



# Prescription Drug User Fee Act Food and Drug Administration and Stakeholders Public Meeting

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American Pharmacists Association  
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# American Pharmacists Association

- Professional Association of pharmacists and others interested in advancing the profession
- More than 53,000 members
- Provide information, education, and advocacy to improve medication use and advance patient care

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Improving medication use. Advancing patient care.



# Assessment of PDUFA Performance

- Met original goals
  - Resources to bring new drugs to market more quickly
- PDUFA should not be main source of Agency funding
  - Additional appropriations necessary
- Focus on speed must not distract from focus on quality

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# Consider Expanding PDUFA Scope

- Expanding postmarketing surveillance
- Develop a systems-based risk management program
  - Means-test to determine ‘when’ a rigorous risk management system is necessary
  - Use standard tools to address similar problems
  - Evaluate performance/effects of interventions
  - Voluntary participation of health care professionals

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