Food and Drug Administration (FDA): Overview and Issues

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Contents

Background

Congress is interested in the issues surrounding the authorities, functioning, and budget of the Food and Drug Administration (FDA) for a range of reasons. The agency has a relationship to at least two broad legislative topics on Congress's radar: health reform and globalization. In addition, congressional oversight of the agency affects areas of public concern, such as food safety and the regulation of medical products. This report provides background information essential to understanding the issues for Congress, and provides an overview of those issues.

The FDA, an agency within the Department of Health and Human Services (HHS), regulates a wide range of products valued at more than $1 trillion. 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 border those of other agencies. (See **Appendix A**.) 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 **Appendix B**.) 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.

FDA has three offices that perform agency-wide functions. The Office of the Commissioner (OC) 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. Its inspection personnel are largely fungible, meaning that the same cadre of employees at different times conducts inspections related to food, drugs, or any other products FDA regulates.

FDA's product-specific regulatory responsibilities are handled by five centers: the Center for Biologics Evaluation and Research (CBER); the Center for Devices and Radiological Health (CDRH); the Center for Drug Evaluation and Research (CDER); the Center for Food Safety and Applied Nutrition (CFSAN); and the Center for Veterinary Medicine (CVM). A sixth center, the National Center for Toxicological Research (NCTR), conducts scientific research and provides expert technical advice and training that inform FDA's science-based regulatory decisions. For combination products (those spanning more than one category, such as drug-device, drug-biologic, and device-biologic products), the review process is conducted by a product-specific center, but assigned and coordinated by the Office of Combination Products, which is housed within the OC.

The House and Senate Appropriations Committees' Subcommittees on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies 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*).

Key Issues for Congress

A range of questions about the safety and availability products that FDA regulates has led Congress to focus attention on complex issues surrounding the authorities, functioning, and budget of the agency.[1] These issues generally rest on the central question of how best to give people access to useful products while protecting them from unsafe ones. For example, creating too many regulatory requirements may raise costs and prevent products from reaching consumers, while creating too few may place consumers at risk.[2] An effective regulatory agency facilitates consumer access to useful and safe goods.

Congress indicated that a stronger federal role was needed when it expanded FDA's regulatory responsibilities, passing the most comprehensive FDA reform legislation in almost a decade: the Food and Drug Administration Amendments Act of 2007 (FDAAA; P.L. 110-85).[3] FDAAA reauthorized four expiring programs and expanded the agency's authority to regulate the safety of prescription drugs and biologics, medical devices, and foods. At this time, 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.

The first two policy areas below (health care and globalization) extend beyond the boundaries of FDA itself, illuminating the role that the agency plays in domestic and international systems. The remaining policy areas are largely FDA-specific, highlighting the range of aspects of the agency itself that are of interest to Congress.

Health Care

Cost, quality, and access are three dimensions of our health care system. FDA's regulation of medical products affects each of these measures. Medical products comprise a large percentage—over 15%—of health care costs.[4] Their effectiveness, which FDA evaluates, is a major component of health care quality. Their availability to consumers, which FDA regulates, is one component of access to health care. In the context of health care, adding regulatory requirements may increase the quality of medical products that reach the market, but may also raise the cost of those products or delay consumer access to them.

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[1] See IS40296, *CRS Issue Statement on Drugs, Biologics and Medical Devices*, Erin D. Williams et al., and IS40286 *CRS Issue Statement on Food Safety*, by Geoffrey S. Becker, et al.

[2] See "Drugs, Biologics, and Medical Devices," *CRS CLI*, at http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=2678&from=3&fromId=13.

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

[4] This percentage is based upon CMS data from 2007. It was generated by dividing$289 billion (Retail Outlet Sales of Medical Products) by $1,878 billion (Personal Health Care). The number does not reflect all of the costs of FDA-regulated medical product involved in health care spending, because it does not include those purchased by hospitals (such as pacemakers and other implantable devices), dentist's offices (such as fillings), or other health care facilities. "Table 4 - National Health Expenditures, by Source of Funds and Type of Expenditure: Calendar Years 2002 - 2007," *CMS website*, at http://www.cms.hhs.gov/NationalHealthExpendData/downloads/tables.pdf.

In addition to affecting the health care system with its regulation of medical products, the agency also affects the system as one component of the medical product development pipeline. This pipeline is governed in part by the requirements of several federal agencies, including the FDA. For example, the early stages of a product's development might be funded by public money from the National Institutes of Health, which is granted based upon a rigorous *peer-review process*.[5] FDA permits products to be marketed if they are *safe* and *effective*. The Patent and Trademark Office provides a window of patent protection for products that are *novel, non-obvious* and have *utility*.[6] The Centers for Medicare and Medicaid Services pays for products that are *reasonable* and *necessary*.[7]

While the mission and function of each agency in the medical product development pipeline is different, a product's path to consumers might be streamlined by aligning requirements of various federal agencies. To the extent that streamlining is possible, products may be able to reach the market more quickly, thus promoting access, and less expensively, thus reducing costs. Of course, if the federal requirements are too lax, safety issues might arise, thus impairing quality.

Globalization

In the context of globalized markets, inspection and importation regulations can help to ensure that food and medical products are safe, but may also require international cooperation.[8] Issues related to product inspection and importation comprise a central element of those under the headings of both *postmarket activities* and *food safety* (below). They are highlighted here because they have been of particular interest to Congress.

FDA's approach to imported products raises several issues, the first two of which extend beyond the boundaries of the agency. One is that FDA's responsibilities with respect to imported products intersect with those of other agencies (primarily U.S. Customs and Border Protection in the Department of Homeland Security), and state and local law enforcement, creating issues where boundaries are blurred.[9] Another is that agency activities that focus on inspecting facilities and products before importation are dependent upon international treaties and agreements, which can complicate both regulation and enforcement.[10] A third is that, because FDA's inspection force is fungible, when inspectors are needed to address a problem in one area (such as tainted spinach),

[5] See, for example, CRS Report RL32324, *Federal R&D, Drug Discovery, and Pricing: Insights from the NIH-University-Industry Relationship*, by Wendy H. Schacht.

[6] See CRS Report RL34422, *U.S. Patent and Trademark Office Reforms: Regulatory Impacts Upon Innovation and Competition*, by John R. Thomas.

[7] See, for example., CRS Report RL34217, *Medicare Program Integrity: Activities to Protect Medicare from Payment Errors, Fraud, and Abuse*, by Holly Stockdale.

[8] See CRS Report RS22660, *Prescription Drug Importation: How S. 1232 (S. 525/H.R. 1298) Would Change Current Law*, by Susan Thaul.

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

[10] See CRS Report RL34198, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*, by Geoffrey S. Becker; CRS Report RL33472, *Sanitary and Phytosanitary (SPS) Concerns in Agricultural Trade*, by Geoffrey S. Becker; and CRS Report RS22713, *Health and Safety Concerns Over U.S. Imports of Chinese Products: An Overview*, by Wayne M. Morrison; CRS Report R40607, *Intellectual Property Rights and Access to Medicines: International Trade Issues* , by Shayerah Ilias; and "Food Safety," *CRS CLI* at http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=2621&from=3&fromId=13.

the number of inspectors available to conduct regular inspections, or to address concurrent problems is diminished.

FDA-Specific Issues

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 assuring that the agency operates cost-effectively.[11] Some secondary budget-related questions center on user fees.[12] The crux of the debate focuses on 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 the FFDCA permits drugs, devices and biological products to be marketed in the United States, it requires FDA to gather evidence that they are safe and effective. (Only limited types of food ingredients require premarket approval.) Premarket approval processes vary by product type.[13] Most processes rely on evidence from clinical trials. The topic of clinical trials raises questions about 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.[14]

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, some interest has been focused on mechanisms for giving people access to certain unapproved medications, for speeding FDA's approval process, and for creating product for small markets of people, such as children.[15]

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[11] See CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*, coordinated by Judith A. Johnson, and CRS Report RL34638, *FDA FY2009 Appropriations*, coordinated by Susan Thaul.

[12] See CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): History, Reauthorization in 2007, and Effect on FDA*, by Susan Thaul), and CRS Report RL34571, *Medical Device User Fees and User Fee Acts*, by Erin D. Williams.

[13] See CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): History, Reauthorization in 2007, and Effect on FDA*, by Susan Thaul and CRS Report RL32826, *The Medical Device Approval Process and Related Legislative Issues*, by Erin D. Williams.

[14] See CRS Report RL33986, *FDA's Authority to Ensure That Drugs Prescribed to Children Are Safe and Effective*, by Susan Thaul.

[15] See CRS Report R40458, *FDA Guidance Regarding the Promotion of Off-Label Uses of Drugs: Legal Issues*, by Vanessa K. Burrows and Kathleen Ann Ruane; CRS Report RS22814, *FDA Fast Track and Priority Review Programs*, by Susan Thaul; and CRS Report RL33986, *FDA's Authority to Ensure That Drugs Prescribed to Children Are Safe and Effective*, by Susan Thaul.

Postmarket Activities

FDA is responsible for ensuring the safety of products it regulates—including foods—once they are on the market. The agency's means of accomplishing this are product tracking, inspection, and enforcement. Attention has been focused on the fact that the agency has different enforcement authorities for different product types. For example, FDA has mandatory recall authority for medical devices and infant formula, but not for other foods or prescription drugs.[16] Questions have also arisen about whether compliance with FDA regulations should prevent manufacturers from liability for certain related tort claims, or whether consumers should have the right sue in such cases.[17]

FDA's role regarding product safety issues dovetails with that of numerous agencies, creating the need for interagency coordination.[18] For products such as tobacco, genetic tests, and compounded drugs, the current patchwork of regulation—or lack thereof—has led to calls for comprehensive FDA oversight.[19] In areas of shared responsibility, such as product importation, advertising, and disposal, FDA's role, and its ability or willingness to use agency resources to fulfill its responsibilities, have caused concern.[20]

Food Safety

There is no premarket approval for foods or most food ingredients. FDA's statutory authority is reactive, focused on foods or ingredients that are found to be unsafe.[21] Many policy makers seek a more preventive approach, and debate how to craft such a system. Proposals include having FDA (1) monitor processes instead of products; (2) establish performance measures; (3) increase industry's responsibility to assure safety; and/or (4) surrender its food safety responsibilities to a separate food safety agency.[22] A successful approach may take into account the variety of foods

[16] See CRS Report RL34167, *The FDA's Authority to Recall Products*, by Vanessa K. Burrows; CRS Report R40450, *Penalties Under the Federal Food, Drug, and Cosmetic Act (FFDCA) That May Pertain to Adulterated Peanut Products*, by Vanessa K. Burrows and Brian T. Yeh; and CRS Report R40109, *FDA Authority to Oversee Private Laboratories that Analyze Imported FDA-Regulated Food*, by Vanessa K. Burrows.

[17] See *Riegel v. Medtronic, Inc.*, 522 U.S. ___ (2008), and *Wyeth v. Levine*, 555 U.S. ___ (2009).

[18] See CRS Report R40534, *Riegel v. Medtronic, Inc.: Federal Preemption of State Tort Law Regarding Medical Devices with FDA Premarket Approval*, by Vanessa K. Burrows, and "Product Safety Authorities and Remedies," *CRS CLI*, at http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=3117&from=3&fromId=13.

[19] See CRS Report R40196, *FDA Tobacco Regulation: History of the 1996 Rule and Related Legislative Activity, 1998-2008*, by C. Stephen Redhead and Vanessa K. Burrows; CRS Report R40475, *FDA Tobacco Regulation: The Family Smoking Prevention and Tobacco Control Act of 2009*, by C. Stephen Redhead and Vanessa K. Burrows; CRS Report RL33832, *Genetic Testing: Scientific Background for Policymakers*, by Amanda K. Sarata; and CRS Report R40503, *FDA's Authority to Regulate Drug Compounding: A Legal Analysis*, by Jennifer Staman.

[20] See CRS Report RL32191, *Prescription Drug Importation: A Legal Overview*, by Vanessa K. Burrows; CRS Report RS21711, *Legal Issues Related to Prescription Drug Sales on the Internet*, by Vanessa K. Burrows; CRS Report R40590, *Direct-to-Consumer Advertising of Prescription Drugs*, by Susan Thaul; CRS Report RL32826, *The Medical Device Approval Process and Related Legislative Issues*, by Erin D. Williams; and CRS Report R40548, *Legal Issues Relating to the Disposal of Dispensed Controlled Substances*, by Brian T. Yeh.

[21] See CRS Report RS22600, *The Federal Food Safety System: A Primer*, by Geoffrey S. Becker; CRS Report RL34612, *Food Safety on the Farm: Federal Programs and Selected Proposals*, by Geoffrey S. Becker; and "Food Safety," *CRS CLI* at http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=2621&from=3&fromId=13.

[22] See CRS Report R40443, *Food Safety: Selected Issues and Bills in the 111th Congress*, by Geoffrey S. Becker; CRS Report RS22797, *Seafood Safety: Background and Issues*, by Geoffrey S. Becker and Harold F. Upton; and CRS Report RS22939, *FDA Authority to Regulate On-Farm Activity*, by Vanessa K. Burrows.

FDA regulates, a growing stream of imported foods, limited global food tracking systems, and the agency's finite resources.

Advisory Committees

In its evaluation of the numerous products it regulates, FDA solicits non-binding input from groups of outside experts known as *advisory committees*. Because the experts in specialized fields may often be those with financial stakes in the resulting products, questions have emerged about managing conflicts of interest in the advisory committees.[23]

Products and Technologies

Questions have been raised about FDA's ability to maintain its scientific expertise in light of the increasing sophistication of some types of products it regulates, such as genetic tests, follow-on (generic) biologics, agricultural biotechnology products, and cell- and tissue-based products.[24] 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.[25] Others have focused on FDA's treatment of politically sensitive products, such as the contraceptive "Plan B."[26] There are also questions about the adequacy of FDA's assessment of the safety of products produced using emerging technologies, such as biotechnology and nanotechnology.[27] All of the above concerns 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 administrative and scientific coordination across FDA centers.

[23] See CRS Report RS22691, *FDA Advisory Committee Conflict of Interest*, by Erin D. Williams, and "FDA Advisory Committees," *FDA website*, at http://www.fda.gov/oc/advisory/default.htm.

[24] See CRS Report RL33832, *Genetic Testing: Scientific Background for Policymakers*, by Amanda K. Sarata; 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 Jr.; CRS Report RL33540, *Stem Cell Research: Federal Research Funding and Oversight*, by Judith A. Johnson and Erin D. Williams; CRS Report RL33554, *Stem Cell Research: Ethical Issues*, by Erin D. Williams and Judith A. Johnson; CRS Report RS21044, *Legal Issues Related to Human Embryonic Stem Cell Research*, by Edward C. Liu; CRS Report RL32809, *Agricultural Biotechnology: Background and Recent Issues*, by Tadlock Cowan and Geoffrey S. Becker; and CRS Report RL33334, *Biotechnology in Animal Agriculture: Status and Current Issues*, by Geoffrey S. Becker and Tadlock Cowan. Note that tissue-based products do not include organs: see CRS Report RL33902, *Living Organ Donation and Valuable Consideration*, by Erin D. Williams, Bernice Reyes-Akinbileje, and Kathleen S. Swendiman.

[25] 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.

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

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

Appendix A. What FDA Regulates (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
Animal Foods, Feeds, Drugs and Devices	**FDA** *(USDA regulates animal biologics)*
Biologics (e.g., vaccines, blood supply, tissues)	**FDA**
Consumer Products (e.g., toys, cigarette lighters, power tools)	Consumer Product Safety Commission
Cosmetics	**FDA**
Drinking Water	Environmental Protection Agency (EPA) *(**FDA** regulates bottled water)*
Drugs (prescription and over-the-counter drug products)	**FDA** *(Drug Enforcement Administration regulates illegal use of drugs)*
Foods (foods and dietary supplements)	**FDA** *(U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service regulates most meat and poultry and some egg products. State and local food safety authorities regulate retail food establishments.)*
Health Insurance	Centers for Medicare and Medicaid Services and state authorities
Medical Devices (e.g., pacemakers, tongue depressors, wheel chairs)	**FDA**
Organ Transplantation	Health Resources and Services Administration's Organ Procurement Transplantation Network
Pesticides	EPA *(**FDA** and USDA regulate pesticides in food based on EPA's allowable levels)*
Radiation-Emitting Electronic Products *(e.g., x-ray machines, microwave ovens)*	**FDA** *(The Nuclear Regulatory Commission formulates policies and regulations governing nuclear reactor and materials safety.)*

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.

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

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