Congress to sponsor a bill that would replace the Wiley Act. The organizations and journalists pushed and protested for coverage of cosmetic and medical devices, additional clarification of the FDA’s right to conduct inspections, mandated identity and quality standards for food and drugs, and control of advertising, specifically for consumer products. These demonstrations included a radium-containing drug that sentenced
patients to a slow and painful death, an inhaler that falsely illustrated a promise to cure pulmonary
diseases and tuberculosis, and an eyelash dye that blinded many individuals. In 1912, there were
no additional standards or regulations for drugs or food (A Brief History of the FDA, 2021). There
were some requirements for labeling, but as long as it was accurately labeled, manufacturers and
producers could add any chemical to the product.

The worst case of false ingredients on labels came in 1937 when a drug company in
Tennessee tried to market a wonder drug that would appeal to children and adolescents. The
untested product was a highly toxic concoction that resembled antifreeze. This drug killed over
100 individuals, most of them children (A Brief History of the FDA, 2021). The public scrutiny and
outcry shaped future drug provisions of the new law that journalists and organizations protested
for. On June 25, 1938, President Franklin Delano Roosevelt signed the Food, Drug, and Cosmetic
Act. This Act introduced regulation of cosmetics and medical devices under the agency’s control.
This Act also required that drugs should be labeled with adequate directions for their safe use,
and mandated the premarket approval for all new drugs. This would necessitate that all
companies submit to the FDA evidence via clinical trials and investigations that a drug product
was safe before it could be introduced to the market (Office of the Commissioner, 2021b). This
law still operates in the US today.

Additional Control Over Devices and Chemicals

From the 1940s to 1960s, the abuse of drugs, especially amphetamines and barbiturates,
required more regulatory and guidance efforts by the FDA. A series of bills and laws were passed
that addressed pesticide residues, food additives, color additives, and drug regulations. These
bills were published from 1954 to 1960 and allowed the FDA to regulate and gain control over the
growing list of chemicals entering the food supply, which put additional stress on manufacturers
to establish safety guidelines (Office of the Commissioner, 2021b). In 1962, the Kefauver-Harris
Amendments, which mandated the safety and efficacy for consumption of a drug before it could be marketed, passed through Congress. These amendments implemented a stricter control over drug trials and investigations and transferred the Federal Trade Commission to the FDA on the regulation of drug advertising, specifically prescription drugs (Office of the Commissioner, 2021a).

In the 1960s and 1970s, the medical industry boomed, which persuaded the FDA to update bills and pass amendments that mandated the reporting of adverse reactions to medical devices and post-market surveillance of products and devices that pose serious health risks. These amendments also allowed the FDA to exercise authority to recall medical devices and products. There was also an introduction of premarket approval for medical devices in 1976 (Office of the Commissioner, 2021a).

In the later 1970s, the FDA began passing bills and amendments aimed at unnecessary exposure to radiation from electronics. In 1980, the FDA was transferred from the Department of Health, Education, and Welfare to the FDA’s current department: the Department of Health and Human Services. Following the department transfer, the FDA passed an act that allowed the expedition of less-costly generic drugs by approving applications to market generic versions of brand name drugs without repeating clinical research evaluations or investigations to prove these drugs are safe and effective (Office of the Commissioner, 2021b).

Continuing into the 1990s, Congress passed the Nutrition Labeling and Education Act, which helped reformulate the way product labels, especially food labels, display basic nutritional information, like calories and serving sizes, to help enforce safety precautions. Throughout the 90s, several bills and laws were passed through Congress that focused on clarifying the safety and nutritional information on labels, including the listing of allergens, trans fats, and sodium in food. Introduction and passages of bills, like the Prescriptions Drug User Free Act and Dietary Supplement Health and Education Act, allowed the FDA to regulate drugs, specifically
prescription medication. (Office of the Commissioner, 2021b). Another milestone in the 1990s came in 1997 when the FDA passed the Food and Drug Administration Modernization Act, which amended the Federal Food, Drug, and Cosmetic Act from 1938. This amendment improved the regulation of drugs, food, devices, biological products, and cosmetics, as well as acknowledge the advancement of technological, public health, and trade complexities. These changes to the Federal Food, Drug, and Cosmetic Act from 1938 paved the way for how the FDA would be operating in the 21st century (Office of the Commissioner, 2021a). At the tail end of the 1990s, the FDA also launched several initiatives to help increase public awareness of the adverse effects of tobacco products in the US.

The early 2000s were about smoking prevention and tobacco control, bioterrorism, medical devices, and animals. Starting in 2002, Congress passed the Public Health Security and Bioterrorism Response Act, which was intended to improve the US’s ability to respond to public health emergencies. Provisions included a requirement that the FDA issues regulations to enhance controls over consumer products, specifically imported and domestically. In the same year, Congress passed the Medical Device User Fee and Modernization Act. This act facilitated fees that were assessed and established for medical device applications, device establishments inspections and audits by third parties, and new requirements for devices (A Brief History of the FDA, 2021). Following the passing of this act, the Office of Combination Products was formed within the Office of Commissioner to oversee and review products that fall into multiple categories within the FDA. After the passage of the Medical Device User Fee Act in 2002, Congress passed the Family Smoking Prevention and Tobacco Control Act in 2009, which gave the FDA authority to regulate the production, manufacture, distribution, and marketing of all tobacco products. This act also placed a ban on cigarettes with flavors, like clove, candy, or fruit (Office of the
Following this bill, the Center for Tobacco Products was established to help regulate and enforce the Control Act of 2009.

In the past decade, the FDA has been introducing new enforcement and regulation policies concerning public health and safety. In 2012, an outbreak of meningitis linked to a contaminated drug product resulted in the death of over 65 people and caused over 750 illnesses. In response to this public health crisis, Congress passed and enacted the 2013 Drug Quality and Security Act that introduced greater regulatory oversight of facilities that create compounded drugs, like the one that was responsible for the meningitis outbreak. Additionally, Congress also enacted the Pandemic and All-Hazards Preparedness Reauthorization Act and the Drug Quality and Security Act. Both of these acts introduce and establishes programs concerning the general public health security and preparedness to handle pandemics and hazards throughout the US. The Drug Quality and Security Act also defines and outlines specific steps for an electronic system to identify and trace drugs, specifically prescription drugs, throughout the US, which is still being utilized by the FDA today (Office of the Commissioner, 2021a.)

Conclusion

Over the last two centuries, the approval and regulation process for food, drugs, medical devices, and biological products has evolved and increased in complexity as acts and bills have been added and as the use of safety measures have been encouraged and regulated. Tracing back to a single chemist in the US Department of Agriculture in 1862, the US Food and Drug Administration was founded to protect the general public from misbranded consumer products. Currently, the protection agency has an annual budget near $4 billion, over 20 district offices, 150 field offices and laboratories, and about 9,100 full-time employees. The FDA's jurisdiction comprises mostly of food products, human and animal drugs, therapeutics agents, medical
devices, radiation-emitting products for occupation, consumer, and medical use. The agency now oversees products that account for about 25 cents of every dollar that is spent by the public.
References


https://www.fda.gov/about-fda/fda-history