
COMMENTS

of the

WASHINGTON LEGAL FOUNDATION

to the

**FOOD AND DRUG ADMINISTRATION,
U.S. DEPT. OF HEALTH AND HUMAN SERVICES**

Concerning

**PRESCRIPTION DRUG USER FEE PROGRAM
[Docket No. 2005N-0410]**

Daniel J. Popeo
David Price
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave., N.W.
Washington, D.C. 20036
(202) 588-0302

December 14, 2005

WASHINGTON LEGAL FOUNDATION
2009 MASSACHUSETTS AVE., N.W.
WASHINGTON, D.C. 20036
(202) 588-0302

December 14, 2005

Andrew C. von Eschenbach, M.D.
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Prescription Drug User Fee Program [Docket No. 2005N-0410]

Dear Dr. von Eschenbach:

The Washington Legal Foundation (WLF) appreciates this opportunity to provide comments on the FDA's prescription drug user fee program. WLF supports the continuation of the user fee program pursuant to a reauthorized Prescription Drug User Fee Act (PDUFA). Although not a panacea, this program has helped American patients by reducing the time a new drug application spends in FDA processing and review, thus making safe and effective new medicines available sooner they would be available without the program. As further detailed below, we believe the program should continue to be guided by the principles under which it has existed since its inception in 1992.

Interests of Commenter

Commenter WLF is a nonprofit public interest law and policy center based in Washington, D.C., with supporters nationwide. Since its founding in 1977, WLF has engaged in litigation and advocacy to defend and promote individual rights and a limited and accountable government, including in the area of patients' rights. For example, WLF successfully challenged

the constitutionality of Food and Drug Administration restrictions on the ability of doctors and patients to receive truthful information about off-label uses of FDA-approved medicines. See *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000). WLF has also litigated and filed comments to oppose FDA policies harmful to patients with unmet needs. See, e.g., *Abigail Alliance for Better Access to Developmental Drugs v. McClellan* (D.C. Cir. No. 04-5350) (pending). WLF's Legal Studies Division has published numerous legal policy papers to educate policymakers and thought leaders about critical FDA issues. See, e.g., Christine P. Bump, *Courts Scrutinize FDA "Disgorgement" Demands* (2005); Donald E. Segal and Sharon D. Brooks, *Streamlining Appeals At FDA: A Modest Proposal* (2005); Christopher A. Brown and Teisha C. Johnson, *Conditioning FDA Approval On Agreement Not To Advertise Violates Law And Constitution* (2005); Erik G. Lasker, *FDA Position On Federal Preemption Consistent With Law And Public Health* (2005); Jeffrey N. Gibbs, *FDA Must Reform Its Arbitrary Drug Name Review Process* (2005). These and other FDA-related publications are available on WLF's web site at <http://www.wlf.org>.

**The User Fee Program Should Continue Under
Its Existing Principles of Operation**

The Prescription Drug User Fee Act (PDUFA), first enacted in 1992, was renewed as part of the FDA Modernization Act of 1997 (FDAMA) and again in 2002 under the Prescription Drug User Fee Amendments of the Public Health Security and Bioterrorism Preparedness and

Response Act of 2002. Under PDUFA, sponsors of new drug applications pay user fees to allow FDA to hire more scientific review staff and improve its information technology for the purpose of expediting the new drug review process. This program has seen a reduction in processing and review times for applications – though it is worrisome that *clinical* phases have lengthened during this time for nearly all therapeutic classes, offsetting the gains in processing and review times. See Kenneth I. Kaitin, Director, Tufts Center for the Study of Drug Development, *Drug Development Timelines and the Prescription Drug User Fee Act* 7, 15 (Nov. 14, 2005).¹

The fees collected under PDUFA – application fees paid with each new drug application, and establishment and product fees paid annually – are significant. FDA collected \$246.4 million in user fees in FY 2004; fees are targeted at a total of \$252 million in FY 2005 and at \$259.3 million in FY 2006 and FY 2007. Application fees for FY 2006 are \$767,400 per application.

In WLF's view, the program offers some benefit to patients and should be continued, but it must respect the following principles:

1. Expenditures of user fees must be fully tied to the program's purpose. PDUFA's purpose is to accelerate the availability of safe and effective new medicines, and PDUFA fees must therefore be expended only to further this goal – i.e., only on direct application-related costs. It would not be appropriate, for example, to allocate this revenue to cover the imputed cost of non-application-related meetings, as FDA has suggested. See *Drug Industry Skeptical of FDA's Proposed User Fee Hikes*, Drug GMP Report, Dec. 1, 2005. Funding of augmented post-market review through user fees may be appropriate to the extent it facilitates pre-market

¹ Available for download at <http://www.fda.gov/cber/summaries.htm>.

approval of promising new medicines.

2. User fees must supplement, not replace, congressional appropriations. The prescription drug user fee program must not evolve into an industry-specific tax to finance FDA's normal regulatory and law enforcement activities. Once the precedent has been set for treating PDUFA user fees simply as an alternative source of general treasury revenue to be expended on FDA activities outside of new drug review, the overall federal budget situation will create inexorable pressure to finance an ever-increasing share of the FDA's activities through those fees. Such a development would dilute PDUFA's original purpose of expediting review of new drug applications while creating a new and undesirable burden on the drug innovation process, deterring investment in medicines that may improve or extend patients' lives.

CONCLUSION

For the foregoing reasons, the Washington Legal Foundation respectfully requests that FDA seek the continuation of the prescription drug user fee program largely in its present form, with any new areas of expenditure closely tied to the new drug application process.

Respectfully submitted,

Daniel J. Popeo

David Price

Counsel for Commenter