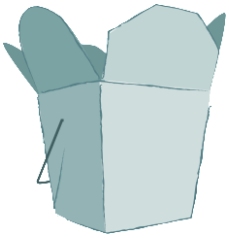


Regulation: The Food and Drug Administration Study Guide

Produced by Intellectual Takeout

The beginnings of the Food and Drug Administration (FDA) can be traced back to the 18th century. But it wasn't until 1906 that it began to exist in its modern form. That year, President Theodore Roosevelt passed the Food and Drug Act, which regulated certain aspects of interstate commerce. An agency of the United States Department of Agriculture (USDA), the FDA took on its current name in 1930. Today, the FDA is a huge government agency regulating almost everything that we consume in this country. In recent decades public opinion of the FDA has been steadily declining. Much of this is due to its oversight of prescription medication and medical devices. Many Americans are not in favor of the heavy regulatory system that the FDA helped create. Furthermore, there have been thousands of cases of food and drug-related illnesses and death despite FDA approval. This calls into question the general use and efficacy of not only the FDA but also the USDA in general. This study guide will look at the origins, role and controversy surrounding the FDA. It includes some helpful charts and graphs, applicable quotes, and several questions for discussion in a group, or to simply ponder on your own.

The FDA

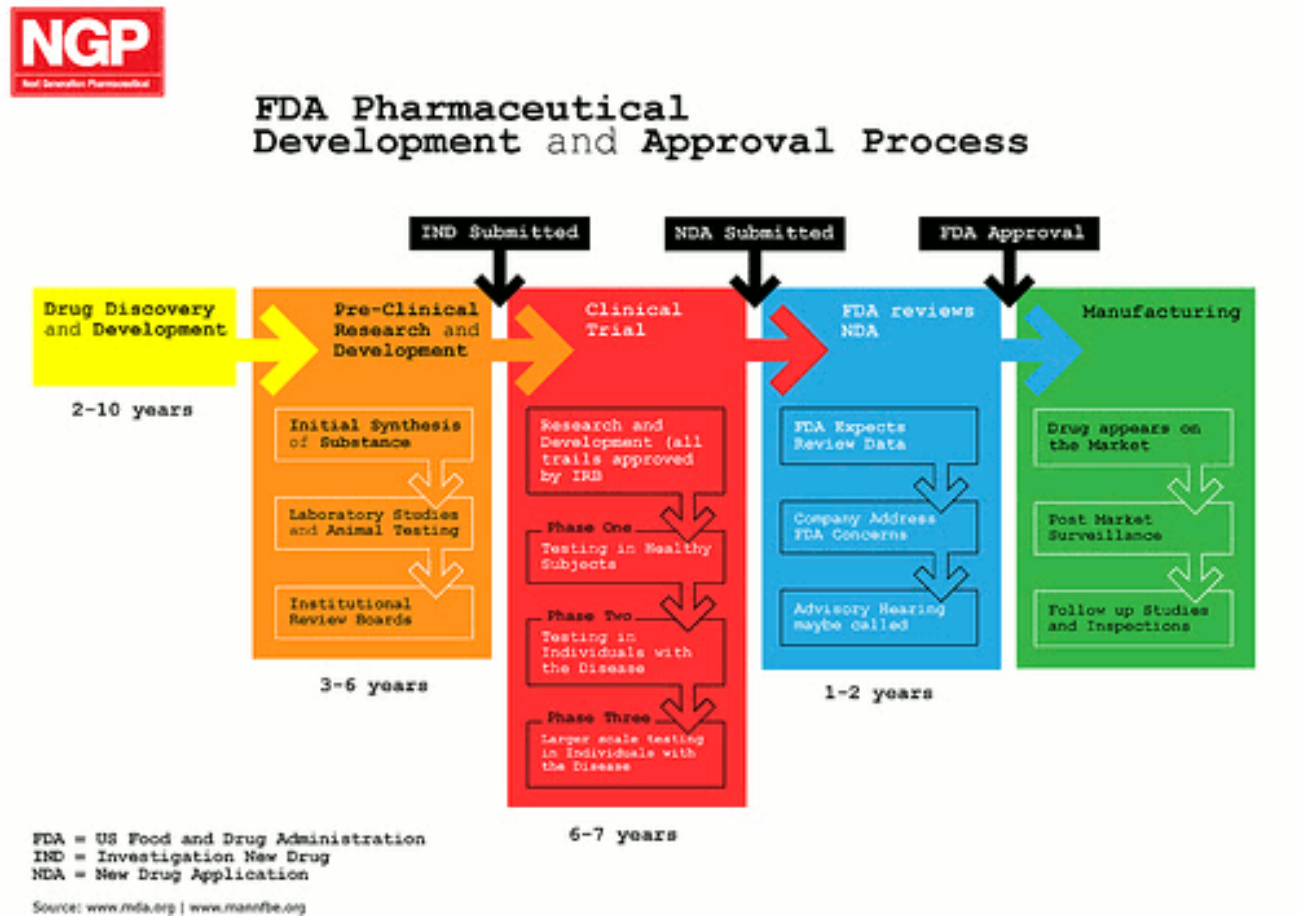
What is the history of the FDA?

- U.S. Pharmacopeia was established in 1820 in order to compile a complete list of all drugs. This organization still exists and works closely with the FDA.
- In 1848, the Drug Importation Act began to regulate the transportation of drugs across national borders.

- In 1905, the American Medical Association (AMA) began a voluntary program of drug approval. Drug companies had the option of getting "certified" in order to promote sales.
- The Food and Drug Act was passed in 1906. In some ways this was an extension of the Drug Importation Act, regulating interstate commerce on top of international commerce. It has been amended and updated numerous times since its inception.
- A large part of the motive for creating the FDA was due to fraudulent "snake oil salesmen." Such swindlers tried to scam people into buying worthless health products. The practice still exists today, of course, though the mark of FDA approval helps prevent a large majority of these cases.
- The FDA was officially established in 1930 under the Agriculture Appropriations Act of that year.
- In one of the most important pieces of legislation regarding the medical industry, the Federal, Food, Drug, and Cosmetic (FDC) Act established a stricter regulatory system on drugs and also created prescription-only drugs. Since then, prescription drugs have become much more regulated and controlled. The Durham-Humphrey Amendment in 1951 helped foment this trend.
- Drugs companies began to be required to prove their products' safety and effectiveness to the FDA under the 1962 Kefauver-Harris Drug Amendments.
- By 1970, the FDA began to control labeling on drugs.
- In 1976, the FDA gained regulatory control over all medical equipment as well as drugs.

What does the FDA do today?

- The FDA is in charge of overseeing the safety of drugs (famously, tobacco has been classified as such), medical devices, food, cosmetics, and other health-related products.
- The issue of dietary supplements has been heavily debated. Currently, the FDA does not ensure that such supplements are effective or work as advertised. It only regulates the supplements if they are deemed to be dangerous.
- The agency has become increasingly complicated over the last several decades. The scope of its regulatory powers continues to widen and the approval process remains extremely long.



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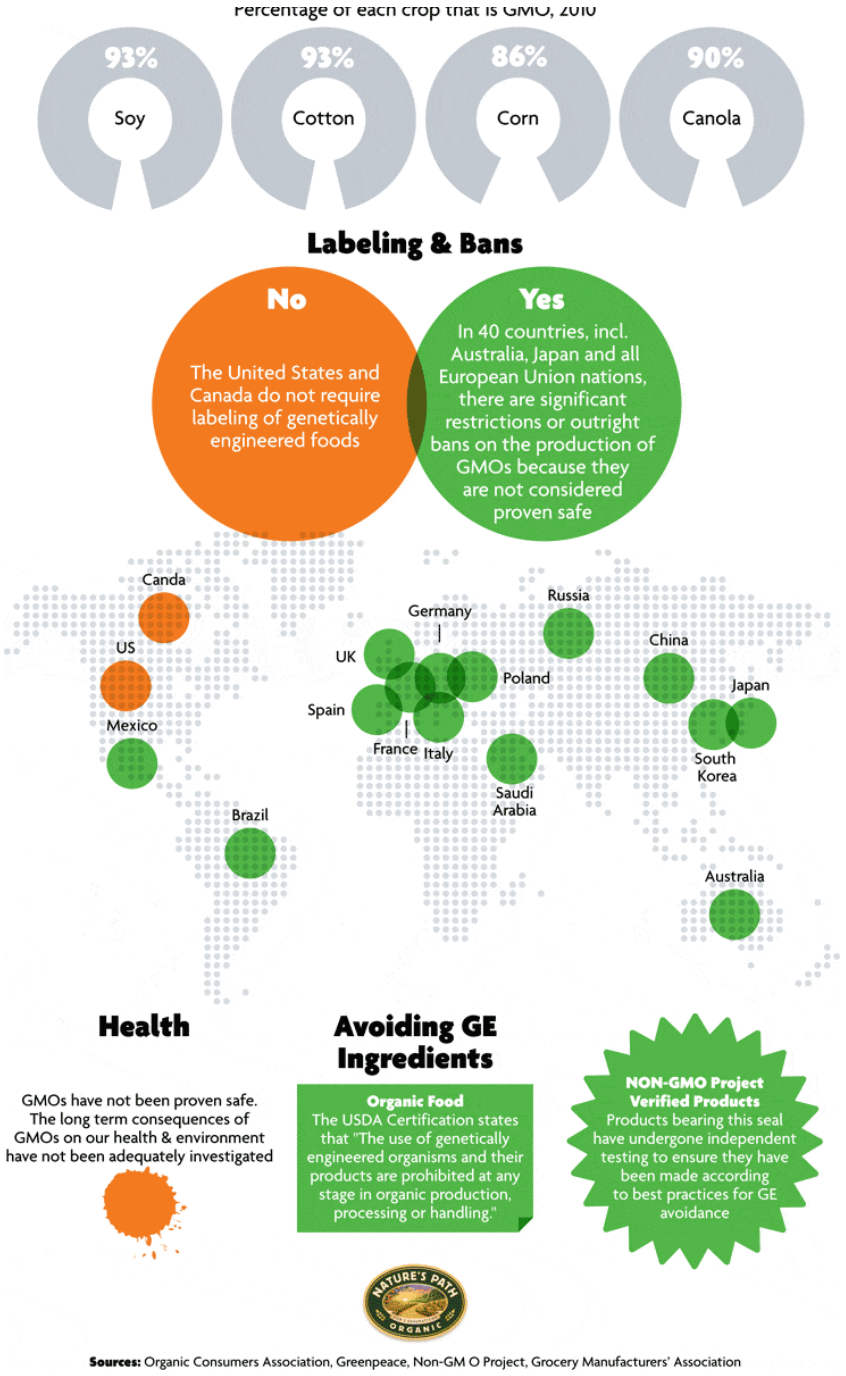
- The food and drug industries add thousands and thousands of new products each year, all of which must be tested and approved by the FDA. The growth of synthetic drugs and genetically modified food has only made this process more arduous and confusing. There is currently a heated debate over the labeling on such food. Currently, no labeling is necessary in the U.S.



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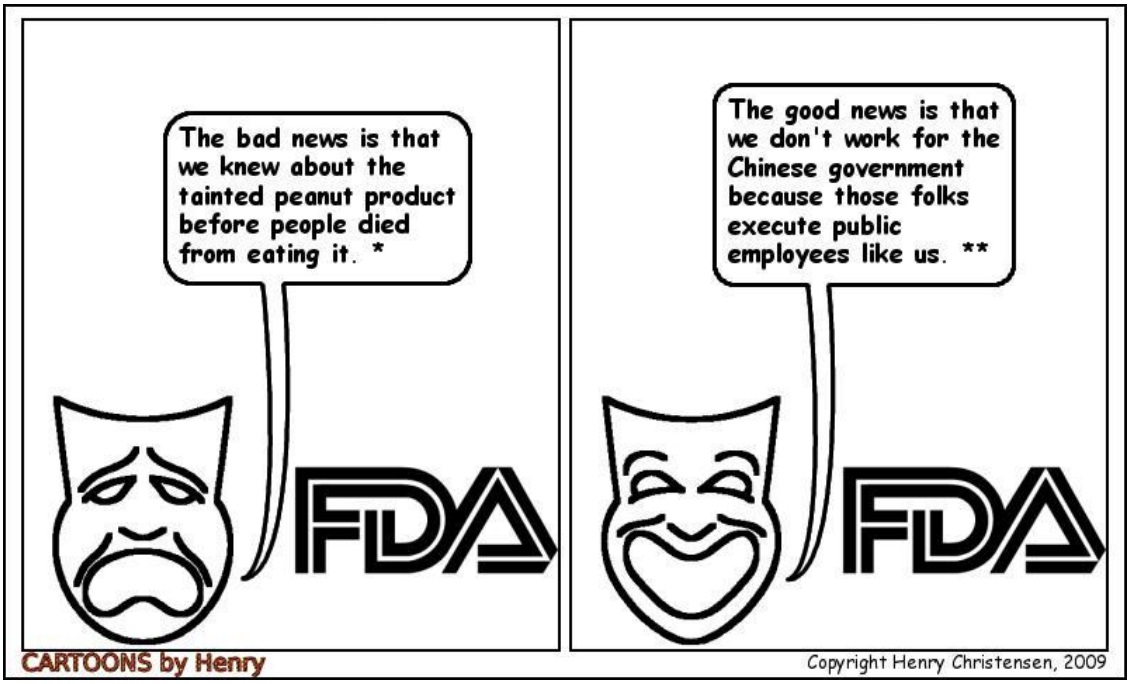
- According to some estimates, the FDA has control over about a quarter of the U.S. economy and is responsible for the "safety and effectiveness" of $2 trillion worth of products.
- Patents are another extremely complicated aspect of FDA regulation. Patents offer a huge incentive to create a new product. In the pharmaceutical industry, the payoff can be incredible. The FDA closely controls the issuance of drug patents.

- Such patents last for 20 years after initial filing.
- Exclusivity is different and often mistaken for being a patent. Exclusivity for a new drug lasts seven years. It is granted upon the approval of the drug, therefore ensuring large profits for the company that developed it.

- The Food and Drug Administration Amendments Act (FDAAA) was signed in 1997 and amended the aforementioned Federal Food, Drug, and Cosmetic Act from 1938. This "modernized" the FDA by changing labeling laws, enhancing the FDA's online capabilities, and giving it more control over medical products.
- Described by the FDA as the "most sweeping reform of our food safety laws in more than 70 years," the FDA Food Safety Modernization Act (FSMA) was signed in 2011. It requires a payment by anybody in the food industry, excluding farms and restaurants. If a person "manufactures, processes, packs, distributes, receives, holds, or imports an article of food," this fee must be paid. The bill has been criticized for harming small businesses. Such a fee can easily create a competitive disadvantage and cause a small or startup company to become financially unsustainable.
- The FDA has instituted a policy called "compassionate use." This allows some sick individuals to be a part of experimental drug trials. The individual must have a life-threatening disease, already tried traditional treatment, have been denied other clinical trials, and get a doctor's approval. This program is only available to a small number of seriously or terminally ill patients.

Why is the FDA so controversial?



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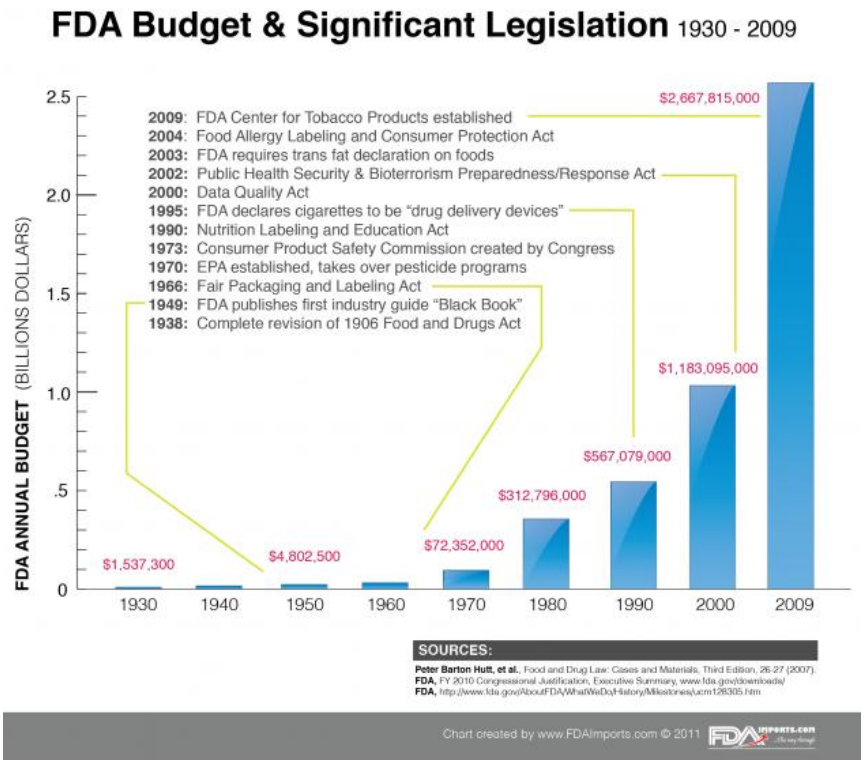
- Many "FDA approved" products have still harmed or killed thousands of people. One of the most famous cases was Vioxx, a popular drug used to fight arthritis symptoms. It was pulled off the market in 2003 after being responsible for causing thousands of fatal heart attacks in users. *The Independent Institute* publishes the FDA Review, outlining its history and failures.
- The FDA has a massive budget. The agency's fiscal year 2013 request is about $4.5 billion. Its 2009 budget was just over $2.5 billion.



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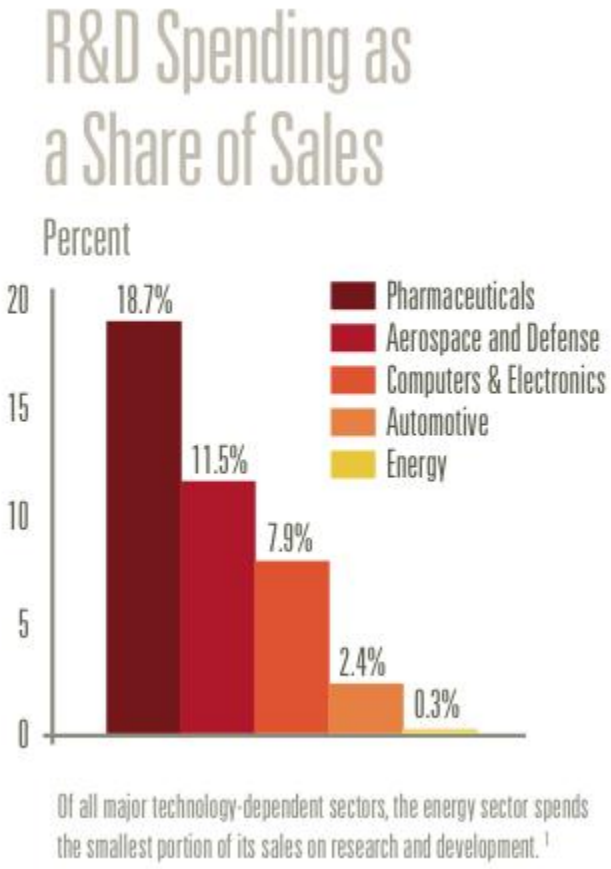
- The FDA prevents many lifesaving drugs from entering the market due to bureaucratic red tape. Many patients are denied the choice of taking experimental drugs. A fascinating and controversial case is Dr. Stanislaw Burzynski's cancer research and treatment. His revolutionary method for cancer treatment has been proven to be harmless yet remarkably effective, but it is denied FDA approval. His story was documented in the 2010 film "Cancer is a Serious Business."
- Clinical trials are not consistent with the philosophy of the FDA. All clinical trials imply that there will be some sort of risk involved. Yet, the FDA heavily regulates these trials, choosing to approve certain trials arbitrarily. There have also been numerous accusations of political motivations. An FDA-approved trial can become extremely lucrative if it leads to an FDA-approved drug. Texas Governor Rick Perry and the Gardasil scandal are a prime example.

- The FDA is in bed with the pharmaceutical companies and has become increasingly corrupt. The more the FDA is able to regulate, the greater its ability to create monopolies and control prices and products. Though the FDA claims to be first and foremost concerned about the public's safety, the only real vociferous supporters are the corporations which stand to benefit from the FDA's stamp of approval.
- The FDA makes it nearly impossible for a start-up or smaller company to enter the market, because it costs millions of dollars of preliminary research and development before the FDA *might* approve the drug. Milton Friedman famously said, "The FDA has done enormous harm to the health of the American public by greatly increasing the costs of pharmaceutical research, thereby reducing the supply of new and effective drugs, and delaying the approval of such drugs as survive the tortuous FDA process."



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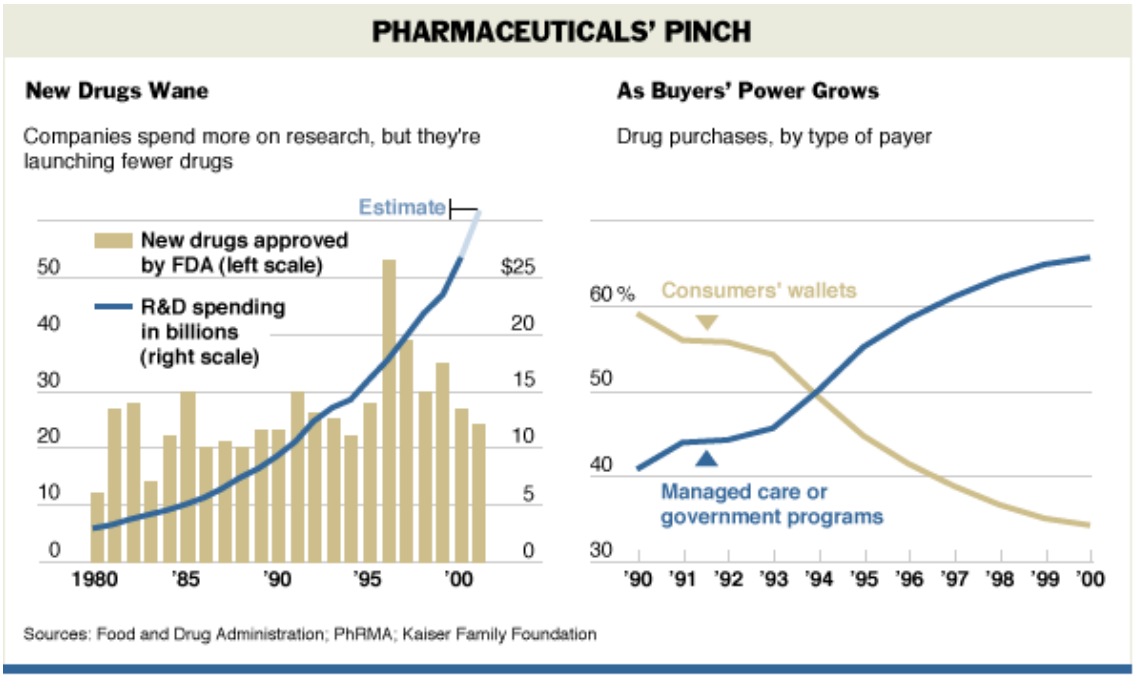
- The FDA has also been accused of creating an "innovation gap" in the pharmaceutical industry. Because of increased regulation, drug companies are forced to spend much more on research and development while producing fewer drugs.



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What might happen if the FDA was abolished?

- This is largely speculative; some claim that the overall safety of drugs would remain the same: "Drug safety would be – that is – certified and assured by a panoply of private-sector, voluntary institutions and by the tort system." Like any other industry, the supplier would have the incentive to provide the safest and most effective product to the consumer in order to ensure remaining profitable.
- Abolishing the FDA would also open the door for hundreds or even thousands of new companies to enter the market. There would be much more innovation in the field because startup costs would plummet. Most likely, a slew of new medicines and cures would emerge.
- Wait times for drugs to go on the market would be far shorter. The FDA has a long history of causing extensive waiting periods for full drug-approval. In fact, these periods are on average longer than in most European nations, nations which also have massive regulatory agencies in the food and drug sector.
- Yet, others believe that the FDA is necessary for keeping unsafe drugs off the market. Without the FDA, the American public would suddenly be subject to new and unknown drugs.
- The FDA is instrumental in delivering information on the harmful effects of smoking, for instance.

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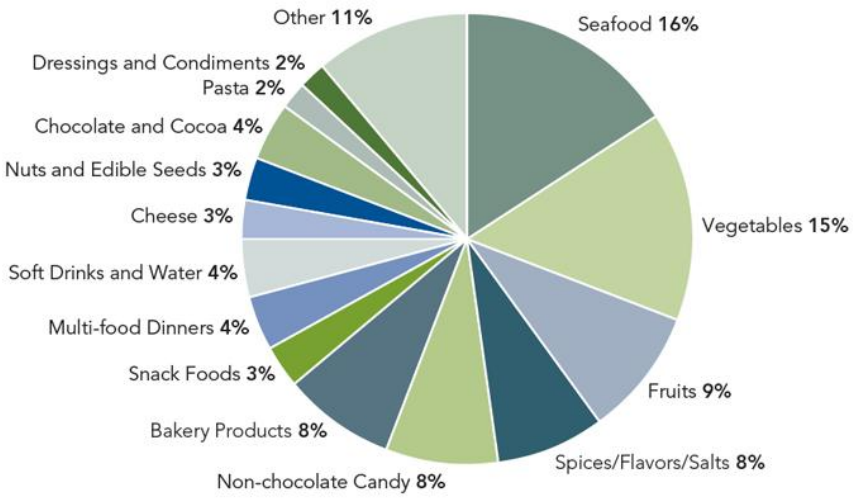
- Also, the FDA prevents thousands of dangerous food products from entering the U.S. market every year.



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- Finally, a large number of people are calling for significant reform to the FDA. Most commonly, the American people seek more freedom in the health and medicine industry. *The Independent Institute* lays out these reforms ideals, calling it "The Sensible Alternative."

Quotes on the FDA

"The FDA serves as the pharmaceutical industry's watchdog, which can be called upon to attack and destroy a potential competitor under the guise of protecting the public."

- James P. Carter, "Racketeering in Medicine: The Suppression of Alternatives," 1992

"The field of U.S. cancer care is organized around a medical monopoly that ensures a continuous flow of money to the pharmaceutical companies, medical technology firms, research institutes, and government agencies such as the Food and Drug Administration (FDA) and the National Cancer Institute (NCI) and quasi-public organizations such as the American Cancer Society (ACS)."

- John Diamond & Lee Cowden, "Alternative Medicine: Definitive Guide to Cancer," 1997

"Top scientists at the FDA have financial conflicts of interest with respect to the drugs that come under their scrutiny. These ties are often in the form of stock options. Such conflicts are commonly waived and hidden from the general public. Allowing these conflicts of interest is a result of lobbying by drug companies. Additionally, as reported in the Washington Times, many scientists are pressured to design and recommend approval of a new drug despite reservations about its safety, effectiveness or quality. This has been going on for years. The results have been, and will continue to be, disastrous."

- Shane Ellison, "Health Myths Exposed," 2006

"Economists have long argued that this one-sided situation creates a fundamental bias toward excessive drug safety. FDA staff knows that if it errs on the side of approving a drug that turns out badly, the effects will be obvious to all, whereas the effects of the opposite error of retarding new approvals will be seen only by a few insiders at the agency and among a few pharmaceutical firms and their friends (Peltzman 1973, 1974). In fact, highly public drug safety 'crises' are a fixture in the modern history of the FDA, an example being events of the late 1990s. Crises over slow drug approvals, on the other hand, are rare. Recent events have reinforced these pressures. The Vioxx episode makes clear that the incentives for FDA staff to maintain drug safety standards at reasonable or higher-than-reasonable levels remain largely undisturbed. Events have made clear that the FDA did not slight safety when it approved Vioxx…

Nonetheless, the fusillade of criticism directed at the agency over Vioxx and Cox-2 inhibitors—especially criticism from its most reliable bases of support, the academic medical community and the most prestigious medical journals—vastly exceeds any criticism it has received in recent years for being too slow to approve new drugs or too quick to remove them. The Vioxx episode has made it even more difficult for the FDA to do its job without tilting toward excessive caution in drug regulation."

- John Calfee, "Playing Catch-up: The FDA, Science, and Drug Regulation," *American Enterprise Institute for Public Policy Research*, 2006

"[FDA] is one of the reasons that industry, patients and consumers support a strong, appropriately funded FDA that has the resources to assure that our foods are safe and our biopharmaceutical, medical devices and vaccines are safe and effective…

Food contributes nearly $1.2 trillion to our economy, or 8% of the U.S. gross domestic product. Ensuring the safety of our food supply is as essential as providing for our national defense. Protecting our food supply is a major part of FDA's mission, and both the food industry and consumers benefit from a strong FDA and a growing economy…

No agency with a critical role like FDA's should be asked to do more, with less. If we are to advance medical progress and improve patients' lives-which will significantly bolster the US economy – we need to start making the FDA a national priority."

- "The U.S. Food and Drug Administration: A Cornerstone of America's Economic Future," *Alliance for a Stronger FDA*, March 7, 2011

Questions for Discussion

1. Is the FDA necessary? Why or why not?

2. There is a lot of talk about reforming the FDA. What do you think are the aspects in the biggest need of reform?

3. Discuss the general idea of patents. Why are they necessary? Are they always beneficial to society?

4. Do you think patients should have an unfettered right to try untested medications or treatments? Why or why not? What are the risks and benefits involved to the patients, their loved ones, and society as a whole?

5. ***Do some research***: Look into the connections between the FDA and the pharmaceutical industry. What are the benefits and problems arising from these connections?