F·D·A³:

PDUFA Reauthorization and Post-Market Authority

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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 on September 27, 2007

What's Not In the Legislation?

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

What's In FDA³ (drug-related)

- PDUFA Reauthorization (User Fees)
- Reauthorization of pediatric rule and exclusivity provisions (PREA and BPCA)
- New labeling and postmarket study 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

- Prescription Drug User Fee Act (PDUFA) reauthorized until October 1, 2012
- User fees for drugs will increase substantially
  - Approximately $375 million added over 5 years for post-market drug safety ($150M proposed by FDA and industry plus $225M added by Congress)
  - Application fees will increase approximately 30%
    - $896,200 in FY07
    - $1.2 million for FY08

PDUFA Reauthorization (cont'd)

- Permitted Uses of PDUFA Funds
  - Removes prior provisions restricting the use of funds for safety activities to drugs approved after Oct. 1, 2002 and only for 3 years after approval
  - Implementation and "enforcement" of REMS and other post-market safety provisions
- Reauthorization Procedures
  - Requires monthly meetings with patient and consumer advocacy groups
  - Public dissemination of minutes of meetings with industry

New DTC User Fee

- Applies only to voluntary submissions to FDA of direct-to-consumer (DTC) television advertisements for advisory review
- Designed to generate $6.25 million annually
- All advisory reviews must be identified and "pre-paid" at the beginning of the fiscal year
- ***The program starts NOW!!!***
  - Companies should begin forecasting immediately
  - Submissions due to FDA in near future

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
- Issues:
  - Rule of Construction: what does it mean?
  - Time frames too compressed
  - No dispute resolution until after FDA issues an "order"

Postapproval Study Authority

- FDA may require postapproval studies or postapproval clinical trials to:
  - Assess a known serious risk related to the drug;
  - Assess signals of serious risk related to the drug;
  - Identify an unexpected serious risk
- Stepped authority
- Questions:
  - What is the difference between a study and a trial?
  - Will current voluntary system co-exist with new authority?

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

Effective Date

FDA's new authority to require postapproval studies and postapproval clinical trials, safety labeling changes and REMS becomes effective:

180 days after enactment.

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 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 signed into law. 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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