FDA Vision and Mission

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A presentation by Dr. **Bill MARTIN**[1] , summarized by **Charlotte MANTON.**

Key Words

FDA Vision; FDA Mission

Abstract

The FDA is responsible for protecting and promoting the public health across all US territories. This Agency regulates the food, drug, cosmetics, and tobacco industries in the United Sates. The FDA is divided in offices and centers that monitor a particular regulated geographical area. The FDA has established several foreign offices worldwide - from Chile to China.

SUMMARY

Largely driven by the efforts of Harvey Washington Wiley, chief chemist of the Bureau of Chemistry in the Department of Agriculture, the passage of the 1906 Pure Food and Drug Act solidified public sentiment and marked the official beginning of federal consumer protection as a public priority. The 1906 Act – which prohibited misbranded and adulterated food and drugs in interstate commerce – charged the Bureau of Chemistry with carrying out its duties. The Bureau eventually evolved into the FDA, undergoing several organizational changes along the way.

The 1906 Act was a massive step forwards in food and drug safety, but came woefully short of the public health needs. It took the Sulfanilamide Elixir disaster of 1937 - which resulted in over 100 deaths - to prompt the passage of the 1938 Food Drug and Cosmetic Act. The Act tightened controls over drugs and food, including new consumer protection against unlawful cosmetics and medical devices, and enhanced the government's ability to enforce the law. It took yet another disaster for the next substantive round of legislation to pass

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through Congress. Thalidomide, a drug used in Europe to support sleep and treat nausea in pregnant women, resulted in severe deformities of thousands of children on the continent. The Thalidomide Disaster - prevented in the United States by the fastidious efforts of Dr. Frances Kelley - inspired the Kefauver-Harris Amendments in 1962 and strengthened the FDA's resolve on promoting both drug efficacy and safety.

During the 1970s, injuries, deaths, and other adverse events caused by medical devices prompted the Medical Device Amendments of 1976. These amendments created three designated classes for medical devices (I, II, III) based on the degree of risk and control required to ensure safety and efficacy. Almost forty years passed before the next significant food safety laws were passed. Representative of the FDA's change in strategy, the FDA Food Safety Modernization Act (FSMA 2011) shifted from a reactive to a proactive stance in aiming to pre-vent food contamination and adulterated/illicit product from ever traveling down the supply chain. The FSMA authorizes the FDA to require importers give prior notice before shipments arrive, as well as the power to deny entry or recall unsatisfactory food and drugs.

The FDA is responsible for protecting and promoting the public health across all US territories - from Guam to the Virgin Islands. This entire region is divided into five regions - Pacific, Southwest, Southeast, Central, and Northeast. The modern economy has brought as many challenges as conveniences: globalization has resulted in astonishingly complex supply chains and has complicated regulatory agencies' task of ensuring only safe and effective products reach the public. Scientific and technological breakthroughs benefit international commerce, but also bring new public health threats that must be addressed – ranging from counterfeit products to bioterrorism. These economic changes have spurred changes within the FDA; the realization that enforcing compliance is a more effective way to ensure quality and safety has precipitated organizational restructuring and increased the Agency's focus on compliance and collaboration.

The "new" FDA is a complicated structure. The Commissioner of Food and Drugs, Margaret Hamburg, oversees a collection of offices and centers each tasked with monitoring a particular regulated type of product or commodity (e.g. biologics, veterinary medicine). Recently its responsibilities have expanded to include tobacco products. In recognizing the need to partner with foreign governments and regulatory bodies, the FDA has established several foreign offices worldwide - from Chile to China. FDA works with these organizations to encourage the development of internationally acceptable standards and quality procedures and is committed to ensuring and improving global product safety and intelligence. The goal is to develop mutual recognition standards and global regulatory coalitions in order to manage the immense task ahead of them.

Ultimately, the ability of the FDA to be successful in regulating the food, drug, cosmetics, and tobacco industries rests on the agency's commitment to continual improvement and proactive policy development. Partnerships with other agencies and foreign bodies will continue to refine this strategy, as will legislative trends focused on ensuring quality and accountability throughout the supply chain. □