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presented to the

United States Chamber of Commerce

Employee Benefits Committee

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Food and Drug Administration Amendments Act of 2007 (FDA³)

- Passed by House on September 19, 2007 by a vote of 407 to 5
- Passed by Senate on September 20, 2007 by unanimous consent
- President Bush signed FDA³ into law today

What's Not In the Bill?

- Separate safety center
- Express anti-preemption language
- Tiering for pediatric exclusivity
- Moratorium on direct-to-consumer ads
- Marketing plan submission requirement
- Limits of one waiver per meeting for FDA advisory committees
- "Lay summary" requirement for databank

What's In the Bill

- PDUFA Reauthorization (User Fees)
- Reauthorization of pediatric rule and exclusivity provisions (PREA and BPCA)
- New labeling authority
- Risk Evaluation and Mitigation Strategies
- Reagan-Udall Foundation and Critical Path funding
- Conflict of interest in advisory committees
- Clinical trial registry and results databank

PDUFA Reauthorization

- User fees for drugs will increase substantially
  - $392 million base revenue of FY08
  - Plus increased workload for FY07 (@$37 million)
  - Plus $225 million over five years for safety
  - Equals more than $100 million increase over FY07
- New user fee for DTC television ads
  - $6.25 million per year
  - Supports voluntary pre-submission of TV ads

BPCA & PREA Reauthorization

- Best Pharmaceuticals for Children Act
  - Provides 6 months exclusivity for pediatric studies
  - Tiering proposals not included
  - New limitations imposed on eligibility for exclusivity
- Pediatric Research Equity Act
  - Requires pediatric studies for certain drug applications
  - Sunsets at the same time as BPCA (October 2012)

New Labeling Authority

- FDA now has authority to force labeling changes related to safety
- Accelerated review process to ensure timely inclusion of new information
- No express anti-preemption language
- Problems:
  - Rule of Construction
  - Time frames too compressed
  - No dispute resolution until after FDA “order”

Risk Evaluation and Mitigation Strategies (REMS)

- FDA can require a REMS if necessary to ensure that benefits outweigh risks
- REMS Elements
  - Timetable for assessments
  - MedGuides and patient package inserts
  - Communication plan to physicians
  - Distribution and use restrictions
- Patient access must be considered

Research Initiatives

- Reagan-Udall Foundation
  - Purpose is to advance the mission of FDA to modernize medical product development
  - Funding: $500K - $1.25 million from FDA plus private donations
- Critical Path Public-Private Partnership
  - FDA to enter into collaborative agreements with universities and non-profits to implement the Critical Path Initiative
  - $5 million authorized to be appropriated

Clinical Trial Disclosure

- Registry of Ongoing Studies
  - Expanded to include all studies except Phase I
  - Requires more detailed information
- Results Databases – created in stages
  - Links to existing FDA and NIH data
  - Basic results – tables of data
  - Expanded results: FDA must issue regulations within 3 years specifying what must be submitted

Final Thoughts

- FDA³ could have been a lot worse (reference slide #3)
- The Chamber deserves a lot of credit for weighing in on critical issues
- FDA implementation is key
  - FDA must issue numerous guidance and regulations and make critical decisions about the meaning of various provisions
  - FDA's decisions will determine the ultimate effect of the legislation

QUESTIONS?

Contact Information

Scott M. Lassman is a Partner in the law firm of Wilmer, Cutler, Pickering, Hale & Dorr (WilmerHale), where he specializes in FDA legal, regulatory and policy issues. Prior to joining WilmerHale, Mr. Lassman served as Senior Assistant General Counsel for the Pharmaceutical Research and Manufacturers of America (PhRMA), where he was responsible for all FDA regulatory and policy matters. Mr. Lassman played a leading role in negotiating the $400 million Prescription Drug User Fee Act (PDUFA) agreement with FDA, which recently was passed by Congress. Mr. Lassman's strong policy background at PhRMA is complemented by more than ten years of experience in private practice solving complex FDA legal and regulatory issues for pharmaceutical, biotechnology and medical device clients.

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