FDLI's Conference on

FDA Implementation of the New Law – The Food and Drug Administration Amendments Act of 2007 (FDAAA)

Direct-to-Consumer Advertising

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FDAAA Advertising Provisions

- Direct-to-Consumer (DTC) Television Advertisement User Fee
- Mandatory Pre-review of Television Advertisements
- Major Statement
- DTC Regulations
- 1-800 Number Disclosure
- Civil Money Penalties

New DTC User Fee

- Designed to generate $6.25 million annually
- Applies only to voluntary submissions to FDA of direct-to-consumer (DTC) television advertisements for advisory review
- All advisory reviews must be identified and “pre-paid” at the beginning of the fiscal year or late fees apply
- An “operating reserve fee” must be paid in a company’s first year of participation in the program

DTC User Fee - Issues

- If FDA does not receive $11.25 million within 120 days of enactment (i.e., January 25, 2008), the Program will cease to exist
- Companies must provide estimates to FDA by November 26, 2007
  - Estimates constitute a “legally binding commitment” to pay fee for number of ads identified
  - Estimates should be as accurate as possible.
- Companies can “carry over” one review to the next fiscal year, so an estimate that errs slightly on the high side may be preferable.

Mandatory Pre-Review

- FDA may require the submission of any television advertisement 45 days prior to broadcast
- FDA may make recommendations:
  - Necessary to "protect consumer good and well-being"
  - Consistent with the prescribing information; or
  - To address efficacy in specific populations
- But the sponsor does not have to accept them
- Required Disclosures
  - Serious risk listed in the labeling
  - Date of approval (up to 2 years after approval)

Major Statement & Regulations

- Major Statement
  - Must be presented in a “clear, conspicuous and neutral manner”
  - Regulations required by March 27, 2010
- FDA advertising regulations no longer need to be promulgated under Part 15 hearing procedures

1-800 Number Disclosure

- "Published" DTC advertisements must include information about how patients can report side effects in "conspicuous text"
  - Are "published" studies broader than "print" ads?
  - What does "conspicuous" mean in this context?
  - Companies must act quickly because of need to get print ads approved internally now for use 180 days after enactment
- FDA must conduct study to determine whether this disclosure requirement should apply to television advertisements

DTC Civil Money Penalties

- FDA may now impose civil money penalties (CMPs) against DTC advertising that is "false or misleading"
- Amounts
  - $250,000 for the first violation in a 3-year period
  - $500,000 for subsequent violations in 3-year period
- Definition of Single Violation
  - Prior to notice of FDA's intent to seek CMPs, repeated dissemination of the same or similar advertisements is considered a single violation
  - After notice, each day is a single violation
- In determining CMP amount, FDA may consider whether or not the advertisement was submitted to FDA for advisory comments

Effective Dates

- DTC User Fee
  - October 1, 2007
- Other DTC Provisions
  - March 25, 2008

Contact Information

Scott M. Lassman is Co-Chair of the FDA practice group at 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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