User-Fee Funding of Human Drug Review

Reauthorization of the Prescription Drug User Fee Act

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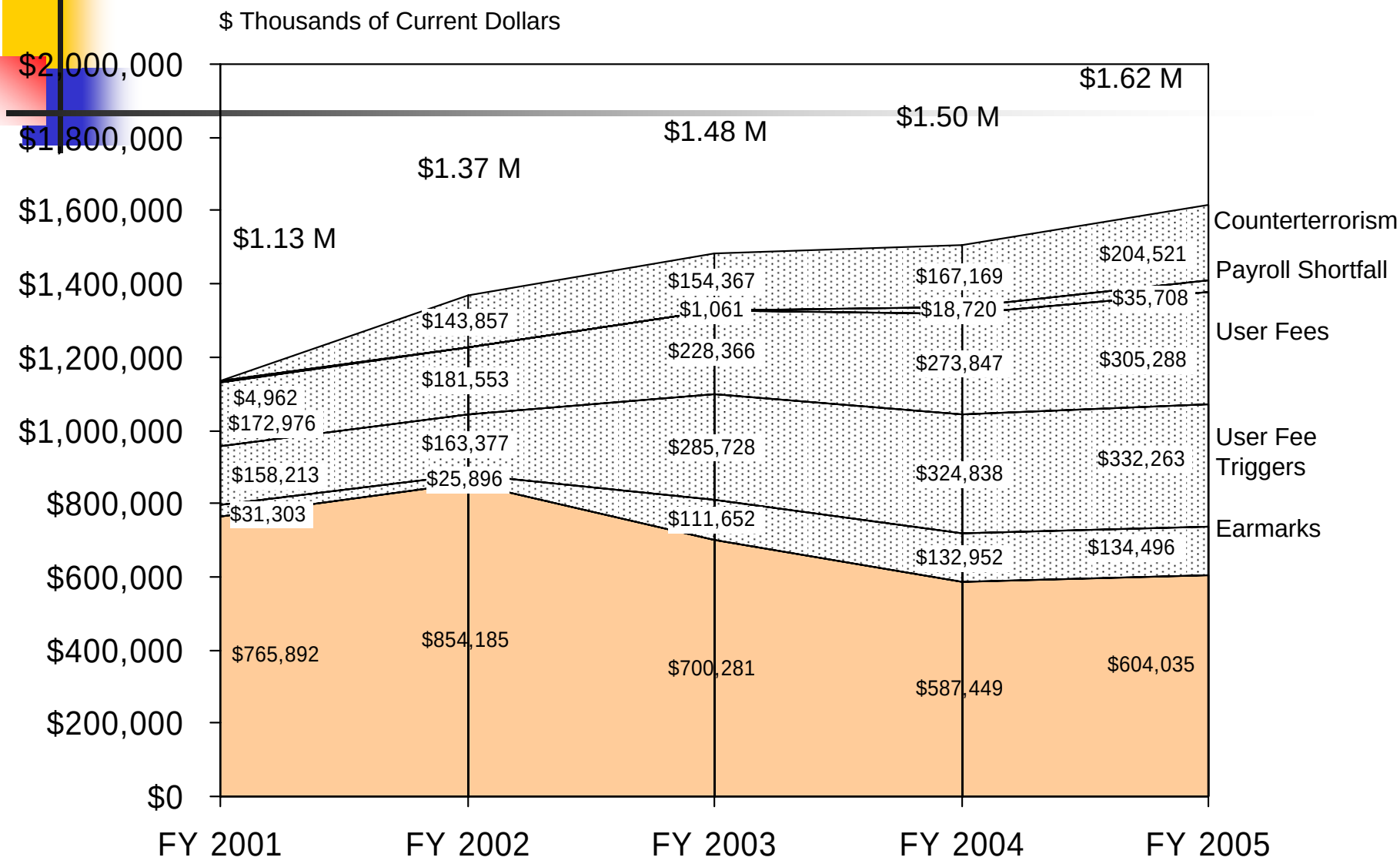
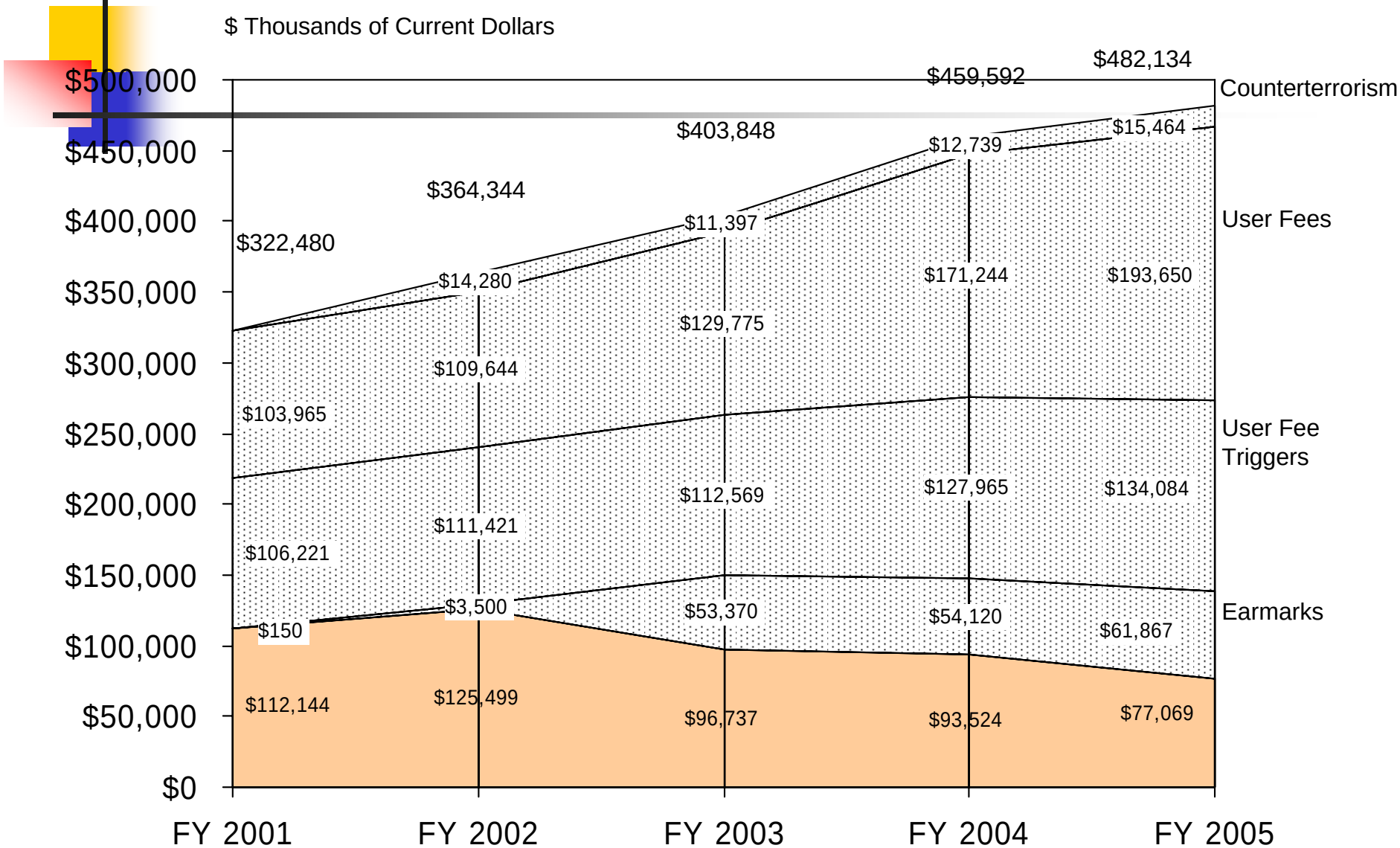
February 16, 2007

Industry User Fees Represent a Growing Share of FDA Funding



Sources: *Comparable All Purpose Tables, Justifications of Estimates for Appropriations Committees*, FY 2002-FY 2007, OFM, OM, FDA; *FDA Appropriation Overview*, FY 2001-FY 2005, OFM, OM, FDA

PDUFA User Fees provided the largest source of increased funds for the Center for Drug Evaluation and Research



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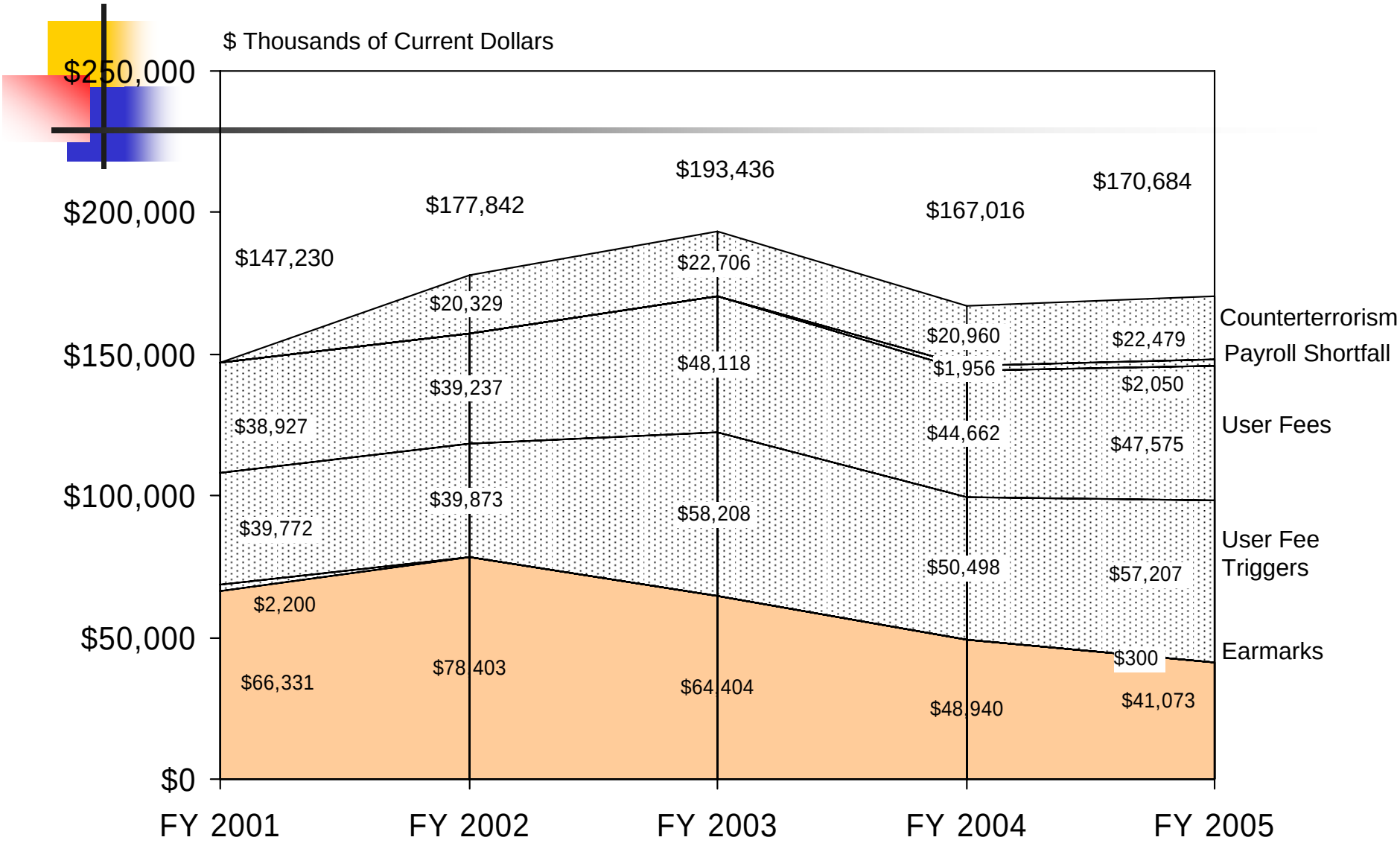
PDUFA fees also provide a significant share of funding for the Center for Biologics Evaluation and Research



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PDUFA Fees Support Process of Human Drug Review

- Human Drug Review has broad scope, e.g.,
  - Pre-clinical testing and consultation
  - Review of Investigational New Drug (IND) applications
  - Meetings with sponsors to review development programs
  - Special protocol assessments
  - Oversight of clinical trials; human subject protection
  - Review of New Drug Applications (NDAs), Efficacy Supplements, Manufacturing supplements
  - Review labeling changes
  - Review risk management plans
  - Review Adverse Event Reports up to 3 years post-approval of new drugs

Volume of Submissions Needing Review Continues to Grow

Submissions for FDA Review (examples)	**FY 01**	**FY 02**	**FY 03**	**FY 04**	**FY 05**	**FY 06**
Original NDA Submissions	**104**	**105**	**109**	**129**	**111**	**122**
Resubmissions	**78**	**77**	**74**	**85**	**59**	**60**
Efficacy Supplements	**170**	**170**	**153**	**204**	**158**	**182**
Manufacturing Supplements	**2,065**	**2,476**	**2,598**	**2,500**	**2,532**	**2,679**
Meeting Requests	**1,662**	**1,745**	**2,119**	**2,284**	**2,487**	**2,548**
Special Protocol Assessments	**125**	**248**	**293**	**346**	**396**	**405**

User Fees Also Leverage Appropriations Funding Key Public Health Initiatives

- Counter-Terrorism
  - FDA work to facilitate development of medical countermeasures
- Best Pharmaceuticals for Children Act & Pediatric Research Equity Act
  - Work by FDA to increase number of drugs adequately labeled for children
- President's Emergency Plan for AIDS Relief (PEPFAR)
  - FDA performing expedited review to provide safe and effective HIV/AIDS drugs to developing countries
- Pandemic Influenza
  - FDA activities to expedite development, evaluation and approval of additional flu vaccines

PDUFA Continuing Importance

- Provides agency opportunity to increase strength and continue to modernize process
- Increases program stability in era of scarce resources and growing public health needs