

# CRS Report for Congress

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## Prescription Drug User Fee Act of 1992: Effects On Bringing New Drugs To Market

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### Summary

The Prescription Drug User Fee Act of 1992 (PDUFA) enabled the Food and Drug Administration (FDA) to assess user fees on research-based pharmaceutical companies to be used solely to accelerate the process for reviewing and approving applications for new drugs. In at least two respects there have tangible accomplishments. First, since 1993, one-third less time was required to review and approve new research-based drugs than in the years prior to PDUFA implementation. Second, the number of new drugs approved by FDA rose by one-third. But PDUFA was not intended to and does not address other related issues of the total regulatory process for new drug development and approval, pricing of new drugs, or the approval of generic drugs.

### Background

The Food and Drug Administration (FDA) has responsibility for the overseeing aspects of the development of and the approval to market new and generic drugs in the United States. This regulatory process includes both the oversight of the human testing of prospective drugs and the review and approval of applications to market them. This overall regulatory process has consumed increasingly more time over the past two or three decades owing to both scientific considerations and the finite and decreasing resources available at FDA to perform its functions.

In 1992, Congress enacted the Prescription Drug User Fee Act (PDUFA) authorizing the assessment of user fees by FDA on producers of new research-based drugs and biotechnology products (or biologics).<sup>1</sup> The objective of the fees was to enable FDA to mitigate the regulatory burden on pharmaceutical companies by augmenting its staff and resources to accelerate the process of reviewing applications for new drugs and certain

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<sup>1</sup> P.L. 102-571.

categories of biologics.<sup>2</sup> The fees were to be *in addition* to regular appropriations for the agency, and in an amount sufficient to add roughly 600 full time equivalent (FTE) staff to the agency.

The research-based pharmaceutical industry, those companies that develop, manufacture, and market new drugs, supported the imposition of these user fees because of the time required to review the applications submitted to FDA for new products. The average time for approval of new drug applications (NDAs) was about 31.3 months in the several years prior to enactment of PDUFA.<sup>3</sup> The review process, along with an increase in the time for testing new drugs in human clinical trials, represented a significant opportunity cost to these companies due to the reduction in effective patent protection. This was especially important to the research-based companies, because the so-called Hatch-Waxman Act of 1984 made it relatively easier for producers of generic equivalents of research-based drugs to gain approval to market their products upon expiration of the patent term.<sup>4</sup> That is, some portion of the term of any patent was consumed in the testing and application review time of the product; the patent holder was not able to benefit from the full term of the patent, and faced potential competition when the patent expired.<sup>5</sup> Thus, there were significant financial implications for the research-based pharmaceutical companies to speed up any part of the process for developing and gaining approval to market new drugs.

### **Affects on the Supply of New Drugs to Market**

From 1993 through 1996, the effective years in the operation of PDUFA, not only did the approval time for NDAs decline, but also the number of new products rose substantially. Table 1 presents data on the average time required to approve a NDA and the number of new drugs approved from 1985 through 1996.

As noted previously, the approval time for NDAs in the 8 years prior to the effective implementation of PDUFA (1985-1992) was about 31.3 months. In these 8 years, the approval time exceeded 30 months in every year except 1990 (27.7 months) and 1992 (29.9 months). From 1993 through 1996, the average approval time fell to about 20.8 months, a decline of about one-third the time required before PDUFA became effective. In these 4 years, the approval time never exceeded 30 months. More important, the

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<sup>2</sup> For more detailed information on the structure for implementing PDUFA, see: U.S. Library of Congress. Congressional Research Service. *Prescription Drug User Fee Act of 1992: Structure and Reauthorization Issues*. CRS Report 97-604 SPR, by Donna U. Vogt. Washington, 1997. 12 p.

<sup>3</sup> Estimated by CRS, using as its source: Pharmaceutical Research and Manufacturers of America. *PhRMA: Opportunities and Challenges for Pharmaceutical Innovation. INDUSTRY PROFILE 1996*. Washington, 1996. p. 15. (Hereafter cited as: PhRMA. *INDUSTRY PROFILE 1996*.)

<sup>4</sup> P.L. 98-417.

<sup>5</sup> The Hatch-Waxman Act of 1984 enabled patent holders on new drugs to be granted an extension of their patents for up to 5 years to offset all of the time consumed in reviewing applications and one-half the time required for human clinical trials.

approval time declined to less than 20 months in the second year after implementation of PDUFA.

In the 8 years before PDUFA became effective, an average of 24 new drugs were approved annually; the approvals ranged from 20 in 1988 to 30 in 1991. In the 4 years under PDUFA, an average of 32 drugs were approved each year, ranging from 22 in 1994 to 53 in 1996. The average number of new products approved each year rose by one-third.

TABLE 1. Average Time For FDA Approval of New Drug Applications and Number of New Drugs Approved, 1985-1996		
Year	Average Approval Times for New Drugs (months)	Number of New Drugs
1985	31.9	30
1986	34.1	20
1987	32.4	21
1988	31.3	20
1989	32.5	23
1990	27.7	23
1991	30.3	30
1992	29.9	26
1993	26.5	25
1994	19.7	22
1995	19.2	28
1996	17.8	53

Sources: Pharmaceutical Research and Manufacturers of America. *PhRMA: Opportunities and Challenges for Pharmaceutical Innovation. INDUSTRY PROFILE 1996*. Washington, 1996. p. 15; and, Pharmaceutical Research Manufacturers of America. *NEW DRUG APPROVALS IN 1996*. p. 16.

## Limitations of PDUFA

But this progress notwithstanding, there are at least three other factors that ought to be recognized in evaluating the success of PDUFA. First, while the review time for NDAs may have declined, other regulatory aspects of the development of new drugs may have obviated the gains from the accelerated review process. Second, PDUFA does not say or imply anything regarding the price at which new drugs come to the market. Third, PDUFA does not address concerns about the time taken to bring generic equivalents to the market. The goal of PDUFA was solely to accelerate the process for reviewing NDAs.

**Other Regulatory Requirements.** As inferred above, the regulatory process for bringing a new, research-based drug to market consumes a great deal of time. PhRMA, the trade association representing the research-based drug industry, estimates that the total time required to develop a new drug rose on average from 11.6 years in the 1970s to 14.8 years in the years from 1990 through 1994, an increase of nearly 28%.<sup>6</sup> Human clinical trials required by FDA accounted for most of this increase, rising from 4.4 years in the 1970s to 6.1 years in the period from 1990 through 1994, or by nearly 39%. FDA not only requires that clinical trials be conducted, it also specifies how many trials. Furthermore, the companies must obtain approval to conduct each trial. Thus, while the NDA approval process requires less time than in years past, the time required for human clinical testing more than offsets the reduction in NDA approval time.

**Effect on Prices of New Prescription Drugs.** While PDUFA has enabled new drugs to come to market faster, it should be understood that PDUFA has nothing to say about the pricing of these new products. Product pricing in the pharmaceutical market is a very complicated matter.<sup>7</sup> Not only do patented research-based drugs compete with similar, but not identical patented research-based drugs; for example, Zantac competes with Tagamet and other products. Pricing is affected by the significant market power of insurers and large buyers, such as HMOs and the federal government. The reduction in NDA approval time brought about by PDUFA means that new drugs are available to patients sooner, and lengthens the period of effective market exclusivity for patent holders during which they can reap the financial rewards of their product development.

**PDUFA and Generic Drugs.** User fees collected under PDUFA are dedicated solely to the approval of NDAs for research-based drugs and applications for covered biologics. User fees cannot be used to augment FDA staff and supporting resources needed to approve applications for generic equivalents of research-based drugs. Obviously, manufacturers of generic drugs pay *no* user fees. In recent years, there has been a decline in staffing in the FDA Office of Generic Drugs, and while the average approval time for generic drug applications has fallen, substantially more time is required to approve a generic drug than a research-based product.<sup>8</sup> The staffing ceilings for the Office of Generic Drugs in FDA fell from 155 persons in FY1994 to 125 persons in FY1996 and FY1997, a drop of about 16%. In spite of this reduction in staff, FDA has been able to accelerate the approval time for generic drugs in 1996. The average time for generic drug approval fell from 34.7 months in 1995 to 28.4 months in 1996, a decline of about 18%. However, the approval times for generics were significantly greater than for research-based drugs. In 1995, the average approval time for a generic drug (34.7 months) was 81% greater than for a research-based drug (19.2 months). In 1996, there was a noticeable improvement, but the average approval time for a generic drug (28.4

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<sup>6</sup> PhRMA. *INDUSTRY PROFILE 1996*. p. 16.

<sup>7</sup> For a more detailed discussion of the pricing of pharmaceutical products, see: U.S. Library of Congress. Congressional Research Service. *Prescription Drugs: Factors Influencing Their Pricing*. CRS Report 96-296 E, by David J. Cantor. Washington, 11p.

<sup>8</sup> Food and Drug Administration. Office of Generic Drugs. *MEMORANDUM: Generic Drug Approval Times and Staffing Ceilings*. Rockville, MD, January 17, 1997. 1 p. This memorandum was addressed to Congressional Research Service in response to a telephone request for the information.

months) was still 60% greater than the average time for approving research-based drugs (17.8 months).

### **Concluding Observations**

The data clearly indicate that the user fees generated by PDUFA have brought about a significant improvement in the process of reviewing applications for approval to market new research-based drugs and biologics. While other aspects of the regulatory process consume increasing amounts of time (with their associated costs), the total time for developing and approving a new drug would conceivably have risen even more absent an accelerated NDA review time. The manufacturer would, arguably, have had a shorter period of time in which to reap the financial rewards of bringing a new product to market. In turn, this could possibly affect the research and development effort for prospective new products. Thus, while product pricing and approval of generic drugs may not be affected by a faster NDA approval process, the accelerated reviews of NDAs may directly or indirectly influence company decisions to undertake new research activity.

It may well be that PDUFA is not the legislative vehicle to address these matters of the total regulatory process for new drugs, pricing, or even the substantially greater time for reviewing and approving new generic drugs. But the consideration of PDUFA gives rise to their consideration, and the possibility of or need for other legislative options to address them.