User Fee Programs for Medical Products at the Food and Drug Administration

Marcia Crosse
Director, Health Care

National Health Policy Forum
September 23, 2011
Introduction

• GAO has conducted a body of work on FDA’s oversight of medical products—drugs, biologics, and medical devices. This work has included reviews of both user fee and non-user fees sponsored activities.

• GAO has also assessed various user fee programs across the government, including those at FDA. User fee programs provide the government with hundreds of billions of dollars annually.
Drug Application Review Times Before User Fees

• In 1989—prior to FDA’s ability to charge user fees—GAO reported that FDA was concerned that it lacked sufficient funding and resources to adequately fulfill its mission.

• GAO subsequently examined review times and reported that review times for New Drug Applications (NDAs) had been long, but that they had been steadily dropping:
  • In 1987 the median review time for an NDA was 27 months;
  • By 1992, the median review time had dropped to 19 months.
Prescription Drug User Fee Act (PDUFA)

- In 1992, PDUFA authorized FDA to collect user fees from drug and biologic sponsors to support the process of reviewing new drug applications and biologics license applications.

- PDUFA user fee funding only partially covers FDA’s costs for reviewing these applications and associated activities. FDA is also required to use a specified amount of its fiscal year appropriations to support its review of these applications.
Drug Application Review Times Following the Enactment of User Fees

• In 2002, GAO again reported on review times for drug applications, covering the period 1993 to 2001:
  • Review times had actually risen in 1993, but subsequently fell through 2001 – to a median of 14 months.

• GAO concluded in that report that PDUFA had been successful in providing FDA with the funding necessary to hire additional drug reviewers to examine new drug applications.
Medical Device Review Times Before User Fees

• Similar to the concerns about long review times for drug applications, industry raised concerns about review times for medical device applications.

• GAO reported that from 1989 through 1991, median review times for 510(k) applications were stable at about 80-90 days.

• Review times then increased sharply, peaking at 230 days in 1993, before dropping to 152 days in 1994.
Medical Device Review Times Before User Fees

• Review times for PMAs had also increased:
  • In 1989, the median review time for a PMA was 414 days.
  • This increased to a peak of 984 days in 1992, before dropping slightly in 1993.

• Other types of device applications showed similar rates of increase across this time period.
Medical Device User Fee and Modernization Act (MDUFMA)

- Ten years after PDUFA’s enactment, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) authorized FDA to collect user fees from device sponsors to support the process of reviewing applications for certain medical devices.

- In 2004, and again in 2005, GAO reported that, while data were limited, FDA was making progress toward meeting the MDUFMA performance goals
  - In 2003, FDA completed its reviews of 75% of 510(k)s in 90 days (the goal for that year); in 2004, it completed 86% in 90 days; and in 2005, of those that were completed, 99% had been finished within 90 days.
User Fees as a Mechanism for Funding Federal Agency Activities

• In 1997, GAO identified a potential concern associated with user fees. GAO’s examination of overall fee collections at 27 agencies from fiscal year 1991 through fiscal year 1996 showed that increased user fee collections sometimes appeared to have replaced appropriated funds.

• Subsequently, in 2008, GAO issued a guide to help federal agencies design user fee programs that encourage greater efficiency, equity, and revenue adequacy, while reducing the administrative burden on both agencies and users.
Among other things, the design guide addresses the concern regarding the portion of program costs covered by general revenues declining in programs partially funded by user fees.

The guide also warns that increased reliance on user fees may lead to a misalignment between those who benefit from the program and the sources of funding and have significant implications for agencies.

The substitution of user fees over appropriations can be a particular concern when new or increased fees are assessed to augment total funding for a service or program.
FDA User Fees

- GAO noted in 2002 that the implementation of PDUFA had the unintended consequence of reducing the share of funding and staffing for non-PDUFA activities.

- PDUFA and MDUFMA preclude the agency from using user fee funding for agency activities that are unrelated to the processing of new drug applications and new biologic license applications.

- In fiscal year 2008, agency activities not funded with user fees included, for example: reviews of generic drug applications, inspections unrelated to new medical products, and some postmarket safety oversight activities.
FDA Challenges in Meeting Its Resources Needs

- Despite the additional funding provided by PDUFA, FDA continued to be challenged by a lack of resources and senior FDA officials continued to testify about the financial challenges it faced.

- In recent years, FDA’s Science Board reported that the agency could not fulfill its growing responsibilities because it did not have sufficient resources. The Congressional Research Service pointed out that the demands on FDA had soared in recent years. The Institute of Medicine expressed concern for the future of drug safety and the HHS-Office of Inspector General included the oversight of drugs and medical devices as one of its top management performance challenges.
FDA Challenges in Meeting Its Resources Needs

• Laws enacted since 1999 added new requirements that expanded FDA’s medical product oversight responsibilities, including premarket review and postmarket safety activities. GAO identified 11 laws that specifically added to FDA’s medical product oversight responsibilities, enacted between 2002 and 2007.

• In addition, other laws enacted during this time period, while not necessarily directed at FDA, also added to the agency’s responsibilities, such as the Pandemic and All-Hazards Preparedness Act, enacted in 2006.
### FDA Challenges in Meeting Its Resources Needs:

**Timeline of 11 Laws That Increased FDA’s Medical Product Oversight Responsibilities**

<table>
<thead>
<tr>
<th>Year</th>
<th>Law</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>Food and Drug Administration Amendments Act of 2007</td>
</tr>
<tr>
<td>2006</td>
<td>Dietary Supplement and Nonprescription Drug Consumer Protection Act</td>
</tr>
<tr>
<td>2005</td>
<td>Medical Device User Fee Stabilization Act of 2005</td>
</tr>
<tr>
<td>2004</td>
<td>Mammography Quality Standards Reauthorization Act of 2004</td>
</tr>
<tr>
<td></td>
<td>Project BioShield Act of 2004</td>
</tr>
<tr>
<td></td>
<td>Medical Devices Technical Corrections Act</td>
</tr>
<tr>
<td></td>
<td>Pediatric Research Equity Act of 2003</td>
</tr>
<tr>
<td>2002</td>
<td>Medical Device User Fee and Modernization Act of 2002</td>
</tr>
<tr>
<td></td>
<td>Public Health Security and Bioterrorism Preparedness and Response Act of 2002</td>
</tr>
<tr>
<td></td>
<td>Best Pharmaceuticals for Children Act</td>
</tr>
</tbody>
</table>

Source: GAO analysis of FDA documents and CRS reports.
FDA Challenges in Meeting Its Resources Needs

- GAO reports identified weaknesses in FDA’s non-user fee funded activities on a variety of topics, including:
  - monitoring postmarket safety,
  - overseeing clinical trials,
  - reviewing drug advertising and other promotional materials, and
  - inspecting foreign drug establishments for compliance with good manufacturing practices.

- Due to these concerns, FDA’s oversight of medical products was added to GAO’s High-Risk List in January 2009. FDA’s oversight of medical products continues to be on the most recent update of this list, issued in February 2011.
In 2009, GAO examined FDA’s funding and staffing resources for its medical products programs for a 10-year period—fiscal years 1999 and 2008.

Funding and staffing resources increased during this period, primarily as a result of increased user fees. While FDA met most of its PDUFA performance goals related to its review of new drug applications, consistent with its 2002 findings, GAO found that funding and staffing for non-PDUFA activities—many of which are essential for ensuring the public health—were not fully supported.

As a result, FDA faced challenges fulfilling its medical product responsibilities and could not complete all of its workload, including fulfilling all of its statutory requirements.
GAO Analysis—Impact of User Fees: Budget Details

• GAO’s 2009 report on FDA’s resources noted that the agency’s total funding is a small portion of federal government and HHS funding. In fiscal year 2008, the federal government’s funding totaled approximately $3 trillion, of which about $722 billion was made available to fund HHS activities, including those at FDA.
GAO Analysis—Impact of User Fees: Budget Details, Federal Government, HHS, and FDA Funding, Fiscal Year 2008

Federal government funding, including HHS ($3 trillion)

HHS funding, including FDA ($722 billion)

FDA funding, including all programs ($2.2 billion)

$500 million user fee funding

$1.7 billion fiscal year appropriations

FDA funding:
With its fiscal year appropriations and user fee funding, FDA’s fiscal year 2008 funding totaled $2.2 billion, and over half of this amount—about $1.2 billion—supported its medical product programs. Below are the program funding levels:

<table>
<thead>
<tr>
<th>Program</th>
<th>Funding (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs program</td>
<td>$681</td>
</tr>
<tr>
<td>Biologics program</td>
<td>$234</td>
</tr>
<tr>
<td>Devices program</td>
<td>$275</td>
</tr>
<tr>
<td>Other programs (primarily food programs)</td>
<td>$1,055</td>
</tr>
</tbody>
</table>

Source: GAO analysis of FDA and OMB data.
In 2009, GAO reported that total funding for medical product programs increased from about $562 million in fiscal year 1999 to about $1.2 billion in fiscal year 2008. User fees accounted for more than half of this increase.

Funding for user fee activities during this period increased 268 percent from about $120 million to $443 million, while fiscal year appropriations increased 69 percent from about $441 million to $746 million.
GAO Analysis—Impact of User Fees: Budget Details, *Annual Medical Product Program Funding from Fiscal Year Appropriations and User Fees, Fiscal Years 1999 through 2008*

![Dollar amounts over time](image)

Source: GAO analysis of FDA data.
GAO Analysis—Impact of User Fees: Budget Details

- Total funding for FDA’s medical product programs’ user fee activities increased 8 times faster than funding for the programs’ other activities between fiscal years 1999 and 2008.

- Funding for user fee activities increased 207 percent over the 10-year period while total funding for the programs’ other activities increased 25 percent.

- As funding for user fee activities increased, a declining share of fiscal year appropriations was available to other program activities between fiscal year 1999 and 2008.
GAO Analysis—Impact of User Fees: Budget Details, *Portion of Total Medical Product Program Funding Allocated to User Fees Activities and Other Program Activities, Fiscal Years 1999 and 2008*

![Pie chart showing the portion of total medical product program funding allocated to user fees activities and other program activities for fiscal years 1999 and 2008.](chart.png)

**Funding for user fee activities and other activities (dollars in millions):**

<table>
<thead>
<tr>
<th></th>
<th>Fiscal year 1999</th>
<th>Fiscal year 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>User fee activities</td>
<td>$267.1</td>
<td>$820.4</td>
</tr>
<tr>
<td>Other agency activities not funded with user fees</td>
<td>$294.6</td>
<td>$369.4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$561.7</strong></td>
<td><strong>$1,189.7</strong></td>
</tr>
</tbody>
</table>

Source: GAO analysis of FDA data.
GAO Analysis—Impact of User Fees: Staffing Details

- Staffing resources for FDA’s medical product programs increased between fiscal year 1999 and fiscal year 2008. The number of full-time equivalent (FTE) staff supporting these programs increased 14 percent from 4,925 FTEs in fiscal year 1999 to 5,626 FTEs in fiscal year 2008. This increase was due solely to a growth in the number of FTEs funded by user fees.

- The number of medical product program FTEs funded by user fees increased 113 percent—from 856 FTEs in fiscal year 1999 to 1,825 FTEs in fiscal year 2008—while FTEs funded by fiscal year appropriations declined 7 percent, or from 4,069 FTEs in fiscal year 1999 to 3,802 FTEs in fiscal year 2008.
GAO Analysis—Impact of User Fees: Staffing Details, Annual Medical Product Program Staffing Resources from Fiscal Year Appropriations and User fees, Fiscal Years 1999 through 2008

![Graph showing staffing resources from fiscal year appropriations and user fees from 1999 to 2008. The graph indicates an overall increase in staffing resources, with fluctuations in the user fees category.](source: GAO analysis of FDA data.)
GAO Analysis—Impact of User Fees on Non-User Fee Activities: Review of Generic Drug Applications

- FDA faced an increasing workload related to its review of generic drug applications. In fiscal year 2004, FDA received 563 generic drug applications compared to 830 in fiscal year 2008—a 47 percent increase.

- FDA also reviewed an increasing number of generic drug applications each year—1,357 in fiscal year 2004 vs. 1,933 in fiscal year 2008—an increase of 42 percent.

- Yet, FDA was not able to review them all. As a result, the number of applications pending review increased 123 percent over the period—from 646 in fiscal year 2004 to 1,441 in fiscal year 2008.
GAO Analysis—Impact of User Fees on Non-User Fee Activities: Medical Product Program Inspections, Fiscal Years 2004 through 2008

- The total number of inspections FDA conducted for its medical product programs decreased from 7,589 inspections in fiscal year 2004 to 6,306 inspections in fiscal year 2008, a decline of 1,283 inspections or 17 percent. The total number of inspections conducted for each program decreased over the time period.
GAO Analysis—Impact of User Fees on Non-User Fee Activities: Review of Adverse Event Reports

• From fiscal years 2004 to 2008, FDA received an increasing number of adverse event reports for medical products. The total number of such reports received increased 81 percent over this time period, funding increased 154 percent and staffing resources increased 100 percent.

• FDA’s financial and staffing resources for the review of adverse event reports also grew—from about $31 million in fiscal year 2004 to about $78 million in fiscal year 2008, an increase of 154 percent.
GAO Analysis—Impact of User Fees on Non-User Fee Activities: Funding for Adverse Event Reviews, Fiscal Years 2004 through 2008

• The increase in funding for adverse event reviews can be attributed to a provision in the Food and Drug Administration Amendments Act of 2007, which allowed FDA to apply user fees collected through PDUFA, to support more postmarket safety activities for drugs, such as the review of adverse event reports.

• FDA attributes about two-thirds of the increase in funding and FTEs between fiscal years 2007 and 2008—142 percent and 40 percent respectively—for the review of drug-related adverse events to user fee funds.
Yet FDA officials acknowledged that it still received more adverse event reports than it could review, but could not provide data showing the number of adverse event reports reviewed during this time period.
GAO Analysis—Impact of User Fees on Non-User Fee Activities: Examination of Advertising and Promotional Materials

- FDA oversees the advertising and promotion of prescription drugs and biologics to ensure that information disseminated about medical products is not false or misleading. FDA regulates the content of advertising and promotions regardless of whether they are directed toward consumers or medical professionals.

- During fiscal years 2004 through 2008, FDA received an increasing number of advertising and promotional materials—particularly for drug-related promotions—that manufacturers were required to submit for review. FDA received 45,394 such submissions in fiscal year 2004 and 70,509 in fiscal year 2008—an increase of 55 percent over the time period.
GAO Analysis—Impact of User Fees on Non-User Fee Activities:
Examination of Advertising and Promotional Materials

• Funding for FDA’s oversight of drug advertising and promotion increased 167 percent from about $4 million in fiscal year 2004 to about $10 million in fiscal year 2008.

• The number of FTEs supporting FDA’s oversight of drug promotions grew 26 percent from 35 FTEs in fiscal year 2004 to 44 FTEs in fiscal year 2008.

• FDA was unable to examine all of the promotional materials for drugs it received between fiscal year 2004 and fiscal year 2008 because it lacked the resources to do so.
Related GAO Products


Contact Information

Marcia Crosse, Director, Health Care
U.S. Government Accountability Office
441 G St. N.W.
Washington, D.C.  20548
202-512-3407
crossem@gao.gov