Talking about Your Product in the New Age: Social Media and the Internet

The FDA Regulatory Paradigm

Social Media Regulatory Affairs Summit
June 25, 2015

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Regulatory Challenge re Social Media

- Application of standards for traditional labeling and advertisements
  - When are companies responsible for content?
    - Information provided by third parties
  - How are traditional rules applied?
- Duty to investigate and report adverse events
Responsibility for Content
Responsibility for Content

- Companies generally responsible for information disseminated by them or on their behalf
- Includes information disseminated over the Internet
  - Regulated as labeling or as an advertisement
- Includes Social Media
Social Media

- Social Networks
  - Facebook, Pinterest, MySpace

- Media Repositories
  - YouTube, Vine

- Blogs
  - Including microblogs such as Twitter

- Wikis
  - Wikipedia, Medpedia
Social Media Challenges

- Independent
- Interactive
  - Constant new content
  - Ephemeral content
  - Real-time interaction
- Sometimes difficult or impossible to control content provided by third parties
FDA 2009 Meeting re Internet and Social Media

- Issues
  - Determining substantive influence of company on content
  - Determining when third-party discussions be treated as information disseminated by or on behalf of the company
  - Disclosure of company involvement or influence
  - Specific or differing criteria for specific social media

- Necessity for Guidance
Traditional Rules re Third-Party Content

- Facilitation of a forum raises FDA concern
  - Knowledge or expectation
  - Who will speak and what they will say
- FDA objections to company-organized programs with expected testimonials
- Traditional exceptions
  - Independent educational programs
  - General unrestricted grants
Third-Party Content in Social Media

- Company sites/locations
- Superimposed information on company sites
- Independent sites
Third-Party Content (cont.)

- Company-controlled sites/locations
  - High level of responsibility in area of company control
    - Traditional regulation of company-facilitated forums
    - Exceptions for independent educational programs
  - Restrictions on communities and postings
    - Terms of use (no product discussions)
    - Monitoring and right of removal
  - Responding to requests for information on off-label use
Third-Party Content (cont.)

- Superimposed information on company website or web page
  - E.g., Facebook
  - Independent provider
  - No company control

- Questions re regulatory obligations/liability
  - Important to monitor
  - Possibly correct misinformation
Third-Party Content (cont.)

- Support for independent sites
- Many variables to consider
  - Nature of company support or involvement
    - Unrestricted grant
    - Sole support
    - Advertising (in context of related content)
  - Functional independence
  - Company knowledge of or influence over content
  - Content favorable to company (promotional in tone)
  - Disclosure of company support or involvement
Participation in Shared-Content Sites

- Forums (Blogs)
  - Ongoing discussions
- Repositories (YouTube)
- Product information presumptively promotion
  - Including corrections of misinformation
  - Exception for political or policy discussions
- Issues re third-party comments re off-label use
Complying with the Traditional Rules
Labeling or Advertisement?

- Labeling/advertisement distinction
  - Written, printed, graphic information or accompanying product
  - Live presentations and advertisements placed in media

- Information on Internet can be either
  - FDA looks to functional similarity

- Distinction usually not significant for Rx drugs because requirements are similar
FDA Regulation of Labeling and Advertisements

- Fair balance
  - Full and balanced information on risks
  - Equal prominence
- Full disclosure
  - Package insert or brief summary
- Misleading content
  - Failure to disclose material facts
- Off-label use
  - Prohibited
Fair Balance, Full Disclosure, and Misleading Content

- Applicable to almost any statement regulated as labeling or advertisement
- Difficulties with real-time presentations
- Space limitations and links
  - 2009 Warning Letters re sponsored links
    - Absence of fair balance (risk information)
  - Possible use of links for full disclosure information
Information on Off-Label Use

- Generally inappropriate to have dialog in public forum
- Response to unsolicited request for information
  - Traditionally permitted
  - Handled by medical Staff
  - Not posted
Reports of Adverse Events

- Responsibility of company to investigate and report to FDA
- Company sites
  - Duty to monitor and investigate
- Sponsored or facilitated sites
- Third-party sites with company promotion or engagement in content
- Third-party sites with no company involvement
FOUR FDA GUIDANCES
Character Space Limitations

Internet/Social Media Platforms with Character Space Limitations - Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (June 2014)

- Primary Recommendations:
  - Benefit information should be accurate and non-misleading and reveal material facts
  - Risk information should accompany and be comparable in scope in each space-limited communication.
  - Mechanism (link) for direct access to additional risk information
  - Inclusion of proprietary name and established name
Postmarketing Submissions

Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics (January 2014)

- Content Responsibility
  - Sites owned, controlled, created, influenced, or operated by, or on behalf of, the firm
  - Content generated by employees or agents acting on firm’s behalf

- Required Submissions
  - All sites for which firm is responsible
  - Third-party sites on which a firm’s participation is limited to interactive or real time communications,
    - Home page alone, interactive page, and first communication
  - At the time of initial display and updated each month
Third-Party Misinformation

Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices (June 2014)

- Firms may correct misinformation
  - Post corrective information on the forum, request removal of information, or request that comments be allowed for posting

- Corrective information
  - Relevant, responsive, tailored to the misinformation, accurate, non-promotional, consistent with FDA-required labeling, supported by sufficient evidence (substantial evidence for Rx drugs), disclosure of relationship of person providing the correction information

- Response in same forum
  - Posted in conjunction with the misrepresentation

- Response to forum operator
  - Identify misinformation and location
  - Correct all misinformation
Unsolicited Requests for Off-Label Information

Responding to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices (December 2011)

- Private Unsolicited Requests (e.g., mail or telephone)
  - Truthful, balanced, non-misleading and non-promotional scientific or medical information, (with additional requirements)
- Public Unsolicited Requests (e.g., social media)
  - Request and response specific to company’s product
  - Convey that question pertains to an unapproved use
  - Suggest that individual contact company medical/scientific personnel for additional information and provide contact information
  - Disclose respondent’s involvement with the firm
  - Responses should not be promotional in nature or tone
Enforcement Since 2009
FDA Meeting
Warning Letter re Tasigna®

Novartis Pharmaceuticals Corporation (7/29/2010)

- “Facebook Share” tool that allows consumers and Facebook users to share Novartis generated information about Rx drug Tasigna®
  - Failure to provide risk information to accompany information efficacy
  - Failure to provide information about patient restrictions
  - Failure to submit to FDA as advertising
Warning Letter re Atelvia®

Warner Chilcott (US), LLC (5/5/2011)

- YouTube video posted by member of Warner Chilcott sales team
  - Failure to provide risk information and indication to accompany information efficacy
  - Discussion of benefits of dosing schedule without disclosure of restrictions
  - Failure to submit to FDA as advertising
Warning Letters re Poly-MVA and Tirosint®

AMARC Enterprises, Inc. (12/11/2012) (Poly-MVA and Poly-MVA for pets)
- Facebook post of the user of the product that contained drug claims treated by FDA as if it was a claim made by the company because they “Liked” the claim.
  - Unapproved drug

Institut Biochimique SA (IBSA) (2/24/2014) (Tirosint®)
- Facebook page for Rx drug
  - Failure to provide risk information to accompany information on intended use
Warning Letter re Viread®

Gilead Sciences, Inc. (6/27/2014):

- Sponsored link used on Google.com for Rx drug

- Broadened indication (prevention)
- Failure to provide risk information to accompany indication
- Failure to provide established name
- Failure to submit to FDA as advertising
THE FUTURE
Future FDA Guidance

Use of Links to Third-Party Sites

[FDA Guidance Agenda for 2015]

- Possible issues
  - Responsibility for violative content
  - Disclosure of to third-party information
  - Unknown changes in third-party content
  - Hashtags - automatic links to posts or other content with same hashtag
Future Legislation

21st Century Cures Bill

- Would require “One Click Rule”
- Linked safety information deemed adequate for meeting content requirements in space-limited settings
QUESTIONS

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