Analysis of FDA Draft Guidance on Direct-to-Consumer (DTC) Advertising

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Michael Misocky, R.Ph., J.D.

Disclaimer

Michael A. Misocky, R.Ph., J.D. is Director, Global Pharmaceutical Regulatory Affairs at Abbott Laboratories.

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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)

Draft DTC Guidance Documents: Taking a Closer Look

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*