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The Prescription Drug  
User Fee Act:  
An Overview

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September 15, 2002

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PDUFA Overview

- Purpose
- Fees
- Triggers in the Law
- Performance Goals
- Fees in Other Countries
- Conclusion

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Purpose

- Supplement FDA's appropriated drug review resources
- Enhance the review of human drug applications without reducing the quality of review
- Reduce total drug development time
- Provide greater access for Americans to new human drug products

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## Fees--Types

- Three types of fees--each type of fee accounts for one-third of the total user fee revenue
  - **Application Fees**--due with certain human drug applications and supplements
  - **Product Fees**--due annually for each marketed prescription drug product
  - **Establishment Fees**--due annually for each establishment manufacturing prescription drugs

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## Fees--Amounts

- No fees are charged for Investigational New Drug applications
- Fees from all sources are used toward *drug review* costs, including the review of investigational new drug applications

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## Fees--Exemptions and Waivers

- PDUFA provides for:
  - Exemptions from paying fees
  - Waivers and reductions of fees
- On average, about 22 percent of applications pay no application fee

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## Application Fees--How Set

- Application fees are set in statute, but adjusted annually for inflation
- Statutory inflation adjuster is the highest of the Consumer Price Index or Federal pay over the past year
- Inflation adjusters are compounded

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## Product and Establishment Fees --How Set

- Number of applications and supplements affects all fees
- Product and establishment fees are set annually so that the total revenue from each will equal the amount expected to receive from application fees

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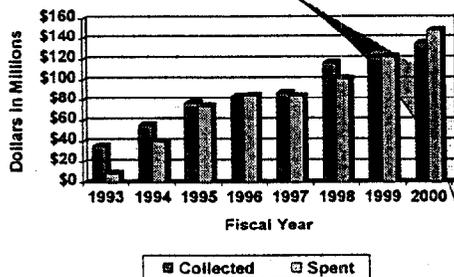
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## Fees Collected and Spent



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## Fees--How Dollars are Spent

- Only for drug review process, not for post-approval work
- Hire and support additional staff to expedite drug review
  - 1147 staff years before PDUFA (all paid from appropriations)
  - 2029 staff years now, expected to increase to 2000 (paid from appropriations and fees)
- Acquire and maintain systems and technology to support paperless submissions

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## Triggers

- FDA authority to collect and spend user fees is dependent on three "triggers"
  - 1 FDA total appropriation level
  - 2 Spending a set minimum amount from appropriations on drug review
  - 3 FDA Appropriations Act must specify the amount of fees we may collect and spend

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## Triggers--Spending of Appropriated Funds

- Plus--Funds provided by fees are in addition to FDA's appropriated drug review resources
- Minus--Demands that FDA spend more appropriated funds on drug review each year to meet trigger (Up from \$120 million in 1995 to \$154 million in 2000)
- Required appropriation spending level each year is a bare minimum
- Has resulted in less appropriations available for other core FDA programs

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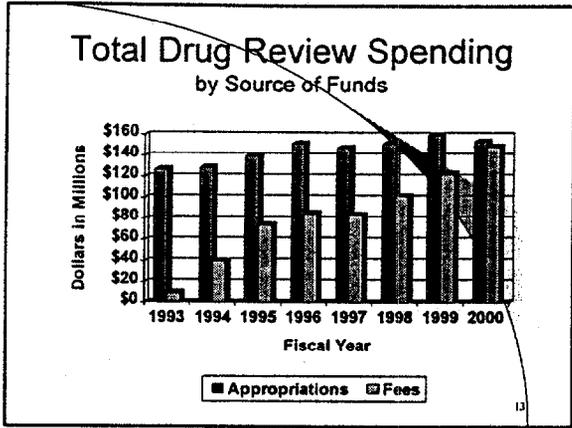
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- ### Performance Goals
- An FDA commitment to faster review was a prerequisite for user fee legislation
  - Goals for faster review--not approved--were agreed to in PDUFA I, and tightened in PDUFA II
  - PDUFA II added new goals for various components of FDA review

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### User Fees in Other Countries Summary

Country	Australia	Canada	UK	USA
Fees Collected?	Yes	Yes	Yes	Yes
Purpose				
Percent of Cost				
Goal Link				

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### User Fees in Other Countries Summary

Country	Australia	Canada	UK	USA
Fees Collected?	Yes	Yes	Yes	Yes
Purpose	Full Cost Recovery	Partial Cost Recovery	Full Cost Recovery	Full Cost Recovery
Percent of Cost	100%+	70%+	100%+	50%
Goal Link				

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### User Fees in Other Countries Summary

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Percent of Cost	100%+	70%+	100%+	50%
Goal Link	Yes	No	No	Yes

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### Conclusion

- Resources from PDUFA have become essential for FDA drug review
- With PDUFA reauthorization, we have opportunity to address perceived weaknesses

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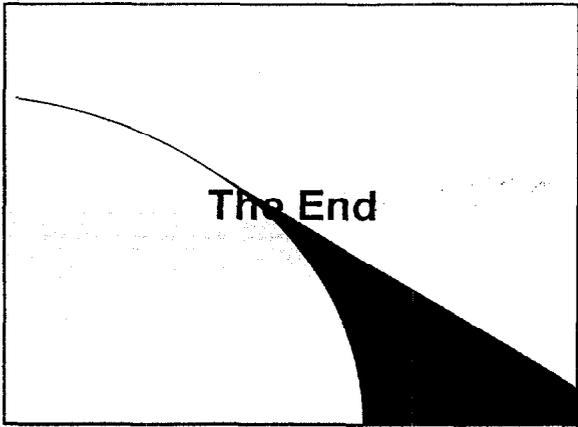
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