FDA: A HISTORY

Written and Directed by Gregory A. Meyer

GUIDEBOOK AND LESSON PLAN

To order this and other programs call:
(888) 570-5400
www.choicesvideo.net

FDA - Timeline of Events

1820: Physicians create U.S. Pharmacopeia, first compendium of standard drugs in the US
1848: Drug Importation Act passed by Congress, prohibits importation of adulterated drugs
1898: Association of Official Agricultural Chemists establishes Committee on Food Standards
1902: The Biologics Control Act ensures safety of serums, vaccines, and similar products
1906: Original Food and Drugs Act passes, bans interstate commerce in misbranded or adulterated foods, drinks and drugs
1912: The Sherley Amendment prohibits labeling medicines with false therapeutic claims
1924: Supreme Court rules that the Food and Drugs Act condemns every statement, design, or device on a product's label that may mislead or deceive, even if technically true.
1930: The Food, Drug, and Insecticide Administration becomes the Food and Drug Administration (FDA)
1937: Elixir of Sulfanilamide kills 107 persons, highlighting need to enact pending drug laws
1938: Federal Food, Drug, and Cosmetic (FDC) Act of 1938 passes in Congress
1940: FDA transfers from the Department of Agriculture to the Federal Security Agency
1949: FDA publishes first guidance to industry, "Procedures for the Appraisal of the Toxicity of Chemicals in Food," known as the "black book."
1954: Miller Pesticide Amendment establishes procedures for safe pesticide residues on raw agricultural products. Large-scale radiological examination of food begins after fears of radioactive fish being imported from Japan
1958: Food Additives Amendment requires manufacturers of new additives to establish safety, includes the Delaney proviso which prohibits food additives shown to produce cancer
1960: Federal Hazardous Substances Labeling Act requires warnings on hazardous household products.
1962: Kefauver-Harris Drug Amendment passes
1970: Environmental Protection Agency established; takes over control of pesticide regulation
1971: PHS Bureau of Radiological Health transferred to FDA to limit human radiation exposure
1972: Regulation of Biologics (vaccines and blood products) transferred from NIH to FDA
1973: Congress draws from FDA programs to create Consumer Product Safety Commission
1976: Medical Device Amendments and Vitamins and Minerals Amendments passed
1982: FDA issues Tamper-resistant Packing Regulations to present poisonings and deaths.
1982: FDA publishes first “Red Book” (successor to “black book”): Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food
1984: Drug Price Competition and Patent Term Restoration Act
1988: Food and Drug Administration Act of 1988
1990: Nutrition Labeling and Education Act
1992: Generic Drug Enforcement Act
1993: FDA issues guidelines encouraging companies to include both sexes in drug studies
1994: Dietary Supplement Health and Education Act
1995: FDA declares cigarettes to be "drug delivery devices" and proposes marketing restrictions
1999: Pearson v. Shalala gives food manufacturers ability to make health claims for foods
2000: Supreme Court ruled that FDA does not have authority to regulate tobacco as a drug.
2002: Public Health Security and Bioterrorism Preparedness and Response Act
2004: Project BioShield Act enables rapid distribution of agents for counter-terrorism methods
2005: Formation of the Drug Safety Board

Reference: http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones//

Summary

FDA: A History traces the growth and evolution of the United States Food and Drug Administration from its origins as a single chemist within the Department of Agriculture to the present. Historical photographs and videos illustrate the trajectory of the FDA, and interviews with former FDA officials, historians, and FDA investigators who provide multiple viewpoints on the FDA's past and present. By examining the limitations of the FDA, as well as its successes, the film provides a balanced view of this century-old agency. As the first American consumer protection agency, the FDA still maintains a significant role in maintaining consumer protection and regulates products that account for 25 cents of every consumer dollar spent in America.

Prior to the twentieth century, few regulations on foods and drugs existed and the burden of choosing safe goods was placed solely on the consumer. Although patent medicines and "miracle" drugs made outlandish claims to cures, they had no evidence to support these claims. In addition, growth in the canned food industry during the Civil War led to an increase in illness and injury from contaminated food products. A lack of enforceable standards for labeling and quality of processed foods was responsible for an increasing number of deaths. Harvey Wiley, the Chief Chemist at the US Department of Agriculture, recognized the need to control these products and protect the consumer from potentially harmful or deadly goods. Wiley faced opposition from Congress, which at the time aligned itself with business interests rather than those of consumers, but a series of scandals in the early twentieth century forced the government to take action. The publication of Upton Sinclair's *The Jungle*, an exposé of the meat industry in America, coincided with the discovery of high amounts of cocaine and opiates in children's medication. After a century of debates over the government's role in the food industry, the Food and Drugs Act of 1906 created government standards for food inspection and drug labeling. This paved the way for the establishment of the Food and Drug Administration.

Over the course of the next century, the FDA underwent a number of changes and expanded to include regulation over drugs, food items, pesticides, medical devices, serums, vaccines, and cosmetics. Throughout its history, the agency has worked to standardize labeling on food products and drugs, regulate health claims made on these labels, and ensure a certain level of safety and control in manufacturing processes.

As demonstrated in *FDA: A History*, a number of crises and unexpected events have increased the responsibilities of the FDA and changed the ways in which they function. Products not covered under the 1906 Food and Drug Act proved to need additional regulation as well. After a brand of eye mascara caused blindness and a new antibiotic sulfa elixir led to the death of over 100 people, the FDA was given broad authority to enforce laws requiring safety in drugs. They were given the responsibility of enforcing truth in labeling for foods, and safety testing before a drug product goes on the market. The agency has responded to outbreaks caused by contaminated vaccines, such as contaminated polio vaccine in the 1950s, and created new testing methods for antiotics and allowing for stricter regulation of the conditions under which the all medical products are produced. After the drug Kevadon (thalidomide) was distributed to over 20,000 Americans without FDA approval and causing damage to unborn fetuses of pregnant women, the FDA and Congress added and important amendment to the 1938 Food and Drug Cosmetic Act - the Kefauver-Harris Drug Amendments of 1962. The Kefauver Harris Amendments required drug manufacturers to provide not only proof of drug safety, but drug effectiveness prior to approval. It also required drug companies to release and label information about side effects. With these amendments, and with increased enforcement in the 1960s and seventies, industry was pushed to be more responsible in regulating themselves.

The FDA has always been a political agency and a scientific innovator. Its first chief chemist, Harvey Wiley was a shrewd politician as well as a capable scientist. His abilities as a politician helped push the creation of the FDA as a separate entity within the government. Later, the additional need to test release antibiotics for soldiers during World War II forced the FDA to develop methods test whole blood and blood plasma, penicillin, vitamins, and malaria drugs for the military. Once businesses saw the success of penicillin, they realized the potential for research to create new life-saving drugs that could be sold for profit and increased their investment in drug research, but from the outset, they relied on FDA and state health and publicly funded laboratory expertise.

In the aftermath World War II, the FDA and the Public Health Service led the response to atomic radiation when concerns over radiation in Pacific tuna fish caused national testing of radiation levels in food products and medical equipment. As a result of this increased radiation testing, it was discovered that concern about radiation should be directed towards x-rays, and the Bureau of Radiological Health – which became part of FDA in the 1970s - was formed.

Breakthroughs in scientific research in the mid-1970s emphasized the importance of micronutrients such as fiber and vitamins. Increasing evidence that sugar, fat, and salt should also be considered in food choices led the FDA to change labeling standards to reflect the amount and type of micronutrients and macronutrients contained within products.

In the 1990s, the AIDS epidemic and the tobacco industry had a profound impact on the policies and procedures of the FDA. Once the FDA recognized tobacco products as an increasing cause of preventable deaths in America, they attempted to regulate cigarettes as a drug. Unfortunately, Congress would not support many of the restrictions on tobacco proposed by the FDA and the Supreme Court ruled in 2000 that the FDA did not have the right to classify cigarettes as a drug. Recently, however, the FDA has been able to have more control over the advertisement and distribution of tobacco products and now Toboacco is regulated by the FDA. With the growth and spread of the HIV/AIDS epidemic, the FDA faced significant consumer pressure to approve new, unproven medications. The FDA educated protesters in the steps to gaining drug approval and many of them became supporters of rational drug regulation. The FDA and Congress responded to such concerns over long drug approval times by passing the Prescription Drug User Fee Act (PDUFA) of 1992, which required industry to pay for the review of their new drugs if they wanted faster review times. Today, almost ½ of the FDA's budget comes from user fees.

These changes within the FDA demonstrate the fine balance the FDA has had to maintain between their relationships with other government agencies, the food and medical products industries, and the American people. Critics of the government have argued that the FDA's intrusion into the realms of medicine and food infringe upon their rights whereas others argue that the agency does not provide enough regulation and allows industry to dictate its rules and actions.

Scientific integrity is always a concern with the study of products for sale. FDA does not have a large budget to run studies that show products are safe or effective themselves, so they have created a system with multiple checks in order to continue in the tradition of providing protection to American consumers at a low cost. The system requires that there be talented scientists, and diligent inspectors to review data submitted on products, and inspect the facilities in which they are made. The FDA maintains its role as a public health, law enforcement, and consumer protection agency by constantly reviewing its methods, but also maintaining its history and mission. It continues to adapt to the changes in food and drug production, government demands, and consumer needs.

Additional Resources:

Online:

- http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm

Print:

- Hawthorne, Fran. *Inside the FDA: The Business and Politics Behind the Drugs We Take and the Food We Eat*. Hoboken, N.J.: J. Wiley, 2005.
- Hilts, Philip J. *Protecting America's Health: the FDA, Business, and One Hundred Years of Regulation*. New York: Alfred A. Knopf, 2003.
- Kessler, David. *A Question of Intent: A Great American Battle With A Deadly Industry*. New York: Public Affairs, 2001.
- Nestle, Marion. *Food Politics: How the Food Industry Influences Nutrition and Health*. Berkeley: University of California Press, 2007.
- Schacter, Bernice Z. *The New Medicines: How Drugs are Created, Approved, Marketed, and Sold*. Westport, Conn.: Praeger, 2006.

Abbreviations:

- CBER: Center for Biologics Evaluation and Research
- CDRH: Center for Devices and Radiological Health
- CEDR Human Drugs: Center for Drug Evaluation and Research
- CFSAN: Center for Food Safety and Applied Nutrition
- CVM: Center for Veterinary Medicine
- EPA: Environmental Protection Agency
- FDA: Food and Drug Administration
- GCP: Good Clinical Practices
- GLP: Good Laboratory Practices
- GMP: Good Manufacturing Practices
- IRB: Institutional Review Board
- ORA: Office of Regulatory Affairs

Discussion Questions and Activities

- Have students bring in a food product with a nutritional label. Have students look at and interpret the label and the packaging for the product. What on this label does the FDA regulate? When did these different regulations, such as allergy and nutritional information, come about? What can we learn from reading this label? Is any important information not included? How can understanding these labels help consumers meet their nutritional needs?
- Divide students into groups. Have each group select a time period represented in the film and summarize the history of the FDA at this time. How have the changes within the FDA at this time built upon what came before? How did the FDA respond to events within this era?
- How have technology and globalization created new opportunities and new obstacles for the FDA?
- Compare and contrast the issues facing the FDA today and in other time periods.
- What world events have influenced the goals and the running of the FDA? How/why?
- Why did the FDA allow industry to take over some of the testing of drug and food products? What are the benefits and consequences of this system?
- What roles have congress and industry played in changes within the FDA?
- In which government departments has the FDA been housed? What do these changing affiliations tell us about the changing roles and views of the FDA?
- How does the FDA impact our daily activities?