PhRMA Voluntary Guidelines on DTC Advertising (and Some FDA Rules)

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Presented To:

EXL Pharma
Philadelphia, PA
March 23, 2009

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Revised PhRMA Principles

Research and Background

- Dec. 2008 – the Pharmaceutical Research and Manufacturers of America revised its voluntary Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines, which originally went into effect in January 2006
- Revised Principles took effect on March 2, 2009
- As of 1/6/09, 24 companies had adopted the Guiding Principles
- 18 Principles

Revised PhRMA Principles

Overview

- " . . . Part of an ongoing effort to enhance the educational potential of DTC communications, while maintaining respect for the patient-provider relationship"
- The Code addresses, among other things
  - ✓ healthcare professionals and celebrities featured in ads
  - ✓ presentation of balanced benefit and risk information
  - ✓ appropriate timing and placement of advertisements with adult-oriented content

(Some) Revision Highlights

Use of Actors

- DTC product advertisements featuring actors in the roles of healthcare professionals should identify that actors are being used
- If actual healthcare professionals are featured and are compensated for their appearance, the advertisement should acknowledge the compensation

Revision Highlights

Endorsers

- DTC television or print advertisements featuring a celebrity endorser should accurately reflect the opinions, findings, beliefs or experience of the endorser
- Companies should maintain verification of the basis of any actual or implied endorsement, including whether the endorser is or has been a user of the product

Revision Highlights

Risk Information

- DTC print advertisements should include FDA's MedWatch number and website for reporting of potential adverse events, and DTC television advertisements should include the company's toll-free number or refer patients to a print advertisement that contains the toll-free MedWatch number and website
- Risks and safety information, including the substance of relevant boxed warnings, should be "presented with reasonably comparable prominence to the benefit information, in a clear, conspicuous and neutral manner, and without distraction from the content"

Revision Highlights

Risk Information

(cont'd)

- In addition, DTC television advertisements should support responsible patent education by directing patients to healthcare professionals, as well as to print advertisements and/or websites where additional benefit and risk information is available
- DTC television advertising that identifies a product by name should clearly state the health conditions for which the medicine is approved and the major risks associated with the medicine being advertised
- Make clear the medicine is prescription drug

Revision Highlights

Education

- Companies should consider setting specific periods of time for education about a new medicine or indication before launching a branded DTC campaign
- Companies should seek and consider feedback from healthcare professionals and consumers during the development of new DTC ad campaigns "to gauge the educational impact for patients and consumers"
- Companies are encouraged to promote health and disease awareness as part of their DTC advertising

Revision Highlights

Other

- Stronger language related to the content and placement of DTC advertisements with adult-oriented content; specifically, the new version states that DTC television or print advertisements "containing content that may be inappropriate for children" should be placed in programs or publications reasonably expected to draw an audience of approximately 90 percent adults (18 years or older
- A clarification that companies should not promote medicines for off-label uses, including in DTC advertisements

Revision Highlights

Other

(cont'd)

- Strengthened language calling for companies to include messages about help for the uninsured and underinsured in DTC communications
- Submission of all new DTC tv ads to FDA before broadcast release
  - ✓ earlier than FDA requires and a "reasonable time in advance" for FDA review and comment
- DTC television and print advertising should include information about the availability of other options, such as diet and lifestyle changes where appropriate for the advertised condition

Revision Highlights

Certification

- The new Guiding Principles provide that company CEOs and Compliance Officers will certify each year that they have processes in place to comply with the Principles
- PhRMA will post on its web site a list of all companies that announce their pledge to follow the Principles and information about the status of companies' annual certifications

FDA Regulation of Product Promotion and DTC Advertising

(Some Highlights)

- Information must be:
  - ✓ accurate and not misleading
  - ✓ supported by substantial evidence
  - ✓ fairly balanced between risks and benefits
  - ✓ consistent with FDA-approved labeling

Key Statutory Definitions

The Federal Food, Drug, and Cosmetic Act

- ***Label*** – "[A] display of written, printed, or graphic matter upon the immediate container of any article . . ."
- ***Labeling*** – "[All] labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article"
- FDA regulates all product labeling and prescription drug advertising
- The FDC Act does not define "advertising"
  - ✓ but see 21 C.F.R. § 201.1

Basic Requirements Relating to DTC Advertisements

- See Guidance for Industry: Consumer-Directed Broadcast Advertisements (August 1999) -- www.fda.gov/guidance/1804fnl.htm
- Information in brief summary relating to side effects, contraindications, and effectiveness
- Advertisements cannot be false, misleading or omit material facts
- Fair balance of risk information and effectiveness, including significant limitations to product use

Broadcast Ads

- Broadcast advertisements must include the product's most important risk-related information in the audio or audio and visual parts of the advertisement (i.e., the major statement)
- The major statement must include all of the most important risk information related to the product
- Broadcast advertisements must contain either a brief summary of the advertised product's risk information, or alternatively, make adequate provision for disseminating the product's approved labeling in connection with the ad

Brief Summary

- The brief summary is generally shorter, sometimes significantly so, from the approved labeling
- The brief summary typically includes only the risk-related sections of the product's labeling
- In contrast, product labeling includes non-risk-related information, including all effectiveness information (sometimes even about the clinical studies used as the basis for product approval), how it should be taken (dosage information), how the drug product is supplied (e.g., the quantity of drug in each pill) and information about how the product works in people's bodies

Chat Rooms, News Groups, And Blogs

- Users exchange thoughts and ideas about conditions and treatments
- Healthcare professionals share treatment experiences and observations with consumers
- Manufacturers can publicly associate themselves with diseases, generate goodwill with patients, physicians and the public, and obtain information about consumer needs and concerns

Chat Rooms, News Groups, And Blogs

(cont'd)

- FDA's concern:
  - ✓ Chat Rooms and News Groups might discuss off-label uses or suggest investigational product is safe and effective

Chat Rooms, News Groups, And Blogs

(cont'd)

- Several issues:
  - ✓ will manufacturers be required to constantly review and moderate their sites?
  - ✓ will manufacturers be permitted to respond or correct information?
  - ✓ should employees disclose their employment when they participate in Chat Rooms or News Groups?

Chat Rooms, News Groups, And Blogs

(cont'd)

- Why some companies don't sponsor or moderate Chat Rooms or News Groups:
  - ✓ concern about product liability
  - ✓ FDA might hold them responsible
  - ✓ edited material might be incorrect or libelous
  - ✓ lose control of content, because it is difficult to control what might be said about a particular treatment
  - ✓ adverse event reporting concerns

(These companies typically provide grants to third parties)

Links

- Clicking on a link takes a viewer immediately from one site to another
- Because it is difficult to monitor links into a site, a company will not likely be held responsible for "incoming" links, but they can control their "outgoing" links
- Notify users that they are leaving a company's site

Links
(cont'd)

- Be careful about the URL address itself
- FDA will take enforcement action if a company links its website to independent sites that promote an unapproved use or have established separate sites to promote unapproved uses

Links
(cont'd)

- What kind of links to external sites might cause a website to misbrand a product?
  - ✓ unapproved uses
  - ✓ unsubstantiated claims
  - ✓ false or misleading statements
  - ✓ pre-approval promotion or commercialization of investigational product

Misbranding*

- See 21 U.S.C. § 352 (or also known as section 502 of the FDC Act)
- Among other reasons:
  - ✓ label or labeling is false or misleading in any particular
  - ✓ inadequate directions for use
  - ✓ inadequate warnings
  - ✓ lack of risk information

* An unapproved new drug is a separate violation

Misbranding

(cont'd)

- Keep in mind that icons, symbols, website addresses, and other forms of communication can misbrand a product
- Failure to provide material information is unlawful
- "False or misleading" is not confined to meaning "untrue, forged, fraudulent or deceptive"
- Ambiguity, misdirection, false comparisons to other products, and creating a false impression are also ways to misbrand a product

Typical Promotional Defects

- Suggestions/representations of unapproved uses
- Non sequiturs, such as drawing conclusions or projecting by inference or implication from inadequate data
- Failure to include material facts
- Use of anecdotal testimonials based on clinical impression
- Minimization or omission of risk information

Typical Promotional Defects

(cont'd)

- Use of *in-vitro* or animal data in a manner to suggest clinical significance, when the data have not been established
- Direct or implied comparison of unlike products
- Half-truths, inadequate qualifications and/or limitations regarding safety or effectiveness
- Vague, open-ended claims or suggestions of superiority

Enforcement Options

- Untitled Letter/Notice of Violation
- Warning Letter
- Court action
- Fines

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Untitled Letter Or Warning Letter

- Typical result for violative promotional claim
- Source of violations
  - ✓ competitor complaints (majority)
  - ✓ FDA monitoring
    - ➢ e.g., review of periodicals, attendance at trade shows, websites, Form FDA-2253
      - ▪ i.e., Form FDA-2253 is submitted to FDA when a promotional piece is initially disseminated or initially published

Untitled Letter Or Warning Letter

(cont'd)

- ✓ inspections (of manufacturing facilities)
- ✓ complaints
- ✓ other agencies
  - ➢ e.g., FTC, SEC

Enforcement Example

- Warning Letter (2008) for tv ads
  - ✓ two 60-second DTC broadcast tv ads for product with black box-warning
  - ✓ misleading
    - ➢ broadened drug's indication
      - ▪ visuals/images of singing happy people and audio presentations
    - ➢ overstatement of efficacy
    - ➢ minimization of risk information

Enforcement Example

(cont'd)

- Public health risk
- Corrective action "to the audience(s) that received the violative promotional materials"

Other Possible Implications

- Corrective advertising
- Loss of credibility with FDA and the marketplace
  - ✓ e.g., consumers, medical community
- Stock drop/class action lawsuits/SEC inquiry
- Competitors will use it against you
  - ✓ e.g., trade complaint letter, Lanham Act lawsuit, National Advertising Division challenge

Other Possible Implications

(cont'd)

- Bad publicity
- Whistleblower complaints
- Product liability
- State prosecution
  - ✓ e.g., consumer protection
- Fraud prosecution and abuse
  - ✓ e.g., False Claims Act
- Diversion of $ from other projects

Keep In Mind

- Everyone acting on behalf of the company is held to the same standards as the company and the company will be held responsible, even if the agent fails to conform to company policies
  - ✓ e.g., investigators, consultants, PR firms, marketing partners
- Make clear in a contract and through training that any company consultants or third parties must comply with applicable laws and company rules

Recommendations

- Comply with FDA's labeling and promotional requirements, such as
  - ✓ required product information (e.g., content and format)
  - ✓ truthful
  - ✓ fair balance

Recommendations

(cont'd)

- Establish procedures before distribution and a team to review all promotional materials, regardless of the intended audience or the form of the promotion
  - ✓ e.g., an internal review checklist that requires signoff by appropriate personnel
  - ✓ make clear in training and in SOPs the roles of individuals, the laws, government guidances, and company policies

Recommendations

(cont'd)

- No handmade materials should be prepared and distributed
- Can report study or scientific findings – scientific exchange of good and bad information – but don't editorialize, promote, exaggerate, or commercialize if the product isn't approved
- Do not draw conclusions of safety or efficacy (including quotes from investigators or company executives) if unapproved product

Recommendations

(cont'd)

- Be careful about symbols, logos, URL addresses, or graphics that can also get a company into trouble with intended use issues
- Remain vigilant in monitoring promotional activities
  - ✓ keep up with enforcement trends
  - ✓ monitor what FDA is doing to competitors
- Disclaimers or qualifying statements are helpful but won't eliminate risk if the whole promotion, when viewed in full and in context, is violative

Recommendations

(cont'd)

- Train employees and third parties you employ about company policies
  - ✓ you don't want renegade salespeople getting the company in trouble
  - ✓ audit and monitor internally to make sure everyone is on the same page
  - ✓ document accordingly