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The Prescription Drug User Fee Act (PDUFA): Background and Issues for PDUFA IV Reauthorization

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The Prescription Drug User Fee Act (PDUFA): Background and Issues for PDUFA IV Reauthorization

Summary

The Prescription Drug User Fee Act (PDUFA), first enacted in 1992 and reauthorized twice (referred to as PDUFA II and PDUFA III), gives the Food and Drug Administration (FDA) a revenue source — fees paid by the pharmaceutical manufacturers — to supplement, not replace, direct appropriations.

The impetus behind the 1992 law was the length of time from a manufacturer's submission of a New Drug Application (NDA) or a Biologics License Application (BLA) to FDA and the agency's issuing its decision on approval or licensure, which FDA attributed to constrained review-staff time. This delay affected patients and the drug manufacturers.

PDUFA I goals were to diminish the backlog of applications at FDA and to increasingly shorten the time from submission to decision. PDUFA II expanded the goals to include activities related to the investigational phases of a new drug's development; it also added the goal of increasing FDA communications with industry and consumer groups. PDUFA III authorized activities both at earlier (preclinical development) and at later (up to three years after drug approval) stages of drug research and development. FDA set these performance goals in conjunction with the drug manufacturers, and the Secretary of Health and Human Services (HHS) submitted them in letters to the chairs of the relevant congressional authorizing committees. The Secretary also submits annual PDUFA performance and financial reports.

Based on its stated goals, PDUFA has generally been viewed as a success. FDA has added review staff and reduced its review times. It has also standardized the information required for applications and developed computer tools to use electronically submitted data.

Criticism of PDUFA fits into three categories. First, the fees have not fully covered FDA's increased costs, despite the provisions that Congress implemented. Second, because PDUFA has directed a majority of the collected fees toward premarket review of applications, some people see PDUFA as responsible for what they view as the agency's increasing focus on premarket activities in contrast to the relatively slower increase in postmarket surveillance and safety studies and enforcement. They point to the fees' funding 20% of the salaries and expenses in FDA overall and 30% within the human drug program (with a yet higher proportion among the premarket drug review staff). Finally, some critics think that, through its provision of fees, the industry has too much influence over FDA actions.

In January 2007, FDA released its proposal for PDUFA IV. The goals, developed through consultation with Congress, industry, and healthcare consumers and professionals, focus on securing FDA's sound financial footing, and enhancing both premarket review and the postmarket safety system.

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Introduction

The 1992 passage of the Prescription Drug User Fee Act (PDUFA) gave the Food and Drug Administration (FDA) a revenue source it had sought for over 20 years. Originally opposed by the drug manufacturing industry, PDUFA passed after industry groups were persuaded that the user fees assessed by the new law, accompanied by performance goals that the agency would negotiate with the industry, would bring new resources aimed at decreasing the time FDA took to approve new drugs and license new biological products (e.g., vaccines).

The law had its origin in the dissatisfaction, which peaked in the late 1980s, of industry, consumers, and FDA itself with the long time between a manufacturer's drug or biologics marketing application submission to FDA and the agency's decision. Finding out whether FDA would approve the new drug or license the new biologic for sale in the United States then took a median time of 29 months.[1] Patients had to wait for access to the products. For some patients, a drug in review — and therefore not available for sale — could be the difference between life and death. Manufacturers, in turn, had to wait to begin to recoup the costs of research and development. At that time, FDA estimated that each one-month delay in a review's completion cost a manufacturer $10 million.[2]

FDA argued that it needed more scientists to review the drug applications that were coming in and the ones already backlogged in its files. It had not received sufficient appropriations to hire them. But while for years FDA had asked Congress for permission to implement user fees, the pharmaceutical industry was generally opposed to them, believing that the funds might go into the Treasury to reduce federal debt rather than help fund drug review.

The 1992 compromise became possible with the addition of performance goals, under which target completion times for various review processes would be set. The agreement also held that the fees would supplement — rather than replace — resources Congress routinely gave FDA.

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[1] Food and Drug Administration (FDA), *Third Annual Performance Report: Prescription Drug User Fee Act of 1992, Fiscal Year 1995 Report to Congress*, Dec. 1, 1995, at [http://www.fda.gov/ope/pdufa/report95.html].

[2] Philip J. Hilts, "Plan to Speed Approval of Drugs: Makers Would Pay Fees to U.S.," *New York Times*, Aug. 11, 1992, p. A1.

This report begins with a brief history of FDA's prescription drug user fee program. The program was originally authorized for five years, and Congress extended it in two subsequent five-year reauthorizations.[3] The current authority expires October 1, 2007, and Congress will likely debate the form and substance of any reauthorization. FDA released its proposal for a reauthorized program in January 2007. In anticipation of those debates, this report summarizes the pros and cons that academics, government and industry policy analysts, and consumer and other interested groups raise over what many are calling "must-pass" legislation to ensure that there is no interruption in FDA's collection and use of the fees to expedite market approval and postmarket monitoring of drugs and biologics.

Prescription Drug User Fees: Law and Practice of User Fee Collection and Use at FDA

PDUFA I

Congress first authorized FDA to collect fees from pharmaceutical companies in 1992 with the Prescription Drug User Fee Act (PDUFA, P.L. 102-571), which amended the Federal Food, Drug, and Cosmetic Act (FFDCA). Its goals were to speed up FDA's review of new drug applications for approval and to diminish its backlog of applications. PDUFA specified the activities on which FDA could spend the fees; most of the collections were to be used to hire additional reviewers.

To keep funding predictable and stable, Congress required three kinds of prescription drug user fees, and specified that they each make up one-third of the total fees collected:

- **application review fees:** a drug's sponsor (usually the manufacturer) would pay a fee for the review of each new or supplemental drug-approval or biologic-license application it submitted;
- **establishment fees:** a manufacturer would pay an annual fee for each of its manufacturing establishments; and
- **product fees:** a manufacturer would pay an annual fee for each of its products that fit within PDUFA's definition.

For FY1993, the standard application fee was approximately $100,000. The law provided exceptions — either exemptions or waivers — for applications from small businesses, or for drugs aimed at orphan diseases or unmet public health needs.

While PDUFA included estimated annual fees, it specified that FDA's annual appropriations legislation would set the total fees allowed each year. It also set two statutory triggers:

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[3] PDUFA is codified at 21 U.S.C. 379g and 379h.

- FDA would assess user fees only if the agency's total annual appropriations — excluding user fees — for salaries and expenses for a given year were at least equal to its total appropriations for FY1992, multiplied by an inflation adjustment factor; and
- FDA would spend on defined activities supporting new drug and biologics applications from its annual allocation of appropriated funds an amount at least equal to what it had spent in FY1992, adjusted for inflation.

PDUFA's basic goal was, each year, to reduce the time from the sponsor's submission of an application to FDA's decision regarding approval. Rather than listing specific performance goals in statutory language, Congress stated in the bill's "Findings" (Section 101) that:

> (3) the fees authorized by this title will be dedicated toward expediting the review of human drug applications as set forth in the goals identified in the letters of September 14, 1992, and September 21, 1992, from the Commissioner of Food and Drugs to the Chairman of the Energy and Commerce Committee of the House of Representatives and the Chairman of the Labor and Human Resources Committee of the Senate, as set forth at 138 Cong. Rec. H9099-H9100 (daily ed. September 22, 1992).

This direction is not codified in the Federal Food, Drug, and Cosmetic Act; instead, Congress, with that "finding," incorporated the performance goals listed in FDA Commissioner David Kessler's September 1992 letters to the committee chairs.[4] The predominant goal was that, by 1997, FDA would review 90% of standard applications within 12 months and 90% of priority applications within six months of application submission.[5]

PDUFA II

Congress reauthorized PDUFA in 1997 as Title I of the Food and Drug Administration Modernization Act (FDAMA, P.L. 105-115). In what is called PDUFA II, FDAMA:

- stated that the fees were to be used to expedite the drug development and application review process as laid out in performance goals identified in letters sent by the Secretary of the Department of Health and Human Services (HHS) to the two authorizing committees;

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[4] James L. Zelenay, Jr., "The Prescription Drug User Fee Act: Is a Faster Food and Drug Administration Always a Better Food and Drug Administration?" *Food and Drug Law Journal*, vol. 60, no. 2, 2005, pp. 261-338.

[5] FDA policy states: "A 'priority' designation is intended to direct overall attention and resources to the evaluation of applications for products that have the potential for providing significant preventative or diagnostic therapeutic advance as compared to 'standard' applications" (FDA, "Review Management: Priority Review Policy," *Manual of Policies and Procedures*, MAPP 6020.3, Center for Drug Evaluation and Research, April 22, 1996, at [http://www.fda.gov/cder/mapp/6020-3.pdf], hereinafter "CDER MAPP 6020.3").

- ordered the goals to be published in the *Congressional Record*; and
- required HHS to send two annual reports — performance and fiscal — to Congress.

In the 1997 reauthorization, Congress mandated tighter performance goals, more transparency in the drug review process, and better communication with drug makers and patient advocacy groups. Congress expanded performance goals for PDUFA II to include activities related to the investigational phases of a new drug's development, in addition to the later phases of a completed application.

PDUFA III

PDUFA III, the most recent five-year reauthorization, passed as Title V of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188). In it, Congress allowed FDA to adjust annual revenue targets based on changes in workload. Again, rather than spelling out specific performance goals, Congress referred in the legislation's "Findings" (Section 502(4)) to the goals specified in the HHS Secretary's letters to the relevant congressional committee chairs and also made public in the *Congressional Record*. The Conference Report for PDUFA III "... for the first time require[d] the agency to meet with interested public and private stakeholders when considering the reauthorization of this program before its expiration."[6]

The 2002 law continued to restrict FDA's use of collected fees to activities related to the "process for the review of human drug applications." In its FY2004 report to Congress, FDA listed such activities. They include investigational new drug (IND), new drug application (NDA), biologics license application (BLA), product license application (PLA), and establishment license application (ELA) reviews; regulation and policy development activities related to the review of human drug applications; development of product standards; meetings between FDA and application sponsor; pre-approval review of labeling and pre-launch review of advertising; review-related facility inspections; assay development and validation; monitoring review-related research; and collecting, developing, and reviewing safety information for up to three years on drugs approved after October 1, 2002 (PDUFA III).[7] FDA review, therefore, covers a drug's preclinical development, clinical development, marketing applications, and post-approval safety surveillance and risk management.[8]

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[6] H.Rept. 107-481, *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, conference report to accompany H.R. 3448, May 21, 2002.

[7] FDA, "Allowable and Excluded Costs for the Process for the Review of Human Drug Applications," Appendix C to *FY 2004 PDUFA Financial Report*, March 2005, at [http://www.fda.gov/oc/pdufa/finreport2004/appendixC.html].

[8] FDA, "Prescription Drug User Fee Act (PDUFA): Adding Resources and Improving Performance in FDA Review of New Drug Applications," white paper, Nov. 10, 2005, at [http://www.fda.gov/cder/pdufa], hereinafter "FDA, PDUFA White Paper."

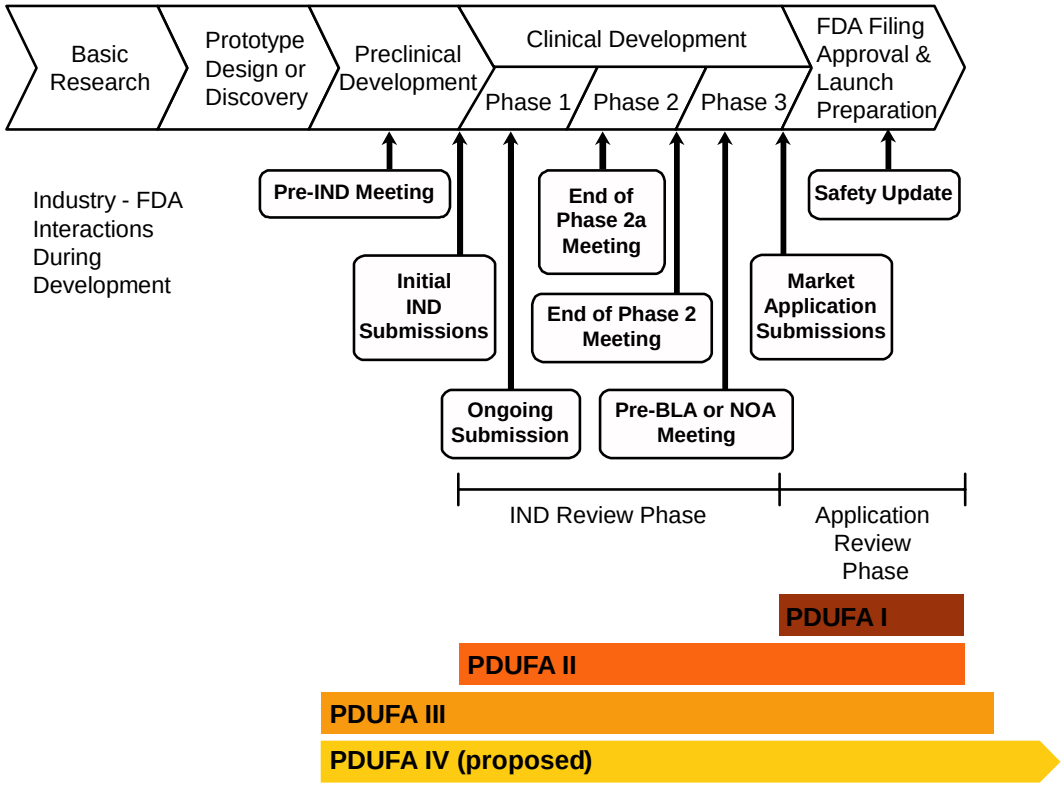
In the 2002 reauthorization, Congress added some new provisions to PDUFA. It:

- allowed biotechnology companies to request that FDA select an independent consultant (for which the sponsor would pay) to participate in FDA's review of protocols;
- authorized two pilot programs for the continuous ("rolling") review of new drug applications for fast track products;
- allowed FDA to use fees to support postmarketing surveillance activities, thereby allowing the agency to double the number of staff monitoring side effects of drugs already on the market;
- encouraged companies to include risk management plans in their pre-NDA/BLA meetings;
- allowed the use of fees to develop databases documenting drugs' use;
- allowed the use of fees for risk management oversight in the "peri-approval" period (i.e., two to three years post-approval);
- provided for "first cycle," preliminary reviews;
- required the HHS Secretary to note on FDA's website if a sponsor did not meet an agreed-upon deadline to complete a study, and to note if the Secretary considers the reasons given for study incompleteness to be unsatisfactory; and
- required any sponsor who failed to complete timely studies to notify health practitioners both of this failure and of unanswered questions related to the clinical benefit and safety of the product.

The top and middle sections of **Figure 1** illustrate the five stages of drug development, beginning with basic research and continuing through preclinical development (which could be research in the laboratory or with animals), clinical research (the Phase 1, Phase 2, and Phase 3 trials that involve people), and FDA review; and the related industry-FDA interactions.[9] The bottom third displays the span of industry R&D activities over which the laws allowed PDUFA fees to cover FDA activities. The law authorized FDA to use PDUFA I fees to fund only those activities from NDA submission through the review decision; PDUFA II allowed FDA to use the funds for meetings with manufacturers during the clinical development stages, going, therefore, from the investigational new drug (IND) submission through review; and PDUFA III extended the time range at both ends, to include the pre-clinical development period and up to three years after marketing begins. FDA's proposal for the next reauthorization addresses extending the postapproval period.

[9] FDA, PDUFA White Paper, 2005, Figure 3.1.

Figure 1. Drug Research and Development Timeline, Industry-FDA Interaction, and PDUFA



Source: Adapted by CRS from FDA, PDUFA White Paper, 2005, Figure 3.1.

Performance Goals

In preparation for each PDUFA reauthorization, FDA and manufacturers meet to discuss workload and revenue needed. FDA then submits a letter to the authorizing committees that presents performance goals to review and take action on a specified percentage of complete applications within a specified number of months. **Table 1** shows the goals since PDUFA began in 1993. Beginning in 1997, the goals distinguish between standard and priority applications, assessed by a medical group team leader when FDA receives an application.[10]

[10] FDA, CDER MAPP 6020.3, April 22, 1996.

Table 1. PDUFA Performance Goals for FDA's Review and Action, FYs 1994-2007

PDUFA version	Fiscal year	Type of application			Completion goal (%)	Goal, in months
I NDA PLA/ELA	1994	unspecified			55	12
	1995	unspecified			70	12
	1996	unspecified			80	12
	1997		standard		90	12
				priority	90	6
II NDA PLA/BLA	1998		standard		90	12
				priority	90	6
	1999		standard[a]		90 30	12 10
				priority	90	6
	2000		standard[a]		90 50	12 10
				priority	90	6
	2001		standard[a]		90 70	12 10
				priority	90	6
	2002		standard		90	10
				priority	90	6
III NDA BLA	2003-2007		standard		90	10
				priority	90	6

Sources: FDA, "Appendix A. PDUFA Performance Goals, FY1993-FY1997," *Third Annual Performance Report: Prescription Drug User Fee Act of 1992, Fiscal Year 1995 Report to Congress*, Dec. 1, 1995; FDA, "PDUFA Reauthorization Performance Goals and Procedures," enclosure to letter, created Nov. 16, 1997, last updated July 7, 2005; and FDA, "PDUFA Reauthorization Performance Goals and Procedures," enclosure to June 4, 2002 letter transmitting the PDUFA III goals and procedures; all at [http://www.fda.gov/cder/pdufa/default.htm].

Note: NDA — New Drug Applications; BLA — Biologics License Applications; PLA — Product License Applications; ELA — Establishment License Applications.

a. For FY1999-FY2001, there are two goals for standard applications (e.g., for applications completed in FY1999, the FDA goal is to review and act on 30% within 10 months and on 90% within 12 months).

Current Status

To prepare its annual appropriations request, FDA calculates the total fee revenues, adjusting for inflation. The per-review fee in the upcoming year is based on FDA's estimate of the number and type of applications to be submitted that year.

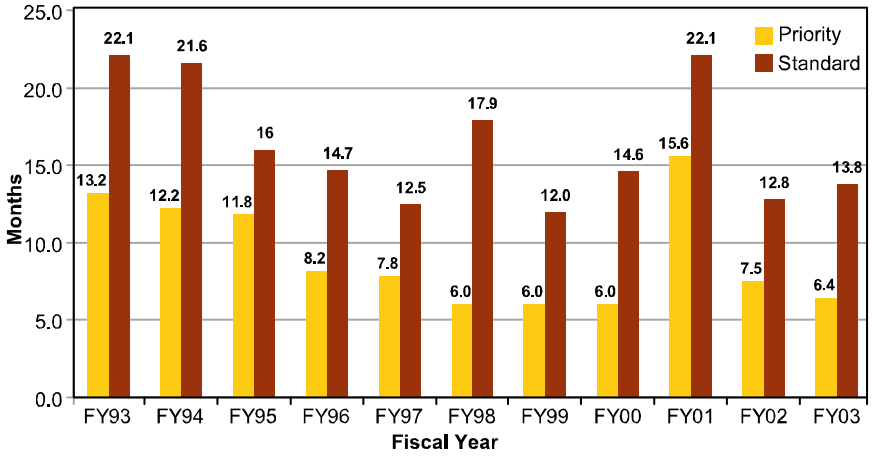
User-fee revenue contributes significantly to FDA's budget. The FY2006 program level for FDA's human drugs program was $517,557,000, of which $219,841,000 (42.5%) was from user fees (the remainder was from direct appropriations).[11] Fee rates for FY2007 are:[12]

per application requiring clinical data	$896,000
per application not requiring clinical data	$448,100
per application supplements requiring clinical data	$448,100
per establishment	$313,100
per product	$49,750

Impact of PDUFA I, II, and III

Based on its stated goals, PDUFA has been generally viewed as a success. FDA has added review staff and reduced its review times. Median time from an NDA or BLA submission to FDA's approval decision was 29 months in 1987; for the first two years of PDUFA I, it fell to 17 months.[13] In later years, FDA presented separate calculations for standard applications and priority applications. **Figure 2** shows median approval times for FY1993 through FY2003.[14]

Figure 2. Median Approval Times for NDAs and BLAs



Source: FDA, PDUFA White Paper, 2005, Figure 1.3.

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[11] FDA, "Consolidated Budget in Brief," Office of Management Budget Formulation and Presentation, FY2007, at [http://www.fda.gov/oc/oms/ofm/budget/2007/PDF/2ConsolidatedBIB.pdf].

[12] FDA, "Prescription Drug User Fee Rates for Fiscal Year 2007," *Federal Register*, vol. 71, no. 148, Aug. 2, 2006.

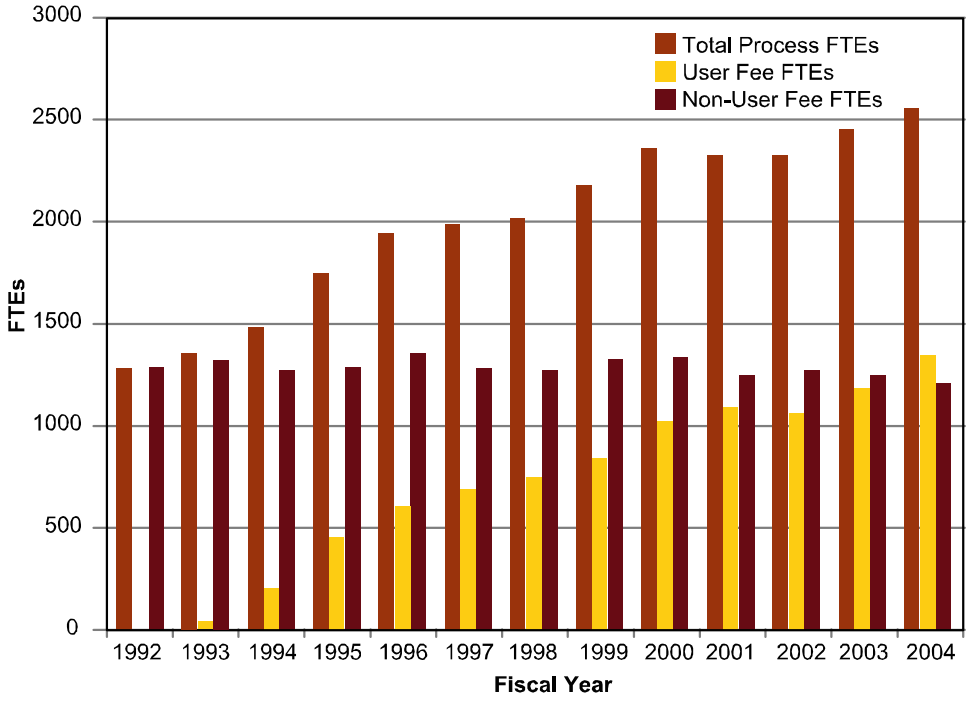
[13] FDA, *Third Annual Performance Report: Prescription Drug User Fee Act of 1992, Fiscal Year 1995, Report to Congress*, Dec. 1, 1995, at [http://www.fda.gov/ope/pdufa/report95.html].

[14] FDA, PDUFA White Paper, 2005, Figure 1.3.

FDA attributes the shorter approval times to both increased FDA staff time available for application review and increasingly more complete applications, also a reflection of FDA staff activities with the sponsor before it submits the NDA or BLA. In its FY2002 performance report to Congress, FDA commented on the spike in approval times, as seen in the FY2001 data, citing an "imbalance between resources and workload [that] resulted in significant stress to the program."[15]

Figure 3 shows the changes in FDA staffing (expressed as full-time equivalents [FTEs]) over the years since PDUFA began. While the number of PDUFA-supported staff has increased steadily, the number of positions funded by direct appropriations has stayed about the same. This reflects the triggers written into PDUFA that require FDA to maintain the budget and level of pre-approval review activities that existed in the year before PDUFA's enactment.[16]

Figure 3. History of PDUFA Total Process and User Fee-Funded FTEs



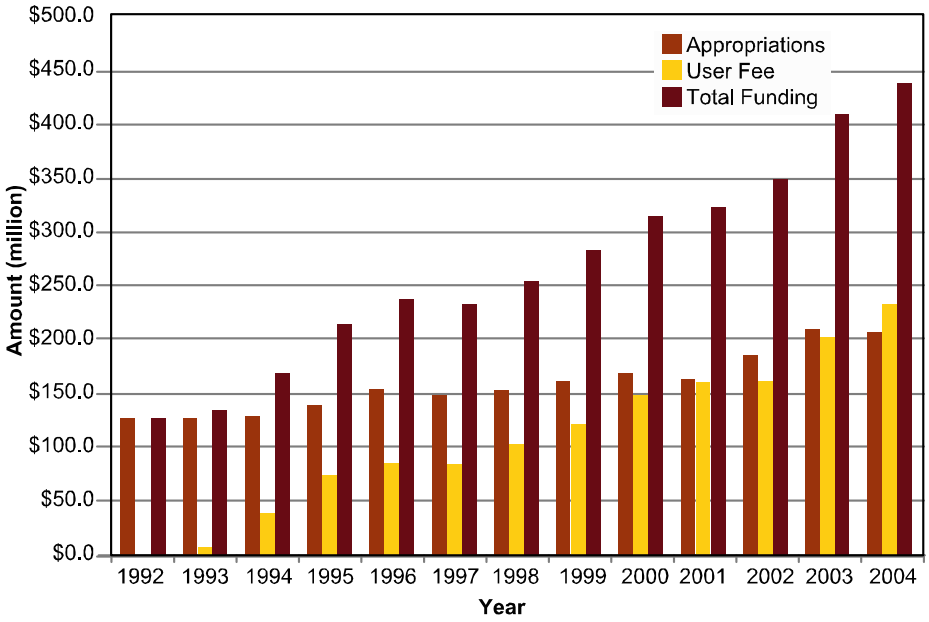
Source: FDA, PDUFA White Paper, 2005, Figure 1.2.

[15] FDA, *FY 2002 Performance Report to Congress for the Prescription Drug User Fee Act of 1992 as reauthorized and amended by the Food and Drug Administration Modernization Act of 1997*, at [http://www.fda.gov/oc/pdufa/report2002/pdf/report.pdf].

[16] FDA, PDUFA White Paper, 2005, Figure 1.2.

Figure 4 — showing user fee and direct-appropriations funding for the review of human drugs — illustrates a similar point.[17]

Figure 4. History of Funding for Review of Human Drugs



Source: FDA, PDUFA White Paper, 2005, Figure 1.1.

PDUFA: Support and Criticism

PDUFA has attracted both criticism and praise from industry, FDA staff, consumers, and Members of Congress. These stakeholders and other FDA observers will likely continue to air their mixed reactions — about PDUFA goals, performance, administrative procedure, and budget — during discussions of reauthorization. Some of the major reactions are discussed below.

Support

Support for PDUFA focuses on the following administrative changes at FDA that are attributable to the added revenues provided through user fees: FDA now completes it reviews of NDA/BLA applications more quickly and runs less of a backlog; it has standardized the medical and statistical information that needs to be included with NDAs; and it has developed computer tools to help standardize, manage, and track electronically submitted data for application review.

[17] FDA, PDUFA White Paper, 2005, Figure 1.1.

As a result of PDUFA, industry faces shorter and more predictable review times. It has treated the per-application fee — about $100,000 FY1993 and almost $900,000 FY2007[18] — as an acceptable cost relative to the estimated $10 million monthly cost of delay in the years immediately before PDUFA was enacted.

Finally, PDUFA has enabled consumers to have access to new drugs sooner. That is a benefit when those drugs are safe and effective. But if it turns out that the PDUFA process somehow allows products to be approved with less attention paid to their safety and effectiveness, then that would obviously diminish the program's benefits. However, many overlapping factors influence whether a drug can be used safely, most unrelated to the source of funding. Congress may opt to consider whether certain safety problems *could* have been identified before public marketing, whether FDA has the authority and resources to identify problems during both the premarket and postmarket periods, whether FDA has the authority and resources to act on its findings, and, finally, whether industry's funding of a significant part of those activities presents what some see as an unresolvable conflict of interest.

Criticism

Critics of PDUFA, and some supporters, have expressed three types of concerns. First, the annual adjustments in fees have not fully covered FDA's increased costs, despite provisions that Congress intended to account for cost changes over time. Examples of incompletely funded expenses are cost-of-living increases, retirement and health benefits, and bonuses to retain the highly skilled scientists whom PDUFA collections allow FDA to hire. Nor do the annual PDUFA increases adequately cover the costs of increased security and the rents for FDA's new facilities.[19]

Second, because PDUFA initially allowed FDA to use the fees on only pre-approval activities (the review of manufacturer applications to market drugs and biologics) and still directs a majority of fees to those tasks, it is widely asserted that PDUFA is responsible for what some observers view as an inappropriate budget imbalance between FDA's premarket drug review and its postmarket safety activities. They point out that triggers squeeze non-PDUFA related programs, giving as an example long review times for generic drugs.

FDA relies on fee revenue for maintaining its expert science base via staff retention. Critics say that FDA is becoming too dependent on industry fees to carry out its normal review activities. A related concern is that the large percentage of FDA's budget being covered by user fees may undercut congressional support for increases in direct appropriations to the agency.

User fees are an increasing part of FDA's budget. **Table 2A** covers all of FDA's programs, not just human drug activities. In FY2006, user fees contributed 19.9% of FDA's salaries and expenses. Looking only at the agency's Human Drug Program (basically that is the Center for Drug Evaluation and Research and related

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[18] Application fee for FY2007 is $896,200 (FDA, "Prescription Drug User Fee Rates for Fiscal Year 2007," *Federal Register*, vol. 71, no. 148, Aug. 2, 2006, pp. 43780-43784).

[19] The FDA Alliance, "Improve Consumer Health & Safety: Increase FDA Funding," at [http://www.StrengthenFDA.org], visited March 7, 2007.

activities of the Office of Regulatory Affairs) in **Table 2B**, for FY2006, user fees contributed 29.8% of the drug program's budget. Not shown on this table: FY2006 user fees were, for the human drug program, 34.3% of the pre-market activities total and about 10% of the postmarket activities total.

Table 2A. Budget Authority, User Fees, and Total Program Level for FDA Salaries and Expenses, Selected Years FY1996-FY2006

(dollars in millions)

Fiscal year	Budget authority[a]	User fees[b]		Total[c]
1996	820	85	**9.4%**	905
1998	858	91	**9.6%**	949
2000	1,038	145	**12.3%**	1,183
2002	1,184	162	**12.0%**	1,345[d]
2004	1,379	287	**17.2%**	1,665
2006	1,469	357	**19.6%**	1,826

Table 2B. Budget Authority, User Fees, and Total Program Level for FDA's Human Drug Program Salaries and Expenses, FY2002-FY2006

(dollars in millions)

Fiscal year	Budget authority[a]	User fees[b]		Total[c]
2002	364	110	**23.1%**	474
2003	404	130	**24.3%**	534
2004	373	163	**30.3%**	536
2005	482	191	**28.3%**	673
2006	518	220	**29.8%**	737

Source: FDA, Office of Management Budget Formulation and Presentation, FDA Budget Summary FY 2007, Consolidated Exhibits: Table of Estimates and Appropriations, S&E, p. 49 of 84, at [http://www.fda.gov/oc/oms/ofm/budget/2007/PDF/5ConsolidatedExhibits.pdf].

a. Includes only direct appropriations; does not include the user fee amount that the appropriations bills also set.
b. Does not include Mammography Quality Standards Act (MQSA), export, or color certification fees. All years include Prescription Drug User Fee Act (PDUFA) fees; Medical Device User Fee and Modernization Act (MDUFMA) fees included beginning in FY2003; Animal Drug User Fee Act (ADUFA) fees included beginning in FY2004.
c. Does not include Facilities & Buildings funding.
d. In Table 2A: FY2002 total does not include $151.1 million from the counter-terrorism supplemental.

Finally, some critics think that, through its provision of fees, the industry has too much influence over FDA actions. Some critics believe that, by structuring industry participation into the setting of performance goals, the law creates conflicts of interest. This is compounded because, they say, the process of setting performance goals is not transparent. While some speculate that industry funding via user fees contributes to quick and suboptimal reviews, others believe that those speculations alone might threaten confidence in FDA reviews. FDA staff reports of pressure to meet performance goal deadlines suggest to some that safety and effectiveness data are being inadequately evaluated.[20]

Leaving aside some critics' distrust of the pharmaceutical industry's motives, other political and health analysts believe that drug application review is a regulatory responsibility that the federal government should shoulder completely. They believe that rather than rely on user fees, Congress should appropriate the full amount necessary to support FDA is its mission to protect the public's health.[21]

PDUFA IV Issues

FDA PDUFA IV Proposal

In January 2007, FDA released its proposal for PDUFA IV, the third reauthorization of the Prescription Drug User Fee Act. The agency press release title emphasizes FDA's intention to use PDUFA as a tool to enhance drug safety activities. That release, an accompanying fact sheet, and the more detailed *Federal Register* announcement describe the plan that FDA developed in consultation "with all of FDA's stakeholders including Congress, industry, patient advocates and

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[20] See, for example: Union of Concerned Scientists, "FDA Scientists Pressured to Exclude, Alter Findings; Scientists Fear Retaliation for Voicing Safety Concerns: Public Health and Safety Will Suffer without Leadership from FDA and Congress," press release, July 20, 2006, at [http://www.ucsusa.org/news/press_release/fda-scientists-pressured.html]; "Text: Andrew C. Von Eschenbach. M.D. Confirmation Questions [from Senator Grassley] for the Record," *FDA Week*, vol. 12, no. 48, Dec. 1, 2006; and "House Energy and Commerce Subcommittee on Oversight and Investigations Holds Hearing on Drug Safety," Congressional Transcripts, Feb. 13, 2007, at [http://www.cq.com].

[21] Note: FDA is not the only federal agency with program elements funded in part by fees that their regulated industries pay. Examples of others include Meat and Poultry Inspection (USDA); Commodity Grading and Certification Services (USDA); the Farm Credit Administration (USDA); Pesticide Registration Improvement Act of 2003 (EPA); Federal Communications Commission Regulatory Fees; and Securities and Exchange Commission Transaction Fees. Other user fee programs within FDA are the Medical Device Use Fee and Modernization Act (MDUFMA); the Animal Drug User Fee Act (ADUFA); the Mammography Quality Standards Act (MQSA); and export and color certification fees. FDA has proposed new user fee programs to help fund reinspections, generic drug reviews, and direct-to-consumer television advertising of prescription drugs.

organizations representing health care professionals and consumers."[22] FDA's proposal for PDUFA reauthorization includes three sets of recommendations.

Proposed Recommendations to Ensure Sound Financial Footing. FDA proposes adjusting the baseline budget for inflation, rent, and workload increases, which earlier adjustment formulae did not include.

Enhancing the Process for Premarket Review. Premarket review items include FDA's providing timelines for review and target dates for discussions with applicants; developing new guidance documents to "clarify regulatory pathways" to expedite drug development; and completing the full automation of drug review.

Modernizing and Transforming the Postmarket Drug Safety System. Proposals addressing postmarket safety include increasing the staff to work with adverse event reports; collecting and analyzing data over a drug's entire life; developing ways to use large datasets to support surveillance and studies; managing "both risk and the communication of risk"; improving communication and coordination between the FDA offices of premarket review and postmarket surveillance; reducing medication errors caused by drugs with similar names; and establishing a separate user fee to fund FDA review of direct-to-consumer television advertisements.

Possible Congressional Approaches

Reviewing FDA's authority to collect prescription drug user fees is likely to be a significant legislative priority for the 110th Congress. By some accounts, PDUFA collections cover more than half of FDA's scientists; losing those fees is widely seen as a step that would affect the agency's ability to review new drugs and to carry out postmarket surveillance, studies, and enforcement of safety requirements. Many stakeholder groups see PDUFA reauthorization as a vehicle for other drug- and FDA-related legislation.

By engaging in the reauthorization discussion with FDA, Congress already may be signaling its next step: to opt for continuing user fee funding of a portion of FDA's activities rather than choose to fully fund the agency through direct appropriations. If so, the remaining decisions would focus on the scope of issues to include in any prescription drug user fee legislation.[23]

Members of Congress have already proposed the inclusion of provisions surrounding:

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[22] FDA, "FDA Proposes New Measures to Strengthen Drug Safety Under PDUFA Reauthorized User Fee Program," *FDA News*, Jan. 11, 2007, at [http://www.fda.gov/bbs/topics/NEWS/2007/NEW01544.html]; FDA, "PDUFA Fact Sheet," Jan. 11, 2007, at [http://www.fda.gov/oc/pdufa4/factsheet011107.html]; and FDA, *Federal Register*, vol. 72, no. 9, Jan. 16, 2007, pp. 1743-1753.

[23] FDA's authority to collect medical device user fees also ends on October 1, 2007, as the program begun with the Medical Device User Fee and Modernization Act of 2002 (MDUFMA, P.L. 107-250) expires.

- direct-to-consumer prescription drug advertising (e.g., requiring or allowing FDA pre-air review or approval of ads; enforcing current regulations more strongly; and banning advertising wholly or in part);
- drug safety and effectiveness (e.g., strengthening FDA's authority and resources; allowing FDA to require label changes; requiring drug distribution restrictions; and improving clinical trial design and analysis);
- clinical trial registration and results databases (e.g., requiring specific information and reports within specified timeframes);
- and others involving, for example, prescription drug importation, drug compounding, follow-on biologics (akin to generic equivalents to branded drugs), Internet pharmacy regulation, and FDA organization and budget.[24]

[24] "PDUFA May Become FDA Reform Bill As Lawmakers Swarm To 'Must Pass' Act," InsideHealthPolicy.com, March 4, 2007.