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Food and Drug Administration: Selected Funding and Policy Issues

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Summary

Under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA), the Food and Drug Administration (FDA) is responsible for ensuring the safety of foods, drugs, medical devices, cosmetics, and other products.[1] Those products account for 25 cents of every dollar U.S. consumers spend. FDA assesses the public health impact from the use of these products, and tries to anticipate and prevent hazards to public health. It evaluates and grants pre-market approval to many products, conducts postmarket surveillance, evaluates reports of adverse reactions, and takes enforcement-related actions when necessary. The Food and Drug Administration Modernization Act of 1997 (FDAMA) created many regulatory changes and new tasks and deadlines for the agency. In the President's FY1999 budget request for FDA, the agency requested a total of $1.264 billion, of which $970 million would be in budget authority, $281 million would be collected in user fees, and $13 million would come from other reimbursable activities. If funded, almost $50 million will be used for the President's food safety initiatives and $134 million will be used to reduce young people's use of tobacco. This report will be updated periodically.

Background

Presidential requests for FDA funding and the actual congressional appropriations reflect four major trends since 1985:

- There have been substantial increases in the volume and complexity of FDA's *traditional tasks*, such as premarket application review and new product approvals. Premarket reviews require trained personnel, particularly for drugs, medical

[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 1988 the FFDCA was amended by the Food and Drug Administration Act, Title V of the Health Omnibus Programs Act of 1988 (P.L. 100-607). That amendment established FDA as a unit of the Public Health Service (PHS) within the Department of Health and Human Services and required that the FDA Commissioner be appointed by the President and confirmed by the Senate.

devices, and food additives. Increases in the number of applications for approval of those products and new biotechnology products have also contributed to the growing competition for agency resources.

- Special *emergencies* arise every year. When *E. coli* O157:H7, in bottled, unpasteurized apple cider, caused an outbreak of food borne illness in November 1996, FDA food scientists and enforcement personnel worked in cooperation with other officials of federal, state, and local governments to detect the cause and to warn consumers nationwide.

- FDA has been given *new tasks.* In November 1997, Congress passed the Food and Drug Administration Modernization Act of 1997 (FDAMA), which changed how FDA reviews and regulates drugs, medical devices, and certain food additives. The Act directed FDA to publish 42 regulations, 23 guidances, and 13 other publications in the *Federal Register,* and to complete 25 other tasks by specific deadlines. In December 1997, FDA implemented a new systematic preventive approach for seafood safety called Hazard Analysis and Critical Control Point (HACCP) because food borne microbial pathogens have emerged as a public health concern. Under this approach, food firms must analyze and identify points in their food production process where risks of hazards are greatest, and they monitor each point to assure that food borne hazards do not occur. Firms must make HACCP plans and records available to FDA's investigators during inspections.

- *Public expectations* have grown with regard to the role that FDA should play in protecting the public from all types of drug, device, and food risks. The public expects FDA to approve new therapies for serious and life-threatening diseases more rapidly than in the past.

Funding

Table 1 shows FDA appropriation funding from FY1985 through FY1998, and requested funding for FY1999. In current dollars, appropriations rose approximately 146% over that time period, while in constant (FY1992) dollars, the increase was 66%. Most of this change occurred between 1990 and 1994, the period during which Congress significantly augmented FDA's responsibilities. In constant (FY1992) dollars, FDA appropriations were flat in FY1995 and FY1996, and declined by 2% in FY1997. Both Houses gave FDA an increase of 4% for FY1998 in current dollars but less than a 1% increase in 1992 dollars. The President is requesting a 23% increase for FY 1999 over last year's appropriation. The reason for the requested increase is in part that the number of applications that the agency must review for all types of FDA-regulated products has been increasing 12% each year for the last 4 years.

User Fees

The President's FY1999 budget request to Congress contained a request for $281 million to be collected in user fees to augment FDA's resources for performing specific services. Approximately $153 million would be used for standing programs, including the Prescription Drug User Fee Act (PDUFA) and the Mammography Quality Standards

Act (MQSA) of 1992, and $128 million would be used to help fund the agency's regular programs in new "general user fees."

Table 1. FDA Funding in Current and Constant (1992) Dollars, Fiscal Years (FY) 1985-1998, Request for FY1999
(in thousands of dollars)

	Current Dollars			FY1992 Constant Dollars[b]	
Fiscal Years	President's Request to Congress[a]	Congressional Appropriation[a]	Percent Change From Previous Year	Congress-ional Appropria-tion	Percent Change From Previous Year
1985	392,554	409,694	7	523,303	3
1986	417,400	420,306[c]	2	521,795	-0.3
1987	453,575[d]	436,430	4	527,535	1
1988	488,604	476,116	9	554,720	5
1989	507,456	507,456	7	570,047	3
1990	582,183[d]	592,691	17	636,481	12
1991	680,420[d]	682,131	15	702,214	10
1992	763,216[d]	751,574	10	751,574	7
1993	782,650[d]	817,647	9	796,694	6
1994	915,914[d]	918,698	12	874,867	10
1995	974,582[d]	943,398	3	876,601	0.2
1996	1,011,756[d]	963,988	2	877,150	0.1
1997	1,010,472[d]	967,197	0.3	858,662	-2
1998E	1,034,029[d]	1,008,965	4	866,809	0.9
1999R	1,236,125[d]	—	—	—	—

[a]Data is for salaries, expenses, and GSA rent. It does not include funds for buildings and facilities, reimbursable activities or certain collected fees.

[b]Prepared by the Congressional Research Service using the Composite Deflator as published in Table 10.1 in the FY1998 Historical Tables of the President's Budget. E= Estimated. R = Requested.

[c]After 1986, the numbers indicate amounts available after the Gramm-Rudman-Hollings sequesters. For example, the amounts originally appropriated were $420,306,000 in FY1986 and $585,883,000 in FY1990.

[d]The numbers include the following amounts to be collected through user fees: 1987:$31,425,000; 1990:$100,000,000; 1991:$157,175,000; 1992:$197,500,000; 1993:$200,000,000; 1994:$254,000,000; 1995:$337,923,000; 1996:$141,667,000; 1997:$145,749,000; 1998:$244,272,000; 1999:$293,380,000.

Source: Data from 1985 through 1995 is from the FY1995 Congressional Budget Submission, pp. 31-33. The FY1995-FY1999 appropriation levels are from the relevant conference reports.

In FDAMA, Congress reauthorized PDUFA, which since 1992 has been FDA's largest and most successful user fee program. PDUFA allows FDA to charge pharmaceutical companies user fees to expedite the drug development process through review of human drug and biologic applications. PDUFA fees are used to supplement existing FDA appropriations. PDUFA mandates that FDA complete certain performance goals[2] and that Congress annually approve the total collections for the program in agency appropriations bills. Both FDA and the pharmaceutical industry consider PDUFA a success because 95% of the applications for new drugs and biologics were reviewed within the time frames specified in the law. For FY1999, the President requested $132 million in fees to be authorized to be collected under PDUFA.

The Mammography Quality Standards Act (MQSA) of 1992 gave FDA authority to collect user fees to pay for certifying mammography facilities and to set national standards that each facility must meet. The current fees pay for annual inspections of approximately 8,300 mammography facilities by federal or state inspectors to ensure compliance with national quality and safety standards. Authorization for this program expired on September 30, 1997. On November 9, 1997, the Senate passed the Mammography Quality Standards Reauthorization Act of 1998 (S. 537). On November 12, 1997, the Senate referred the bill to the House Commerce Subcommittee on Health and the Environment where the House version, H.R. 1289, has already been referred. In the FY1999 budget request, the President requested $14.4 million to continue annual inspections of mammography facilities.

The President's FY1999 request also includes $6.6 million to be collected from requesters for certifying color additives, exports, and for information sent to requesters under the Freedom of Information Act (FOIA).

FDA has requested "general user fee" authority in its annual budget requests to Congress in 1987 and from 1990 to the present. (See Table 1.) These repeated requests are because user fee programs have been successful in supplementing the agency's budget. Supporters of user fee programs think that the beneficiaries of agency services should pay for the services they receive: FDA approval increases consumer confidence, improves the competitive position of U.S. firms worldwide, and gives firms significant protection from product liability. Others are concerned that such dependence on fees may lead FDA to focus on facilitating commerce of consumer products and medical therapies at the cost of diminishing its efforts to protect the public health.

For FY1999, FDA requested "general user fee" authority to collect $128 million in fees. The agency justified this new request for "general user fees" by stating that the industry should share some of the regulatory cost with the taxpayer because industry derives a direct commercial benefit from consumer's confidence in FDA's review process and product surveillance activities.

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[2] For FY1999, the performance goals include the review and processing of 90% of new drug applications within one year of submission and 90% of new drug applications for priority drugs within 6 months.

Members of both the House and Senate Appropriation Committees have not looked favorably on the request for "general user fees." The Chairman of the House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Representative Joe Skeen, stated at a recent hearing that appropriations for new general user fees "were not going to happen." [3] Previously, both the House and Senate Appropriations Subcommittees had expressed displeasure that the Administration had not proposed a legislative package to authorize such user fees.

Agency Staffing

Employee positions referred to as full-time-equivalents (FTEs), are shown in Figure 1. From FY1988-94, many new employees were hired to implement programs established by Congress, particularly the Nutrition Education and Labeling Act, PDUFA, and MQSA. Since 1996, staffing at the agency has leveled off with user fees adding resources to hire a few more employees. In FY-1994, user fees paid for 244 FTE positions; in FY1995, 453 positions; in FY1996, 685 positions; in FY1997, 677 positions; and in FY1998, 825 positions. For FY1999, FDA is requesting that 2,128 FTE's be paid for by user fees.

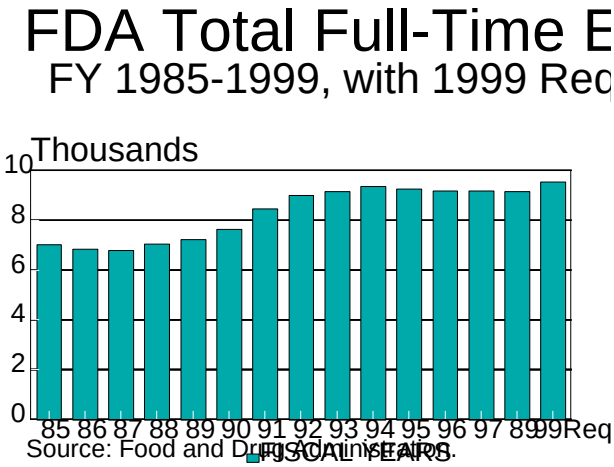

Figure 1

Current Legislative Issues

The 105th Congress is facing two related FDA issues. First, Congress is being asked to appropriate a 23% increase in FDA's appropriations for FY1999 over FY1998. The President's request is for $1.264 billion, of which $970 million is in budget authority, $281 million in user fees, and $13 million in other reimbursable activities. The request includes funding increases for two presidential initiatives and resources to carry out tasks mandated by the Food and Drug Administration Modernization Act of 1997 (FDAMA, P.L. 105-115). (See CRS Report 98-263 STM, *Food and Drug Administration Modernization Act of 1997 — The Provisions*.) Second, Congress is being urged to monitor closely how the agency is implementing FDAMA. The new law has created many regulatory changes and deadlines for the agency.

As part of this FY1999 budget request, the President has asked for authority to collect "general user fees" to pay for basic agency functions. Some in Congress are concerned that without "general user fee authorization" and with increased funding for specific initiatives, the base resources for the agency will decline and that will affect other program areas. If the appropriation subcommittees do not authorize the collection of user fees, Congress may be asked to appropriate funds to cover the cost of some of those basic

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[3] Comment by Representative Joe Skeen at a February 25, 1998, hearing before the House Appropriations Subcommittee on Agriculture.

functions. Since the conference committee has not yet met to agree on a FY 1999 budget resolution, there is concern that there may not be enough resources to cover these functions.

One such program, for which the President has asked for an increase, is the Food Safety Initiative (FSI). The President requested a total of $50 million for FDA's FSI for FY 1999, an increase of $25 million. The agency intends to use $25 million to continue to monitor the nation's food supply, particularly seafood plants. The other $25 million would be spent on expanding oversight of fresh produce, particularly imports. In FY1996, approximately 430,000 entries of fresh produce were imported. FDA inspectors examined only 0.2% of these entries for pathogen contamination.

FDA also requested an additional $100 million for a total of $134 million to fund tobacco-related outreach and enforcement activities. By the end of FY1998, the agency will have contracts with all 50 states to enforce its regulation aimed at reducing underage tobacco use. Some Members believe that state and local governments could absorb more FDA tobacco-related responsibilities. Critics in the medical device industry are concerned that FDA may over stretch its resources with those tobacco-related responsibilities. The comprehensive tobacco legislation currently under consideration by the Senate would expand the agency's anti tobacco program.

A related concern has to do with funding activities mandated by FDAMA. FDA must now meet many additional statutory requirements. The Act directed FDA to publish series of regulations, and guidances, and to execute other tasks that include negotiating international recognition agreements, harmonizing global standards, reviewing post marketing studies, and providing reports to Congress. Some say that FDA, however, has not yet been given resources necessary to carry out some of these responsibilities. Many in the regulated industries, patient groups, and consumer organizations are lobbying for increased FDA appropriations for FY 1999 to help carry out these tasks. The Administration, however, believes its request will be adequate.

Many interest groups are urging Congress to monitor closely how the agency implements FDAMA's new regulatory requirements for drug and medical device approvals. For example, FDAMA directs FDA to identify drugs that should undergo further studies to determine their optimum use in pediatrics. On May 20, 1998, FDA named 330 drugs that need pediatric research; industry has criticized the agency for not issuing guidance on how the drug list should be used by manufacturers. Some in Congress have also complained that the list did not carry out the intent of FDAMA. Other FDAMA mandates may have long term effects. FDAMA allows the dissemination of journal articles about uses of unapproved drugs if the manufacturer promises to do studies to support the claim in the article. Critics point out that an article's publication on an unapproved use of a drug in a peer-reviewed journal is no guarantee of safety or efficacy. Supporters claim that, with this incentive, manufacturers will now make an effort to get off-label uses on the label more expeditiously.

Some in Congress are also concerned about what appears to be the agency's priorities on medical devices. FDA issued a guide on managed care promotion mandated in FDAMA that some congressional staff believe went beyond the Act's requirements. The agency has issued, without complaint, several other guidance documents implementing FDAMA's requirements. One guidance laid out how industry should

collaborate on applications that declare their conformity with other devices; another set out the procedures for how the industry should file manufacturing changes in premarket approval applications.