Analysis of FDA Draft Guidance on Direct-to-Consumer (DTC) Advertising

Pharma Congress 2004

National Audio conference
March 23, 2004

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Disclaimer

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Draft DTC Guidance Documents: First Impressions

- *Eagerly anticipated* – publication of these Draft DTC Guidance documents forecast for months
- *High-profile topic* – receiving much attention from media, professional and consumer associations, and congress

- *Public Meeting on DTC Advertising* – held in September 2003 not a direct link but relevant to information/evidence gathering
- *Evidence-based regulatory guidance* - FDA struggling with some jurisdictional questions and evidence/statutes are non-conclusive
Draft DTC Guidance Documents: An Overview

- **Brief Summary: Disclosing Risk Information in DTC Ads** – designed to encourage manufacturer to create and deliver more user-friendly information to public

- **Help-seeking and other disease awareness communications** – attempts to clarify distinction between disease awareness communications and product promotion

- **Broadcast Advertising of Restricted Devices** – closely parallels 1999 Guidance for Drugs
Draft DTC Guidance Documents: Taking a Closer Look

Brief Summary: Disclosing Risk Information in DTC Print Ads

- *Now have more alternatives to physician labeling* (goal is consumer-friendly brief summary that is easier to comprehend based on format and language)

- *With so many choices, which is the best approach and doesn’t this disfavor consistency?* (industry dilemma and evidentiary questions are widespread)

- *Format recommendations for risk information in core ad raises interesting issues* (bullet format and risk window proposal ideal for FDA but does it stifle creative options)
Help-seeking and other disease awareness communications

- *Uses non-statutory criteria to establish boundaries/provide guidance* (jurisdictional and regulatory rationale sufficient?)

- *Reminder ad and disease awareness ad link* (when taken together either perceptually or temporally can be regulated?)
Draft DTC Guidance Documents: Taking a Closer Look

Broadcast DTC Guidance for Restricted Devices

- **Major statement requirement** (parallels 1999 Guidance for Drugs)

- **Manufacturers encouraged to create patient labeling** (device labeling for physicians viewed by FDA as highly technical)

- **Hearing-aids** (FDA recommends adequate provision for receipt of user instructional brochure in connection with broadcast ad)
Draft DTC Guidance Documents: Some final thoughts

- Guidance documents are non-binding recommendations so are we really talking about safe harbors?
- Guidance documents are complex and raise some interesting jurisdictional/evidentiary issues
- Anticipate many comments to docket
- Industry has choices regarding brief summary – may need to develop/translate patient labeling as a first step
Draft DTC Guidance Documents: Some final thoughts

- Identifying most important risks could be a challenge – may need FDA opinions
- Structure of contracts/communications with TV networks and periodicals could come into play for temporal linkage issue
- Core themes throughout encourages industry to conduct research and more research on the issues