Balancing Budgets & Innovation: User Fee Programs at the FDA

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Overview

As American patients demand new, more effective ways to diagnose, treat and cure disease, the Food and Drug Administration (FDA) plays a vital role in ensuring patients have access to safe and effective drugs and devices. At the same time, a growing federal debt means FDA is relying more than ever on user fees paid by drug and device manufacturers to review new medical technologies. The existing FDA user fee programs sunset on September 30, which means the FDA can't collect user fees after that date unless Congress extends these programs.

Where does FDA funding come from?

Traditionally, FDA received 100 percent of its funding from taxpayers through the regular Congressional appropriations process. In 1992, in response to years of complaints about the FDA's slow drug review process, Congress authorized the first FDA user program ("PDUFA") to support the Agency's review of prescription drugs. In exchange for paying user fees, drug companies received commitments from FDA to meet specific performance goals for timely reviews and assurances from Congress that user fees would supplement appropriations rather than replace them. Later, facing a slowdown in medical device reviews, Congress replicated this model, establishing fees for devices ("MDUFA"). Today, user fees support approximately 65% of the FDA's prescription drug review costs and 20% of device review costs. This year, Congress plans to authorize two new user fee programs to support the expanded FDA review of generic and biosimilar drugs.

How do user fees work?

To ensure a fair process, FDA negotiates each user fee agreement with the industry trade groups that represent the individual companies that will pay the fees. During these negotiations, FDA and industry develop a framework that determines how much in fees will be paid by industry each year and what types of user fees the Agency will establish. For PDUFA, drug companies pay three types of fees: a fee paid for each new drug application, an annual fee for each drug manufacturing establishment, and an annual fee for each drug that does not have generic competition. For MDUFA, device companies pay two fees: a fee for each device application and an annual fee for each manufacturing establishment. Fees within these categories vary extensively. For instance, in Fiscal Year 2012, the application fee for a "PMA" device review is $220,050, while the standard application fee for the less resource-intensive 510(k) review process is $4,049.

Why is Congress concerned about user fee agreements?

While user fees have allowed the FDA to hire a substantial number of new reviewers, the Agency has often missed performance goals established in user fee agreement negotiations, raising questions about the return on investment for fee-paying companies. Despite these concerns, companies paying user fees support these programs, since they are essential to ensuring FDA has the resources necessary to review new technologies in a timely and efficient manner. As a result, Congress continues to consider ways to improve these user fee programs.

Key Facts

- American Jobs in FDA User Fee-Paying Industries (2008 & 2009): **1,096,970**
- Year Congress Established User Fees:
  - Brand-Name Drugs: **1992**
  - Medical Devices: **2002**
  - Generic Drugs (tent.): **2012**
  - Biosimilar Drugs (tent.): **2012**
- Percentage of FY2011 FDA Spending From User Fees (approx.):
  - Total FDA Budget: **33%**
  - Prescription Drugs: **65%**
  - Medical Devices: **20%**
- Total Amount of User Fees in FDA-Proposed Agreements (in millions, over 5 years):
  - Brand-Name Drugs: **$3,600**
  - Medical Devices: **$595**
  - Generic Drugs: **$1,495**

Other Resources

- Food & Drug Administration —
  - PDUFA
  - MDUFA
- PEW Charitable Trusts — Testimony on 2012 User Fee Package
- Pharmaceutical Manufacturers Association (PhRMA) — PDUFA Issue Overview
- Advanced Medical Technology Association (AdvaMed) — MDUFA Issue Overview
- Generic Pharmaceutical Association (GphA) — User Fee Main Page

Links to Other Resources

- Food & Drug Administration — PDUFA
  http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm

- Food & Drug Administration — MDUFA
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm236902.htm

- PEW Charitable Trusts — Testimony on 2012 User Fee Package
  http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Speeches/TestimonyofAllanCoukellbeforeSenateHELPCommittee.pdf

- Pharmaceutical Manufacturers Association (PhRMA) — PDUFA Issue Overview
  http://www.phrma.org/issues/prescription-drug-user-fee-act

- Advanced Medical Technology Association (AdvaMed) — Testimony on MDUFA III Agreement
  http://www.advamed.org/NR/rdonlyres/43F74379-C17D-4005-904D-D6CD46F664AE/0/FinalNexonTestimonyHELP32912.pdf

- Generic Pharmaceutical Association (GphA) — User Fee Main Page
  http://www.gphaonline.org/issues/user-fees