



# The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007

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## Summary

Considerable attention has been focused on the ability of the Food and Drug Administration (FDA) to accomplish its mission with the funds provided by congressional appropriations and user fees. FDA regulates a wide range of products valued at more than \$1 trillion in the U.S. economy. The agency plays a key public health role. FDA 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), medical devices, and animal drugs.

In congressional hearing testimony and at other public venues, former FDA Commissioners, interest group representatives, and former high-ranking individuals in the agency or in the Department of Health and Human Services have argued that FDA is underfunded and at risk of being unable to fulfill all the statutory responsibilities assigned by Congress. Reports by the Institute of Medicine, the Government Accountability Office, and the FDA Science Board have made similar observations. The main voices in support of FDA budget levels, past and present, have been representatives of the various presidential administrations. Calls for cutting the FDA budget or maintaining it at the current level come from organizations, such as CATO and the Hoover Institute, that propose limitations on the agency's authority and, therefore, its need for funding. Some agency critics have expressed concerns about inefficiencies within FDA and its ability to manage its resources.

In order to inform the ongoing discussion about FDA, this report presents FDA's appropriations history and traces the evolution of the agency's statutory responsibility. It first provides a 28-year budget history for the agency along with personnel levels as shown by the number of full-time equivalent employees (FTEs). This report found that direct congressional inflation-adjusted appropriations (budget authority) to FDA doubled, and that the contribution of other funds, mostly user fees, increased more than 12-fold, resulting in an overall budget in FY2007 almost 2½ times that in FY1980. Between FY1980 and FY2006, the latest year with final FTE data, the agency's FTE level increased 19% overall, from a less than 1% increase in budget authority-funded FTEs and an almost fourfold increase in FTEs funded by other sources (mostly user fees).

The report also provides a more detailed examination of the budget and personnel levels for each of FDA's major activity areas: Foods, Human Drugs, Biologics, Animal Drugs and Feeds, and Devices and Radiological Health. Findings include the relationship of user fees to budget authority, declining funding of research, and summaries of the major laws enacted since FY1980.

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## Introduction

There is growing debate about whether the Food and Drug Administration (FDA) has the ability to accomplish its mission with the resources provided by congressional appropriations and industry user fees. FDA plays a central role in protecting the public health in the United States by regulating most of the food supply and vitally important medical products, including drugs, devices, and biologics that affect American lives on a daily basis. A 2006 report on drug safety by the Institute of Medicine (IOM) made the following observation in a chapter devoted to FDA resources:

The Food and Drug Administration lacks the resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future.... There is little dispute that FDA in general is ... severely underfunded.<sup>1</sup>

Several individuals who previously held high-ranking positions in FDA or the Department of Health and Human Services (HHS) have organized advocacy groups to lobby for increased funding for the entire agency.<sup>2</sup> These groups present data to support their position that FDA has fallen behind in overall funding in the last 25 years. They warn that the agency is at risk of being unable to adequately fulfill the many statutory responsibilities that Congress has assigned it. While the call for more resources has been heard from many quarters, including some in Congress, some agency critics are concerned about inefficiencies within FDA and that it needs to do a better job managing what resources it does have.<sup>3</sup>

In general, former FDA Commissioners and interest groups argue that FDA is underfunded for its mission. Calls for cutting the FDA budget or maintaining it at the current level come from organizations, like CATO and the Hoover Institute, that propose limitations on FDA's authority and, therefore, the need for funding. The main voices in support of FDA budget levels, past and present, have been representatives of the various presidential administrations. Over the last 25 years, incumbent FDA Commissioners, when asked during congressional hearings about the adequacy of the FDA budget, have testified that the budget is sufficient to accomplish the job before the agency. However, in non-congressional venues, those same Commissioners have expressed concerns about the constraints on FDA resources and that the agency's core budget has not increased in concert with its rising responsibilities. They have expressed concern about whether the agency can continue to be considered the world's premier consumer protection agency when it is forced to focus its priorities based on the current level of resources that it receives.<sup>4</sup>

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<sup>1</sup> Institute of Medicine (IOM), *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, Alina Baciuc, Kathleen Stratton, Sheila P. Burke, Editors, Committee on the Assessment of the US Drug Safety System, Board on Population Health and Public Health Practice (Washington, DC: National Academies Press, 2006), p. 193.

<sup>2</sup> The Coalition for a Stronger FDA, at <http://www.fdacoalition.org/the-coalition-for-a-stronger-fda>, and the FDA Alliance, at <http://www.StrengthenFDA.org>. In December 2007 the boards of these two groups announced their intention to merge; details of the merger have not been finalized ("Coalitions Lobbying for More FDA Money Are Merging," *FDA Week*, vol. 13, December 14, 2007).

<sup>3</sup> IOM, *The Future of Drug Safety*, 2006, p. 81; and Representative Rosa DeLauro, "Statement on FDA Science Board Report," December 3, 2007, at <http://delauro.house.gov/release.cfm?id=697>.

<sup>4</sup> Andrew C. von Eschenbach, "State of the FDA," *Food and Drug Law Journal*, vol. 62, 2007, pp. 423-427; and Jane E. Henney, "Remarks of the Commissioner of Food and Drugs," *Food and Drug Law Journal*, vol. 54, 1999.

This report examines FDA's appropriations history and traces the evolution of the agency's statutory responsibilities. The information is presented to help inform the ongoing discussion about FDA. *CRS takes no position on whether the agency has the necessary resources to meet its statutory responsibilities.*

The report first provides an overview of FDA's budget and personnel levels from FY1980 through FY2007.<sup>5</sup> That is followed by a more detailed examination of the budget and personnel level over the same period in each of the agency's major activity areas. For each activity area, the report also summarizes the major pieces of legislation that have been enacted since FY1980. Unless noted otherwise, all budget data have been adjusted for inflation to permit comparison across the 28-year period under investigation. The information presented in this report is intended to facilitate an examination of the impact that administrations' budget requests and congressional decision making have had on the ability of FDA to accomplish its public health mission.

## Agency Scope and Congressional Jurisdiction

FDA regulates a wide range of products valued at more than \$1 trillion in the U.S. economy. About 25% of American consumer dollars are spent on these FDA-regulated products.<sup>6</sup> As one of the agencies within HHS that comprise the Public Health Service,<sup>7</sup> FDA is responsible for the *safety* of most foods (human and animal) and cosmetics. FDA also regulates both the *safety* and the *effectiveness* of human drugs, biologics (e.g., vaccines), medical devices, and animal drugs.

The Federal Food, Drug, and Cosmetic Act (FFDCA), as amended, is the principal source of FDA's authority.<sup>8</sup> The agency also derives some of its authority from certain provisions in other laws, most notably the Public Health Service (PHS) Act. Under the PHS Act, FDA licenses biological products<sup>9</sup> and performs other activities, such as setting standards for mammography quality.<sup>10</sup> An extensive list of the public laws that significantly affect FDA activities is in **Table A-4** in the **Appendix**.

In addition to statutory responsibilities that directly involve product regulation, the FDA must also comply with statutory requirements affecting all or most federal executive agencies, regarding such matters as information management, strategic planning, performance measurement, financial management, property management, and human resources management.<sup>11</sup> Additional requirements apply only to those agencies, including FDA, that have regulatory

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<sup>5</sup> Congress had not acted on FDA appropriations for FY2008 at the time this report was being prepared. Except for **Figure 4**, the figures in this report do not include FY2008 budget or FTE levels.

<sup>6</sup> Food and Drug Administration (FDA), "Frequently Asked Questions (FAQs)," at <http://www.fda.gov/opacom/faq/faq.html>.

<sup>7</sup> CRS Report RL34098, *Public Health Service (PHS) Agencies: Background and Funding*, by (name redacted), coordinator.

<sup>8</sup> P.L. 75-717, 1938, currently 21 U.S.C. § 301 et seq.

<sup>9</sup> PHS Act § 351, 42 U.S.C. § 262.

<sup>10</sup> PHS Act § 354, 42 U.S.C. § 263b.

<sup>11</sup> For a listing of these laws, see CRS Report RL30795, *General Management Laws: A Compendium*, by (name redacted). Examples of general management laws with which FDA must comply include the Government Performance and Results Act of 1993 and the Data Quality Act.

responsibilities.<sup>12</sup> FDA's role in implementing provisions of some general federal management laws is substantial. For example, the agency supports more than 50 advisory committees, most of which are mandated in statute and are subject to requirements of the Federal Advisory Committee Act.<sup>13</sup> Also, the agency reports that in FY2006 it processed more than 20,000 information requests pursuant to requirements of the Freedom of Information Act.<sup>14</sup>

The congressional authorizing committees that oversee FDA activities are those with jurisdiction over public health issues: the Senate Committee on Health, Education, Labor, and Pensions, and the House Committee on Energy and Commerce. Because Medicare pays for FDA-regulated products, the agency also falls under the jurisdiction of the Senate Committee on Finance and the House Committee on Ways and Means. Other committees that exercise oversight roles regarding FDA include the House Committee on Oversight and Government Reform, and the Senate Committees on Aging, Homeland Security and Governmental Affairs, and the Judiciary.

The House and Senate Appropriations subcommittees on agriculture have jurisdiction over FDA's appropriations. This arrangement reflects, in part, the agency's origin within the Department of Agriculture as the Bureau of Chemistry in 1862. Since 1940, FDA has administratively been part of federal health agencies, specifically HHS and its predecessors.<sup>15</sup>

Advocates for increasing FDA funding point to this jurisdictional separation of FDA appropriations decisions from the rest of PHS and HHS as a contributing factor to what they see as underfunding. In 2002, former Acting FDA Commissioner Michael Friedman recommended moving the FDA budget process from the purview of the agriculture appropriations subcommittees to the Labor, Health and Human Services, Education and Related Agencies subcommittees.<sup>16</sup> Five years later, former FDA Commissioner Frank Young raised the same concern and made the same recommendation in congressional testimony.<sup>17</sup> Former FDA Commissioner Jane Henney made a similar observation in February 2007:

[T]here are other things Congress can do that directly impact this agency's resources ... if they really wanted to look long and hard, FDA would no longer be under the purview of the Agriculture Appropriations Committees. Those people that serve on those committees do it with honor, but they do it primarily because of their interest in agricultural issues. By the time the allocations come out and the interest of the agriculture areas are satisfied, there are very limited resources that the agency [FDA] can ever hope to receive out of that process. If somebody wanted to do something bold ... it would be looking at appropriations in an area that is more compatible ... with the interests of the members of that committee particularly the ones that oversee health issues.<sup>18</sup>

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<sup>12</sup> Examples of regulatory management laws with which FDA must comply include the Administrative Procedure Act and the Regulatory Flexibility Act of 1980.

<sup>13</sup> 5 U.S.C. Appendix. For more information, see "FDA Advisory Committees" at <http://www.fda.gov/oc/advisory/default.htm>.

<sup>14</sup> For more information, see FDA, "Freedom of Information Annual Report—FY2006," at <http://www.fda.gov/foi/default.htm>, and 5 U.S.C. § 552.

<sup>15</sup> For histories of FDA and USDA, see their respective websites, at <http://www.fda.gov/opacom/backgrounders/miles.html> and [http://www.fsis.usda.gov/About\\_FSYS/Agency\\_History/index.asp](http://www.fsis.usda.gov/About_FSYS/Agency_History/index.asp).

<sup>16</sup> Michael A. Friedman, "Strengthening the FDA," *Science*, vol. 298, December 20, 2002, p. 2332.

<sup>17</sup> Frank E. Young, statement before the Committee on Oversight and Government Reform, U.S. House of Representatives, May 1, 2007, p. 5, at <http://oversight.house.gov/documents/20070501193917.pdf>.

<sup>18</sup> Policy Workshop on Strengthening the FDA, Project on Scientific Knowledge and Public Policy, George (continued...)

# FDA Budget and Personnel

## Overall FDA Budget

The primary indicator of FDA resources is its budget. The agency's FY2007 total budget is approximately \$2 billion.<sup>19</sup> The total FDA budget, also called the *program level*, consists of (1) direct appropriations and (2) other funds (i.e., funding from other sources that are acknowledged in the appropriations acts). Direct appropriations are the amount of funds that Congress assigns to the agency from the annual total available for appropriations as set by the budget committees. Other funds include reimbursables, cooperative research and development agreement (CRADA) resources, intra- and inter-agency services (such as the Parklawn Computer Center), mammography fees, color certification fees, export certification fees, prescription drug user fees, medical device user fees, and animal drug user fees.

FDA annually prepares budget data for Congress that it presents in the *Justification of Estimates for Appropriations Committees (Justification)* documents. FDA transmits its draft through HHS to the White House Office of Management and Budget (OMB). The final *Justification* documents, reflecting any HHS and OMB adjustments, are published with the President's annual budget request to Congress. The final *Justifications* are the major source of FDA budget figures and tables in this report. Like most federal agencies, FDA has, over time, reorganized its structure, activities, and budget accounting, which makes historical budget analysis a difficult endeavor. For further information on the difficulties in compiling a budget history of the agency, and the steps taken to address those problems for this report, see the Methodology section in the **Appendix**.

Until FY1992, direct appropriations formed over 95% of FDA's total program level, with other funds contributing the small remainder. A shift began in FY1992 when Congress authorized: (1) the assessment and collection of user fees from pharmaceutical manufacturers for the review of human drug and biologics applications, and (2) fees for the inspection of mammography facilities. Congress subsequently authorized the collection of user fees for the review of medical device applications in FY2002 and animal drug applications in FY2004. By FY2007, other funds, primarily user fees, accounted for almost a quarter of FDA's total program level budget.

Another indicator of agency resources is personnel, available in the *Justification* documents as the number of full-time equivalent employees (FTEs). This is, however, an imperfect measure of personnel strength because it is not weighted by type of position, pay grade, or responsibility, each of which would provide a different measure of the agency's human resources. FDA has described how adjusting salaries for standard measures of inflation is inadequate because of the unique elements of its staff expenses, such as higher than average employee salaries, cost of health and retirement benefits, and resources required for recruitment and retention.<sup>20</sup> FTE numbers do not include contractors and, therefore, provide only a partial measure of workforce

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Washington University School of Public Health and Health Services, Washington DC, February 21, 2007, transcript at [http://www.kaisernet.org/health\\_cast/uploaded\\_files/022107\\_gwu\\_workshop\\_transcript2.pdf](http://www.kaisernet.org/health_cast/uploaded_files/022107_gwu_workshop_transcript2.pdf).

<sup>19</sup> FDA *Operating Plan* for FY2007 (March 2007), reflecting final funding levels under P.L. 110-5, Revised Continuing Appropriations Resolution, 2007.

<sup>20</sup> FDA, PDUFA IV proposal, and "PDUFA Fact Sheet," January 11, 2007, at <http://www.fda.gov/oc/pdufa4/factsheet011107.html>.

strength. If FDA's use of non-employee workers has changed during the 28-year period covered in this report, the numbers of FTEs may be an inaccurate measure of agency personnel strength.

**Figure 1** shows the total FDA budget (i.e., program level) for FY1980 through FY2007, all adjusted to FY2000 dollars.<sup>21</sup> The FDA program level is composed of direct congressional appropriations, what FDA calls budget authority, and other funds.<sup>22</sup> Using constant FY2000 dollars allows comparisons of purchasing power over the 28-year period. The stacked bars of the figure show the two broad sources of budget dollars: direct appropriations and other funds (primarily user fees). The figure also provides FTE data over the same fiscal years: FTEs funded by budget authority and total FTEs funded at program level (budget authority plus other funds, primarily user fees).

As can be seen in **Figure 1**, inflation-adjusted budget authority was relatively flat from FY1980 to FY1988, began to increase from FY1989 until FY1993 when it leveled off, coincident with the introduction of user fees in 1993. **Figure 1** also shows a decline in budget authority FTEs from FY1993 to FY2001, although the total FTEs remained relatively constant due to positions funded by user fees.

Congressional intent in authorizing user fees was that these fees would supplement—rather than replace—resources provided by Congress to FDA. Level funding from Congress—without adequate allowances for inflation, mandatory salary and health insurance increases, as well as other workload-related unfunded mandates—has resulted in declines in FTEs in areas of the agency that do not receive user fees. A 2002 Government Accountability Office (GAO) report on the impact of user fees resulting from the Prescription Drug User Fee Act (PDUFA) states that:

According to FDA officials, the agency reduced staffing levels ... to cover the costs of unfunded pay raises. From fiscal years 1994 through 2001, FDA paid about \$250 million to cover mandatory federal pay raises for which it did not receive increases in its appropriations. ... [T]his situation reduced the agency's ability to support activities not funded by PDUFA. FDA reduced the staffing levels for non-PDUFA activities each year, leaving the agency fewer resources to perform its other responsibilities. For example, in its budget justification for fiscal year 2002, FDA reported that inspection of medical device manufacturers has decreased and the agency does not routinely inspect the manufacturers of lower-risk products. Although FDA staffing in fiscal year 2001 was about the same as in fiscal year 1992, about 1,000 more FTEs were allotted to drug and biologic review activities in fiscal year 2001 and about 1,000 fewer FTEs were allotted to other FDA programs that ensure food safety, approve new medical devices such as heart valves and pacemakers, and monitor devices once on the market.<sup>23</sup>

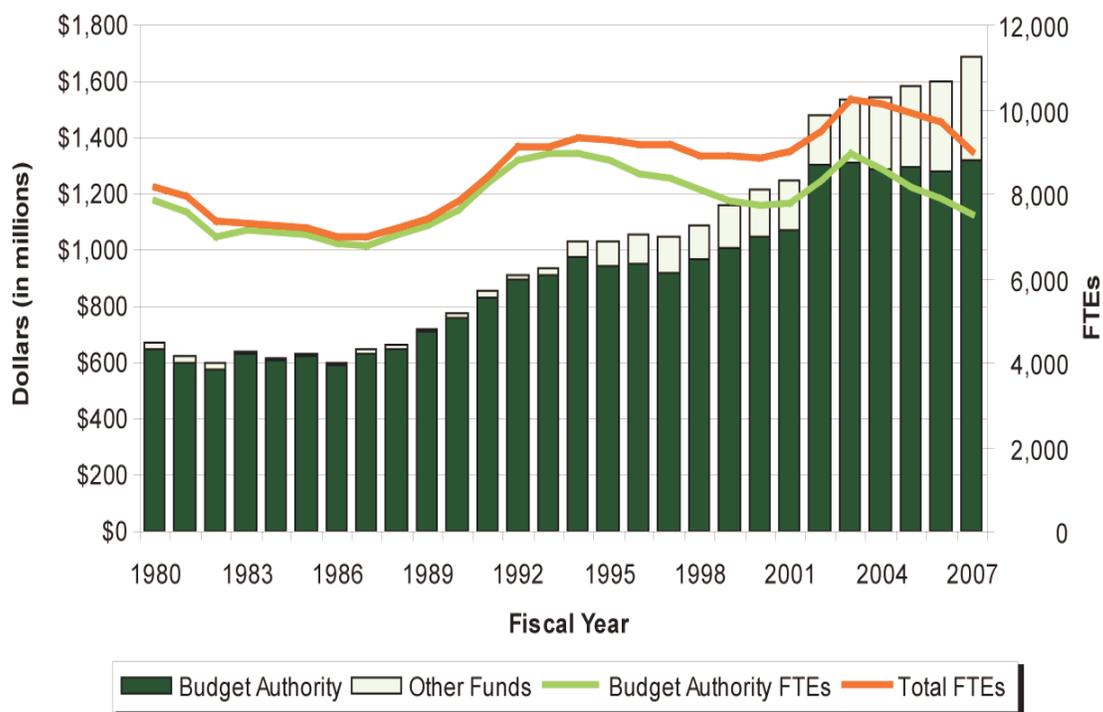
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<sup>21</sup> "Total Non-Defense" deflators were used from Table 10.1, Gross Domestic Product and Deflators Used in the Historical Tables: 1940-2012, found in *Historical Tables, Budget of the United States, Fiscal Year 2008*, pp. 192-193.

<sup>22</sup> Direct congressional appropriations and funds from user fees (often called offsetting collections) both provide budget authority to FDA. The agency, however, refers to congressional appropriations as budget authority, but not user fee-related sources of funding (which also provide budget authority but are referred to as user fees by FDA).

<sup>23</sup> U.S. General Accounting Office, *Food and Drug Administration Effect of User Fees on Drug Approval Times, Withdrawals, and Other Agency Activities*, GAO-02-958, September 2002, pp. 17-18.

**Figure I. FDA: Budget and FTEs**  
(Constant FY2000 \$)



**Sources:** For FY1980-FY2006, FDA *Justification of Estimates for Appropriations Committees* documents. FY2007 FTE data are based on an interim continuing resolution used in the FY2008 *Justification* and therefore do not reflect final action by Congress. FY2007 budget data reflect the Operating Plan developed after passage of P.L. 110-5, Revised Continuing Appropriations Resolution, 2007.

**Notes:** Total FTEs = Budget Authority FTEs + User Fee FTEs. Program Level \$ = Budget Authority \$ + User Fees \$.

**Figure 1** also shows that budget authority and FTEs increased markedly between FY2001 and FY2002, coincident with increased emergency funding following the domestic terrorist attacks. However, during the FY2002 through FY2007 period, while budget authority remained flat and other funds increased, FTEs once again declined.

In a related matter, the 2002 GAO report expressed concern about attrition among FDA staff which it found to be noticeably greater than in similar disciplines at the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC).<sup>24</sup> The 2002 GAO report states that:

[T]he agency continues to experience high turnover for reviewers because of the high demand for regulatory review personnel in the pharmaceutical industry and the higher salaries that experienced FDA reviewers can obtain in the private sector.... FDA officials

<sup>24</sup> *Ibid.*, pp. 21-23.

reported that to retain experienced staff with certain skills, they have increased the pay for approximately 250 [product] reviewers. Specifically, FDA conducted studies of staff turnover and found that toxicologists, pharmacologists, pharmacokineticists, and mathematical statisticians were leaving FDA to work in private industry and academia for higher salaries. Under [federal personnel] regulations, FDA is authorized to pay retention allowance of up to 10 percent of an employee's basic pay to a group or category of employees in such circumstances.<sup>25</sup>

The GAO report also found that “FDA reviewers, particularly those in CBER [Center for Biologics Evaluation and Research], did not participate in training and professional development activities ... to ensure that the agency meets PDUFA goals.”<sup>26</sup> The 2006 IOM report commented on the attrition of FDA personnel by stating that “although one explanation for the turnover is that FDA staff leave for promising opportunities in industry ... it is possible that turnover is indicative of a less-than-ideal organizational culture that requires attention.”<sup>27</sup>

A potential indicator of the difficulty FDA has in keeping experienced staff is the agency's issuance of retention bonuses to some employees. This practice is controversial and is under investigation by the House Committee on Energy and Commerce:

The payments ... attracted bipartisan criticism from lawmakers ... [who] say that at the FDA many of the bonuses went to the highest-paid officials rather than the scientists, inspectors and doctors most at risk of jumping to the private sector. To critics, the payments bore little relationship to the agency's performance and reputation or to the likelihood that someone might depart. Agency officials disagree and call the program a success.... In 2002, the FDA lost 12 to 13 percent of its employees, while in 2006, with the bonus program in place, it lost 5 percent.... The bonuses—which are funded in part with fees paid by industry for product reviews—bring no guarantee of retention.<sup>28</sup>

## Comparison of FDA Budget with Other Agency Budgets

**Figure 2** compares the funding, over time, for FDA, NIH, and CDC, the primary federal agencies with public health duties. In FY1980, CDC and FDA had similar funding and NIH funding was sevenfold greater than the other two agencies, as shown in **Figure 2**. Since FY1980, Congress has increased the budget ninefold for CDC, almost fourfold for NIH and about twofold for FDA (in FY2000 adjusted dollars). Other regulatory agencies similar to FDA, in that they are science-based and health-related, such as the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and the Consumer Products Safety Commission (CPSC), have received flat or declining budgets (adjusted for inflation) over this same time period.<sup>29</sup>

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<sup>25</sup> Ibid., pp. 21-22.

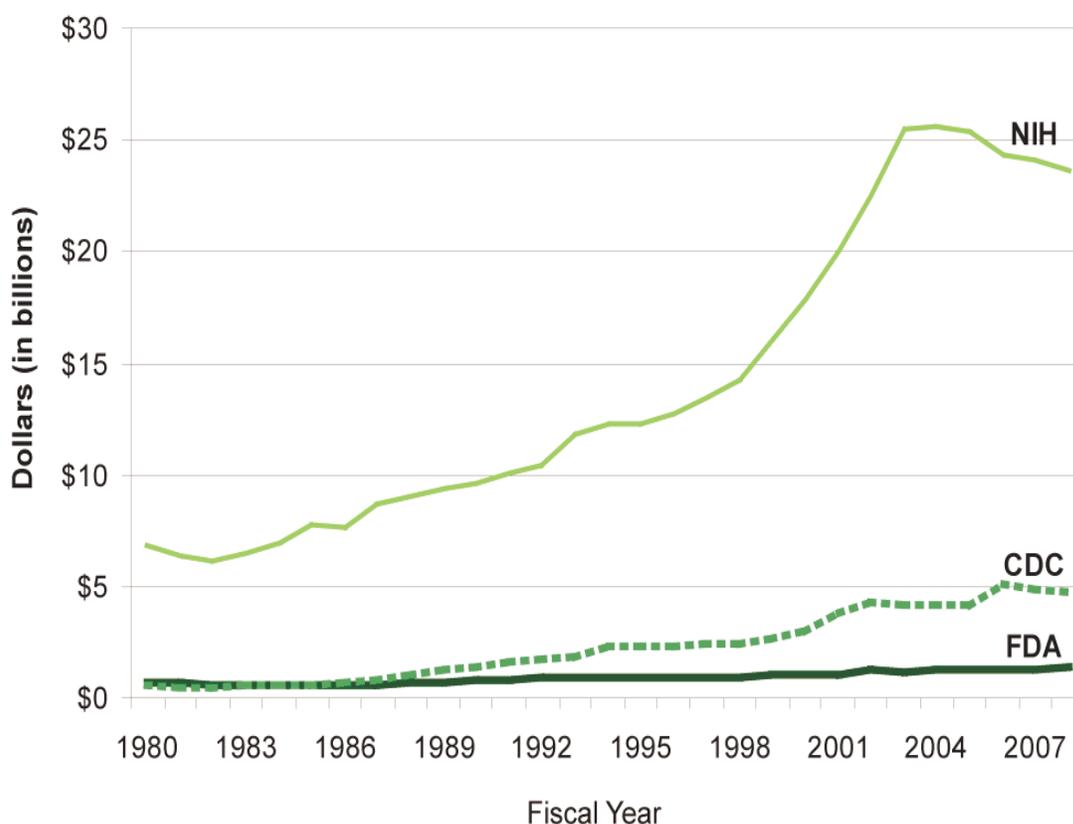
<sup>26</sup> Ibid., p. 23.

<sup>27</sup> IOM, *The Future of Drug Safety*, 2006, p. 81.

<sup>28</sup> John Solomon and Marc Kaufman, “FDA's Retention Bonuses Rise to the Top,” *The Washington Post*, August 2, 2007, p. A1.

<sup>29</sup> For EPA, see Figure 1 in CRS Report RL32856, *Environmental Protection Agency: Appropriations for FY2006*, by (name redacted) and (name redacted); for OSHA and CPSC, see budget data available on the OMB website at <http://www.whitehouse.gov/omb/budget/fy2008/db.html>.

**Figure 2. Budget Authority for FDA, CDC, and NIH**  
(Constant FY2000 \$)



**Source:** Office of Management and Budget, Budget Authority file, Public Budget Database, Budget of the United States Government, Fiscal Year 2008. Data available on the OMB website at <http://www.whitehouse.gov/omb/budget/fy2008/db.html>.

**Note:** Does not include FDA offsetting collections (user fees), which have provided an additional 20% to 25% to the FDA budget in recent years.

Concerns raised in the late 1970s about the cumulative effects of federal regulations on business resulted in the substantial changes made by the Reagan Administration in the 1980s in “how federal agencies develop and publish rules, and the degree to which federal regulations were overseen by the Executive Office of the President.”<sup>30</sup> The relatively flat funding experienced by FDA and other regulatory agencies may in part be due to the Reagan regulatory reform efforts combined with attempts to control federal spending and shrink the overall size of government.

Former FDA Commissioners, speaking on various public panels, have addressed FDA funding.<sup>31</sup> In prepared testimony for a May 1, 2007 hearing before the House Committee on Oversight and

<sup>30</sup> CRS Report RL32356, *Federal Regulatory Reform: An Overview*, by (name redacted).

<sup>31</sup> Remarks by former FDA Commissioners Jane Henney, Donald Kennedy, and Frank Young at the Policy Workshop on Strengthening the FDA, the SKAPP Project on Scientific Knowledge and Public Policy, George Washington University School of Public Health and Health Services, Washington DC, February 21, 2007, transcript at [http://www.kaisernetwork.org/health\\_cast/uploaded\\_files/022107\\_gwu\\_workshop\\_transcript2.pdf](http://www.kaisernetwork.org/health_cast/uploaded_files/022107_gwu_workshop_transcript2.pdf); and Remarks by former FDA Commissioners David Kessler and Mark McClellan at “Public Policy Implications of the Food and Drug Administration Revitalization Act (FDARA),” Center for Congressional and Presidential Studies, American University (continued...)

Government Reform, four former FDA Commissioners, Donald Kennedy, Frank Young, David Kessler, and Jane Henney, all agreed that FDA is underfunded. Dr. Kessler made the following observations on the funding Congress has provided for NIH, CDC, and FDA.

While Congress has attempted to provide resources for burgeoning public health needs on other fronts, support for the FDA has faltered in comparison. In 1986, FDA's budget was comparable to 97% of the budget for CDC and 8% of the NIH's budget. By [2006], it had dropped to 28% of CDC's budget and 5% of NIH's. Significantly, while the NIH's budget to fund the research that leads to discoveries that ultimately fill the FDA's drug pipeline has doubled over the last five years, FDA's budget has not grown.<sup>32</sup>

On this same point, former Acting FDA Commissioner Michael Friedman made the following observations:

It is myopic to fund a minimal FDA when we have doubled the NIH budget roughly every 10 years for the past 40 years ... or when the pharmaceutical industry annually invests more than \$30 billion in research and development. Because regulatory review is the final common pathway for all translational medicine, this lack of resources is rate-limiting. I cannot predict everything that our citizens demand from FDA, but I am sure they are not currently getting it. The issue is not what the FDA "needs;" it is rather what the American public deserves.<sup>33</sup>

The 2006 IOM drug safety report notes that over the years various groups have examined the same questions about the FDA and its budget and have made a variety of proposals and recommendations to improve the agency that have not been fully implemented. The IOM report goes on to state that:

A primary obstacle ... may be the chronic underfunding of core FDA activities owing to inadequate attention to resource needs by Congress and the Office of Management and Budget.<sup>34</sup>

Some Members of Congress also have expressed concern over the FDA funding level, and have voiced their frustration at the inability to obtain clarification from the agency on the adequacy of the FDA budget. A source of apparent frustration to those Members, including some who serve on the appropriations subcommittees and have indicated their willingness to increase appropriations to the agency, are the FDA officials who, year after year, neither ask for increased funding in their testimony, nor, in response to Members' questions, acknowledge what some observers perceive to be the agency's needs for additional resources. For example, in written testimony regarding the FY2004 proposed budget, FDA Commissioner Mark McClellan stated:

We believe our budget request will allow FDA to fund ongoing operations at the current level and also support more than 1,000 recently hired investigators and analytical staff to fight counterterrorism [sic]... The President's 2004 Budget was developed within a framework

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(...continued)

School of Public Affairs and FORA.tv, Washington DC, September 12, 2007.

<sup>32</sup> David Kessler, "FDA's Critical Mission and Challenges for the Future," testimony before the U.S. House of Representatives, Committee on Oversight and Government Reform, May 1, 2007, p. 2, at <http://oversight.house.gov/documents/20070501193354.pdf>.

<sup>33</sup> Friedman, "Strengthening the FDA," 2002, p. 2332.

<sup>34</sup> IOM, *The Future of Drug Safety*, p. 18.

that set a proposed total for discretionary spending in 2004, and each agency and program request reflects the [George W. Bush] Administration's relative priority for that operation, activity or program.<sup>35</sup>

In contrast to the above testimony which occurred when he was Commissioner, *former* FDA Commissioner Mark McClellan made the following statement at a March 2007 hearing of the Senate Committee on Health, Education, Labor, and Pensions:

First, the FDA will need significantly greater appropriations to improve post-market safety. The FDA is over-stretched, and a lack of trained staff and technical capabilities to perform the oversight necessary on thousands of prescription drugs is an even more pressing issue than providing the FDA with new regulatory authorities.<sup>36</sup>

Current FDA Commissioner Andrew von Eschenbach provided the following statement when commenting on the adequacy of the FY2008 budget at a Senate Appropriations Committee hearing:

These resources are an essential step in building a 21<sup>st</sup> century FDA that responds to the new opportunities and new challenges of science and technology. Our budget allows FDA to strengthen the tools we use to ensure the safety of foods, evaluate new products, and better predict—earlier and more accurately—the safety and efficacy of drugs, biologics and medical devices. With these resources, we will work to ensure that Americans enjoy the benefits of personalized medicine, a safe and wholesome food supply, and the promise of a better, healthier future.<sup>37</sup>

The IOM committee that worked on the 2006 drug safety report also was not able to ascertain the agency's funding requirements:

Convention dictates that federal agencies do not publicly articulate resource needs that differ from those offered in the President's budget, so the [IOM] committee was unable to understand fully what ... FDA leadership estimate[s] is needed to meet current objectives, let alone the expanded responsibilities the committee envisions for the future.<sup>38</sup>

In his May 1, 2007 testimony, former Commissioner Donald Kennedy confirmed this point:

I hope you and your staff will be diligent about pursuing FDA resource needs. But you may have to rely on grizzled veterans like me, because budget authorities at HHS and OMB specifically prohibit present officials in the agency from speaking out publicly about the need for more funding.... [I]t is important that Americans know, when they hear FDA

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<sup>35</sup> Written testimony of Mark McClellan, Commissioner of the Food and Drug Administration, in U.S. Congress, House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies, *FY2004 FDA Budget Request*, hearing, 108<sup>th</sup> Cong., 1<sup>st</sup> sess., March 6, 2003, at <http://www.fda.gov/ola/2003/fy2004budget.html>.

<sup>36</sup> Testimony of Mark McClellan, former FDA Commissioner, in U.S. Congress, Senate Committee on Health, Education, Labor and Pensions, *Prescription Drug Safety and User Fees*, hearing, 110<sup>th</sup> Cong., 1<sup>st</sup> sess., March 14, 2007.

<sup>37</sup> Statement of Andrew von Eschenbach, Commissioner of the Food and Drug Administration, in U.S. Congress, Senate Committee on Appropriations, Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies, hearing, 110<sup>th</sup> Cong., 1<sup>st</sup> sess., February 27, 2007, at <http://www.fda.gov/ola/2007/budget0227.html>.

<sup>38</sup> *Ibid.*, p. 199.

officials say they are satisfied with their budget allocations, that they have their fingers crossed underneath the witness table.<sup>39</sup>

Like all federal agencies, FDA's budget history reflects both Administration requests and congressional decisions on appropriations. In general, previous Administrations have not argued before Congress for increased FDA funding over the years. In some situations, however, Congress has decided to grant additional funds to agencies above an Administration's request. For example, the relevant House and Senate appropriations bill reports demonstrate that Congress has often chosen to increase NIH funding when an Administration has not requested additional appropriations. Congress is supported and encouraged in its efforts to increase the NIH budget by various health and research advocacy groups which promote their individual causes.

Some agencies are able to bypass budget adjustments made by HHS and OMB via alternative mechanisms. For example, the National Cancer Institute (NCI) at NIH is mandated by the National Cancer Act of 1971 (P.L. 92-218) "to prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institute) for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of NIH, and the Institute's advisory council."<sup>40</sup> The so-called NCI Bypass Budget received by Congress describes the increase required to maintain NCI's present level of operations and the increases required to expand existing initiatives.<sup>41</sup> Similarly, CDC has prepared a "Professional Judgment" budget in response to requests from a congressional appropriations committee.<sup>42</sup>

A regulatory agency, such as the FDA, may be perceived as an impediment to achieving the goals of advocacy groups concerned with the expeditious approval of new drugs or devices for the treatment of specific diseases. However, when drug or device adverse events occur, there is heightened concern about FDA's approval process. In general, attention to FDA's state of affairs seems to be dependent on reaction to crisis. The public and Congress tend to focus on the agency when its regulatory processes fail to meet their expectations. This phenomenon is perhaps best exemplified by the thalidomide episode in 1962.<sup>43</sup> However, even significant legislative solutions, such as the Kefauver-Harris Drug Amendments of 1962 (which required demonstration of effectiveness prior to drug approval), were not accompanied by an increase in funding for FDA. In his history of FDA and its regulation of the pharmaceutical industry, Philip J. Hilts, referring to passage of Kefauver-Harris, reported that:

Unfortunately, when Congress took this step forward, getting serious about science and testing to protect the public, it did what it had often done before: it voted to give the agency new duties and responsibilities while failing to provide the money to allow the agency to

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<sup>39</sup> Donald Kennedy, testimony before the U.S. House of Representatives, Committee on Oversight and Government Reform, May 1, 2007, p. 4, at <http://oversight.house.gov/documents/20070502110032.pdf>.

<sup>40</sup> PHS Act, Section 413(b)(9).

<sup>41</sup> U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, *The Nation's Investment in Cancer Research: A Plan and Budget Proposal for Fiscal Year 2008*, October 2006, NIH Publication Number 06-6090, p. 40, at [http://plan2008.cancer.gov/pdf/nci\\_2008\\_plan.pdf](http://plan2008.cancer.gov/pdf/nci_2008_plan.pdf).

<sup>42</sup> Centers for Disease Control and Prevention, Professional Judgment for Fiscal Year 2008, April 20, 2007, at [http://www.fundcdc.org/documents/CDCFY2008PJ\\_000.pdf](http://www.fundcdc.org/documents/CDCFY2008PJ_000.pdf).

<sup>43</sup> Philip J. Hilts, *Protecting America's Health: the FDA, Business, and One Hundred Years of Regulation*, Alfred A. Knopf, New York, 2003.

carry them out. The error would cause years of dissension and trouble, and would not be remedied for three decades.<sup>44</sup>

Presumably, the remedy Hilts is referring to is PDUFA and the implementation of user fees by FDA in 1993. Some critics argue that user fees have not solved FDA's funding problems and have led to additional complications for the agency.<sup>45</sup> Critics also suggest that the way the agency has been managed and the resource structure imposed by statute contribute to the agency's perceived problems in accomplishing its mission.

## FDA Activity-Area Budgets

FDA is organized into six centers, which cover the broad activity areas for which the agency has responsibility, and two offices that perform agency-wide functions.<sup>46</sup> The traditional *activity areas* are somewhat parallel to the current centers. FDA's major activity areas are: Foods; Human Drugs; Biologics; Animal Drugs and Feeds; and Medical Devices and Radiological Health. This report focuses on the activity areas rather than the centers, to be consistent with the presentation in the historical *Justification* documents. Center names and their activity area responsibilities have changed over time to reflect shifts in agency organization, but the agency's activity areas have stayed fairly constant over the past 25 years.

Although FDA consistently reports its budget recommendations broken out by activity areas, it is not possible, using the publicly available *Justifications*, to determine whether these categories have always included the same activities. Therefore, as with other federal agencies, it is not always possible to accurately compare categories of budget or staffing over long periods of time. An example of this, as discussed below, is the changing placement of Biologics in the agency's budget. Biologics was encompassed for a time within the Human Drug budget, and FDA's *Justifications* provide no means of separating the two activities. This report contains the most consistent accounting that was possible from the information provided in the FDA *Justifications*.<sup>47</sup> For further information on the difficulties in compiling a budget history of the agency, and the steps taken to address those problems in this report, see the Methodology section in the **Appendix**.

The Office of the Commissioner and the National Center for Toxicological Research do not have direct regulatory responsibilities and, therefore, are only described briefly in this report. Their funding and personnel are included, however, in the FDA totals. The Office of Regulatory Affairs (ORA) conducts FDA's compliance activities, including inspection and enforcement, across all activity areas. The agency's budget justification documents allocate ORA funding to each activity area as "field activities."

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<sup>44</sup> Ibid., p. 165.

<sup>45</sup> Frank E. Young, testimony before the U.S. House of Representatives, Committee on Oversight and Government Reform, May 1, 2007, p. 4, at <http://oversight.house.gov/documents/20070501193917.pdf>; and Rena Steinzor and Margaret Clune, "The Hidden Lesson of the Vioxx Fiasco: Reviving a Hollow FDA," Center for Progressive Reform, October 2005, at [http://www.progressivereform.org/articles/Vioxx\\_514.pdf](http://www.progressivereform.org/articles/Vioxx_514.pdf).

<sup>46</sup> The Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), Center for Drug Evaluation and Research (CDER), Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), National Center for Toxicological Research (NCTR), Office of the Commissioner (OC) and the Office of Regulatory Affairs (ORA). The organization tables of FDA overall and its components are available at <http://www.fda.gov/opacom/7org.html>.

<sup>47</sup> FDA cited constraints on its staff time and indicated that it would only be able to provide data for recent years.

**Table 1. Summary of Increase in Total Budget and FTEs, FY1980 and FY2006  
(Constant FY2000 \$)**

Activity Area	Measure	FY1980	FY2006	% Increase
Food	Budget	\$188,967,000	\$376,262,000	99.1%
	FTEs	2,408	2,774	15.2%
Human Drugs	Budget	\$143,292,000	\$436,454,000	204.6%
	FTEs	2,102	2,947	40.2%
Biologics	Budget	\$44,004,000	\$169,562,000	285.3%
	FTEs	507	979	93.1%
Animal Drugs & Feeds	Budget	\$46,688,000	\$83,914,000	79.7%
	FTEs	516	592	14.7%
Devices & Radiological Health	Budget	\$97,427,000	\$218,732,000	124.5%
	FTEs	1,399	1,498	7.1%
<b>FDA Total<sup>a</sup></b>	<b>Budget</b>	<b>\$675,271,000</b>	<b>\$1,597,508,000</b>	<b>136.6%</b>
	<b>FTEs</b>	<b>8,182</b>	<b>9,698</b>	<b>18.5%</b>

**Source:** FDA *Justification of Estimates for Appropriations Committees* documents.

**Note:** Detailed unadjusted budget amounts and FTE numbers can be found in this report's **Appendix, Table A-2, and Table A-3.**

a. Activity area numbers do not add to FDA totals because not all FDA functions are listed in the table.

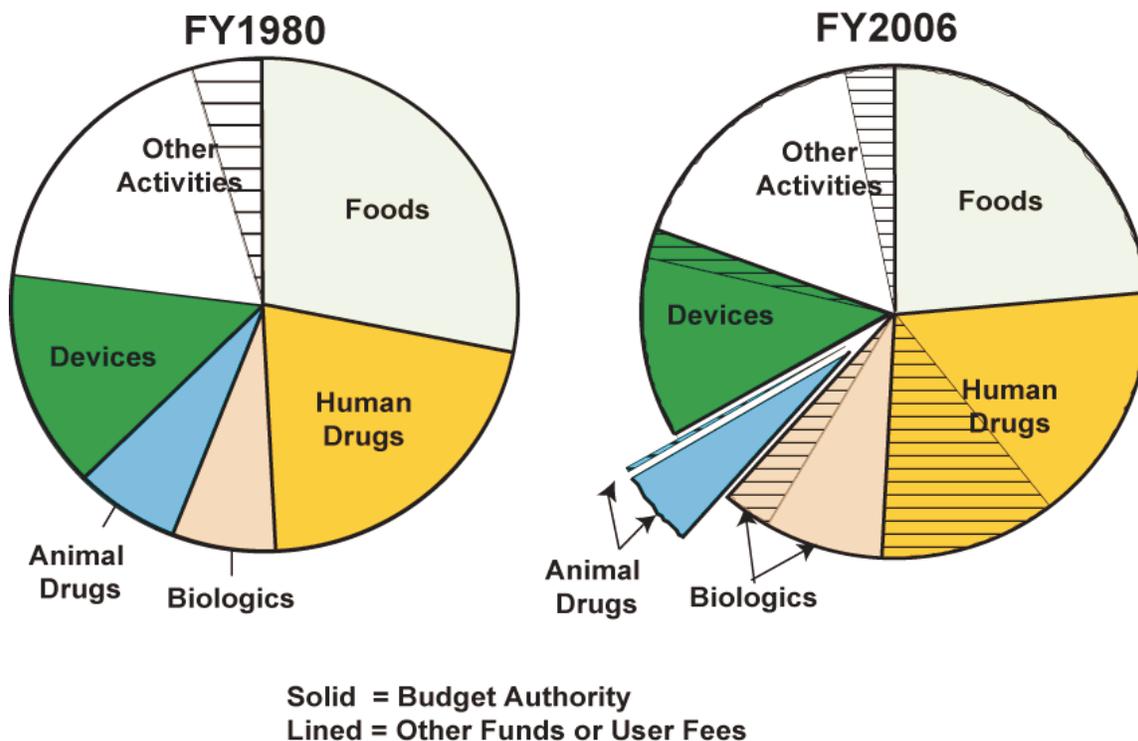
After adjusting for inflation, FDA's total budget increased by 136.6% between FY1980 and FY2006 (see **Table 1**). Over the same period, total FTEs increased by 18.5%. Each activity area within the agency reflects a greater increase in budget than in FTEs during the period. As noted above, tracking FTEs is typically an imperfect measure of changes in an agency's level of effort over time.<sup>48</sup> A variety of factors might account for the differing rates of growth of FDA's budget and staffing. A precise accounting of the possible causes of these differences was not available in FDA budget *Justifications*.<sup>49</sup> Further exploration of the reasons for the differing rates of growth in budget and FTEs is, however, beyond the scope of this report.

**Figure 3** compares the FDA budgets for FY1980 and FY2006, displaying the major activity area budgets relative to each other and to the whole agency. The figure also illustrates the relative proportions of the activity-area budgets that user fees finance. In FY2006, user fees comprised 41% of the Human Drugs budget, 30% of Biologics, 14% of Devices and Radiological Health, 8% of Animal Drugs and Feeds, and 0% of Foods. The proportion of the total FDA budget provided in direct appropriations as budget authority was 96% in FY1980 and 80% in FY2006.

<sup>48</sup> See discussion of FTEs beginning on p. 5.

<sup>49</sup> The authors requested further information from FDA which, as of the date of this report, has not been provided.

**Figure 3. FDA Budgets for FY1980 and FY2006, by Major Activity Area and Type of Funding**



**Source:** FDA *Justification of Estimates for Appropriations Committees* documents.

**Notes:** Total FDA budget without adjustment for inflation was \$340 million in FY1980 and \$1,863 million in FY2006. “Animal Drugs” is Animal Drugs and Feeds, and “Devices” is Devices and Radiological Health.

## Impact of New Statutory Authorities on FDA Budget

New statutory authorities, assigned to specific FDA activity areas, frequently mandate initiatives without resources for implementation. The implementation of major new initiatives requires adequate time and resources to meet congressional intent. Former FDA Commissioner Frank Young indicated that, while he was Commissioner, there were “mandates for 22 new activities without accompanying appropriations,” which he categorized as unfunded mandates.<sup>50</sup> He also attested to the difficulty for the agency in the implementation of new statutory language. In the case of implementing the Hatch-Waxman Act for the expeditious evaluation of generic drug products, he stated the following:

[T]here were major problems in the development of procedures within FDA, inadequate resources available for crafting the regulations, and difficulties in the implementation of the initial ANDA [Abbreviated New Drug Application] processes. Similarly, there were

<sup>50</sup> Frank E. Young, testimony before the U.S. House of Representatives, Committee on Oversight and Government Reform, May 1, 2007, p. 6, at <http://oversight.house.gov/documents/20070501193917.pdf>.

substantial budgetary needs for adequate enforcement of procedures, for approval of products developed by industry during the initial implementation of the act. The agency was in uncharted water.<sup>51</sup>

Likewise, implementation of the FDA Modernization Act of 1997 (FDAMA), required the agency to “develop 42 new regulations, 23 guidances and numerous reports and studies,” many within a year.<sup>52</sup> At the time, HHS Secretary Shalala commented on the complications and costs of carrying out the effort, which she estimated to be \$50 million.<sup>53</sup>

The \$1.58 billion that FDA has collected in prescription drug user fees since FY1993 has helped the agency improve the timeliness of its drug review process. These benefits may mask what some FDA advocates see as PDUFA’s distorting effects on within-activity-area budgeting. Congress included in PDUFA an important limitation, often referred to as a trigger, to ensure that the user fees would supplement rather than supplant appropriated funds. To collect and spend the drug user fees, FDA must maintain at least the same level of effort on activities related to human drug review as it had before PDUFA. That limitation would not affect other parts of the FDA budget if other funding were to keep pace with both inflation and the needs of the agency. However, according to FDA documents and the observations of external experts, FDA’s financial situation has changed over the 15 years since PDUFA began. FDA has had to use directly appropriated funds to keep the PDUFA-related activities at least constant over time, thereby diverting those funds from other uses. FDA financial reports, required under PDUFA, have claimed that this unanticipated PDUFA effect has resulted in “an erosion of core FDA programs.”<sup>54</sup>

## FDA Regulatory Research

The research program at FDA provides scientific support for regulatory issues addressed by the agency. Research has been a part of the agency almost from the time of its inception in 1906.<sup>55</sup> All five FDA activity areas support research with Foods conducting the largest program in FY2006, followed by Biologics, Devices and Radiological Health, Animal Drugs and Feeds, and Human Drugs, which has a very small research program. Research performed in the five FDA activity areas comprises about 50% of the FY2006 FDA research budget. Other entities within FDA that perform research are the National Center for Toxicological Research (33%), Office of Orphan Products (11%), Program Management (3%), and Buildings and Facilities (3%).<sup>56</sup> **Figure**

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<sup>51</sup> Ibid.

<sup>52</sup> Jill Wechsler, “The ‘R’ in CDER and CBER,” *Pharmaceutical Technology*, April 1998, p. 14.

<sup>53</sup> Ibid.

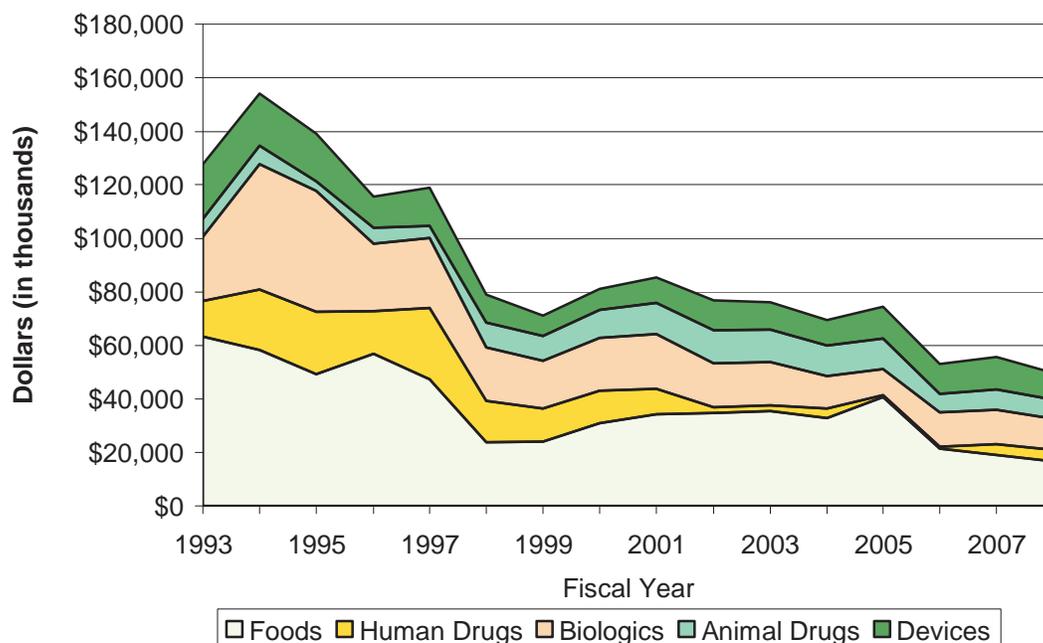
<sup>54</sup> See discussion of “triggers” in “Human Drugs” section of this report, as well as the FDA *White Paper Prescription Drug User Fee Act (PDUFA): Adding Resources and Improving Performance in FDA Review of New Drug Applications*, at <http://www.fda.gov/oc/pdufa/whitepaper11-10/whitepaper11-10.html>, and the *FY2001 PDUFA Financial Report*, at <http://www.fda.gov/oc/pdufa/finreport2001/financial-fy2001.htm>, and the *FY2000 PDUFA Financial Report*, at <http://www.fda.gov/cder/pdufa/financial-fy2000.htm>, and the *FY1999 PDUFA Financial Report*, at <http://www.fda.gov/oc/oms/ofm/accounting/pdufa/1999Report.htm>.

<sup>55</sup> The Bureau of Chemistry established a Food Research Laboratory shortly after it was created within the Department of Agriculture. See the Science Board Subcommittee on FDA Research, “Recommendations to the Science Board of the Food and Drug Administration,” Final Draft Report, March 13, 1997, Appendix D, “An Abbreviated History of at Least Four Decades of Efforts to Upgrade the Quality of Science in the FDA,” at <http://www.cfsan.fda.gov/~frf/sxsbrd.html>.

<sup>56</sup> FDA research budget data from RAND Corporation RaDiUS database, November 7, 2007. RaDiUS, which stands (continued...)

4 shows the amount of support for research within the five FDA activity areas from FY1993 through FY2008.

**Figure 4. FDA Research in Five Activity Areas (Constant FY2000 \$)**



**Sources:** FDA research budget data was provided by Donna Fossum of the RAND Corporation using the RaDiUS database on November 7, 2007. Data collection for RaDiUS began with FY1993. FDA data collected for FY2006 through FY2008 were received by RAND from FDA Office of Budget Formulation and Presentation (OBFP) via Edward King, HHS Office of the Assistant Secretary for Management and Budget, in March 2007. Amounts for Foods for FY2006 through FY2008 were adjusted per personal communication with Robert Miller, FDA-OBFP, on November 19, 2007.

The appropriate role of research in fulfilling FDA’s mandate to license and approve safe and effective products has been a contentious issue at least since the early 1970s.<sup>57</sup> At the request of former Deputy Commissioner for Operations Michael Friedman, a review of FDA research was conducted in 1996 by a subcommittee of the FDA Science Board. The Chairman of the subcommittee, Dr. David Korn, stated that “Congress has not been asked to support research explicitly; [research] has always been buried in the agency’s budget.”<sup>58</sup> Dr. Korn suggested that it would require a major educational effort by industry to convince Congress that research is essential to the function of FDA because “industry is, in a sense, the FDA’s customer,” and “if the

(...continued)

for “Research and Development in the United States,” tracked all research and development activities and resources of the government from FY1993 through FY2008. The contract for RaDiUS operations and maintenance has ended and the database is no longer available. See <https://radius.rand.org/>.

<sup>57</sup> Charles Marwick, “FDA Funding Problems Imperil Safety of Biological Products in the United States,” *Journal of the American Medical Association*, March 25, 1998, pp. 899-901.

<sup>58</sup> *Ibid.*, p. 900.

thrust came from industry, it would carry weight with the Congress.”<sup>59</sup> The final report of the subcommittee, dated March 1997, stated that:

The decreasing agency [research] budget is of overarching concern. Although there is general appreciation of the fact that in times of constrained resources the agency must take particular care that its mandated regulatory responsibilities are competently discharged, there is a widely held perception among agency scientists that the research programs do not have strong advocacy at the highest levels of agency leadership and are front-line targets for curtailment or elimination as discretionary resources decline. The subcommittee believes strongly that starving the agency’s base of intramural scientific expertise must inevitably compromise the quality of review and regulatory activities.<sup>60</sup>

The role of FDA research and the level of resources required for its support continues to be identified as an issue for the agency. During the May 1, 2007, congressional hearing, the former Commissioners specified the lack of financial support for the research program at FDA as a major concern. Former commissioner Frank Young stated that “research at CBER has been eviscerated through a recent reorganization and is almost non-existent in CDER. To maintain the expertise necessary for expeditious but highly competent decisions on new breakthrough products,... it is essential to have a well trained scientific staff that is given the time to not only maintain scientific expertise but to pursue career development in their chosen field of science.”<sup>61</sup> On this same point, former commissioner David Kessler stated that:

The erosion of funding has struck hard at the Agency’s ability to support its proud tradition of groundbreaking research in regulatory science. While in the past, the Agency led the way in developing new scientific paradigms for approving biologics and assessing food contaminants—to the benefit of both industry and consumers—resources for FDA to lend its intellectual firepower to addressing key regulatory questions are increasingly scarce.<sup>62</sup>

## **FDA Science Board Report**

A report that assessed “whether science and technology at the FDA can support current and future regulatory needs” was released in November 2007.<sup>63</sup> The report was requested by FDA Commissioner Andrew von Eschenbach in December 2006 and was prepared by the FDA Science Board, a group of independent advisors. It found that FDA “suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities.”<sup>64</sup> The report points at two reasons for the deficiency: the demands on FDA have soared, and resources have not increased in proportion to the demands. It states that “due to constrained resources and

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<sup>59</sup> *Ibid.*, p. 901.

<sup>60</sup> The Science Board Subcommittee on FDA Research, “Recommendations to the Science Board of the Food and Drug Administration,” Final Draft Report, March 13, 1997, at <http://www.cfsan.fda.gov/~firf/sxsbr.html>.

<sup>61</sup> Frank E. Young, testimony before the U.S. House of Representatives, Committee on Oversight and Government Reform, May 1, 2007, p. 3, at <http://oversight.house.gov/documents/20070501193917.pdf>.

<sup>62</sup> David Kessler, “FDA’s Critical Mission and Challenges for the Future,” testimony before the U.S. House of Representatives, Committee on Oversight and Government Reform, May 1, 2007, p. 3, at <http://oversight.house.gov/documents/20070501193354.pdf>.

<sup>63</sup> FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk*, November 2007, at [http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b\\_02\\_01\\_FDA%20Report%20on%20Science%20and%20Technology.pdf](http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf).

<sup>64</sup> *Ibid.*, p. 2.

lack of adequate staff, FDA is engaged in reactive regulatory priority setting or a fire-fighting regulatory posture instead of pursuing a culture of proactive regulatory science.”<sup>65</sup>

The FDA Science Board was specifically asked to review the status of science and technology at FDA, and *not* to evaluate the available resources. However, the report states that the status of science and technology was “so intertwined with two decades of inadequate funding that it was impossible to assess technology without also assessing resources.”<sup>66</sup> The Science Board also looked at reports on FDA issued by previous review committees, each given a similar charge over the past 50 years. It found that the concerns outlined in past reports were the same as those in the present and that FDA has consistently been unable to implement the needed changes. An advisor to the Science Board, Garret A. FitzGerald, blamed a faction of “congressional majorities and presidential administrations that has serially stripped the agency of assets.”<sup>67</sup>

Representative Rosa DeLauro, who in the 110<sup>th</sup> Congress was appointed chair of the House Appropriations Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies, stated that the November 2007 report confirms facts that she believes have been apparent to Congress and FDA for some time. “[S]cience at the FDA is deteriorating and the agency lacks the planning, management structure, and resources to restore their scientific capabilities.”<sup>68</sup> She further states that although her subcommittee is working on providing additional funds for the agency, “money alone will not resolve the problems at FDA—these additional funds need to be supported by an adequate management structure and a sound plan on how these funds will be used to ensure that they are not wasted.”<sup>69</sup>

The FDA Science Board report concluded that “FDA can no longer fulfill its mission without substantial and sustained additional appropriations,” and that the agency is in danger of “losing its remaining dedicated staff” if the “chronic underfunding of the agency” is “not addressed immediately.”<sup>70</sup> The report stated that there is “insufficient investment in professional development [for FDA staff], which means that the workforce does not keep up with scientific advances.... Inadequately trained scientists are generally risk-averse, and tend to give no decision, a slow decision or, even worse, the wrong decision on regulatory approval or disapproval.”<sup>71</sup> The report also concluded that funding increases recommended by other groups, such as IOM and the Coalition for a Stronger FDA, are insufficient to allow all the changes necessary for the agency to fulfill its mission. “Without a substantial increase in resources, the agency is powerless to improve its performance, will fall further behind, and will be unable to meet either the mandates of Congress or the expectations of the American public. This will damage not only the health of the population of the U.S., but also the health of the economy.”<sup>72</sup>

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<sup>65</sup> Ibid., p. 4.

<sup>66</sup> Ibid., p. 6.

<sup>67</sup> Gardiner Harris, “Advisers Say FDA’s Flaws Put Lives at Risk,” *The New York Times*, December 1, 2007.

<sup>68</sup> DeLauro Statement on FDA Science Board Report, December 3, 2007, at <http://delauro.house.gov/release.cfm?id=697>.

<sup>69</sup> Ibid.

<sup>70</sup> FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk*, p. 7.

<sup>71</sup> Ibid., pp. 4-5.

<sup>72</sup> Ibid., p. 8.

## Major Activity Areas: Budget and FTEs

The next sections of this report provide, for each FDA major activity area, a brief description of the statutory responsibilities in 1980 and an overview of how the agency's responsibilities have expanded over the years up through 2007. Juxtaposed with the presentation of increasing responsibilities for the activity area is a presentation and analysis of the budget and number of FTEs for the period FY1980 through FY2007.<sup>73</sup> The descriptions of FDA's responsibilities and resources provide a background against which to examine FDA funding needs. Other CRS reports examine the particulars of many FDA activities and their funding.<sup>74</sup>

### Foods<sup>75</sup>

FDA is responsible for promoting and protecting the public's health in part by ensuring that the food supply is safe, sanitary, wholesome, and accurately labeled. The agency regulates all foods, except for meat and poultry which are regulated by the U.S. Department of Agriculture (USDA).<sup>76</sup> It is also responsible for assuring that cosmetic products are safe and properly labeled. The agency regulated \$417 billion worth of domestic food, \$49 billion worth of imported food, and \$60 billion worth of cosmetics in 2001.<sup>77</sup> These numbers encompass the economic activity of about 50,000 food establishments (manufacturers, processors, and food warehouses) and 3,500 cosmetic firms.<sup>78</sup> Not included in these figures are the roughly 600,000 restaurants and institutional food service establishments and 235,000 supermarkets, grocery stores, and other food outlets that are regulated by state and local authorities, for which FDA provides guidance, model codes, and other technical assistance.

Although FDA is responsible for ensuring the safety of the food supply, its role is primarily reactive since most foods and their ingredients are not subject to prior approval or even review before they enter interstate commerce. The agency does have responsibility over some product ingredients that require premarket approval, such as food and color additives. FDA also performs postmarket monitoring of food labels and investigates food safety problems that arise. The agency's surveillance program tests food samples to determine if pesticide residues or heavy metals are present in unacceptable amounts. It also sets standards for label information to assist consumers in determining the ingredient and nutrient content of the foods that they are purchasing. The agency's current activities related to foods are primarily conducted by the Center for Food Safety and Applied Nutrition (CFSAN).

The Pure Food and Drug Act of 1906 gave the agency its initial authority to prohibit the interstate commerce of adulterated or misbranded food products, along with the authority to assess criminal penalties for violations and seize offending products. The Federal Food, Drug, and Cosmetic Act

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<sup>73</sup> Budget size varies across the activity areas within FDA. The budget range shown in each figure reflects a scale appropriate to allow clear illustrations of the within-activity area budget variation across years.

<sup>74</sup> See listings of CRS products relating to FDA-regulated foods, human drugs, biologics, devices, animal drugs, and cross-cutting issues at [http://apps.crs.gov/cli/cli.aspx?PRDS\\_CLI\\_ITEM\\_ID=2678](http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=2678) and [http://apps.crs.gov/cli/cli.aspx?PRDS\\_CLI\\_ITEM\\_ID=2621](http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=2621).

<sup>75</sup> This section was prepared by (name redacted), Specialist in Food Safety and Nutrition.

<sup>76</sup> CRS Report RS22600, *The Federal Food Safety System: A Primer*, by (name redacted) and (name redacted).

<sup>77</sup> FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk*, 2007, p. 11.

<sup>78</sup> See <http://www.cfsan.fda.gov/~lrd/cfsan4.html>.

of 1938 (FFDCA), building on the provisions of the 1906 Act, required the agency to promulgate definitions and standards for foods and informative labeling. It also prohibited false advertising and the addition of substances that would render the food adulterated. Over the years, several amendments to the act added authorities that required FDA to establish (1) tolerances (safe levels) for pesticides on agricultural commodities; (2) premarket approval systems for food and color additives, and packaging substances; (3) rules for labels to facilitate price comparisons; and (4) rules to assure that packages contain the amount of product the label claims.

By FY2007, Congress had added a number of new FDA authorities to those that existed before FY1980 (see **Table 2**). Under the Infant Formula Act of 1980 (P.L. 96-359) FDA established requirements for the manufacturing, labeling, and nutrient standards for these products. The Nutrition Labeling and Education Act of 1990 (NLEA, P.L. 101-535) provided authority for (1) mandating nutrition labels on most food products, and (2) following the agency's review, allowing nutrient content and health claims. In addition, NLEA preempted most state and local requirements for labeling, giving FDA responsibility for regulating all aspects of nutrition labeling information. NLEA resulted in the promulgation of a significant number of new regulations and revisions of old rules for consistency with the new authorities. The Dietary Supplement Health and Education Act of 1994 (DSHEA, P.L. 103-417), provided specific authority for the regulation of supplements and placed the burden of proof on the agency to demonstrate that a supplement already on the market was unsafe and needed to be removed.

The Food Quality Protection Act of 1996 (P.L. 104-170) established a single health-based standard for pesticides in all foods and provided special safety provisions for infants and children. After FFDCA provisions were amended by the FQPA of 1996, FDA continued to monitor pesticide residue levels in food in interstate commerce (which it does through its total diet study) and enforce tolerances through its food inspection programs, while EPA remains the lead agency on setting tolerances and related issues. The Food and Drug Administration Modernization Act of 1997 (P.L. 105-115) eliminated premarket approval of food-contact substances (i.e., packaging materials), replacing it with a notification process, along with expanding procedures for FDA authorization of health and nutrient content claims under the NLEA statutory standard.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) required all domestic and foreign facilities that manufacture, process, pack, or hold food for U.S. consumption to register with FDA and maintain records for agency inspection. The act also required prior notice to FDA of products being imported into the United States and provided the agency with administrative detention authority and penalties.

The Food Allergen Labeling and Consumer Protection Act of 2004 (P.L. 108-282) required that a specific statement appear on a food label when any of the most common allergens are present in a food. In 2006, the Dietary Supplement and Nonprescription Drug Consumer Protection Act (P.L. 109-462) was enacted, which created a system for reporting to FDA any serious adverse events associated with the use of a dietary supplement, as well as record keeping and inspection authority that may be necessary in cases of a reported adverse event.

Food safety provisions within the Food and Drug Administration Amendments Act of 2007 (P.L. 110-85) required the creation of a registry for reportable information on foods with safety problems. It also allowed for the identification of the supply chain of the questionable food item.

Adjusted for inflation, FDA's foods budget doubled between FY1980 and FY2007; the number of FTEs increased by 15.2% during the same period. Despite substantial increases in statutory

authority during the period, FDA's Foods activity did not gain the authority to collect user fees, unlike the other activity areas (discussed below).

**Table 2. Foods Statutory Authorities in 1980 and 2007**

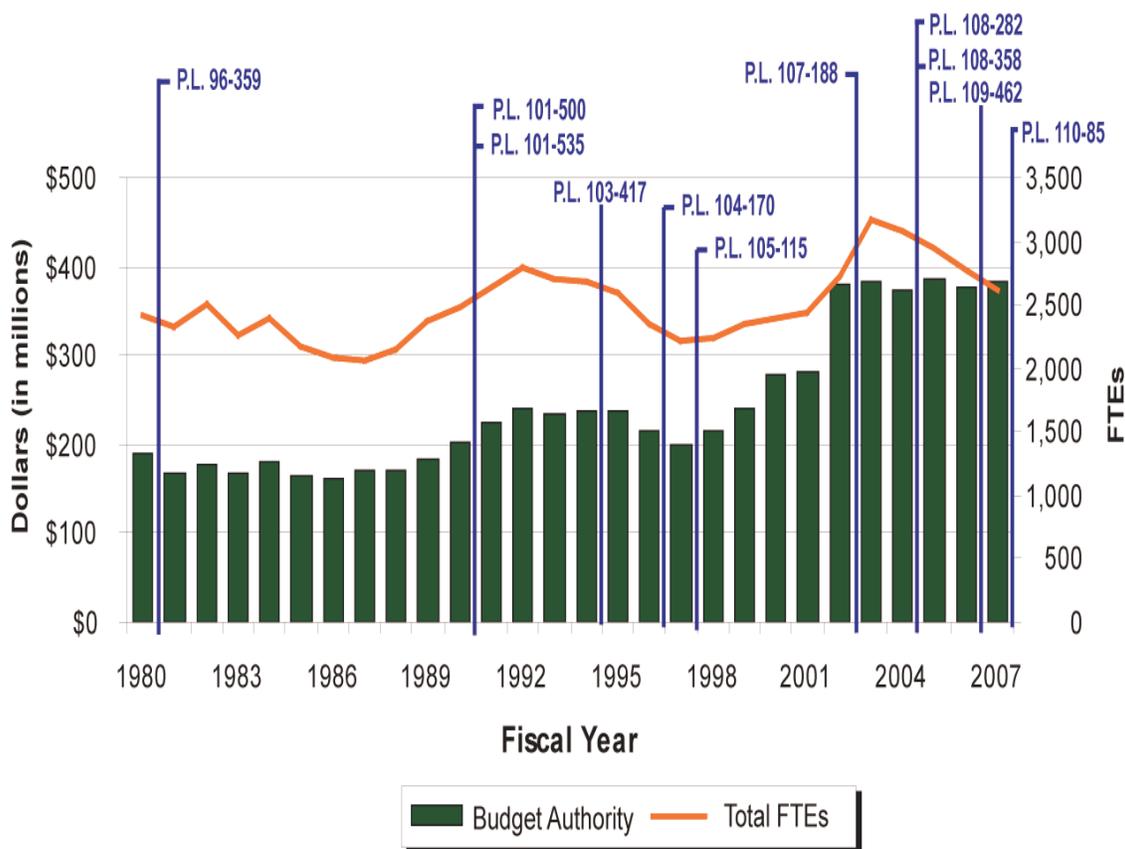
<b>Authorities in 1980</b>
Prohibited interstate commerce in adulterated or misbranded products; provided criminal penalties for violations and authorized seizures of offending products (P.L. 59-384).
Defined filled milk and considered it adulterated, injurious to health and a fraud (P.L. 67-513).
Required the issuing of valid permits for importation of milk and cream (P.L. 67-625).
Required definitions and standards for foods and informative labeling; prohibited false advertising and the addition of substances that rendered the food adulterated (P.L. 75-717).
Established premarket approval system for new food additive and packaging substances (P.L. 85-929).
Established premarket approval system for colors used in food, drugs, and cosmetics (P.L. 86-618).
Required rules to prevent non-functional fill of packages and to require legible, prominent label statements for net quantity of contents (P.L. 89-755).
Required inspection of egg products and established uniform standards for grading eggs (P.L. 91-597).
Limited authority to regulate the composition and promotion of dietary supplements (P.L. 94-278).
<b>Authorities Added Between 1980 and 2007</b>
Required rules for reporting, quality control, recall, exemption labeling and nutrient content for infant formulas; amended for additional recall, microbiological testing and record retention requirements (P.L. 96-359).
Required assistance with food transportation inspections (P.L. 101-500).
Mandated nutrition labeling and review of nutrient content and health claims; preempted state and local requirements, transferring to FDA the regulation of all aspects of nutrition labeling information (P.L. 101-535).
Provided specific authority to regulate dietary supplements and placed the burden of proof for safety on FDA for products already on the market; required rules for notification for statements of nutritional support, ingredient and nutrition information, petition process and review of new dietary ingredients, and good manufacturing practices (P.L. 103-417).
Required a single health-based standard for all pesticides in raw and processed foods; provided special pesticide safety standards for infants and children; limited consideration of benefits and allowed civil penalties for tolerance violations; required tolerance levels reevaluation in a decade; required endocrine testing, the right to know, and national uniformity of tolerances. Required FDA to monitor pesticide residue levels on foods it regulated in interstate commerce and enforce tolerance levels through its inspection programs (P.L. 104-170).
Eliminated premarket approval of food contact substances and substituted a notification process contingent on funding to cover FDA's cost; expanded procedures for authorizing health and nutrient content claims without reducing the statutory standards (P.L. 105-115).
Required all domestic and foreign facilities that manufacture, process, pack or hold food for U.S. consumption to register and maintain records for inspection for any product believed to be adulterated; required prior notice of products being imported into the United States; provided administrative detention authority and penalties for credible evidence that a product presents a threat of serious adverse health consequences or death to humans or animals (P.L. 107-188).
Required a specific statement about most frequent allergens to appear on the label when any of those allergens are present in a food (P.L. 108-282).
Reclassified as controlled substances any product containing an anabolic steroid or a precursor that would be converted to a steroid in the body (P.L. 108-358).
Required the reporting to FDA of any serious adverse events that result from the use of a dietary supplement or nonprescription drug; provided record keeping requirements and inspection authority needed for an investigation (P.L. 109-462).
Required the creation of a registry for reportable information on foods with safety problems that allows for identification of the supply chain of the reportable food (P.L. 110-85).

In **Figure 5**, changes in the foods budget and FTEs reflect certain events and policy initiatives during the 28-year period. The budget was relatively flat through the 1980s with requests primarily for mandatory costs and no program increases. The increase in budget and FTEs in the early 1990s reflect the considerable amount of work required to implement NLEA and the simultaneous CFSAN reorganization. Food safety activities also contributed to the modest increase in FTEs and funding. The subsequent drop off of FTEs from FY1992 to FY1997 represents both deficit reduction efforts and a shift in FTEs to elsewhere in the agency as noted in the 2002 GAO report. The new CFSAN building opened in College Park, MD, in 2001; construction costs were part of the budget increases from 1997 until 2001. Increases in both funding and FTEs in the late 1990s also signaled President Clinton's food safety initiative. Increases in the FY2002 budget and FY2003 FTEs represent increased agency attention to the food supply following the domestic terrorist attacks and subsequent passage of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. However, the increases did not continue. The foods budget has remained flat, while the number of FTEs has decreased since FY2002. Another reorganization of the foods portion of the agency occurred after 9/11 as a result of a reordering of the Center's work and priorities. Recent concerns about food safety problems have drawn attention to both the foods budget and FTEs.<sup>79</sup>

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<sup>79</sup> For more information, CRS Report RS22779, *Food Safety: Provisions in the Food and Drug Administration Amendments Act of 2007*, by (name redacted).

Figure 5. Foods: Budget and FTEs (Constant FY2000 \$)



**Sources:** For FY1980-FY2006, FDA *Justification of Estimates for Appropriations Committees* documents. FY2007 FTE data are based on an interim continuing resolution used in the FY2008 *Justification* and therefore do not reflect final action by Congress. FY2007 budget data reflect the Operating Plan developed after passage of P.L. 110-5, Revised Continuing Appropriations Resolution, 2007.

**Notes:** Total FTEs = Budget Authority FTEs. Program Level \$ = Budget Authority \$.

## Human Drugs<sup>80</sup>

No manufacturer may offer a prescription or over-the-counter drug for sale in the United States without first obtaining FDA’s approval. The agency’s Center for Drug Evaluation and Research (CDER) works with a manufacturer throughout the application process, from permitting human clinical trials of an Investigational New Drug (IND), to evaluating for evidence of safety and effectiveness the data from those trials that are part of a New Drug Application (NDA). Up to a drug’s approval, CDER wields tremendous influence, as the law authorizes, on required studies for the decision to grant marketing approval (hence, known as “premarket approval” or “premarket review”), wording and layout of materials for the prescribing clinician and the patient, and other aspects of the drug’s labeling.

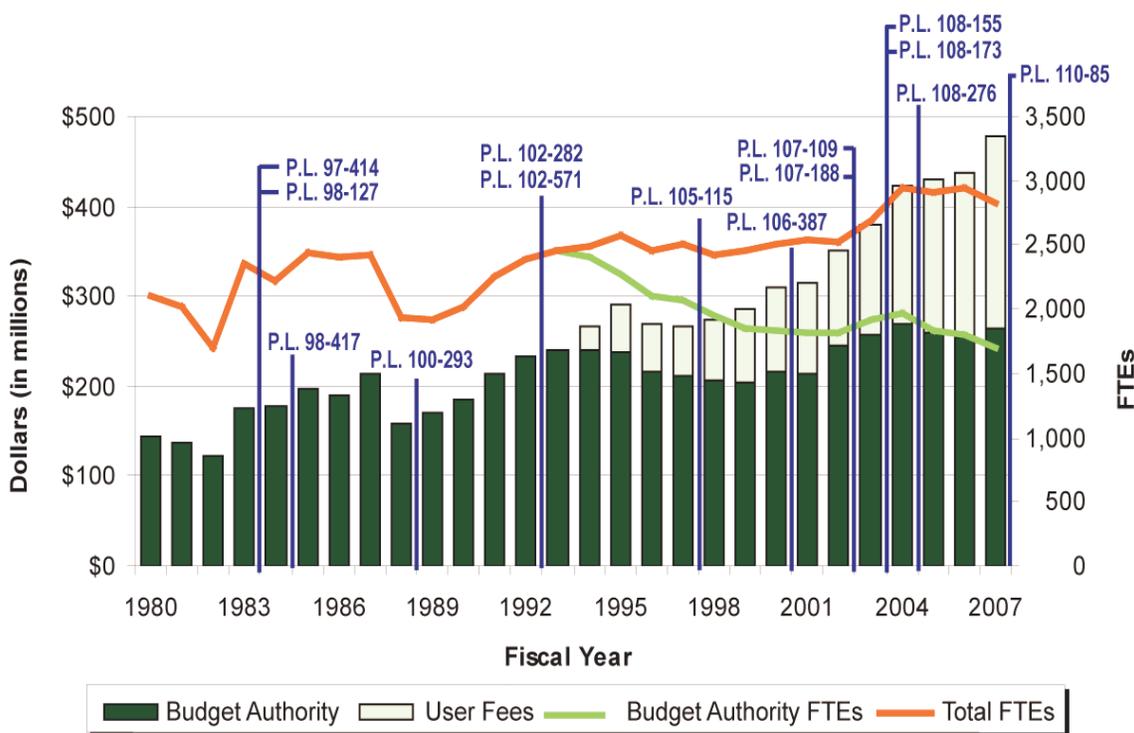
Once a drug is on the market—a period known as both “postmarket” and “postapproval”—FDA continues its activities to ensure the product’s safety and effectiveness, although the law does not

<sup>80</sup> This section was prepared by (name redacted), Specialist in Drug Safety and Effectiveness.

provide the agency with postapproval authority equivalent to its preapproval function. FDA staff examine the results of studies conducted and submitted by manufacturers; review adverse event reports from manufacturers, clinicians, and consumers; follow the scientific literature regarding other drugs with similar mechanisms of action; and review labeling, packaging, and promotional items to both consumers and clinicians. CDER staff also analyze data that the manufacturer submits and look for trends in large databases of pharmaceutical use.<sup>81</sup>

**Figure 6** illustrates the resource history of the FDA Human Drugs program from FY1980 through FY2007. Between FY1980 and FY2007, the total inflation-adjusted funding available for FDA human drug activities increased 234% (that is, it more than tripled) and the number of FTEs increased 34%.<sup>82</sup>

**Figure 6. Human Drugs: Budget and FTEs (Constant FY2000 \$)**



**Sources:** For FY 1980-FY2006, FDA *Justification of Estimates for Appropriations Committees* documents. FY2007 FTE data are based on an interim continuing resolution used in the FY2008 *Justification* and therefore do not reflect final action by Congress. FY2007 budget data reflect the Operating Plan developed after passage of P.L. 110-5, Revised Continuing Appropriations Resolution, 2007.

**Notes:** From FY1983 through FY1987, the appropriations acts and the FDA-produced budget justifications included funding for biologics activities in the human drug activities totals. Therefore, **Figure 6** shows a peak in those years and **Figure 7** shows a concomitant trough for biologics. Total FTEs = Budget Authority FTEs + User Fee FTEs. Program Level \$ = Budget Authority \$ + User Fees \$.

<sup>81</sup> For further information, see CRS Report RL32797, *Drug Safety and Effectiveness: Issues and Action Options After FDA Approval*, by (name redacted).

<sup>82</sup> **Table A-2** in the **Appendix** displays the actual numbers (not adjusted for inflation). Using the unadjusted numbers, FDA's budget increased almost eightfold (690%) between FY1980 and FY2007. When the dollar figures are adjusted to indicate comparable purchasing value, the increase diminishes to more than threefold (234%).

Beginning in FY1994, user fees have made up an increasing proportion of FDA's budget for human drug activities. While total funding has increased over the period, this has been entirely due to the increase in user fees. Congressional appropriations have remained essentially flat.

Separating FTEs by funding source shows that the overall increase in personnel comes solely from the user fees first collected in FY1993 and that the overall increase in FTEs obscures a 19% *decrease* in congressionally funded (budget authority) personnel from FY1992 to FY2007.

The 1992 Prescription Drug User Fee Act, in providing FDA with an additional source of funding, explicitly stated that the funds were to supplement, not supplant congressional appropriations. The law included complex formulas, known as "triggers," to enforce that goal. FDA may collect and use fees only if the direct appropriations for the activities involved in the review of human drug applications and for FDA activities overall remain funded at a level at least equal to the pre-PDUFA budget, adjusted for inflation as specified in the statute.<sup>83</sup>

These triggers, in particular, and the relative contributions of appropriations and user fees to FDA's budget for human drugs have implications for budget planning both within the human drugs activity area and in agency-level decisions across all activities.

The drug-related tasks for which FDA is responsible have evolved along with the social, economic, scientific, and technologic developments in the United States. Even before there was a Bureau of Chemistry in the Department of Agriculture (established in 1862, the ancestral origin of the current FDA), Congress passed legislation to "prevent the importation of adulterated and spurious drugs and medicines." The 1906 Food and Drugs Act heralded the future influence of the federal government on drug (and food) regulation to protect the public's health. Many laws followed (see brief descriptions in the **Appendix, Table A-4**). Among the most significant are: the 1938 FFDCAs, which required that drugs be safe; and the 1962 Kefauver-Harris Amendments to the FFDCAs, which required that drugs also be effective.

Subsequent laws addressed many issues for FDA, such as aiming to boost pharmaceutical research and development; to speed the approval of new medicines, including by supplementing FDA resources with user fee revenue; and to encourage research in pediatric drugs.<sup>84</sup> Between FY1980 and FY2007, Congress added to FDA's responsibilities new areas (or expanded existing ones) that involved scientific, legal, and enforcement expertise (see **Table 3**). Most recently, the FDA Amendments Act of 2007 (P.L. 110-85) amended dozens of FFDCAs sections. These included human drugs provisions to reauthorize certain programs (such as the assessment, collection, and use of prescription drug user fees); to enhance FDA's authority in ensuring safety and effectiveness over a product's life (both pre- and postapproval). It required the Secretary to maintain an Internet website with extensive drug safety information. New authorities include civil monetary penalties for failure to comply with certain postmarket study, labeling, and television advertisement requirements; mandates and incentives for pediatric drug research and labeling; and requirements for making available to the public material such as minutes of agency-industry performance goal negotiations, pediatric assessment findings and reviews, reviews of adverse event reports, and advisory committee recommendations on action.

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<sup>83</sup> For further information, see CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): History, Reauthorization in 2007, and Effect on FDA*, by (name redacted).

<sup>84</sup> For further information, see CRS Report RL33986, *FDA's Authority to Ensure That Drugs Prescribed to Children Are Safe and Effective*, by (name redacted).

**Table 3. Human Drugs Statutory Authorities in 1980 and 2007**

<b>Authorities in 1980</b>
Inspect drugs from abroad for quality, purity, and fitness for medical purposes (30 <sup>th</sup> Congress; predates use of the current public law numbering format).
Regulate interstate commerce in food, drink, and drug products; prohibit adulteration and misbranding (P.L. 59-384), including false statements of curative or therapeutic effect (P.L. 62-301).
Review evidence of safety (P.L. 75-717) and effectiveness (P.L. 87-781) before approving a drug for interstate commerce.
Require records of shipments; inspect manufacturing, processing, packing, or holding facilities, including equipment, materials, containers, and labeling (P.L. 75-717, expanded by P.L. 83-217).
Certify batches of color additives (P.L. 75-717); promulgate regulations for the listing of color additives in or on drugs (or other FDA-regulated products) based on conditions, uses, and labeling to assure safe use (P.L. 86-618).
Enforce enhanced labeling and packaging requirements (P.L. 75-717).
Test and certify each batch of insulin (P.L. 77-366) and penicillin (P.L. 79-139) for strength, quality, and purity; promulgate regulations covering, among other things, standards and tests.
Regulate certain drugs as prescription-only (P.L. 82-215).
Regulate prescription drug advertising (P.L. 87-781).
Regulate all antibiotics (P.L. 87-781).
Enforce enhanced regulations covering manufacture, recordkeeping, inspections, prescription refills, of depressant and stimulant drugs; authorized to appoint expert advisory committees (P.L. 89-74).
Enforce enhanced labeling requirements (P.L. 89-755).
Notify Attorney General when a submitted new drug application involves a drug with an abuse potential (P.L. 91-513).
<b>Authorities Added Between 1980 and 2007</b>
Provide incentives for pharmaceutical manufacturers to develop drugs, biotechnology products, and medical devices for the treatment of rare diseases and conditions (P.L. 97-414).
Investigate tampering with packaged consumer products (P.L. 98-127).
Review generic drug applications (P.L. 98-417).
Promulgate and enforce enhanced regulations on the distribution of drug samples (P.L. 100-293, expanded by P.L. 102-282).
Assess and collect fees from the pharmaceutical manufacturers and use the resulting revenue to support its review of new drug applications (P.L. 102-571, P.L. 105-115, P.L. 107-188, P.L. 110-85).
Establish fast track approval process for drugs that would treat life-threatening conditions (P.L. 105-115).
Streamline the drug review process and provide a means for resolving controversial scientific issues (P.L. 105-115).
Enforce refined requirements regarding the dissemination of information about “off-label” uses of drugs or devices not yet approved by the FDA, patient access to investigational therapies, international harmonization and national uniformity in the regulation of nonprescription drugs and cosmetics (P.L. 105-115).
Conduct regulatory functions under a mission statement that will obligate it to maintain a public health protection role while seeking to expedite the marketing of regulated products (P.L. 105-115).
Grant a manufacturer an additional six months of marketing exclusivity in exchange for completing FDA-requested studies of use in children (P.L. 105-115; expanded by P.L. 107-109, P.L. 110-85).
Establish program allowing pharmacists and drug wholesalers to import lower-priced prescription drugs from specific countries. [Not implemented due to trigger requirement.] (P.L. 106-387, P.L. 108-173).
Require a pediatric assessment of safety and effectiveness as part of an application to market a new active ingredient,

new indication, new dosage form, new dosing regimen, or new route of administration for a drug or biologic, or, if the Secretary considers it necessary, for an approved drug or licensed biologic (P.L. 108-155, expanded by P.L. 110-85).

Study the use of technologies to provide prescription drug information to the blind and visually impaired (P.L. 108-173).

Expedite review of countermeasures to chemical, biological, and nuclear agents that may be used in a terrorist attack (P.L. 108-276).

## Biologics<sup>85</sup>

Biologics are medical preparations made from living organisms. Examples of such products include traditional biologics (such as vaccines, blood, blood products, antitoxins, and allergenics<sup>86</sup>) and human therapeutic agents produced by the biotechnology industry (such as insulin, interferon, growth hormone, and epoetin). FDA ensures the purity and effectiveness of biologics by (1) issuing a license for each new product that is shown to be safe, pure, and potent and (2) inspecting manufacturing facilities to assure the product continues to be safe, pure, and potent. Unlike most chemically synthesized drugs (e.g., aspirin) with a known structure, biologics are often complex mixtures that are not easily identified or characterized. Biologics might also be living entities, such as cells and tissues. Biologics may be isolated from a variety of natural sources (human, animal, or microorganism) or may be produced by biotechnology methods and other cutting-edge technologies. FDA is also responsible for the safety of the nation's blood supply and routinely examines blood bank operations for record keeping and testing of donations for contaminants.

Regulatory responsibility for biologics was first delegated in the early 1900s to the Hygienic Laboratory, a precursor of the National Institutes of Health (NIH).<sup>87</sup> In 1972, regulatory authority for biologics was transferred from the NIH Division of Biological Standards to the FDA Bureau of Biologics.<sup>88</sup> During the early 1980s, the FDA merged the Bureau of Drugs and the Bureau of Biologics to form the National Center for Drugs and Biologics. In 1984, all of the "National Centers" within FDA were redesignated simply as "Centers." In 1987, the FDA's Center for Drugs and Biologics was split into the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). CBER continues to use NIH facilities and buildings until the expected move in 2012 to the new FDA headquarters in White Oak, MD.

Because biotechnology products frequently cross the conventional boundaries between biologics, drugs, and devices, determining the jurisdictional status of these new products has been difficult for both the FDA and industry. Some products have had characteristics that met multiple statutory and scientific definitions. In 1991, the FDA published an Intercenter Agreement between CBER and CDER. In general, the agreement stated that traditional biologics as well as most biotechnology products, would be regulated by CBER.<sup>89</sup> In 2002, however, the FDA announced

<sup>85</sup> This section was prepared by (name redacted), Specialist in Biomedical Policy.

<sup>86</sup> Allergenic extracts are used to diagnose and treat allergic reactions such as hay fever.

<sup>87</sup> The NIH Almanac—Historical Data: Chronology of Events, at [http://www.nih.gov/about/almanac/historical/chronology\\_of\\_events.htm](http://www.nih.gov/about/almanac/historical/chronology_of_events.htm).

<sup>88</sup> Donna Hamilton, "A Brief History of the Center for Drug Evaluation and Research," FDA History Office, November 1997, at <http://www.fda.gov/cder/about/history/Histext.htm>.

<sup>89</sup> Except for a small set of biologics (hormones, such as insulin, human growth hormone, and a few medical enzymes) that would continue to be regulated by CDER. These biologics have historically been regulated as drugs under the (continued...)

its intention to reorganize review responsibilities, consolidating review of new pharmaceutical products under CDER; CBER retains review responsibility for vaccines, blood safety, gene therapy, and tissue transplantation.<sup>90</sup> On June 30, 2003, responsibility for most therapeutic biologics was transferred from CBER to CDER.<sup>91</sup> Remaining at CBER are traditional biologics such as vaccines, allergenic products, antitoxins, antivenins, venoms, and blood and blood products, including recombinant versions of plasma derivatives (clotting factors produced via biotechnology).

**Figure 7** shows the total FDA budget for Biologics, composed of budget authority and user fees, for FY1980 through FY2007, adjusted to FY2000 dollars. It also provides FTE data over the same years: FTEs funded by budget authority; and total FTEs funded at program level (budget authority plus user fees). The impact on funding and FTEs of the FDA reorganization in the 1980s can be clearly seen in **Figure 7**. Although budget authority and FTEs for biologics were rising in the late 1980s and early 1990s, the graph shows that both decline and then remain flat coincident with the introduction of user fees in 1993. Budget authority and FTEs increased between FY2001 and FY2003, coincident with increased emergency funding following the domestic terrorist attacks. The drop in biologics funding and FTEs from FY2003 to FY2004 is due to the reorganization of review responsibilities for therapeutic biologics. Following the reorganization, budget authority and FTEs for biologics have remained relatively flat.

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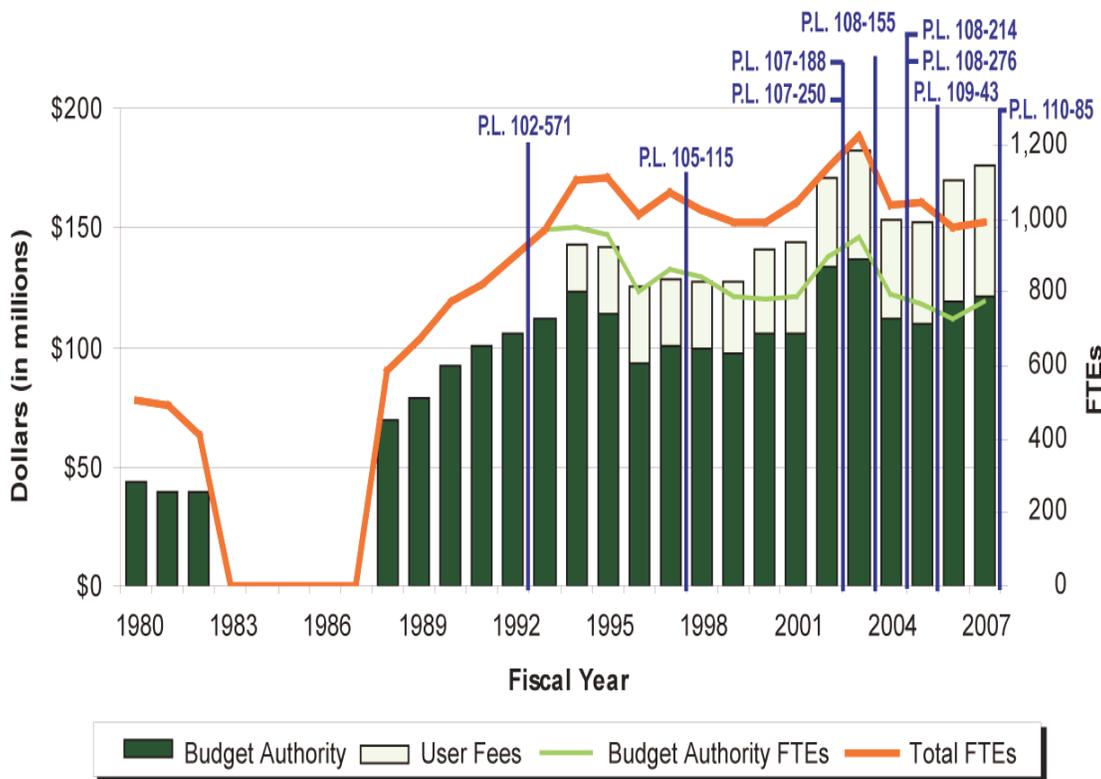
(...continued)

Federal Food, Drug, and Cosmetic Act rather than licensed under the Public Health Service Act.

<sup>90</sup> FDA Press Release, "FDA to Consolidate Review Responsibilities for New Pharmaceutical Products," September 6, 2002, at <http://www.fda.gov/bbs/topics/NEWS/2002/NEW00834.html>.

<sup>91</sup> *Federal Register*, vol. 68, no. 123, June 26, 2003, pp. 38067-38068. Examples of products transferred to CDER include monoclonal antibodies; proteins intended for therapeutic use (interferons, thrombolytic enzymes); immunomodulators (other than vaccines and allergenic products); and growth factors, cytokines, and monoclonal antibodies intended to alter production of blood cells. See Transfer of Therapeutic Products to the Center for Drug Evaluation and Research <http://www.fda.gov/cber/transfer/transfer.htm>; Approved Products Transferring to CDER <http://www.fda.gov/cber/transfer/transprods.htm>; and Therapeutic Biological Products <http://www.fda.gov/cder/biologics/default.htm>.

**Figure 7. Biologics: Budget and FTEs (Constant FY2000 \$)**



**Sources:** For FY1980-FY2006, FDA *Justification of Estimates for Appropriations Committees* documents. FY2007 FTE data are based on an interim continuing resolution used in the FY2008 *Justification* and therefore do not reflect final action by Congress. FY2007 budget data reflect the Operating Plan developed after passage of P.L. 110-5, Revised Continuing Appropriations Resolution, 2007.

**Notes:** For FY1983 through FY1987, FDA managed Biologics activities and Human Drugs activities in one Center. The *Justifications* for those years provide only combined dollar and FTE numbers, which are included in **Figure 6** (Human Drugs) and not in **Figure 7** (Biologics). Total FTEs = Budget Authority FTEs + User Fee FTEs. Program Level \$ = Budget Authority \$ + User Fees \$.

FDA’s responsibilities related to the approval and regulation of biological products have changed somewhat between 1980 and 2007 (see

**Table 4**). In 1980, FDA’s authority with respect to the approval of biological products was governed primarily by Section 351 of the Public Health Service Act (P.L. 78-410). In addition, because most biological products also meet the definition of “drugs,” they are subject to regulation under the FFDCA (P.L. 59-384). FDA also regulates medical devices involving biologics under various medical device laws. Examples include devices used in blood banks to produce various blood products, such as automated cell separators, empty plastic containers and transfer sets, and blood storage refrigerators and freezers.

By 2007, the passage of additional laws had created more responsibilities and authorities for FDA in the area of biologics. The Pediatric Research Equity Act of 2003 (P.L. 108-155) requires a pediatric assessment of safety and effectiveness as part of an application to license a new biologic, or, if the Secretary considers it necessary, for an already licensed biologic. The Project

Bioshield Act of 2004 (P.L. 108-276) requires FDA to provide an expedited review of vaccines and other countermeasures to bioterrorism agents.

Congress is also currently considering proposed legislation that would expand the agency's regulatory activities by opening a pathway for the approval of so-called follow-on biologics, which are similar, but not identical, to the brand-name products made by the pharmaceutical or biotechnology industry.<sup>92</sup> The new regulatory pathway would be analogous to the FDA's authority for approving generic chemical drugs under the Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 84-417), often referred to as the Hatch-Waxman Act. FDA personnel have been actively involved for some time in working with Congress on this potential new responsibility.

**Table 4. Biologics Statutory Authorities in 1980 and 2007**

<b>Authorities in 1980</b>
Licenses new biological products that are shown to be safe, pure, and potent and inspects manufacturing facilities to assure the product continues to be safe, pure, and potent (P.L. 78-410).
Regulates medical devices involving blood products or other biologics (P.L. 75-717).
Regulates biological products (P.L. 87-781).
Regulates advertising of biological products (P.L. 87-781).
<b>Authorities Added Between 1980 and 2007</b>
Assesses and collects fees from biologics manufacturers and uses the resulting revenue to support the review of new biologic products (P.L. 102-571, P.L. 105-115, P.L. 107-188).
Collect user fees for premarket device review (P.L. 107-250, P.L. 108-214, P.L. 109-43).
Requires a pediatric assessment of safety and effectiveness as part of an application to license a new biologic, or, if the Secretary considers it necessary, for a licensed biologic (P.L. 108-155).
Expedites review of countermeasures to agents that may be used in a terrorist attack (P.L. 108-276).

## Animal Drugs and Feeds<sup>93</sup>

The FDA Center for Veterinary Medicine (CVM) regulates animal feeds (such as livestock feeds and pet foods), and veterinary drugs and devices.<sup>94</sup> CVM is responsible for premarket approval of veterinary drugs, based on a sponsor's demonstration of safety and effectiveness. CVM regulates veterinary devices, but does not require their premarket approval.<sup>95</sup> Veterinary biologics are regulated by the USDA.<sup>96</sup> Much of CVM's authority is based in FDA's general authorities in the FFDCAs, such as the authority to take enforcement actions if a regulated product is adulterated, to

<sup>92</sup> For further information, see CRS Report RL34045, *FDA Regulation of Follow-On Biologics*, by (name redacted).

<sup>93</sup> This section was prepared by (name redacted), Specialist in Public Health and Epidemiology.

<sup>94</sup> See <http://www.fda.gov/cvm/>.

<sup>95</sup> FDA can take appropriate regulatory action if a veterinary device is misbranded, mislabeled or adulterated. Also, firms that manufacture radiation-emitting veterinary devices must register their products under the radiological health regulations, administered by the FDA Center for Devices and Radiological Health (CDRH). See FDA CVM, "How FDA Regulates Veterinary Devices," May 2003, at <http://www.fda.gov/cvm/regofdevices.htm>.

<sup>96</sup> Veterinary biologics, such as vaccines and clinical laboratory tests, are regulated by the USDA, Animal and Plant Health Inspection Service, Center for Veterinary Biologics. See [http://www.aphis.usda.gov/animal\\_health/vet\\_biologics/](http://www.aphis.usda.gov/animal_health/vet_biologics/).

require facility registration, and to conduct inspections. For example, animal feed is included in the definition of “food” in Section 201 of the FFDCA, and must meet the same general standards of safety as human food, pursuant to Sections 401 et seq. of the act. Additional specific requirements may also be applied to CVM-regulated products.

Though USDA and FDA-CFSAN have primary responsibility for the safety of products intended for human food,<sup>97</sup> CVM is responsible for some specific aspects of the safety of human foods derived from animals, such as determining tolerances (safe levels) of certain chemicals in meat and poultry, and evaluating the food safety aspects of animal clones and their offspring. Also, before CVM approves an animal drug, its use in animals must be shown to be safe for humans as well. Drug sponsors must demonstrate that a method is available to detect and measure any drug residues left in edible tissues of food-producing animals. Farmers and veterinarians who use drugs on food-producing animals must adhere to guidelines about how much time must elapse before a treated animal can be slaughtered, or before its milk can be marketed, and any other constraints or warnings that are stated on the drug label.

**Figure 8** shows the total FDA budget for animal drugs and feeds, composed of budget authority and user fees, for FY1980 through FY2007, adjusted to FY2000 dollars.<sup>98</sup> **Figure 8** also provides FTE data over the same period: FTEs funded by budget authority; and total FTEs funded at program level (budget authority plus user fees). During that time, the budget in adjusted dollars increased from \$46.7 million in FY1980 to \$87.6 million in FY2007. FTEs totaled 516 in FY1980, and 619 in FY2007, though there were fewer than 500 FTEs for most of the intervening years. Drug user fees provided a small portion of CVM’s overall budget between FY2004 and FY2007, and made up about 11% of the FY2007 total. (FDA did not have authority to collect user fees for new animal drug reviews until FY2004.)

The budget for animal drugs and feeds, in adjusted dollars, almost doubled in the three-year period from FY1999 to FY2002, from \$44.3 million to \$82.4 million. FTEs increased from 393 to 570 in the same period. (The budget was relatively stable in the years before and after this period of growth, when adjusted for inflation.) The funding increases largely paralleled increasing budget requests for those years. Increases were requested to support new statutory requirements as well as several initiatives, some of which were agency-wide. These initiatives included activities in food safety, antimicrobial resistance, and postmarket surveillance of drug safety, as well as efforts to reduce drug review times. They also included a bioterrorism preparedness initiative, and the expansion of feed safety programs to protect against Bovine Spongiform Encephalopathy (BSE, or “Mad Cow disease”). In each case, funding was expanded *prior to* a related high-profile incident, namely the 2001 anthrax attacks, and the 2003 emergence of BSE in North America.

Prior to 1980, CVM was responsible for evaluating veterinary drugs for approval based on demonstrations of safety and efficacy, and for assuring the safety of animal feeds and feed additives. Several laws enacted since 1980 were aimed at improving the availability of veterinary drugs (which are typically not as lucrative for sponsors as are human drugs), clarifying the use of human drugs in animals, or streamlining the drug approval process. FDA’s authority for animal

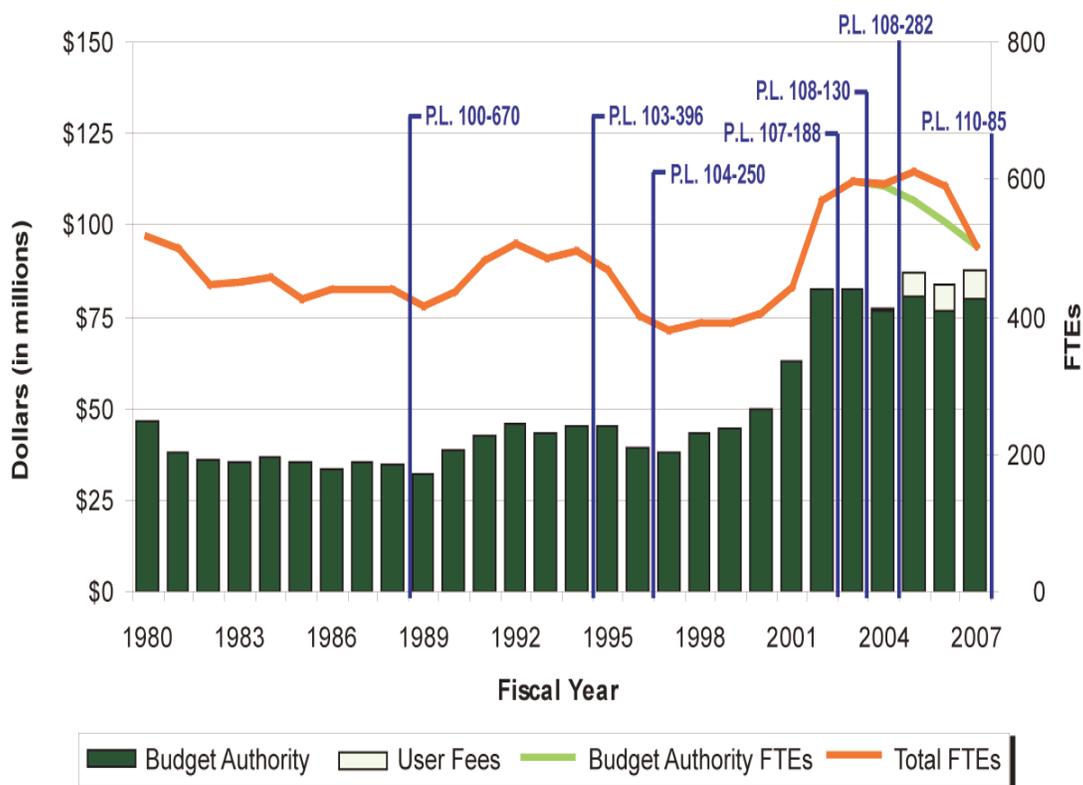
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<sup>97</sup> See CRS Report RS22600, *The Federal Food Safety System: A Primer*, by (name redacted) and (name redacted).

<sup>98</sup> Though CVM was called the Bureau of Veterinary Medicine prior to 1984, the Center and the Animal Drugs and Feeds budget line have, for practical purposes, encompassed the same activities for several decades, and references to each are used interchangeably.

products generally begins with the same statutes as those that regulate human drugs and foods (see **Table 2** and **Table 3**), with additional specific requirements applied in some cases.<sup>99</sup> This is consistent with FDA’s long-standing obligation to assure that veterinary drugs and animal feeds are manufactured and used in ways that are safe for *both* animals and humans.

**Figure 8. Animal Drugs and Feeds: Budget and FTEs (Constant FY2000 \$)**



**Sources:** For FY1980-FY2006, FDA *Justification of Estimates for Appropriations Committees* documents. FY2007 FTE data are based on an interim continuing resolution used in the FY2008 *Justification* and therefore do not reflect final action by Congress. FY2007 budget data reflect the Operating Plan developed after passage of P.L. 110-5, Revised Continuing Appropriations Resolution, 2007.

**Notes:** Total FTEs = Budget Authority FTEs + User Fee FTEs. Program Level \$ = Budget Authority \$ + User Fees \$.

Major laws affecting CVM’s regulation of animal drugs and feeds are summarized in **Table 5**.<sup>100</sup> In 1988, the Generic Animal Drug and Patent Term Restoration Act (P.L. 100-670) authorized abbreviated applications for generic new animal drugs. In 1994, the Animal Medicinal Drug Use

<sup>99</sup> An exception to this general rule is the Dietary Supplement and Health Education Act (DSHEA) of 1994, which requires that FDA not designate substances added to “food for humans” as food additives or drugs if the product meets the definition of a dietary supplement. FDA has interpreted that DSHEA does not apply to products added to animal feeds. Consequently, CVM regulates any animal feed supplement as either a food, food additive, or animal drug, depending on the intended use, and does not apply the additional dietary supplement category.

<sup>100</sup> The Center’s statutory authorities are discussed in greater detail on a public website, “Chronological History of CVM,” at <http://www.fda.gov/cvm/chronological.htm>.

Clarification Act (P.L. 103-396) permitted veterinarians to prescribe, for animals, extra-label uses of certain approved animal and human drugs, under certain conditions. In 1996, the Animal Drug Availability Act (P.L. 104-250) granted FDA more flexibility in evaluating and approving new animal drugs by amending the definition of substantial evidence of effectiveness. Among other provisions, the law also permitted the use of veterinary drugs in animal feeds, with veterinary prescription.

In 2002, the Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188) required the registration of all domestic and foreign facilities that manufactured, processed, packed or held animal feeds.<sup>101</sup> In 2003, the Animal Drug User Fee Act (P.L. 108-130) authorized FDA to collect fees for the review of certain animal drug applications.<sup>102</sup> In 2004, the Minor Use and Minor Species Animal Health Act (P.L. 108-282) authorized, along with other approaches and incentives for limited-market drugs, the conditional approval for drugs to treat minor animal species and uncommon diseases in major animal species,<sup>103</sup> which allows the sponsor to make a drug available before collecting all necessary effectiveness data, but after proving that the drug is safe. In 2007, the FDAAA (P.L. 110-85) required, for pet foods, the development of ingredient, processing and labeling standards, and a surveillance system to detect disease outbreaks. Additional provisions that apply to both human foods and animal feeds require, among other things, that FDA establish a reportable food registry, and that persons in charge of FDA-registered food facilities report any instances of tainted foods that may harm humans or animals.

**Table 5. Animal Drugs and Feeds Statutory Authorities in 1980 and 2007**

<b>Authorities in 1980</b>
Prohibits interstate commerce in adulterated and misbranded feeds; provides criminal penalties for violations and authorizes seizures of offending products (P.L. 59-384).
Review evidence of safety (P.L. 75-717) and effectiveness (P.L. 87-781) before approving an animal drug.
Review safety and effectiveness of animal drugs for intended use, including safety for use in food-producing animals (P.L. 90-399).
<b>Authorities Added Between 1980 and 2007</b>
Authority for abbreviated applications for generic animal drugs (P.L. 100-670).
Authority for veterinarians to prescribe, for animals, extra-label uses of certain approved animal and human drugs, under certain conditions (P.L. 103-396).
Added flexibility in approving new animal drugs, including an amended definition of substantial evidence of effectiveness. Granted authority for the use of veterinary drugs in animal feeds, with veterinary prescription (P.L. 104-250).
Requirements for facilities that manufacture, process, pack, or hold animal feed for domestic consumption to register and maintain records (P.L. 107-188).
Authority to collect user fees for certain animal drug applications (P.L. 108-130).
Conditional approval of veterinary drugs for minor uses or minor species, based on demonstration of safety without all necessary effectiveness data (P.L. 108-282).
Required, for pet foods, the development of ingredient, processing and labeling standards, and a surveillance system to detect disease outbreaks. Required, for both human foods and animal feeds, the establishment of a reportable food registry, and mandatory reporting of instances of tainted foods (P.L. 110-85).

<sup>101</sup> The law applied similarly to human food facilities.

<sup>102</sup> The law is similar to the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFMA) for human products.

<sup>103</sup> For more information on minor uses and minor species, see <http://www.fda.gov/cvm/minortoc.htm>.

## Devices and Radiological Health<sup>104</sup>

FDA is responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation from medical, occupational, and consumer products.<sup>105</sup> There are thousands of types of medical devices, from heart pacemakers to contact lenses. Radiation-emitting products regulated by the agency include microwave ovens, video display terminals, and medical ultrasound and x-ray machines. FDA reviews requests to research or market medical devices; collects, analyzes, and acts on information about injuries and other experiences in the use of medical devices and radiation-emitting electronic products; sets and enforces good manufacturing practice regulations and performance standards for radiation-emitting electronic products and medical devices; monitors compliance and surveillance programs for medical devices and radiation-emitting electronic products; and provides technical and other nonfinancial assistance to small manufacturers of medical devices. The agency's current activities related to devices and radiological health (DRH) are primarily conducted by its Center for Devices and Radiological Health. As previously noted, CBER regulates some devices—specifically those associated with blood collection and processing procedures, as well as with cellular therapies (e.g., stem cell treatments).

In FY1980, after adjusting for inflation, FDA's DRH budget was \$97,427,000, which supported 1,399 FTEs (see **Figure 9**). At that time, the agency's responsibilities with respect to devices were governed primarily by the Medical Device Amendments of 1976 (MDMA, P.L. 94-295). MDMA was the first major legislation passed to ensure the safety and effectiveness of medical devices, including diagnostic products, before they could be marketed. The amendments required manufacturers to register with FDA and follow quality control procedures in their manufacturing processes. They also required FDA to conduct premarket review of some products, and to generate performance standards that devices had to meet before they could be marketed.

Between FY1980 and FY2007, several major pieces of device legislation were passed (see **Table 6**). Some of these added new types of responsibilities. In 1990, Congress gave FDA the authority to enforce postmarket requirements for devices, to act on postmarket adverse event reports, and to recall unsafe devices (P.L. 101-629). In 1992, Congress gave FDA the authority to require that manufacturers of defective products implement certain consumer accommodations and pursue penalties for postmarket surveillance noncompliance (P.L. 102-300). In 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA), major FDA reform legislation that tasked the agency with accelerating its premarket review and regulating unapproved uses of approved devices (P.L. 105-115).

Other legislation contained provisions that could reduce or minimize, rather than simply increase, the regulatory burden on FDA. For example, while the Mammography Quality Standards Act (MQSA) added the responsibility of requiring the agency to certify mammography facilities, it also provided the authority to collect associated certification fees, creating a new revenue stream (P.L. 102-539). MQSA also allowed certain accredited third-parties to conduct inspections in order to relieve FDA of some of that responsibility.

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<sup>104</sup> This section was prepared by (name redacted), Specialist in Public Health and Bioethics.

<sup>105</sup> For further information, see CRS Report RL32826, *The Medical Device Approval Process and Related Legislative Issues*, by (name redacted).

In 2002, Congress passed the largest revenue-generating, non-appropriations legislation for FDA's DRH-related activities in the 28-year period under examination: the Medical Device User Fee and Modernization Act (MDUFMA, P.L. 107-250).<sup>106</sup> The law gave FDA the authority to collect user fees for premarket device review, creating another significant source of revenue. It also accredited third-parties to conduct inspections, a measure designed to reduce FDA's regulatory burden. To preclude user fees from supplanting direct appropriations, MDUFMA contained a "trigger," requiring a certain amount of DRH-related direct appropriations for the collection of user fees to continue. In 2005, direct appropriations did not meet the trigger amount. Congress subsequently reduced the trigger amount so FDA could continue to collect the user fees (P.L. 109-43).

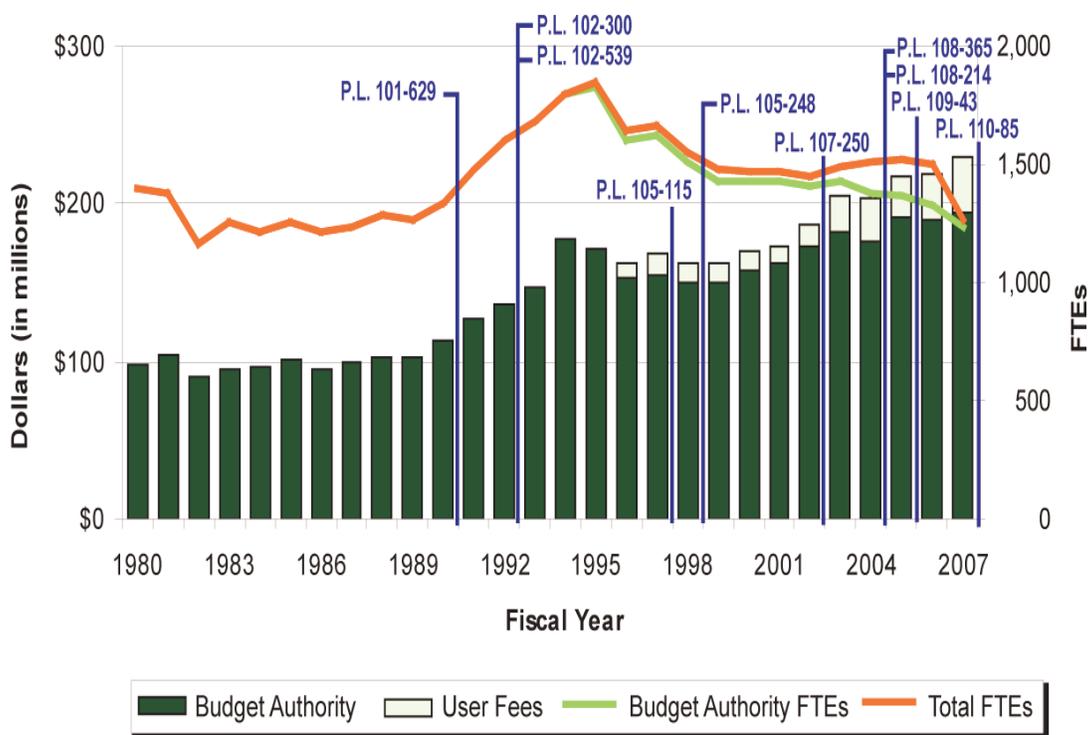
Between FY1980 and FY2007, congressional appropriations for DRH-related activities generally followed the agency's budget requests. As **Figure 9** indicates, the number of FTEs and budget remained relatively flat through the 1980s. Both then increased in the early 1990s. Beginning in the late 1990s, the budget and FTEs began to track somewhat differently than they had in the past.<sup>107</sup> The flat budget in the late 1990s did not occur with a fairly constant number of FTEs as it had in the 1980s, but rather with a decrease in FTEs. Likewise, the budget increases that have occurred thus far in the 2000s have increased the number of FTEs, but not by as much as with similar budget increases in the early 1990s. Readers should note that the drop in FTEs between FY2006 and FY2007 apparent in **Figure 9** is misleading, as the FTE numbers are based upon a continuing resolution (which had no allowance for user fees), while the budget numbers are based upon a cost estimate (which did include user fees).

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<sup>106</sup> For further information about medical device user fees, see CRS Report RL34571, *Medical Device User Fees and User Fee Acts*, by (name redacted).

<sup>107</sup> For a general discussion of the relationship between FTE data and budget data, see "Overall FDA Budget" and "FDA Activity-Area Budgets" sections of this report.

**Figure 9. Devices and Radiological Health: Budget and FTEs (Constant FY2000 \$)**



**Sources:** For FY1980-FY2006, FDA *Justification of Estimates for Appropriations Committees* documents. FY2007 FTE data are based on an interim continuing resolution used in the FY2008 *Justification* and therefore do not reflect final action by Congress. FY2007 budget data reflect the Operating Plan developed after passage of P.L. 110-5, Revised Continuing Appropriations Resolution, 2007.

**Notes:** Total FTEs = Budget Authority FTEs + User Fee FTEs. Program Level \$ = Budget Authority \$ + User Fees \$.

The net result of the changes described above was that, over the 28-year period studied, FDA’s budget and its number of FTEs dedicated to DRH-related activities increased, although by different amounts. Adjusted for inflation, the total DRH-related budget has increased by 124.5%. The number of FTEs increased by 7.1%. Over the same 28-year period, adjusting for inflation, the budget authority for DRH-related activities increased by 94.2%, while the number of FTEs supported by the budget authority decreased by 5.1%. User fees, which comprised none of the device-related budget in FY1980, comprised 13.5% of it in FY2006. User fee-funded FTEs, which comprised none of the FY1980 budget, comprised 11.3% of the FY2006 budget.

**Table 6. Devices and Radiological Health Statutory Authorities in 1980 and 2007**

<b>Authorities in 1980</b>
Regulates devices as drugs (Court interpretation of P.L. 75-717).
Enforces label truthfulness, accuracy (P.L. 89-755).
Ensures safety, effectiveness prior to marketing (P.L. 94-295).
Creates, enforces manufacturing quality control procedures (P.L. 94-295).
Maintains manufacturer registry (P.L. 94-295).
<b>Authorities Added Between 1980 and 2007</b>
Enforces postmarket requirements (P.L. 101-629).
Receives, acts on postmarket adverse event reports (P.L. 101-629).
Recalls unsafe devices (P.L. 101-629).
Orders certain consumer accommodations by defective product manufacturers (P.L. 102-300).
Pursues penalties for postmarket surveillance noncompliance (P.L. 102-300).
Certifies mammography facilities, collects associated fees (P.L. 102-539, P.L. 105-248, P.L. 108-365).
Accelerates premarket review (P.L. 105-115).
Regulates unapproved uses of approved devices (P.L. 105-115).
Collects user fees for premarket device review (P.L. 107-250, P.L. 108-214, P.L. 109-43).
Accredits third parties to conduct inspections (P.L. 107-250).
Enforces new regulatory requirements for reprocessed single-use devices (P.L. 107-250).

## Other Activities and Responsibilities

The above analysis focuses on areas in which FDA has product-specific regulatory responsibilities. However, certain components of FDA's budget and responsibilities do not fall within these categories (e.g., toxicological research, and headquarters and office of the FDA Commissioner) or whose funding is included within each activity area budget (e.g., FDA's field activities). While an in-depth analysis of these areas is not included in this report, we have provided a brief description of each one below.

### Toxicological Research

FDA's activities related to toxicological research are conducted by the National Center for Toxicological Research (NCTR), in Jefferson, AR. NCTR, which was established by Executive Order in 1971, does not have an explicit authority in law, and does not have direct regulatory responsibilities.<sup>108</sup> NCTR conducts peer-reviewed scientific research and provides expert technical advice and training to support FDA regulatory activities. NCTR uses Interagency Agreements, CRADAs, informal collaborations, and visiting scientists to advance its research activities.

<sup>108</sup> See <http://www.fda.gov/nctr/>.

## Headquarters and Office of the Commissioner

The FDA Commissioner has broad authority and responsibility to conduct research to support the agency's mission.<sup>109</sup> The Office of the Commissioner (OC) is made up of several components, including the Ethics Program, Good Clinical Practice Program, History Office, Office of Combination Products, and Office of Crisis Management, among others.<sup>110</sup>

As reported in the FY1982 budget *Justification*, FY1980 funding for the OC was included in FDA's *Program Management* budget line. This line also included funding for the Associate Commissioners and the general management personnel responsible for the central program direction and administrative support functions of the agency. As reported in the FY2008 budget *Justification*, funding for the OC in FY2006 was included under the title *FDA Headquarters and Office of the Commissioner*. It consisted of agency-wide program direction, and administrative services to ensure that FDA's consumer protection efforts were managed and that available resources were put to the most efficient use.

## Field Activities: The Office of Regulatory Affairs

The lead office for FDA's inspection and enforcement activities (which FDA calls "field activities") is the Office of Regulatory Affairs (ORA). ORA is comprised of its Headquarters, the Office of Resource Management, the Office of Regional Operations, the Office of Enforcement, and the Office of Criminal Investigations.<sup>111</sup> In almost every *Justification*, field activity budget and FTEs are included in each activity area.

## Concluding Comments

This report provides information on changes in FDA's resources, both budget and FTEs, as well as the evolution of its statutory responsibilities. Resources and responsibilities are juxtaposed because, as Congress requires more from the agency, it is important to assess whether FDA has the necessary financial resources to meet all those statutory responsibilities. The report is intended to assist Members and their staff in evaluating whether FDA's resources have fallen short, and, if so, how to enhance FDA's performance.

The status of FDA resources and agency performance is important to Congress because each day FDA-regulated products touch the lives of every American citizen as well as people around the world. As stated previously, about 25% of American consumer dollars are spent on these FDA-regulated products. Among the industries that FDA regulates are some of the most successful and innovative in the U.S. economy. The agency regulates a wide range of products valued at more than \$1 trillion. Problems with their safety or effectiveness could affect anyone, as is evident from the following sample of things FDA regulates:

- the calorie and fat content information on food labels;
- permissible and required information in televised prescription drug ads;

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<sup>109</sup> 21 U.S.C. § 393(d)(2)(C).

<sup>110</sup> See <http://www.fda.gov/oc/>.

<sup>111</sup> See <http://www.fda.gov/ora/about/default.htm>.

- the coloring in foods, medicines, and cosmetics;
- the purity of ingredients in prepared foods—for people and animals;
- inspection requirements for mammography and MRI equipment; and
- antibiotics in the feed fed to animals bred for human consumption.

The data in this report, assembled from the annual material that each President submits to Congress for the next year's appropriation, indicate some year-by-year variation, but mostly illustrate a few trends. For FDA as a whole, comparing FY2006, the most recent year for which we have parallel data sources for both dollars and FTEs, to FY1980 yields these inflation-adjusted findings (see **Figure 1**):

FDA Budget:

- almost a doubling of direct congressional appropriations (budget authority);
- more than a 10-fold increase in other funds, mostly user fees;
- resulting in an overall budget in FY2006 almost 2-1/2 times that in FY1980.

FDA FTEs:

- less than a 1% increase in budget authority-funded FTEs;
- an almost fourfold increase in FTEs funded by other sources, mostly user fees;
- resulting in an overall 19% increase from FY1980 to FY2006.

Similar relationships are observed in each of the major activity areas that receive user fees (the Foods program does not have user-fee funds) and are discussed in this report. The human drugs program, along with biologics, was the first to include user fee revenue in its budget and is a good example to illustrate the relationship over time between congressionally appropriated dollars and user fee generated dollars. Again from FY1980 to FY2006, the data show that the human drugs total budget (program level), which included user fee revenue, more than tripled (a 231% increase) although the direct congressional appropriations (budget authority) increased by 78%. The effect of user fees is even more evident in comparing the number of FTEs. The budget authority funded FTEs decreased by 14%, but the overall human drug FTE level increased by 40% because of user fee funding. For the human drug program in FY2006, user fees contributed 46% of the budget and funded 39% of the FTEs.

In general, Congress has either kept direct appropriations in line with inflation (FY1980-FY1988, FY1994-FY1997, and FY2002-2007) or increased them gradually (FY1989-FY1993 and FY1998-FY2001). The exception is FY2002, when Congress increased direct appropriations to FDA by 23%, along with increases to other public safety agencies in response to the attacks of September 11, 2001, and the anthrax mailings soon after.

Congress and various administrations have allowed FDA's research program to diminish and its many data systems are not meeting the agency's needs. The context of this report does not allow a distinction between program decisions made by budget constraints and those made by policy intent.

The focus of this report is the FDA budget. The discussion does not, therefore, explore other possible constraints on FDA's meeting its responsibilities and the public's expectations. Such

factors could include the agency's lack of strong advocates, both externally (such as NIH has with its patient advocacy groups) and internally (because of chronic vacancies in key leadership positions, including the Commissioner). Independent of whether the FDA budget is sufficient to cover agency responsibilities is how FDA manages the resources it does have. The influence of non-budgetary factors likely complicates agency actions, though analyzing that is beyond the scope of this report.

From 1980 through 2007, 36 new major statutes were enacted that address FDA activities.<sup>112</sup> This report does not evaluate the impact of individual statutory requirements on the workload and resources needs of the agency. However, an examination of the FDA Amendments Act of 2007 (FDAAA, P.L. 110-85) provides examples of the funding issues discussed in this report. Some news coverage of FDAAA hailed it as “the most sweeping overhaul of the Food and Drug Administration in a decade.”<sup>113</sup> In addition to the widely expected reauthorization of drug and device user fees and pediatric drug research incentives, FDAAA, among other things, authorized demonstration grants, including ones for improving pediatric device availability; established mechanisms for public-private partnerships to support FDA's mission to accelerate medical product innovation, translational therapeutics, and enhanced medical product safety; required an expanded clinical trial registry databank; and strengthened FDA's authority to require studies and labeling changes for drugs already on the market.

Implementation of these and other provisions is to involve the development of new regulations and extensive communication with industry and the public. Carrying out these new responsibilities will require time and resources. To fund all these provisions, FDAAA authorized annually an additional \$250 million in appropriations and \$32 million in user fee revenue.<sup>114</sup> Absent appropriations, these authorizations remain congressional statements of intent.

This report has focused on the presentation of FDA's financial and human resources and statutory responsibilities over time. In presenting that information in context, the report also identifies actions—other than a straightforward increase in direct appropriations—that others have suggested as possible steps to help FDA's budget situation. These propose to:

- Restructure the PDUFA trigger mechanism to minimize its unintended effect of pulling resources from non-PDUFA activities.
- Authorize FDA to bypass the HHS and OMB budget offices in submitting its request for appropriations to Congress.
- Require, in addition to the OMB-processed budget request, that the FDA Commissioner submit to Congress a Professional Judgment budget based on his or her personal expertise and experience.

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<sup>112</sup> This number is held down by the concatenation of many introduced bills into large packages passed as single items. For example, FDAAA of 2007 is counted once although it included the Prescription Drug User Fee Amendments of 2007, the Medical Device User Fees Amendments of 2007, the Pediatric Medical Device Safety and Improvement Act of 2007, the Pediatric Research Equity Act of 2007, and the Best Pharmaceuticals for Children Act of 2007, among many other items.

<sup>113</sup> Drew Armstrong, “Major Elements of the FDA Overhaul,” *CQ Weekly: Health*, September 24, 2007, p. 2767.

<sup>114</sup> FDAAA included other provisions that could (but do not necessarily) affect FDA's total program level. These are direction to transfer appropriated funds for specified purposes, authority to assess certain civil penalties, and authority to appropriate funds for certain grants and contracts.

- Move FDA appropriations from the appropriations subcommittees on agriculture to the Labor-HHS subcommittees, which handle most other agencies involved in protecting the public's health.

## Appendix. Methodology

This report tracks, as consistently as possible with publicly available material, the FDA budget numbers and employee numbers (FTEs) from FY2007 back to FY1980. The goal was to provide about 25 years of budget and FTE history accompanied by changes in the agency's statutory responsibilities. Only limited budget and FTE data are available from bills and reports of the congressional appropriations committees. Citing constraints on its staff time, FDA indicated that it would only be able to provide data for recent years. Therefore, this report used data prepared annually by FDA for Congress at the beginning of each budget cycle and presented in the *Justification* documents. The *Justifications* are prepared initially by FDA and transmitted through HHS to OMB, often with adjustments made by HHS and OMB. These documents provide detailed budget and FTE data along with an extensive narrative.

Over the years, changes in agency organization, accounting methods, definitions, and other conditions resulted in variations in data presentation in the *Justification* documents. Although some data inconsistencies found in the documents could be explained, other inconsistencies could not. This section of the report provides the basic approach used to calculate historical budget and FTE numbers, highlights inconsistencies among the *Justification* documents, and describes the steps taken to make the data as consistent as possible. There may be additional data inconsistencies that were not found because they were less readily apparent.

The annual *Justification* documents present first the overall FDA information (narrative, and budget and FTE data) followed by information for the various activity areas within the agency. Except as noted below, this report uses data from the *Actuals* column in tables labeled: *All Purpose Table—Total Program Level*; *All Purpose Table—Budget Authority*; and *All Purpose Table—User Fees*. These tables are found at the beginning of each *Justification* document. The report also uses activity-specific data from similar tables that are included at the beginning of the *Justification's* narrative section on each activity area.

### Overall FDA Budget

The FDA's total budget, also called the *program level*, consists of (1) direct congressional appropriations, referred to by FDA as *budget authority*, and (2) funds collected or transferred from other sources, which this report refers to as *other funds* and which FDA lists under *user fees* in recent *Justifications*. Other funds include all of the financial and FTE resources that are available to FDA as itemized in the *Justifications* that are from sources other than direct congressional appropriations. In recent years, the largest component of other funds comes from user fees collected under the authority of the Prescription Drug User Fee Act, the Medical Device User Fee and Modernization Act, and the Animal Drug User Fee Act. Grouped separately in some years' *Justifications* are other fees obtained under the Mammography Quality Standards Act, and fees collected for color certification, export certification, and Freedom of Information Act (FOIA) requests. Additional sources itemized in the *Justifications* include advances and reimbursements; Parklawn Computer Center FTEs; CRADAs; and P.L. 83-480 (Agricultural Trade Development and Assistance Act of 1954) funds. Note that overall FDA budget authority includes appropriations for both "Salaries and Expenses" and "Buildings and Facilities." (In contrast, as indicated below, activity-area budgets include only "Salary and Expenses.")

## Activity Area Budgets

This report follows the order in the FY2008 *Justification* document in presenting information on FDA's five major activity areas: Foods, Human Drugs, Biologics, Animal Drugs and Feeds, and Medical Devices and Radiological Health. For each activity area, the *Justification* provides the amount given by direct congressional appropriations (*budget authority*) and *user fees* (a narrower category than *other funds*), the total of which is the *program level*.

The *Justification* documents do not allocate an amount for Buildings and Facilities to each activity-area. Buildings and Facilities is recorded as a separate line within the overall FDA budget. Activity area amounts in this report's tables and graphs are for Salaries and Expenses.

The report groups remaining FDA activities (Toxicological Research), agency-wide responsibilities (Headquarters and Office of the Commissioner) and expenditures (Rent, Buildings and Facilities) into an "Other Activities" category. **Tables A2** and **A3** in the **Appendix** of this report include budget and FTEs for Other Activities within the FDA Total columns, but do not provide a separate Other Activities column. Budget amounts for Other Activities are included in **Figure 1** and **Figure 3**, which present overall FDA data.

## Inflation Adjustment

Data in **Table A-2** in the **Appendix** are as reported in the *Justifications* and have not been adjusted for inflation. For **Figures 1** and **2** as well as **Figures 4-9**, data have been adjusted for inflation using "Total Non-Defense" deflators from Table 10.1, Gross Domestic Product and Deflators Used in the Historical Tables: 1940-2012, found on pages 192-193 in: Office of Management and Budget, *Historical Tables, Budget of the United States, Fiscal Year 2008*.

## Basic Approach

As stated above, this report uses data found in the Actuals column of tables in the *Justification* documents.<sup>115</sup> Budget and FTE information for each activity area found in the overall summary tables at the front of the *Justification* document was compared with information found in the tables within the activity-area sections of the same document for confirmation. When a *Justification* included inconsistent information, *Justification* documents from the preceding and succeeding fiscal years were used to resolve the problem. The steps taken to resolve specific inconsistencies are described below in **Table A-1** in the **Appendix**. The reporting format that FDA has used within the *Justification* documents to describe both its overall budget and those of its various activities has changed over the past 28 years. The format in this report was kept as consistent as possible with the format found in the FY2008 *Justification*.

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<sup>115</sup> Actuals data for a specific fiscal year can be found in the *Justification* document proposing the agency's budget two fiscal years later. For example, the Actuals data for FY2001 come from the FY2003 *Justification*.

**Table A-I. Actions Taken to Address FDA Budget Data Limitations**

Fiscal Year	Limitation in Source Material	Authors' Decision for Report Presentation
1980-1982	FTE and budget amounts for Medical Devices and for Radiological Health were reported separately.	Medical Devices and Radiological Health numbers were added together to create a category consistent with the current <i>Justification</i> .
1980-1985	FTE and budget amounts for Foods were separated into three categories: food safety, food labeling or food economics, and cosmetics.	The three categories were added together to create a category consistent with Foods in the current <i>Justification</i> .
1980-1985	For FY1980-FY1985, the <i>Justifications</i> did not have a summary Budget Authority table that included both Salaries & Expenses and Buildings & Facilities.	Salaries & Expenses and Buildings & Facilities were added together to obtain the budget authority total for the agency.
1980-1985	In contrast to the FY2008 All Purpose tables, the Appropriation Summary tables in the FY1981-FY1986 <i>Justifications</i> contained only direct appropriations (budget authority) amounts and did not provide amounts for other funds or program level. The "Total Resources Available" table reported other funds available to FDA. These other funds amounts are reported only for the request year and the preceding year. The table labels did not indicate whether the amounts are estimates or actuals.	For FY1980-FY1985, data from the "Total Resources Table" in the FY1981-FY1986 <i>Justifications</i> were used to construct an other funds amount.  Other funds and budget authority amounts were added to obtain program level totals.
1983-1987	Human Drugs and Biologics activities merged in 1983 to form the Center for Drugs and Biologics which split in 1987 to form CDER and CBER. <i>Justifications</i> reports combined Human Drugs and Biologics FTE and budget amounts for these years.	Tables and figures in this report include footnotes explaining the absence of Biologics data and the jump in Human Drugs resources for these years.
1986-1988	In contrast to the FY2008 All Purpose tables, the Appropriation Summary tables in the FY1988-FY1990 <i>Justifications</i> contained only direct appropriations (budget authority) amounts and did not provide amounts for other funds or program level. The "Total Resources Available" table reported other funds available to FDA. These amounts are reported as estimates for the request year and the preceding year and as actuals for the year two years prior to the request.  The amount labeled "Total" in the "Total Resources Available" table is equal to program level and the amount labeled "Program Expenses" is equal budget authority. The "Program Expenses" amount is the same as the amount labeled "Total Appropriation" or "Total Obligational Authority" in the FDA Appropriation Summary table.	Amounts labeled Actual in the "Total Resources Available" table were used to calculate other funds.  Other funds and budget authority amounts were added to obtain program level totals.
1989-1991	In contrast to the FY2008 All Purpose tables, the Appropriation Summary tables in the FY1991-FY1993 <i>Justifications</i> contained only direct appropriations (budget authority) amounts and did not provide amounts for other funds or program level. The "Total Resources Available" table reported other funds available to FDA. These amounts are reported as estimates for the request year and the preceding year and as an actual amount for the year two years prior to the request.	In contrast to above, the amounts labeled Actual in the "Total Resources Available" table were not used to calculate other funds.
1989-1991	In the "Total Resources Available" table, the amount labeled "Total" is equal to program level; however, the amount labeled "Program Expenses" is not equal to budget authority. The "Program Expenses" amount is not the same as the amount labeled "Total	Other funds were calculated by subtracting the amount labeled "Total Obligational Authority" in the FDA Appropriation Summary table from

Fiscal Year	Limitation in Source Material	Authors' Decision for Report Presentation
1992-1993	<p>Obligational Authority" in the FDA Appropriation Summary table.</p> <p>The "FDA Budget Authority by Activity" table in the FY1994 and FY1995 <i>Justifications</i> contained information similar to that presented in the "All Purpose Tables" of FY2000-FY2008. However, the tables in the FY1994 and FY1995 <i>Justifications</i> categorize the information differently: excluding several items from the recent years' "User Fee" category; and omitting a summary equivalent to either "All Purpose—Budget Authority" or "All Purpose—Program Level" as provided in the FY2000-FY2008 <i>Justifications</i>.</p>	<p>the amount labeled "Total" in the "Total Resources Available" table.</p> <p>Individual items from the FY1994 and FY1995 "FDA Budget Authority by Activity" tables were placed in "program level," "budget authority," and "other funds" categories in a manner consistent with their presentation in the "All Purpose Tables" in the FY2000-FY2008 <i>Justifications</i>.</p>
1994-1997	<p>The FY1996-FY1999 <i>Justifications</i> contained tables at the beginning of the document that, although not labeled as such, have formats and information similar to the "All Purpose Tables" in the FY2000-FY2008 <i>Justifications</i>. The tables are titled "FDA Budget Authority by Activity" in the FY1996 and FY1997 <i>Justifications</i> and "FDA Congressional Budget Request" in the FY1998 and FY1999 <i>Justifications</i>.</p>	<p>The "FDA Budget Authority by Activity" tables and the "FDA Congressional Budget Request" tables were used as the data source.</p>
1993	<p>The overall FDA amount for other funds includes \$8,949,000 in Prescription Drug User Fee Act (PDUFA) fees, but a comparable entry is not included in the budget of Human Drugs or Biologics (as is the case for FY1994 through FY2008).</p>	<p>The PDUFA user fee amount was included in the other funds category of the overall FDA budget. In the absence of activity-level data for the PDUFA fees, the PDUFA user fee amount was not included in the user fees category of Human Drugs, Biologics, or any other activity area budget.</p>
2003	<p>The FY2005 <i>Justification</i> reported two different overall FDA budget authority amounts in the All Purpose Tables. The overall FDA budget authority is \$1,390,071,000 in the All Purpose Table—Budget Authority, and \$1,398,350,000 in the All Purpose Table—Total Program Level, a difference of \$8,279,000.</p>	<p>Other sections in the FY2005 <i>Justification</i> indicated that the table labeled All Purpose Table—Total Program Level likely contained incorrect amounts for the Offices of External Relations and International &amp; Constituent Relations. The overall FDA budget authority amount of \$1,390,071,000 from the All Purpose Table—Budget Authority was used.</p>
2004	<p>The FY2006 <i>Justification</i> organized data—including Actual data for FY2004—in a format different than other <i>Justifications</i>. That year, activity totals did not include amounts for Office of Regulatory Affairs, but did include rent. In the FY2007 and FY2008 <i>Justifications</i>, FDA reverted to the previous format for all activities except for Human Drugs and Biologics.</p>	<p>For Human Drugs and Biologics, FY2004 numbers were reconstructed by adding in Office of Regulatory Affairs amounts and subtracting rent to make them consistent with other years. For the remaining activities (Foods, Animal Drugs and Feeds, and Medical Devices and Radiological Health), amounts from the FY2008 <i>Justification</i> were used.</p>
2007	<p>FY2007 ended without passage of an Agriculture appropriations bill. The FY2008 <i>Justification</i> used FY2007 amounts from a continuing resolution in effect at the time. Later, a Revised Continuing Appropriations Resolution was enacted. An FDA <i>Operating Plan</i> for FY2007 (dated March 2007) reflected the final funding levels under P.L. 110-5, the Revised Continuing Appropriations Resolution, 2007 but did not contain FTE numbers.</p>	<p>The FDA <i>Operating Plan</i> was used as the source of budget data. The FY2008 <i>Justification</i> was used as the source of FTE data.</p>
2008	<p>Amounts for FY2008 in the FDA FY2008 <i>Justification</i> are the President's Budget Request, and, therefore, do not reflect any final action by Congress.</p>	<p>Amounts for FY2008 are labeled "Request" in the <b>Appendix</b> tables and are not included in any graphs.</p>

**Table A-2. FDA Appropriations, Overall and by Major Program, Budget Authority and Other Funding, FY1980 through FY2008, Unadjusted for Inflation**

(dollars in thousands)

Fiscal Year	Program Level <sup>a</sup>	FDA		Foods	Human Drugs		Biologics		Animal Drugs & Feeds		Devices & Radiol.	
		Budget Authority	Other Funds	Budget Authority	Budget Authority	User Fees	Budget Authority	User Fees	Budget Authority	User Fees	Budget Authority	User Fees
1980	339,864	324,829	15,035	95,107	72,119	0	22,147	0	23,498	0	49,035	0
1981	346,294	331,420	14,874	92,373	76,476	0	21,638	0	21,000	0	58,218	0
1982	353,861	341,624	12,237	104,253	72,284	0	23,174	0	21,499	0	53,364	0
1983	397,896	391,387	6,509	103,294	108,472	0	— <sup>b</sup>	0	22,011	0	58,836	0
1984	400,502	392,649	7,853	116,000	114,335	0	— <sup>b</sup>	0	23,913	0	62,568	0
1985	423,935	414,345	9,590	110,541	130,996	0	— <sup>b</sup>	0	23,427	0	67,263	0
1986	412,361	404,361	8,000	109,753	129,609	0	— <sup>b</sup>	0	22,778	0	65,561	0
1987	457,351	447,144	10,207	120,449	151,642	0	— <sup>b</sup>	0	24,866	0	70,972	0
1988	486,051	477,504	8,547	126,401	117,132	0	51,379	0	25,406	0	74,911	0
1989	552,447	542,343	10,104	141,211	131,215	0	60,471	0	24,452	0	78,457	0
1990	611,551	600,979	10,572	161,082	146,519	0	73,241	0	30,670	0	89,365	0
1991	707,467	688,392	19,075	183,899	176,402	0	83,086	0	35,256	0	104,778	0
1992	777,850	761,830	16,020	206,304	198,538	0	90,531	0	39,000	0	116,731	0
1993	824,105	796,869	27,236	204,690	211,647	0	98,281	0	38,017	0	129,025	0
1994	920,745	875,968	44,777	213,014	214,855	23,108	110,748	16,843	40,318	0	159,359	0
1995	948,268	869,230	79,038	216,398	217,940	48,413	104,113	25,651	41,684	0	157,021	0
1996	988,341	889,527	98,814	200,941	202,024	50,863	87,315	29,991	36,814	0	143,717	8,557
1997	997,005	880,743	116,262	191,183	201,079	53,336	96,256	26,384	36,216	0	147,372	12,449
1998	1,050,299	931,883	118,416	206,249	199,579	63,069	95,479	27,533	41,354	0	144,329	11,376
1999	1,129,993	985,279	144,714	235,168	200,423	77,876	95,023	29,342	43,253	0	145,790	13,218
2000	1,213,983	1,048,149	165,834	279,704	215,538	95,696	106,133	34,584	49,593	0	157,656	12,601

Fiscal Year	Program Level <sup>a</sup>	FDA		Foods	Human Drugs		Biologics		Animal Drugs & Feeds		Devices & Radiol.	
		Budget Authority	Other Funds	Budget Authority	Budget Authority	User Fees	Budget Authority	User Fees	Budget Authority	User Fees	Budget Authority	User Fees
2001	1,278,147	1,099,311	178,836	287,504	218,515	103,965	108,303	38,927	64,070	0	165,306	12,259
2002	1,536,959	1,354,366	182,593	393,256	254,700	109,644	138,605	39,237	85,643	0	179,962	13,695
2003	1,627,656	1,390,071	237,585	406,824	274,073	129,775	145,318	48,118	87,659	0	193,350	23,935
2004	1,678,904	1,401,214	277,690	407,052	292,118	167,474	122,354	44,662	83,458	983	191,143	30,363
2005	1,777,474	1,452,274	325,200	435,517	291,484	190,650	123,109	47,575	90,484	7,538	214,962	29,320
2006	1,862,694	1,493,580	369,114	438,721	297,715	211,190	138,518	59,191	89,580	8,264	220,563	34,478
2007	2,007,727	1,574,194	433,533	457,105	315,138	255,238	144,547	65,738	94,749	9,537	230,710	42,237
2008 <sup>c</sup>	2,084,649	1,640,659	443,990	466,726	324,438	232,358	155,073	60,762	94,809	11,523	240,122	45,254

**Sources:** FDA Justification of Estimates for Appropriations Committees documents.

**Notes:** FDA's foods program budget does not include user fee revenue. Devices and Radiological Products were added for 1980, 1981, and 1982. User Fees in 1992 are Revolving Fund—Certification Fees. User Fees in 1993 are PDUFA plus Revolving Fund—Certification Fees. Unclear how 1993 PDUFA user fees were allocated.

The FY2007 is Operating Plan for 2007 (Dated March 2007) reflecting funding levels under P.L. 110-5.

- a. Total program level = budget authority (direct appropriations) + other funding (e.g., user fees).
- b. For FY1983 through FY1987, FDA managed Biologics activities and Human Drugs activities in one Center. The *Justifications* for those years provide only combined dollar amounts which are included in Human Drugs and not in Biologics.
- c. FY2008 amounts are the Administration request levels.

**Table A-3. Full-time Equivalents, Overall and by Major Program, Budget Authority-Funded and Other-Funded, FY1980 through FY2008**

Year	FDA FTEs			Food FTEs	Human Drugs FTEs			Biologics FTEs			Animal Drugs & Feeds FTEs			Devices & Radiological Health FTEs		
	BA	Other Funds	Total	Total	BA	User Fee	Total	BA	User Fee	Total	BA	User Fee	Total	BA	User Fee	Total
1980	7,816	366	8,182	2,408	2,102	0	2,102	507	0	507	516	0	516	1,399	0	1,399
1981	7,558	374	7,932	2,319	2,023	0	2,023	490	0	490	499	0	499	1,375	0	1,375
1982	7,011	374	7,385	2,496	1,703	0	1,703	410	0	410	446	0	446	1,161	0	1,161
1983	7,122	184	7,306	2,257	2,356	0	2,356	— <sup>a</sup>	— <sup>a</sup>	— <sup>a</sup>	450	0	450	1,258	0	1,258
1984	7,089	188	7,277	2,396	2,228	0	2,228	— <sup>a</sup>	— <sup>a</sup>	— <sup>a</sup>	458	0	458	1,211	0	1,211
1985	7,024	188	7,212	2,164	2,446	0	2,446	— <sup>a</sup>	— <sup>a</sup>	— <sup>a</sup>	426	0	426	1,259	0	1,259
1986	6,832	169	7,001	2,091	2,406	0	2,406	— <sup>a</sup>	— <sup>a</sup>	— <sup>a</sup>	441	0	441	1,217	0	1,217
1987	6,794	169	6,963	2,071	2,423	0	2,423	— <sup>a</sup>	— <sup>a</sup>	— <sup>a</sup>	441	0	441	1,238	0	1,238
1988	7,039	171	7,210	2,146	1,942	0	1,942	584	0	584	441	0	441	1,282	0	1,282
1989	7,228	170	7,398	2,377	1,913	0	1,913	674	0	674	414	0	414	1,263	0	1,263
1990	7,629	185	7,814	2,475	2,026	0	2,026	775	0	775	438	0	438	1,332	0	1,332
1991	8,267	183	8,450	2,637	2,263	0	2,263	824	0	824	483	0	483	1,482	0	1,482
1992	8,792	302	9,094	2,793	2,390	0	2,390	898	0	898	506	0	506	1,604	0	1,604
1993	8,939	200	9,139	2,695	2,449	0	2,449	969	0	969	485	0	485	1,683	0	1,683
1994	8,963	389	9,352	2,675	2,412	78	2,490	977	126	1,103	495	0	495	1,799	0	1,799
1995	8,811	453	9,264	2,590	2,278	295	2,573	954	158	1,112	468	0	468	1,831	0	1,831
1996	8,487	685	9,172	2,348	2,108	351	2,459	804	206	1,010	403	0	403	1,603	43	1,646
1997	8,354	817	9,171	2,226	2,069	446	2,515	861	209	1,070	382	0	382	1,619	48	1,667
1998	8,083	821	8,904	2,239	1,959	470	2,429	841	186	1,027	391	0	391	1,507	48	1,555
1999	7,851	1,059	8,910	2,339	1,846	610	2,456	791	198	989	393	0	393	1,432	48	1,480
2000	7,728	1,102	8,830	2,386	1,838	671	2,509	780	211	991	406	0	406	1,426	46	1,472
2001	7,805	1,184	8,989	2,445	1,824	711	2,535	786	255	1,041	442	0	442	1,428	45	1,473

Year	FDA FTEs			Food FTEs	Human Drugs FTEs			Biologics FTEs			Animal Drugs & Feeds FTEs			Devices & Radiological Health FTEs		
	BA	Other Funds	Total	Total	BA	User Fee	Total	BA	User Fee	Total	BA	User Fee	Total	BA	User Fee	Total
2002	8,311	1,157	9,468	2,734	1,817	700	2,517	894	242	1,136	570	0	570	1,407	47	1,454
2003	8,940	1,317	10,257	3,167	1,920	776	2,696	947	282	1,229	596	0	596	1,432	53	1,485
2004	8,567	1,574	10,141	3,082	1,977	972	2,949	792	246	1,038	592	3	595	1,376	139	1,515
2005	8,181	1,729	9,910	2,943	1,837	1,081	2,918	768	273	1,041	571	39	610	1,367	149	1,516
2006	7,893	1,805	9,698	2,774	1,801	1,146	2,947	730	249	979	538	54	592	1,328	170	1,498
2007	7,510	1,529	9,039	2,613	1,703	1,122	2,825	776	215	991	502	0	502	1,235	34	1,269
2008 <sup>b</sup>	7,987	1,902	9,889	2,702	1,826	1,205	3,031	838	263	1,101	561	58	619	1,359	180	1,539

**Source:** FDA Justification of Estimates for Appropriations Committees documents.

**Note:** FDA's foods program budget does not include user fee revenue.

- a. For FY1983 through FY1987, FDA managed Biologics activities and Human Drugs activities in one Center. The *Justifications* for those years provide only combined FTEs which are included in Human Drugs and not in Biologics.
- b. FY2008 based on Administration request.

**Table A-4. Selected Public Laws Since 1848 Significantly Affecting FDA Activities**

Public Law	Title and Brief Description of Law	Activity <sup>a</sup>
	<b>Drug Importation Act (An Act to Prevent the Importation of Adulterated and Spurious Drugs and Medicines, 30<sup>th</sup> Congress, Session I, Chpt. 70; 1848; 237-239)</b> required the Department of the Treasury (U.S. Customs Service) to inspect drugs from abroad for quality, purity, and fitness for medical purposes.	Drugs
59-384	<b>Pure Food and Drug Act of 1906</b> , administered by the then-USDA Bureau of Chemistry, required the food division to prohibit interstate commerce in food, drink, and drug products that were adulterated and misbranded. It provided criminal penalties for violations and also authorized the seizure of offending products. It defined <i>drug</i> (substance intended to be used for the cure, mitigation, or prevention of disease of either man or other animals), <i>adulteration</i> (differing from established standards of strength, quality, or purity), and <i>misbranding</i> (contents not as labeled, including quantities of alcohol and certain narcotics). The act also referred to drug descriptions in the <i>United States Pharmacopeia</i> and the <i>National Formulary</i> as referents for judging purity and label accuracy. Regarding food, misbranding was confined to making false or misleading statements on the package or label, and adulteration was limited because no standards existed, so generalities described the intermixture or substitution of substances that reduced quality, the concealment of damage or inferiority, the addition of deleterious ingredients, and the use of spoiled products.	Foods, Drugs, Animal
62-301	<b>Sherley Amendment of 1912</b> expanded the definition of misbranding to include false statements of curative or therapeutic effect.	Drugs
63-223	<b>Harrison Narcotics Act of 1914</b> required “every person who produces, imports, manufactures, compounds, deals in, dispenses, sells, distributes, or gives away opium” or certain other narcotics to register with the collectors of internal revenue, pay a special tax, and keep records. It also required a written prescription (on a form provided by the Commissioner of Internal Revenue) for the dispensing of quantities of those narcotics above the amounts specified.	Drugs
67-513	<b>Filled Milk Act of 1923</b> defined filled milk as any milk, cream or skimmed milk, regardless of its form, to which is added, blended, or compounded any fat or oil other than milk fat so that the resulting product is an imitation of milk, cream, or skimmed milk. The act declared that filled milk is an adulterated article or food, injurious to the public health and that its sale constituted a fraud upon the public.	Foods
67-625	<b>Import Milk Act of 1927</b> regulated the importation of milk and cream into the United States for the purpose of promoting the U.S. dairy industry and protecting public health. The act required that a valid permit be obtained from the Secretary of Health and Human Services for milk and cream to be imported into the country.	Foods
75-447	<b>Wheeler-Lea Act of 1938</b> assigned to the Federal Trade Commission oversight of advertising associated with products otherwise regulated by FDA.	Drugs
75-717	<b>Federal Food, Drug, and Cosmetic Act of 1938</b> is considered the primary foundation of current food and drug law on which subsequent statutes have been added. The food provisions specifically required FDA to promulgate definitions and standards for foods and informative labeling. In addition, it prohibited false advertising and the addition of substances that would render the food adulterated, unless safe tolerance levels were provided for such substances. The drug provisions required that drugs be proven safe before they could be sold in interstate commerce; prohibited the adulteration and misbranding of a drug, the introduction of such a drug into interstate commerce, and the receipt of such a drug; increased penalties if misbranding involved an intent to defraud; required records of shipments; authorized inspection of a facility that manufactures, processes, packs, or holds drugs (and other FDA-regulated products), including its equipment, materials, containers, and labeling; and required regulations for the certification of batches of color additives. The act expanded the definition of <i>drug</i> beyond substances intended to be used in the cure, mitigation, and prevention of disease to include articles intended for use in the diagnosis and treatment of disease; and further expanded the definition to include “articles ... intended to affect the structure of any function of the body of man or other	Foods, Drugs, Biologics, Animal, Devices

Public Law	Title and Brief Description of Law	Activity <sup>a</sup>
	animals.” It expanded the scope of <i>misbranding</i> , including requirements for labeling, packaging, quantity, directions for use, and warnings, among others. The courts have allowed FDA to apply these drug regulations to medical devices.	
77-366	<b>Insulin Amendment of 1941</b> required that the Federal Security Administrator (FSA; from 1940 to 1953, FDA resided in the Federal Security Agency) provide for the testing and certification of each batch of insulin for strength, quality, and purity. The law also directed the Administrator to promulgate regulations covering, among other things, standards and tests.	Drugs
78-410	<b>Public Health Service Act of 1944</b> required individuals or companies who manufacture biologics that enter into interstate commerce to hold a license for such products. Authorizes the inspection of manufacturing establishments involved in the preparation of biological products, and the recall of products without a license or that present an imminent hazard to the public health; and provides civil and criminal penalties for violations.	Biologics
79-139	<b>Penicillin Amendment of 1945</b> required that the FSA provide for the certification of each batch of penicillin for strength, quality, and purity; and that the FSA promulgate regulations.	Drugs
82-215	<b>Durham-Humphrey Amendment of 1951</b> restricted to <i>prescription only</i> the sale of a drug that is habit-forming or that is not safe for use except under the supervision of a licensed practitioner. It also authorized the Secretary to remove the prescription requirement from a drug if the requirement is not necessary for the protection of public health.	Drugs
83-217	<b>Factory Inspection Amendment of 1953</b> expanded the FFDCa section on factory inspection to require that the inspector give the owner and send to the Secretary a written report of unsatisfactory conditions. The amended version of the section no longer required an owner’s permission to enter the facility for inspection, which the 1938 law had included.	Drugs
83-518	<b>Miller Pesticide Amendment of 1954</b> provided FDA with authority to establish tolerances for pesticides on agricultural commodities.	Foods
85-929	<b>Food Additive Amendments of 1958</b> established a premarket approval system for new food ingredients and many food contact substances.	Foods, Animal
86-618	<b>Color Additive Amendments of 1960</b> established a premarket approval system for colors used in food, drugs and cosmetics. Required that the Secretary promulgate regulations for the listing of color additives in or on food, drugs, and cosmetics based on conditions, uses, and labeling to assure safe use.	Foods, Drugs
87-781	<b>Kefauver-Harris Drug Amendments of 1962</b> to the FFDCa required that drugmakers prove the effectiveness of their products as well as safety. The law also reassigned the authority to regulate prescription drug advertising from the Federal Trade Commission to the Food and Drug Administration and included expanded FDA authority to all antibiotics.	Drugs
89-74	<b>Drug Abuse Control Amendments of 1965</b> restricted the manufacture, compounding, and processing of depressant and stimulant drugs; required that manufacturers, sellers, and others keep records and allow the Secretary to verify records and inspect facilities. The law limited the number of prescription refills, and authorized the Secretary to exempt a drug and to appoint expert advisory committees under certain circumstances; and it specified penalties.	Drugs
89-755	<b>Fair Packaging and Labeling Act of 1966</b> required any packaged consumer product in commerce to display a legible, prominent label that states the identity of the contents, quantity, and name and place of the manufacturer, packer, or distributor. The act also authorized FDA to adopt regulations to prevent the non-functional fill of packages. It designated the HHS Secretary to promulgate regulations for food, drugs, devices, and cosmetics.	Foods, Drugs, Devices

Public Law	Title and Brief Description of Law	Activity <sup>a</sup>
90-399	<b>Animal Drug Amendments of 1968</b> established a new section 512 of the FFDCA to apply specifically to the approval of animal drugs, extended the requirements for FDA to review the safety and effectiveness of animal drugs for intended use, and included a review of safety for their use in food-producing animals.	Animal
91-513	<b>Controlled Substances Act (part of the Comprehensive Drug Abuse Prevention and Control Act of 1970)</b> authorized the Attorney General (AG) to categorize certain drugs across five schedules based on their potential for abuse, potential for physical or psychological dependence, and accepted medical uses. Required that the AG request scientific advice from the HHS Secretary. Required the Secretary (via FDA) to notify the AG when a submitted new drug application involves a drug with an abuse potential.	Drugs
91-597	<b>Egg Products Inspection Act of 1970</b> required FDA to inspect certain egg products and established uniform standards for grading eggs. In addition, the agency is responsible for the regulation of processing and distribution of eggs and egg products to prevent the movement or sale for use in human food of eggs and egg products that are adulterated or misbranded.	Foods
94-278	<b>Vitamin-Mineral Amendment of 1976</b> limited FDA's authority to regulate the composition and promotion of dietary supplements, marking a rejection of the agency's decade-long effort to control high potency nutritional products and health food.	Foods
94-295	<b>Medical Device Amendments of 1976</b> This law was the first major legislation passed to ensure safety and effectiveness of medical devices, including diagnostic products, before they could be marketed. The amendments required manufacturers to register with FDA and follow quality control procedures in their manufacturing processes. Some products were required to undergo premarket review by FDA, while others had to meet performance standards before marketing.	Devices
96-359	<b>Infant Formula Act of 1980</b> enlarged FDA's authority over infant formulas by establishing reporting requirements, quality control procedures, recall requirements, exemptions, and labeling and nutrient requirements. The Anti-Drug Abuse Act of 1986 (P.L. 99-570) added additional requirements for infant formula recalls and new microbiological testing and record retention requirements.	Foods
97-414	<b>Orphan Drug Act of 1983</b> provided incentives for pharmaceutical manufacturers to develop drugs, biotechnology products, and medical devices for the treatment of rare diseases and conditions.	Drugs
98-127	<b>Federal Anti-Tampering Act of 1983</b> made it a crime to tamper with packaged consumer products and authorized the FDA to investigate violations.	Foods, Drugs, Biologics, Animal, Devices
98-417	<b>Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act)</b> changed patent law to allow earlier market entry of generic drugs, while also extending brand-name patent terms to reflect regulatory delays during FDA approval.	Drugs
100-293	<b>Prescription Drug Marketing Act of 1987</b> banned the sale, trade, and purchase of drug samples; mandated storage, handling, and accounting standards for drug samples; and required that drug wholesalers be licensed by the states.	Drugs
100-670	<b>Generic Animal Drug and Patent Term Restoration Act of 1988</b> amended the FFDCA to authorize abbreviated applications for the approval of a new animal drug.	Animal
101-500	<b>Sanitary Food Transport Act of 1990</b> was primarily focused on the transportation of food under the jurisdiction of the Secretary of the Department of Transportation (DOT). The act required DOT to work with other departments, including HHS, to provide assistance in food transportation inspections.	Foods, Animal
101-535	<b>Nutrition Labeling and Education Act of 1990</b> provided authority for the agency to mandate nutrition labels on most food products and	Foods

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	allow nutrient content and health claims. Most state and local requirements for labeling were preempted, giving FDA responsibility for regulating all aspects of nutrition labeling information.	
101-629	<b>Safe Medical Devices Act of 1990</b> established postmarket requirements for medical devices, and required facilities that use medical devices to report to FDA any incident that suggested that a medical device could have caused or contributed to the death, serious illness, or injury of a patient. The act authorized FDA to carry out certain enforcement actions, such as device product recalls, for products that did not comply with the law.	Devices
102-282	<b>Generic Drug Enforcement Act of 1992</b> imposed debarment and other penalties for illegal acts involving abbreviated drug applications (i.e., for generic drugs).	Drugs
102-300	<b>Medical Device Amendments of 1992</b> authorized FDA to order a manufacturer, importer, or distributor to repair or replace a device, or refund the purchase price to the customer, when the device was improperly designed or manufactured; revised reporting requirements. It made failure to comply with a requirement imposed by provisions of the FFDCa concerning postmarket surveillance a prohibited act subject to criminal and civil penalties, and deemed any device product misbranded if there was a failure or refusal to comply with postmarket surveillance requirements.	Devices, Biologics
102-539	<b>Mammography Quality Standards Act of 1992</b> amended the Public Health Service Act to require certification in order for a facility to perform or interpret mammograms, inspect equipment, or provide for the processing of mammography film. It mandated standards to assure the safety and accuracy of mammograms, and directed the Secretary to conduct annual inspections of certified facilities. It also mandated fees to cover the costs of inspections. This law was amended and reauthorized by the Mammography Quality Standards Reauthorization Act of 1998 (P.L. 105-248) and the Mammography Quality Standards Reauthorization Act of 2004 (P.L. 108-365).	Devices
102-571	<b>Prescription Drug User Fee Act of 1992 (PDUFA)</b> authorized, for five years, FDA to assess and collect fees from the pharmaceutical manufacturers and to use the resulting revenue to support its review of new drug and biologics applications.	Drugs, Biologics
103-396	<b>Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA)</b> allowed veterinarians to prescribe for animals, under certain conditions, certain approved animal and human drugs for use in a manner that is not in accordance with the approved label directions (extra-label use). Among other requirements, any extra-label use must be by or on the order of a veterinarian within the context of a veterinarian-client-patient relationship and must not result in violative residues in food-producing animals.	Animal
103-417	<b>Dietary Supplement Health and Education Act of 1994</b> provided specific authority for the agency to regulate supplements, by defining the products, and placing the burden of proof on FDA to demonstrate that a supplement already on the market is unsafe and should be removed. The law allows third party literature on the use of supplements and statements of nutritional support to be exempt from labeling regulations. Supplements are required to provide ingredient and nutrition labeling information. The law required manufacturers of a new dietary ingredient entering the market to petition FDA with evidence of safety under its intended conditions of use. Finally, good manufacturing practices (GMPs) were to be promulgated by the agency; so far FDA has only proposed, but not finalized the GMPs for supplements.	Foods
104-170	<b>Food Quality Protection Act of 1996</b> affected pesticide provisions of both the FDA's FFDCa and the Environmental Protection Agency's Federal Insecticide, Fungicide, and Rodenticide Act. Under FFDCa, FQPA established a single, health-based standard for all pesticides in all foods, eliminating the longstanding problems posed by multiple standards for pesticides in raw and processed foods. It also provided special safety provisions for infants and children, limited consideration of benefits, and allowed FDA to impose civil penalties for tolerance violations for the foods it monitored through its inspection programs. The act required tolerance level reevaluation in ten years, and added provisions	Foods

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	for endocrine testing, the right to know, and required national uniformity of tolerances, unless a state petitions for an exception.	
104-250	<b>Animal Drug Availability Act of 1996</b> amended the FFDCA to grant FDA more flexibility in evaluating and approving new animal drugs, by amending the definition of substantial evidence of effectiveness. Among other provisions, the law also permitted the use of veterinary drugs in animal feeds, with a veterinary prescription.	Animal
105-115	<b>Food and Drug Administration Modernization Act of 1997 (FDAMA)</b> reauthorized the prescription drug user fee program for five years; provided fast track approval consideration to drugs that would treat life-threatening conditions; eased certain requirements for drug approval; required guidance documents to streamline the drug review process and provide a means for resolving controversial scientific issues; allowed expanded patient access to investigational therapies; encouraged international harmonization agreements and established national uniformity in the regulation of nonprescription drugs and cosmetics; and required that FDA conduct its regulatory functions under a mission statement that will obligate it to maintain a public health protection role while seeking to expedite the marketing of regulated products. FDAMA contained a limited number of provisions specific to food regulations. It eliminated the requirement of FDA's premarket approval for most packaging and other substances that come in contact with food and may migrate into the food product. Instead, the law established a process for the manufacturer to notify the agency about its intention to use certain food contact substances and unless FDA objected within 120 days, the manufacturer could proceed to market the new product. Implementation of the notification process is contingent on additional appropriations to cover its cost to the agency. Another food provision expanded procedures under which FDA can authorize health claims and nutrition content claims without reducing the statutory standard. Medical device provisions included measures to accelerate premarket review of devices and to regulate company advertising of unapproved uses of approved devices.	Foods, Drugs, Biologics, Animal, Devices
105-115	<b>Better Pharmaceuticals for Children Act (part of FDAMA)</b> authorized, for five years, FDA to grant a drug manufacturer an additional six months of marketing exclusivity in exchange for completing FDA-requested studies of the use of a drug in children.	Drugs
105-248	<b>Mammography Quality Standards Reauthorization Act of 1998</b> reauthorized provisions relating to the certification of mammography facilities, including standards for accreditation bodies, inspection of facilities, and civil money penalties for failure to comply with standards.	Devices
106-387	<b>Medicine Equity and Drug Safety Act of 2000 (MEDS Act, part of the FY2001 Agriculture appropriations bill)</b> authorized a five-year program allowing pharmacists and drug wholesalers to import lower-priced prescription drugs from specific countries. The law required that the Secretary, before implementing the program, demonstrate that it would pose no additional risk to the public's health and safety, and would result in a significant reduction in the cost of covered products to the American consumer. [Never implemented.]	Drugs
107-109	<b>Best Pharmaceuticals for Children Act of 2002</b> renewed the agency's authority (from FDAMA) to give an additional six-month period of marketing exclusivity to a manufacturer in return for FDA-requested pediatric use studies and reports. The act also added provisions to encourage pediatric research in products that are no longer covered by patent or other marketing exclusivity agreements, and in products for which a patent-holding manufacturer declined to conduct an FDA-requested study.	Drugs
107-188	<b>Public Health Security and Bioterrorism Preparedness and Response Act of 2002</b> required all domestic and foreign facilities that manufacture, process, pack, or hold food for consumption in the United States to register and maintain records for FDA inspection when it reasonably believed a product to be adulterated, or presenting a threat of serious adverse health consequences or death to humans or animals. The act also required prior notice to FDA of products being imported into the United States and provided the agency with administrative detention authority and penalties where there is credible evidence that a product presents a threat of serious adverse health consequences or death to humans or animals. Reauthorized the prescription drug user fee program.	Foods, Drugs, Biologics, Animal, Devices
107-250	<b>Medical Device User Fee and Modernization Act of 2002</b> amended the FFDCA to enact three significant provisions for medical devices: (1) it established user fees for premarket reviews of devices; (2) it allowed establishment inspections to be conducted by accredited persons	Devices, Biologics

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	(third parties); and (3) it instituted new regulatory requirements for reprocessed single-use devices. It was modified by the Medical Device Technical Corrections Act (P.L. 108-214), and the Medical Device User Fee Stabilization Act of 2005 (P.L. 109-43).	
108-130	<b>Animal Drug User Fee Act of 2003 (ADUFA)</b> amended the FFDCAs, authorizing FDA to collect fees for certain animal drug applications, and for the establishments, products, and sponsors associated with these and previously approved animal drug applications, in support of the review of animal drugs. The law is similar to PDUFA and MDUFMA. ADUFA program authority sunsets after October 1, 2008.	Animal
108-155	<b>Pediatric Research Equity Act of 2003</b> required a manufacturer to submit, along with an application to market a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration for a drug or biologic, a pediatric assessment of the safety and effectiveness (and data to support dosing and administration) of the product for the claimed indications in all relevant pediatric subpopulations; and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The act also authorized the Secretary to require the manufacturer of an approved drug or licensed biologic to submit a pediatric assessment in situations in which not having pediatric use information on the label could pose significant risks.	Drugs, Biologics
108-173	<b>Medicare Prescription Drug Improvement and Modernization Act of 2003</b> replaced the drug importation provisions from the MEDS Act with a similar section that also required the Secretary's certification of safety and cost savings; it also directed the HHS Secretary to study and report to Congress on the importation of prescription drugs into the United States. The act also required the Secretary to study how to use technologies to provide prescription drug information to the blind and visually impaired.	Drugs
108-214	<b>Medical Devices Technical Corrections Act</b> amended the FFDCAs (as amended by the Medical Device User Fee and Modernization Act of 2002) to revise provisions concerning medical devices user fees, third-party inspection and accreditation requirements, and electronic labeling.	Devices, Biologics
108-276	<b>Project BioShield Act of 2004</b> authorized FDA to expedite its review procedures to enable rapid distribution of treatments as countermeasures to chemical, biological, and nuclear agents that may be used in a terrorist attack, among other provisions.	Drugs, Biologics
108-282	<b>Food Allergen Labeling and Consumer Protection Act of 2004</b> required that a specific statement about the most frequent allergens appear on a food product when any of those allergens are present in a food.	Foods
108-282	<b>Minor Use and Minor Species Animal Health Act of 2004 (MUMS)</b> enhanced the availability of drugs to treat minor animal species, and uncommon diseases in major animal species (cattle, swine, chickens, turkeys, horses, dogs, and cats). The law amended the FFDCAs to authorize: (1) conditional approval, which allows the sponsor to make a drug available before collecting all necessary effectiveness data, but after proving the drug is safe; (2) addition of the drug to an index of legally marketed unapproved new animal drugs, when the potential market for a drug is too small to support the costs of the approval process even under a conditional approval; and (3) certain incentives for approval (similar to the human Orphan Drug Act), including grants to support safety and effectiveness testing, and seven years of marketing exclusivity.	Animal
108-358	<b>Anabolic Steroid Control Act of 2004</b> reclassified certain drug and dietary supplement products as controlled substances. Included were any products that contained an anabolic steroid or a precursor to that steroid that would be converted in the body.	Foods
108-365	<b>Mammography Quality Standards Reauthorization Act of 2004</b> amended the PHSA to authorize the HHS Secretary to issue a temporary renewal certificate or a limited provisional certificate to a mammography facility seeking reaccreditation in certain circumstances; made certain requirements of the Secretary regarding the National Mammography Quality Assurance Advisory Committee; and authorized related appropriations through FY2007.	Devices
109-43	<b>Medical Device User Fee Stabilization Act of 2005</b> amended the FFDCAs to adjust medical device user fees, repeal fee revenue target	Devices, Biologics

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109-462	<p>amounts, eliminate fee setting adjustments, and deem as branded any reprocessed single use device unless it identifies the manufacturer.</p> <p><b>Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006</b> amended FFDCa to require a manufacturer, packer, or distributor whose name appears on the label of a nonprescription drug or supplement to report to FDA, within 15 business days, any serious adverse event associated with use of the product, report any followup information, and maintain and permit inspection of related records.</p>	Foods
110-85	<p><b>FDA Amendments Act of 2007</b> reauthorized existing FDA programs (prescription drug and medical device user fees, pediatric research incentives); and expanded the agency's authority to regulate the safety of food (including animal feeds), prescription drugs, biologics, and medical devices. Among the new authorities were those concerning clinical trial databases, civil monetary penalties, a new nonprofit entity to support the FDA mission, and information to be made available to the public.</p>	Foods, Drugs, Biologics, Animal, Devices

a. Drugs = Human Drugs; Animal = Animal Drugs and Feeds; Devices = Devices and Radiological Health.

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