# Promotional Implications of REMS: The Good, The Bad, and The Ugly

Scott M. Lassman

Partner, WilmerHale

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# The Good . . .

- No moratorium provisions on direct-to-consumer (DTC) advertising in either the House or Senate bills.
- New User Fee for DTC Television Ads
  - Additional resources for FDA, particularly DDMAC ($6.25 million per year)
  - More timely, predictable reviews of pre-submitted ads
  - House bill (H.R. 2900) places new user fee program in legal jeopardy because it expands user fee requirement to include “required” pre-submissions

# The Bad . . .

- Marketing Plans
  - House bill (H.R. 2900) gives FDA authority to require as part of a REMS the submission of information on an applicant's "marketing plans and practices"
  - Provides regulatory agency with broad, unprecedented access into a company's internal business documents with little or no justification
  - Implementation problems: What is a "marketing plan"? Does the submission need to be updated whenever the "marketing plan" is updated?

# The Bad . . .

- New Civil Money Penalties (CMPs)
  - Applies to DTC ads that are “false or misleading”
  - $250K for first violation in 3 year period/$500K for subsequent violations
  - FDA likely will face heavy pressure to make frequent use of new CMP authority
- 1-800 Number Disclosure
  - Increased consumer adverse event (AE) reportling is likely to overburden an already strained AE monitoring system with a flood of information of limited utility

# The Ugly . . .

- Mandatory Pre-Review Authority
  - New section 503B in House bill (H.R. 2900) gives FDA broad authority to require submission of TV ads 45 days before dissemination
  - No standard to guide or limit FDA's discretion
  - FDA may make recommendations on, inter alia,
    - Changes "necessary to protect the consumer good and well-being";
    - Statements addressing efficacy of the drug in special populations
  - <u>But</u> . . . FDA is not allowed to make or direct any changes

# The Ugly . . .

- Required Rule-Making on “Major Statement”
  - New requirement that the “major statement” in radio and TV ads must be presented in a “clear and conspicuous manner”
  - FDA must promulgate regulations establishing standards for determining the meaning of “clear and conspicuous”
  - Open Question: Are these regulations subject to the Part 15 Public Hearing procedures?
  - If so (and perhaps even if not), any rule-making likely will be much broader than specifically required and also quite onerous and contentious

# Back to the Good . . .

**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 is currently under consideration 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.

**Contact Information**:

1875 Pennsylvania Avenue, N.W.

Washington, D.C.  20006

202-663-6892 (p)

Scott.lassman@wilmerhale.com

www.wilmerhale.com