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Food and Drug Administration (FDA): Overview and Issues

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Summary

The Food and Drug Administration (FDA) is the agency within the Department of Health and Human Services (HHS) that regulates human and animal drugs, medical devices, biologics, and most foods. This report describes FDA, surveys agency-related issues Congress faces, and cites CRS reports where readers can find more information.

FDA Overview

FDA is an agency within HHS that regulates a wide range of products valued at more than $1 trillion. (See **Table 1**.) The agency is responsible for the *safety* of most foods (human and animal) and cosmetics, and it regulates both the *safety* and the *effectiveness* of human drugs, biologics (e.g., vaccines, blood and blood components), medical devices, and animal drugs. In many cases, its responsibilities abut those of other agencies. (See **Table 1**.) In such cases, interagency agreements may define the regulatory boundaries.

The primary law authorizing FDA activities is the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 USC Chapter 9). (See **Table 2**.) FDA is also responsible for implementing provisions in other laws, most notably the Public Health Service Act (PHSA; 42 USC Chapter 6A). For example, FDA's authority to regulate most human biologics flows both from the PHSA (§351) and from the FFDCA. (See **Table 2**.)

FDA has three offices that perform agency-wide functions. The Office of the Commissioner conducts overall agency coordination. The Commissioner, FDA's top official, requires Senate confirmation. The Office of Chief Counsel handles the agency's legal needs. FDA's largest office, the Office of Regulatory Affairs (ORA), handles FDA's inspection and enforcement activities. It employs about one-third of the agency's personnel.

FDA's product-specific regulatory responsibilities are handled by five centers: the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Drug Evaluation and Research, the Center for Food Safety and

Applied Nutrition, and the Center for Veterinary Medicine. A sixth center, the National Center for Toxicological Research, conducts scientific research and provides expert technical advice and training that inform FDA's science-based regulatory decisions.

Table 1. What FDA Does and Does Not Regulate

Product or Activity	Regulatory Agency
Advertising	Federal Trade Commission (FTC) *(FDA regulates prescription drug and restricted device advertising)*
Alcohol	Treasury Department's Bureau of Alcohol, Tobacco, Firearms and Explosives
Biologics	**FDA**
Consumer products *(e.g., toys, cigarette lighters, power tools)*	Consumer Product Safety Commission
Cosmetics	**FDA**
Drinking water	EPA *(**FDA** regulates bottled water)*
Drugs	**FDA** *(Drug Enforcement Administration regulates illegal drug use)*
Foods	**FDA** *(U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service regulates most meat and poultry and some egg products)*
Health insurance	Centers for Medicare and Medicaid Services and state authorities
Medical Devices	**FDA**
Organ transplantation	HHS's Organ Procurement Transplantation Network
Pesticides	Environmental Protection Agency (EPA) *(**FDA** and USDA regulate pesticides in food according to EPA's allowable levels)*
Radiation-emitting electronic products	**FDA**
Restaurants and grocery stores	State and local food safety officials
Animal foods, feeds, drugs and devices	**FDA** *(USDA regulates animal biologics)*

Source: Adapted from "What FDA Regulates," at [http://www.fda.gov/comments/regs.html], and "What FDA Does Not Regulate," at [http://www.fda.gov/comments/noregs.html].

The House and Senate Appropriations subcommittees on agriculture have jurisdiction over FDA's appropriations. FDA's budget consists of two types of funds: public funds appropriated by Congress (called *budget authority* or *direct appropriations*) and private (i.e., industry) funds (called *user fees*).

Table 2. Location of Subjects Within the FFDCA

FFDCA	Subject
Chapter I	Short Title
Chapter II	Definitions
Chapter III	Prohibited Acts and Penalties
Chapter IV	Food
Chapter V Subchapter A Subchapter B Subchapter C Subchapter D Subchapter E Subchapter F	Drugs and Devices Drugs and Devices Drugs for Rare Diseases and Conditions Electronic Product Radiation Control Dissemination of Treatment Information General Provisions Relating to Drugs and Devices New Animal Drugs for Minor Use and Minor Species
Chapter VI	Cosmetics
Chapter VII Subchapter A Subchapter B Subchapter C Subchapter D Subchapter E Subchapter F Subchapter G Subchapter H Subchapter I	General Authority General Administrative Provisions Colors Fees Information and Education Environmental Impact Review National Uniformity for Nonprescription Drugs and Preemption for Labeling or Packaging of Cosmetics Safety Reports Serious Adverse Event Reports Reagan-Udall Foundation for the Food and Drug Administration
Chapter VIII	Imports and Exports
Chapter IX	Miscellaneous

FDA-Related Issues

FDA-related issues of interest to Congress generally rest on the central question of how best to give people access to useful products while protecting them from unsafe ones. Creating too many regulatory requirements raises costs and prevents products from reaching consumers. Creating too few places consumers at risk.[1]

The 110th Congress placed a new focus on FDA's regulatory responsibilities, passing the most comprehensive FDA reform legislation in almost a decade: the Food and Drug

[1] See CRS Report RL33802, *Pharmaceutical Costs: A Comparison of Department of Veterans Affairs (VA), Medicaid, and Medicare Policies*, by Gretchen A. Jacobson, Sidath Viranga Panangala, and Jean Hearne, and "Drugs, Biologics, and Medical Devices," *CRS CLI*, at [http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=2678&from=3&fromId=13].

Administration Amendments Act of 2007 (FDAAA; PL 110-85).[2] FDAAA reauthorized four expiring programs and expanded the agency's authority to regulate the safety of prescription drugs and biologics, medical devices, and foods. In the wake of that legislation, issues remain both in areas that FDAAA did not comprehensively address and in areas raised by its implementation. The following is an introduction to the types of issues that Congress now faces with respect to FDA. For further assistance with any FDA-related issue, see **Table 3** (at the end of the report) for a list of CRS experts.

Budget. The primary budget-related question faced by Congress is how to fund the agency sufficiently for it to carry out its responsibilities, while also funding competing national needs, and ensuring that the agency operates cost-effectively.[3] Some secondary budget-related questions center on user fees.[4] They ask to what extent FDA should be funded by money from the industries it regulates, and for which activities such funds should be collected and used (e.g., premarket review, inspection and enforcement).

Premarket Approval. Before FDA will permit drugs, devices, and biological products to be marketed in the United States, the agency requires evidence that they are safe and effective. (Only limited types of food ingredients require premarket approval.) Premarket approval processes vary by product type.[5] Most processes rely on evidence from clinical trials. The topic of clinical trials raises questions of when it is appropriate to test new products on people, particularly on children, and in what circumstances it is appropriate to publicize the trials and their results.[6]

The approval process for new products can take time. While this may be of little consequence for people with manageable conditions, special issues arise for people with life-threatening diseases or conditions for which there is no current treatment. As a result,

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[2] See CRS Report RL34465, *FDA Amendments Act of 2007 (P.L. 110-85)*, by Erin D. Williams and Susan Thaul, and CRS Report RS22779, *Food Safety: Provisions in the Food and Drug Administration Amendments Act of 2007*, by Donna V. Porter.

[3] See CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*, by Judith A. Johnson, Donna V. Porter, Susan Thaul, and Erin D. Williams, and CRS Report RL34638, *The FDA FY2009 Budget*, by Judith A. Johnson, Sarah A. Lister, Donna V. Porter, Pamela W. Smith, Susan Thaul, and Erin D. Williams.

[4] See CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): History, Reauthorization in 2007, and Effect on FDA*, by Susan Thaul (hereinafter RL33914); CRS Report RL34571, *Medical Device User Fees and User Fee Acts*, by Erin D. Williams; and CRS Report RL34459, *Animal Drug User Fee Programs*, by Sarah A. Lister (hereinafter RL34459).

[5] See RL33914; RL34459; and CRS Report RL32826, *The Medical Device Approval Process and Related Legislative Issues*, by Erin D. Williams (hereinafter RL32826).

[6] See CRS Report RL32909, *Federal Protection for Human Research Subjects: An Analysis of the Common Rule and Its Interactions with FDA Regulations and the HIPAA Privacy Rule*, by Erin D. Williams; CRS Report RL33986, *FDA's Authority to Ensure That Drugs Prescribed to Children Are Safe and Effective*, by Susan Thaul; and CRS Report RL32832, *Clinical Trials Reporting and Publication*, by Erin D. Williams.

some interest has been focused on mechanisms for giving people access to unapproved medications, and for speeding FDA's approval process.[7]

Products on the Market. FDA is responsible for ensuring the safety of products it regulates — including foods — once they are on the market. It accomplishes this goal through product tracking, inspection, and enforcement. Some attention has been focused on the fact that the agency has different enforcement authorities for product types. For example, FDA has mandatory recall authority for medical devices and infant formula, but not for other foods or for prescription drugs.[8] Questions have also arisen regarding whether marketing with FDA approval should preempt certain tort claims.[9]

FDA's role dovetails with product safety issues that cut across numerous agencies, creating the need for interagency coordination.[10] For products such as tobacco and genetic tests, the current patchwork of regulation — or lack thereof — has led to calls for comprehensive FDA oversight.[11] In areas of shared responsibility, such as product importation and advertising, FDA's role, and its ability or willingness to use agency resources to fulfil its responsibilities, has caused concern.[12]

Food Safety. As noted above, there is no premarket approval for foods or most food ingredients. FDA's statutory authority and historical approach are reactive, focused on foods or ingredients that are found to be unsafe.[13] Many policy makers seek a more preventive approach and debate how to craft such a system. Proposals include having FDA inspect processes instead of products, set performance measures, or increase industry's burden to assure safety. A successful approach may take into account the variety of foods FDA regulates, a growing stream of imported foods, limited global food tracking systems, and the agency's finite resources.

Advisory Committees. In its vetting of the numerous products it regulates, FDA relies on non-binding input from groups of outside experts known as *advisory committees*. Because the experts in specialized fields may often be those with a financial stake in the

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[7] See CRS Report RS22814, *FDA Fast Track and Priority Review Programs*, by Susan Thaul.

[8] See CRS Report RL34167, *The FDA's Authority to Recall Products*, by Vanessa K. Burrows.

[9] See *Riegel v. Medtronic, Inc.* (552 U.S. __ (2008); No. 06-179 (U.S. February 20, 2008)).

[10] See "Product Safety Authorities and Remedies," *CRS CLI*, at [http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=3117&from=3&fromId=13].

[11] See CRS Report RL32619, *FDA Regulation of Tobacco Products: A Historical, Policy, and Legal Analysis*, by C. Stephen Redhead and Vanessa K. Burrows; CRS Report RL33719, *Tobacco: Selected Legal Issues*, by Vanessa K. Burrows; CRS Report RS22944, *Federal Trade Commission Guidance Regarding Tar and Nicotine Yields in Cigarettes*, by Vanessa K. Burrows; and CRS Report RL33832, *Genetic Testing: Scientific Background for Policymakers*, by Amanda K. Sarata (hereinafter RL33832).

[12] See CRS Report RL32191, *Prescription Drug Importation and Internet Sales: A Legal Overview*, by Vanessa K. Burrows; CRS Report RS21711, *Legal Issues Related to Prescription Drug Sales on the Internet*, by Vanessa K. Burrows; and RL32826.

[13] See CRS Report RS22600, *The Federal Food Safety System: A Primer*, by Geoffrey S. Becker and Donna V. Porter, and "Food Safety and Nutrition," *CRS CLI*, at [http://apps.crs.gov/cli/level_2.aspx?PRDS_CLI_ITEM_ID=13].

resulting products, questions have emerged about managing conflicts of interest in the advisory committees.[14]

Products and Technologies. Questions have been raised about FDA's ability to keep up with the increasing sophistication of some types of products it regulates, such as genetic tests, follow-on (generic) biologics, and cell- and tissue-based products.[15] A similar concern has been raised about its ability to assess health threats that may arise from combined exposures to multiple types of FDA-regulated products, and other exposures.[16] Others have focused on politically sensitive products, such as the contraceptive "Plan B."[17] There are also questions about the adequacy of FDA's assessment of the safety of products produced using emerging technologies, such as biotechnology. [18] All of the above questions are intensified for *combination products* — those composed of two or more regulated components (e.g., a drug/device, or a biologic/device) — whose regulation requires coordination across FDA centers.

Table 3. CRS Experts

Area	Analyst(s) and Phone Number(s)
FDA Team Leader	Erin D. Williams (7-4897)
Foods	Donna V. Porter (7-7032), Geoffrey S. Becker (7-7287)
Human Drugs	Susan Thaul (7-0562)
Biologics	Judith A. Johnson (7-7077)
Animal Drugs and Feeds	Sarah A. Lister (7-7320)
Devices and Radiological Health	Erin D. Williams (7-4897)
Blood and Plasma Products	C. Stephen Redhead (7-2261)
Human Cellular and Tissue Products	Bernice Reyes-Akinbileje (7-2260), Erin D. Williams (7-4897)
Legal Issues	Vanessa K. Burrows (7-0831)

[14] See CRS Report RS22691, *FDA Advisory Committee Conflict of Interest*, by Erin D. Williams.

[15] See RL33832; CRS Report RL34045, *FDA Regulation of Follow-On Biologics*, by Judith A. Johnson; CRS Report RL33901, *Follow-On Biologics: Intellectual Property and Innovation Issues*, by Wendy H. Schacht and John R. Thomas; CRS Report RL34614, *Nanotechnology and Environmental, Health, and Safety: Issues for Consideration*, by John F. Sargent; CRS Report RL34332, *Engineered Nanoscale Materials and Derivative Products: Regulatory Challenges*, by Linda-Jo Schierow; CRS Report RL33540, *Stem Cell Research: Federal Research Funding and Oversight*, by Judith A. Johnson and Erin D. Williams; and CRS Report RL33554, *Stem Cell Research: Ethical Issues*, by Erin D. Williams and Judith A. Johnson.

[16] See CRS Report RL34572, *Phthalates in Plastics and Possible Human Health Effects*, by Linda-Jo Schierow and Margaret Mikyung Lee, and CRS Report RS22869, *Bisphenol A (BPA) in Plastics and Possible Human Health Effects*, by Linda-Jo Schierow and Sarah A. Lister.

[17] See CRS Report RL33728, *Emergency Contraception: Plan B*, by Judith A. Johnson and Vanessa K. Burrows.

[18] CRS Report RL33334, *Biotechnology in Animal Agriculture: Status and Current Issues*, by Geoffrey S. Becker and Tadlock Cowan.