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Food and Drug Administration: Selected Funding and Policy Issues

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Summary

The Food and Drug Administration (FDA) is responsible for ensuring the safety of foods, drugs, medical devices, cosmetics, and other products. The Food and Drug Administration Modernization Act of 1997 (FDAMA) [P.L.105-115], which amended the Federal Food, Drug, and Cosmetic Act (FFDCA), created many regulatory changes and reauthorized the Prescription Drug User Fee Act (PDUFA) through FY2002. The FY2001 Agriculture Appropriations Act increased FDA's appropriation by 4% over FY2000; some say, however, that given the increase in regulatory responsibilities, this funding is not enough for FDA to ensure the safety of the public's health. The appropriations act also contained a 5-year prescription drug import program that would allow pharmacists and wholesalers to import FDA-approved prescription drugs into the United States. The former Secretary of Health and Human Services refused to request money for the program unless the statutory language could be changed to eliminate certain "flaws." Congress will also be facing requests to continue funding for the Food Safety Initiative. Most of its activities attempt to prevent the occurrence of foodborne illnesses. The 107th Congress will also be debating FDA's proposed rule on regulating bioengineered foods and its decision not to require the labeling of this food. This report will be updated once a year.

Background

The Food and Drug Administration (FDA) is the agency responsible for regulating the safety of foods, drugs, cosmetics, and medical devices. FDA is part of the Department of Health and Human Services' Public Health Service. Its legislative mandate comes from the FFDCA,[1] and the Public Health Service (PHS)Act. FDA also funds scientific

[1] Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA), as amended, (21 U.S.C. 301 et seq.) gives FDA its broad regulatory and enforcement authority. In 1968 FDA became part of the Public Health Service (PHS) within the Department of Health, Education and Welfare. In 1988 the FFDCA was amended by the Food and Drug Administration Act, Title V of the Health (continued...)

research on which it bases its regulations, and uses expert scientific advisory panels, when needed, to help with difficult policy and technical decisions.

FDA's mission is to promote and protect the public health. FDA also is responsible for ensuring that regulated products are honestly, accurately, and informatively labeled. In some cases, if the agency finds that the products do not conform to standards, FDA will identify, warn, and, if necessary, force a product's removal from the marketplace. FDA also monitors, through inspections, whether manufacturers adhere to their legal responsibility of producing products that are not defective, unsafe, filthy, or produced under unsanitary conditions.

FDA approves products — human and animal drugs, biological products (such as vaccines and blood products), medical devices, and food and color additives — through a pre-market application review program under the authority in the FFDCA. The system starts when the manufacturer or sponsor of a new drug or other product contacts the agency with an application to gain approval to test the product. (Often there are discussions prior to this application between the parties as the product is being developed.) After clinical testing has been completed, and the results of the clinical research are incorporated into a final application, the agency reviews these applications. Under the PHS, FDA must require the same evidence for biologics. If the products are shown to be safe and effective, FDA will approve them; if products are found not to be safe and effective, FDA will postpone or deny approval. The agency is required to complete reviews within statutory time frames. Most of FDA resources are used to give pre-market approval to these products.

FDA also ensures that food is safe and not adulterated. Since the FFDCA prohibits the entry into interstate commerce of adulterated or misbranded foods, FDA establishes guidance and regulatory requirements for assuring that food is safe. The agency then uses inspections to make sure that food manufacturers adhere to their legal responsibility of producing safe foods. Critics, however, claim that these inspections are infrequent because FDA would need more resources to inspect on a regular basis.

All these activities help the agency provide a broad safety net to maintain public confidence in all FDA-regulated products. As products are developed, produced, distributed, and consumed, the agency maintains contact with stakeholders (manufacturers and sponsors of products) and monitors how well industries comply with FDA-regulations. The agency maintains a monitoring system for reported injuries and illnesses from the use of FDA-regulated products that allows them to intervene with enforcement actions when necessary. It also has a surveillance system for imports of all regulated products that allows the agency to target high risk imports for sampling at U.S. borders. Although these systems appear adequate, critics contend that FDA has only the resources to investigate after a problem is identified and not to prevent problems from occurring.

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[1] (...continued)
Omnibus Programs Act of 1988 (P.L. 100-607) which required that the FDA Commissioner be appointed by the President and confirmed by the Senate.

Funding

FDA is funded through both congressional appropriations and user fee programs. The Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2001, P.L. 106-387 (October 28, 2000, 114 Stat. 1549), Congress appropriated $1.069 billion for salaries and expenses. Congress also set at $149 million the total level of collections under for Prescription Drug User Fee Act (PDUFA). Congress also appropriated $31million for FDA's buildings and facilities, and the agency will receive $21 million in collected fees authorized under different laws. These sums total $1.270 billion in budget authority for FY2001 or a 4.3% increase over the FY2000 appropriations.

Table 1. FDA Funding in Current and Constant (1996) Dollars, FY1986-FY2001

(in thousands of dollars)

FY	Current dollars		FY1996 constant dollars[b]	
	Total appropriation for FDA programs[a]	Percent change from previous year	Total appropriation for FDA programs	Percent change from previous year
1986[c]	422,833[c]	2.5%	559,451	0.3%[d]
1987	439,322	3.9%	566,283	1.2%
1988	478,764	9.0%	597,857	5.6%
1989	510,544	6.6%	613,782	2.7%
1990[c]	597,301	17.0%	691,801	12.7%
1991	685,564	14.8%	765,737	10.7%
1992	755,255	10.2%	824,514	7.7%
1993	821,039	8.7%	874,190	6.0%
1994	923,524	12.5%	961,203	10.0%
1995	948,392	2.7%	966,662	0.6%[d]
1996	981,937	3.5%	981,937	1.6%
1997	982,627	0.1%[d]	966,202	-1.6%[d]
1998	1,026,499	4.5%	996,601	3.1%
1999	1,141,849	11.2%	1,094,354	9.8%
2000	1,217,636	6.6%	1,149,798	5.1%
2001	1,270,267	4.3%	1,175,955	2.3%

Source: Data comes from the annual "Justification of Estimates for Appropriations Committees."

[a] The total includes salaries, expenses, GSA rent, reimbursable activities, and user fees. The total does not include funds for a separate account for buildings and facilities. Reimbursable activities include collections of fees when FDA certifies batches of insulin, color additives used in foods, drugs, medical devices, and cosmetics, the certification of exports, and fees collected under the Freedom of Information Act (FOIA). User fees include collections authorized under the Prescription Drug User Fee Act (PDUFA), and the Mammography Quality Standards Act (MQSA).

[b] Computed by the Congressional Research Service using the Composite Deflator as published in Table 10.1 in the FY2001 Historical Tables of the President's Budget.

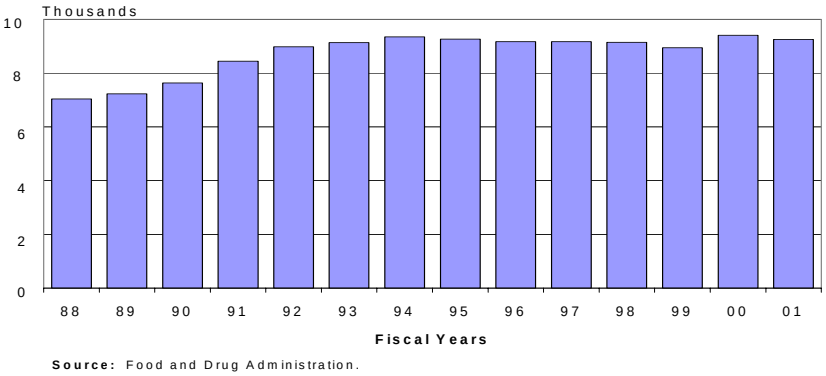
[c] The FY1986 and FY1990 amounts were available after the Gramm-Rudman-Hollings sequesters. The amounts originally appropriated were $420,306,000 in FY1986 and $585,883,000 in FY1990.
[d] Less than 1%.

Table 1 shows FDA appropriations over 16 years from FY1986 through FY2001 and includes collections from all the user fee programs and reimbursable activities. FDA's appropriations increased substantially between 1990 and 1994, the period during which Congress significantly augmented FDA's responsibilities with the passage of legislation mandating changes in food labeling and drug approval activities, for example. Appropriations leveled off from 1995 through 1998. Recently, Congress has increased FDA's appropriations by 6.6% in FY2000 and 4.3% in FY2001. FDA officials anticipate that more funding will be needed in FY2002 to continue to carry out additional responsibilities such as managing the safety risks of drugs, food products, medical devices, or biological products in the marketplace.

In FDA's total budget, excluding the amount appropriated for buildings and facilities and fees collected under other statutes, the Center for Food Safety and Applied Nutrition (CFSAN) received $285.3 million; the Center for Drug Evaluation and Research (CDER) received $317.5 million; the Center for Biologics Evaluation and Research (CBER) received $140.5 million; the Center for Veterinary Medicine (CVM) received $64 million; the Center for Devices and Radiological Health (CDRH) received $165.2 million; and National Center for Toxicological Research (NCTR) received $35.6 million. Congress also appropriated $79 million for the Office of the Commissioner and other activities, and $130.8 million for rent.

Agency Staffing

Figure 1. FDA Total Full-Time Equivalent Positions FY1998-FY2001



Source: Food and Drug Administration.

From FY1988 to FY1994, many new employees were hired to implement programs established by Congress. At the same time, user fees added resources to hire specific staff. Since 1994, staffing at the agency has been level. Employee positions, or full-time equivalents (FTEs), are shown in **Figure 1**. As user fee income increased, FDA was able to increase its numbers of FTEs paid for by these fees from 204 FTE positions in FY1993 to 1,183FTEs in FY2001. In fact, 13% of FDA's total 9,249 FTEs for FY2001 are positions paid for by user fees.

User Fees

PDUFA authorizes FDA to charge pharmaceutical companies user fees to expedite the review process for human drug and biologic applications. There are three types of fees: 1) application fees are paid when human drug applications or supplements are

submitted; 2) product fees are due annually for each marketed prescription drug product; and 3) establishment fees are also due annually for each establishment manufacturing prescription drugs. PDUFA mandates performance goals for the review process, and the fees are used to supplement existing FDA appropriations to allow FDA to hire more reviewers to meet its goals. Congress annually approves the total collections for the program in FDA's appropriations bill. Both FDA and the pharmaceutical industry consider PDUFA a success because 95% of the applications for new drugs and biologics are reviewed within the time frames specified in the law.

The Mammography Quality Standards Act (MQSA) gives FDA authority to collect user fees to pay for certifying mammography facilities and to set national standards that each facility must meet. The fees pay for annual inspections of more than 9,000 facilities by federal or state inspectors to ensure compliance with national standards.

Current Legislative Issues

Congress, in the Food and Drug Administration Modernization Act (FDAMA), revised some of the ways that FDA reviews new products and codified some of FDA's own procedures. For example, FDAMA mandated reforms in the approval processes of drugs, medical devices, biological products, and food additives. It also harmonized the rules for biologics (serums, toxins, antitoxins, vaccines, etc.) with those for drugs. It streamlined the process for reviewing manufacturing changes for drugs, and codified procedures for enhancing collaboration between FDA and manufacturers. It placed certain drugs and biologics on a faster review track and codified rules facilitating patients' access to experimental therapies. Meanwhile, although annual appropriations have grown over time (see Table 1), FDA officials complain that current resources do not allow the agency to complete some of the tasks Congress assigned to it. (See CRS Report 98-263, *Food and Drug Administration Modernization Act of 1997 — The Provisions*)

With user fees collected under PDUFA, FDA has reduced its backlogs of pending drug and biologic applications and reduced review times to 12 months in FY2001. Critics, however, have charged that the shortened review time is compromising the quality of the data review, leading to more recalls of prescription drugs. Even with a recent cluster of drug recalls, FDA officials claim that no evidence has surfaced that shows shortened review times cause more recalls than usual. Congress is considering several policy changes related to PDUFA reauthorization in FY2002. For example, some have suggested increasing the fees to widen the scope of activities funded by PDUFA, to extend the use of these resources to cover more oversight of direct-to-consumer advertising, and/or to strengthen the post-approval risk management of drugs.

As the cost of prescription drugs has risen in the United States in recent years, some U.S. consumers began asking why they were paying more than citizens in other countries for identical drugs. In the FY2001 Agricultural Appropriations Act, Congress established a program to increase the supply of drugs in this country. The Act requires that FDA promulgate regulations to establish a 5-year drug import program that would allow pharmacists and wholesalers to import FDA-approved prescription drugs into the United States. Known as the Medicine Equity and Drug Safety Act, it required that the imported drugs be manufactured in an FDA-approved facility, have a documented chain of custody, be tested by qualified laboratories, and have a brand name attached that is identical to the drugs produced in the United States. It also included a 5-year sunset provision, and

restricted countries from which the drugs can be imported. It authorized an appropriation of $23 million subject to a President's submission to Congress of an official budget request and justification. (See CRS Report RS20750, *The Prescription Drug Import Provisions of the FY2001 Agriculture Appropriations Act, P.L. 106-387*)

On December 26, 2000, Secretary of Health and Human Services, Donna Shalala, said in a letter to President Clinton that she could not request money for this program because of flaws and loopholes in the legislation. She claimed that these flaws would not provide cost savings for consumers and could pose unnecessary risks to public health. The Act prohibited manufacturers, for example, to contract with foreign buyers to interfere with the sale and distribution of the reimported drugs. However, critics note that manufacturers could circumvent this prohibition by demanding that distributors sell the drugs only at a more expensive U.S. price. Others are concerned that drug companies could limit the number of drugs available for reimportation. Still others complain that the information needed to authenticate the purity of the imported drugs is proprietary, and that this program opens the door for counterfeit drugs to enter the United States. Some Members of the 107th Congress have asked that the Bush Administration implement the program immediately; others have introduced legislation to remedy some of the flaws identified by former Secretary Shalala.

Even though the last two Congresses have supported activities of the President's Food Safety Initiative (FSI), it is unclear whether the 107th Congress will continue to do so. For FY2001, Congress appropriated a total of $217 million for FDA to use to support, among other things, food safety research, including the development of rapid screening for microbial contamination and to develop regulations for on-farm standards for the prevention of *Salmonella Enteritidis* (SE) illnesses due to shell egg consumption.

Separate from FSI funding, the 107th Congress is likely to be debating concerns over foods developed through biotechnology. There is pressure from consumers to ensure that these foods are safe, allergy-free, and not harmful to the environment. On January 18, 2001, FDA published a proposed rule that would require all food companies to notify the agency 120 days prior to marketing a bioengineered food and submit safety test data. After a data review, as proposed, FDA would send the notifying company a letter which would indicate that the agency has reviewed their tests and finds either no problems, or extends the agency review period, or that the data are inadequate. The agency, also on January 18, 2001, reaffirmed its policy that most genetically engineered foods are substantially equivalent to their conventional counterparts and that no special labeling would be required. However, they did publish guidelines for voluntary labeling. Some in Congress disagree over whether bioengineered foods are substantially equivalent. They are concerned about allergenic properties and long-term ecological risks from bioengineered food. Legislation is likely to be introduced that would require the agency to review independently the safety of the genetically modified food and to grant formal approval prior to its marketing. Other Members want to require mandatory labeling of all genetically modified food. (See CRS Report RL30198, *Food Biotechnology in the United States: Science, Regulation, and Issues*, and CRS Report RS20507, *Labeling of Genetically Modified Foods*.)