

# FDAAA and the Evolving Pharmaceutical Marketplace

Industry Perspective

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# FDAAA Provisions

## Industry Perspective (1)

- Safety Provisions
  - REMS
  - Safety related labeling changes
  - Postmarketing requirements (PMRs)
- Active Postmarketing Risk Identification & Analysis
  - Sentinel

# FDAAA Provisions

## Industry Perspective (2)

- Transparency
  - Clinical trial registration requirements
  - Conflict of interest
- Reagan-Udall and the Critical Path Initiative
- Competing International and State Initiatives
  - Safety regulations
  - Transparency requirements
  - Public-private partnerships and consortia
- Unaddressed issues
  - Balkanized US clinical research regulations