
# Prescription Drug User Fee Act
# February 16, 2007 Public Meeting

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# Academy of Managed Care Pharmacy

- Professional society
- Individual pharmacists and other health care practitioners
- Apply managed care principles
- 5,000+ members nationwide
- Servicing 200 million Americans

# PDUFA Renewal

- Necessary to assist agency in achieving its fundamental goal:
  - Promote and protect public health both by determining in a timely manner a drug or biologic's safety, and, by taking appropriate action on the marketing of these products
  - Adequate funding to allow the FDA to fulfill its obligations to ensure medication safety is absolutely essential

# PDUFA Renewal

- Essential for continuance of the prescription drug review program
- Imperative for:
  - Postmarket drug safety systems
  - Managing and monitoring of direct-to-consumer (DTC) advertising of prescription products


# Postmarket Drug Safety System

- Need to improve completion rate of Postmarketing Study Commitments (PCMs)
- Agree FDA should give earlier notice in the premarket approval process of need for PMCs
- FDA should be given the authority to **mandate** PMCs

# Postmarket Drug Safety System

- AMCP agrees with FDA's recommendation to remove the limitations on spending of user fees to within three years after a drug's approval date
  - Limited breadth of premarket clinical trials
  - Safety issues can arise as long as eight or more years on the market

# Postmarket Drug Safety System

- AMCP recommends that the FDA's authority to monitor a drug after approval must be expanded
- AMCP believes the FDA must have authority to enforce requests for a PMC short of withdrawing the drug's approval

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# Postmarket Drug Safety System

- AMCP recommends that FDA funding for postmarket surveillance must be of an amount sufficient to recognize that:
  - It is as important as the drug approval process and
  - It is part of the primary mission of the Agency

# Direct-to-Consumer Advertising

- AMCP supports DTC that educates patients about disease symptoms and treatment options
- AMCP discourages DTC that promotes specific prescription drug products



# Direct-to-Consumer Advertising

- AMCP supports the idea that the FDA should oversee content of DTC advertising to ensure that it:
  - Focuses on raising awareness of disease and symptoms
  - Addresses alternative treatment options
  - Reasonable describes both benefits and potential risks
  - Stimulates patient/provider dialogue


# Direct-to-Consumer Advertising

AMCP recommends that:

- FDA be given the authority to *mandate* prior approval of advertising,
- The authority extend to all media of DTC advertising, and
- Funding for the monitoring of DTC advertising be of an amount sufficient to allow timely pre-approval of advertising

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# Bottom Line

- The FDA needs sufficient funding to fulfill its mission through the combination of user fees and appropriations
- The FDA Alliance – a union of 100 organizations committed to helping the Agency improve consumer health and safety – is campaigning for adequate funding levels