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The Role of Chemical Scientists in the Food and Drug Administration

The Food and Drug Administration, or FDA, is one of the most powerful government agencies in the United States, yet few are familiar with the extent of its authority. The FDA, a branch of the U.S. Department of Health and Human Services, is one of the oldest consumer protection agencies, and is responsible for protecting consumers by enforcing the Federal Food, Drug, and Cosmetic Act. The importance of the chemical sciences in the work of the FDA is invaluable for its regulatory duties and for promoting public health. The team of 2,100 scientists at the FDA includes 900 chemists and 300 microbiologists who work in laboratories nationwide in the pursuit of safety regulation. The research of chemical scientists determines whether products are contaminated and ensures that products such as drugs and medical devices are safe and effective.

History

The first national drug law, passed in 1848, banned the importation of adulterated drugs but did not regulate adulterated and dangerous domestic medicines. The foundations of the current FDA were established by a chemist, Harvey Washington Wiley, who recognized the need for a government agency to establish uniform standards for food and drug regulation. At the end of the 19th century, public concern grew for consumer safety as adulterated and potentially hazardous foods and drugs were available in the marketplace. In response to a need for federal regulation, Wiley established the Division of Chemistry under the Department of Agriculture which became the foundation

of the FDA as we know it today. Under the bureau of Chemistry, The Pure Food & Drug Act of 1906 was implemented and prohibited interstate transport of unlawful foods and drugs. However, the Division of Chemistry did not have great jurisdiction until June 25, 1938 when President Franklin Delano Roosevelt signed into law the Food, Drug, and Cosmetic Act (FD&C Act). The Act gave federal regularity authority to inspect drugs before being marketed and to ban drugs that made false therapeutic claims. In addition, the law brought under jurisdiction cosmetics and therapeutic devices, which increased its enforcement power. Today, the FDA regulates human and animal drugs, biological products, cosmetics, medical and radiation-emitting devices, and all foods except meat and poultry.

The Role of Chemical Scientists

The FDA is organized into eight divisions, each with particular regulatory responsibility.[i] Chemical scientists play a fundamental role in the Office of Science and Engineering Laboratories (OSEL) that are responsible for product testing, investigating emerging technologies, and contributing to national and international standards used in FDA policies. Under OSEL, the Division of Chemistry and Materials Science (DCMS) conducts research, testing, and evaluation focused on chemical and materials issues related to safety of medical devices and their impact on public health. The focal points of the research are chemistry and materials issues concerning the inorganic and organic materials that comprise medical devices. Extensive materials research by chemical scientists ensures regulatory decisions are based on scientific and engineering expertise and the collection of independent laboratory data. In addition, information on materials

characterization, materials degradation, and materials-tissue interactions contributes to promoting the public health policies of FDA.

Currently, DCMS laboratory research is comprised of two areas. The materials characterization laboratory focuses on materials composition, formulation, and chemical/physical parameters for structure determination. The experimental pathology area conducts experimental research in an effort to create clinical models of dental, orthopedic, and cardiovascular device applications. The technical expertise of the DCMS staff includes analytical chemistry, physics, polymer science, pharmacology, pathology, biomedical and chemical engineering.

Controversies

It was a chemist who first conceived the need for protecting consumers, and it is legitimate to ask if the scientific community is able to assure us that we are indeed protected today. Unfortunately, the current prevailing image of the FDA is one of a complicated bureaucracy that is increasingly in the hands of big corporations and engaged in unfocused research. We all agree that the system needs to be modified, but various perspectives on this issue exist. In the first 86 years of the FDA's existence, from 1906-1992, all of FDA's funding came from the U.S. Treasury. In 1992, a new law mandated that the work done by the FDA on new drug applications would come directly from industry. The pharmaceutical or biotech company thus pays the FDA to review their drug. Pharmaceutical companies advocate the need to limit the time and scrutiny of the FDA to approve new drugs and procedures, if not completely eradicate the cumbersome and costly procedures. Indeed, the average cost of researching, developing, and testing drugs that receive FDA approval is $800 million per drug. However, consumers are

demanding more protection and reassurance that the FDA is able to protect itself from unwanted intrusion of big businesses and excessive influence of drug companies. Other problems facing the FDA is that it has few employees, less than 0.5% of the nation's 2 million government workers, undermining its ability to regulate products that are worth 29 cents of every dollar spent in the U.S. The FDA is unable to respond adequately to the growing responsibilities and is losing its ability to foster scientific advances. To combat these threats to public safety, FDA's federal budget request for 2008 totaled $2.1 billion, a $105.8 million increase from what it received in 2007.

Though there is no consensus on the type of research that the FDA should be doing, it is clear that FDA's credibility rests on its scientific expertise. Only by rigorous and relentless efforts to bring science and scientists back to the table and giving them better funding and less mingling with big businesses can we protect the role of the FDA in ensuring consumer safety.

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[i] Divisons of the FDA:

1) The Office of the Commissioner (OC)
2) The Center for Drug Evaluation and Resarch (CDER)
3) The Center for Biologics Evaluation and Research (CBER)
4) The Center for Food Safety and Applied Nutrition (CFSAN)
5) The Center for Devices and Radiological Health (CDRH)
6) The Center for Veterinary Medicine (CVM)
7) The National Center for Toxicological Research (NCTR)
8) The Office of Regulatory Affairs (ORA)