# Medical Device User Fees: The Time is Now

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# Why Consider User Fees Now?

- FDA has changed
  - streamlined its processes
- Industry has changed
  - robust and rapid growth
  - increasingly complex products
  - operating in global market
- Administration has changed its approach
  - proposing *additive* user fees for first time
- PDUFA has shown user fees can benefit industry, government, and consumers

# Top 10 Reasons Industry Has Hated Device User Fees

**10**. FDA already has enough appropriated dollars.

**9**. Fee revenues will simply replace appropriated revenues.

**8**. Existing resources can be reallocated to get devices out more quickly.

**7**. FDA review processes are inefficient.

# Top 10 Reasons Industry Has Hated Device User Fees

6. Rigid reviewers created backlogs.
5. Review processes are fast enough.
4. Device manufacturers are very small businesses.
3. Fees could stifle innovative, start-up companies (and are un-American anyway).

# Top 10 Reasons Industry Has Hated Device User Fees

**2.** _ _ _ _ _ _ _ _ _

**1.** _ _ _ _ _ _ _ _ _

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# We've Streamlined and Reengineered:

- modular PMAs
- real time reviews
- downclassifications
- exemptions from 510(k)
- increased use of standards
- 3P Pilot
- 510(k) Paradigm

➡ *Result: Review times have improved and 510(k) backlogs have been eliminated.*

# We Shifted Resources to Premarket Review from Other Parts of Program

- Shift has occurred even while overall resources are declining
- Demands of increasing complexity of workload have exceeded reallocated resources
- Cannot shift additional resources without undermining other public health responsibilities

# Resources Are Shrinking

- **Bad news**:
  - Flat line budgets have meant actual decrease in funds available for program.
  - CDRH FTEs have declined each of past three years — down 113 FTEs since FY 1996.
  - FDAMA added new responsibilities without funding.
  - Workload complexity is increasing.
  - Review timeframes are still too long (*e.g.*, PMAs – 12.4 months total elapsed time).
  - Administration's FY 2000 budget does not request additional premarket resources.

# Why Consider User Fees Now?

- **Bottom line**:
  - We've gone about as far as we can go; diminishing returns from reengineering
  - FDAMA premarket provisions cannot be fully implemented without funding
  - Product review program cannot meet all the demands placed on it; review times may slip
  - CDRH cannot shift any more resources from other programs without jeopardizing public health
  - The Administration proposal for additive fee legislation is opportunity for industry as well as FDA

# Overview of the Legislation

- FDA Review Fee Act of 1999 provides for fees relating to medical devices, food and color additive petitions, and food contact substance notifications.

- Fees would go into effect October 1, 1999.

# Proposed Medical Device Fees

- PMAs / PDPs — $40,000 each.
- PMA supplements — $4,500 each.
- Periodic PMA report — $1,000 each.
- Establishment registration — $200 annually.

■ *No fees for 510(k)s*

➡ ***Would generate about $7 million***

# Exceptions and Exemptions

- No *additional* fee for re-submissions.
- *No fee* for labeling changes that improve safety.
- Fees may be *waived or reduced* for —
  - Humanitarian devices.
  - When necessary to protect public health.
  - When fee would present significant barrier to innovation.
  - Small businesses with <20 employees.
  - Start-up business with no prior PMA or 510(k).

# Safeguards on the Use of Fees

- Legislation specifically requires all user fee revenues to be *additive.*
- Additive fee revenues *cannot* be used to replace appropriated revenues.
- Legislation conditions use of user fee revenues on *unreduced* appropriations; can guarantee stable funding.
- Additive fees mean *real* increases in premarket review program budgets.

# What Can the Money Buy?

- Improved performance in FDA's medical device premarket review program.
- PMA first actions within 180 days --
  - FY99 -- 70%
  - With fees -- 85% in FY2000, 95% in FY2002
- Determination and IDE agreement meetings within 30 days --
  - FY99 -- 65%
  - With fees -- 95% in FY2000

# What Can the Money Buy?

- Investment in enhanced science at FDA
  - increased training for reviewers on newest technologies and risk assessment tools
  - increased standards development activities
  - enhanced harmonization/international activities
  - more staff with clinical experience
  - strengthened premarket testing and methods validation capabilities
  - increased number of workshops on specific product or health-related premarket issues
  - fully automated device databases to make information easily accessible to scientific premarket review staff

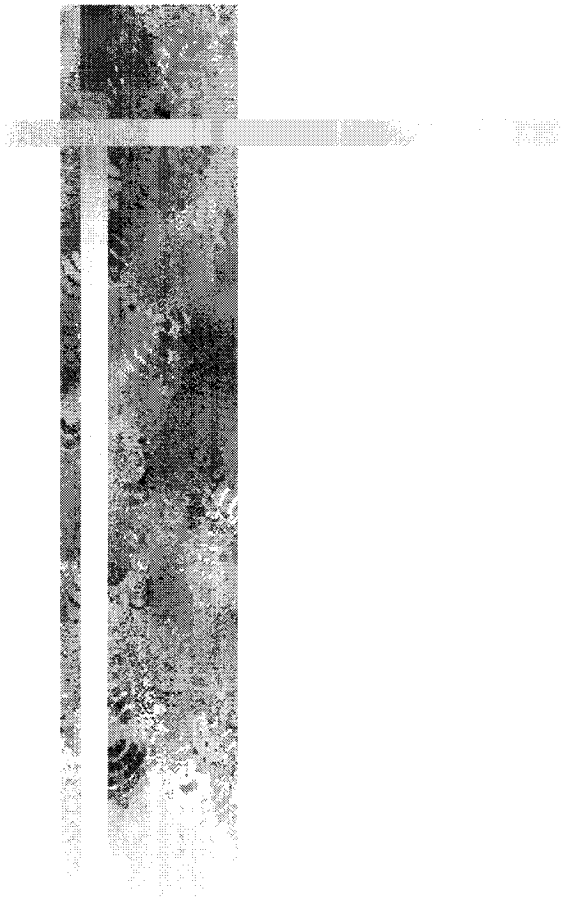
# What Can the Money Buy?

- Scientific expertise helps reviewers understand type and amount of data necessary to establish safety and effectiveness
- Enhanced premarket review program permits FDA to understand new technologies, regulate them in least burdensome manner
- Staff armed with "cutting edge" science can make decisions more efficiently

➡ *Better science = less burdensome and more timely reviews commensurate with product risk*

# What Can the Money Buy?

- **Bottom line**:
  - More rapid product development and approval
  - More rapid generation of income for companies; quicker access for patients
  - Stable funding for device program at FDA
  - More predictability about review process
  - Other mutually beneficial deliverables



# The End