

Pharmaceutical Company Perspective on Social Media

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Introduction

- Recognition by Industry that Patients/Healthcare Professionals Are Increasingly Turning to the Internet and Social Media For Health and/or Product Information
- FDA has not issued specific guidance on social media
 - Historically, general direction to companies has been that the FDA will apply the same standards and principles about risk disclosure and promotion of pharmaceutical products regardless of what media is being used
 - April 2009 Enforcement Letters Re: Sponsored Links; end of one-click rule
- Challenges for the industry therefore are to comply with applicable regulatory requirements in this arena without explicit FDA guidance
- FDA conducting public hearing on November 12-13 which is “intended to help guide FDA in making policy decisions on the promotion of . . . prescription drugs and biologics and medical devices using the Internet and social media tools”

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What is Meant by Social Media?

- Technology has evolved such that the Internet means more than mere static content on a website
- Social media tools allow for significantly more enhanced communication, information sharing and distribution, collaboration, two-way dialogue, etc.
 - User-generated content - wikis
 - Social networking – on-line communities of people with common/shared interests and activities
 - Chat rooms/discussion boards
 - Micro blogging (Twitter) – real-time exchange of people's thoughts and activities
 - Patient blogs/articles
 - Video sharing, e.g., You Tube
 - Podcasts

What Company Activities Could Involve Social Media?

- Extremely broad range of activities for pharmaceutical companies to consider using social media, including:
 - Corporate Communications (public affairs, media relations)
 - Product promotion
 - Disease awareness
 - Investor Relations
 - Recruiting/Careers
 - Interactions with Clinical Investigators, Scientific Leaders
 - Communications Related to Clinical Data, Key Studies, Etc.

Who Is In Charge of Social Media Initiatives Within the Company?

- Can there really be a singular group? One ambassador?
- Public Affairs?
- Marketing?
- Cross-functional team?
- One governing council?
- What's the appropriate infrastructure to support these initiatives?
- Regardless – important to engage legal/compliance

Issues/Considerations When Thinking About Using Social Media

- Product Promotion
 - Presenting Risk Information; Providing Fair Balance
 - Not endorsing off-label use
 - Branded or unbranded?
- Adverse Event Reporting
- Third Party Communications or Content on Third Party Sites
- Posting or Otherwise Communicating Corrective Information on Sites Controlled by Third Parties
- Miscellaneous

Promotion

- Existing FDA regulations are applicable framework –even though no detailed or comprehensive guidance on Internet/social media promotion of prescription drugs/biologics
- Questions to Ask:
 - Branded or Unbranded? Does the posting even trigger fair balance requirements?
 - Advertising or Promotion?
 - Directed to healthcare professionals or consumers?
 - Are you presenting risk information in an appropriate manner? Links to PI/PPI? Ensuring that safety information travels with efficacy claims/product messages? See FDA Draft Guidance relating to Presenting Risk Information (May 2009)
 - Given space constraints, character limits, etc., what is a reasonable way?
 - April 2009 DDMAC Enforcement Letters – “one-click” to safety info not OK
 - Are you somehow endorsing or facilitating off-label use?
 - Does the specific posting constitute DTC advertising?
 - Process questions: 2253 submission; application to user-generated content, etc.

Adverse Event Reporting: Several Challenges and Considerations

- How is adverse event information being received, reviewed, and processed?
- What are company's obligations relative to third party sites/blogs/wikis/chatrooms that it does not own or sponsor?
- Who takes responsibility within the company to monitor and report AEs?
- What is the extent of such monitoring?
- Are the 4 criteria met to trigger reporting? (identifiable patient, identifiable reporter, specific product mention, AE)
 - Not always apparent in social media
- Need for training of appropriate personnel

Third Party Communications or Content on Third Party Sites

- Who is generating or controlling the content?
 - User-generated?
 - Company content?
 - Who has ability to modify content?
- Who is paying for the content?
- What is the nature of the content?
 - Celebrity endorsement?
 - Patient testimonial?
- Who is hosting the content?
- Who is publishing the content?
- Has the company fully disclosed its role in influencing or sponsoring this third party communication, i.e. has the company been sufficiently transparent?

The more influence the company has on placement or creation of content on a third party site or some other social media, the more likely the company is to be considered accountable for that content, although the lines are difficult to draw.

Posting or Publishing Corrective Information In Social Media

- Real possibility that inaccuracies, negative comments, other misstatements are posted on third party sites and within user-generated content, e.g., blogs, wikis, etc.; in addition, individuals can create accounts or profiles that include company names or product names that come across as being official statements from the company, but are not
- How should a company address these statements or situations, if at all?
- Considerations
 - Are these corrective postings or statements regulated like promotion or something else?
 - Context (audience, who is correcting, content, etc.) is important to assess
 - Does it do more harm than good from a product liability or public affairs perspective?
 - Would there be adequate controls?
 - Who within the Company makes the most sense to address the mis-statements?
 - Public Affairs, Marketing, Medical Affairs?
 - Does it depend on the issue?

Miscellaneous Other Considerations

- Privacy
 - Is the company collecting or receiving any personally identifiable information through its participation in social media?
- Corporate Reputation Issues
 - Employees on their own personal blogs can be associated with the company based on profile, name, etc., and therefore their own activity in social networking could impact their company's reputation
 - Need for guardrails
- How to Address Feature that Allows Any Visitor/User to Comment on Any Website, even when such comments are not solicited, e.g., Google Sidewiki; what's the company responsibility?
- Impact on Litigation: postings subject to litigation hold, potential discovery, use at trial?
- Consider clear written employee guidance or corporate policies

Summary

- Proliferation of use of social media and Internet provides opportunities for pharmaceutical companies to connect with customers, stakeholders, and others in a way that had not previously existed
- However, such use in a regulated environment raises several questions and poses considerable challenges from a regulatory and legal perspective
- The hope is that FDA will issue explicit and clear guidance on these issues; the public hearing is a good first step