



# Laying the Groundwork for Pharmaceutical Companies' Engagement in Social Media

By Mark Gaydos and Craig M. Audet

Digital technology has permeated our culture, with the Internet now a leading source of information of all sorts. People have access to a vast array of online libraries, databases and other resources, and can join online communities involving thousands of other people seeking information on, or wishing to discuss, particular topics. Boundaries and limitations of traditional one-way media have given way to forums that allow open exchange, user contributions and participation in an interactive environment.

This burgeoning field of communications has the potential to facilitate dissemination of reliable and accurate health information in the interest of public health. Indeed, people in the US are increasingly utilizing the Internet to access health information.<sup>1,2</sup> Healthcare professionals, caregivers and patients and other consumers are interacting within online communities where health-related topics are discussed. Unfortunately, this abundance of readily available health information is accompanied by serious concerns regarding its source, quality and credibility.<sup>3</sup>

Engaging in these online communities allows pharmaceutical, biological and medical device manufacturers to interact in real time with healthcare professionals and consumers seeking health and treatment information. As authorities on medical products and the conditions and diseases they treat, medical product manufacturers contribute to, and participate in, these communities to help ensure the accuracy and completeness of the information presented and discussed.

Industry's challenge is how to engage in these new and rapidly evolving media in a manner compliant with applicable US Food and Drug Administration (FDA) regulations, which were written before the Internet's emergence and proliferation, while allowing uncensored dialogue within communities where people expect to freely obtain and share health-related information.

## Current Climate for Social Media in the Pharmaceutical Industry

There is an absence of formal guidance from FDA on engagement in social media by pharmaceutical companies. Due to significant concerns about adverse event (AE) reporting obligations and perceived off-label promotion, the pharmaceutical industry has lagged behind others in participating in this online space. FDA's existing regulations and guidance on direct-to-consumer (DTC) advertising offer some direction since many web-related activities have non-professional consumers as their main audience. However, these regulations and related guidance documents were not written with the Internet in mind, let alone today's social media platforms such as blogs, chat rooms, forums, message boards and social networks (e.g., Facebook, MySpace, Sermo).

Although no formal policy announcements have been made, members of FDA have commented fairly recently on regulatory considerations pertaining to social media. During a 4 March 2008 talk entitled, "Social Media and the Public Health," hosted by public relations firm Manning Selvage & Lee (MS&L), Dr. Paul Seligman, associate director, Safety Policy & Communication at FDA, provided insight into the agency's (possibly no longer current) thinking in this area. Dr. Seligman, expressing his own views and not those of FDA, acknowledged that FDA has no formal position on social media and no clear guidance as to how industry should handle potential AE reports found in social media. He commented that FDA was not acting on blog-reported information in terms of identifying a safety signal. Nor did he believe this type of information should generally be submitted as AE reports. However, he noted that online reports may prompt the agency to search its own database to determine if there is an emerging signal. Dr. Seligman strongly suggested that the pharmaceutical industry work with FDA to develop best practices in this area.

During her presentation at DTC Perspectives' April 2008 National Conference in Washington, DC, Kristin Davis, FDA's deputy director of the Division of Drug Marketing, Advertising, and Communications (DDMAC), responded to a question regarding the applicability of the agency's 1999 *Guidance for Industry: Consumer-Directed Broadcast Advertisements*<sup>4</sup> to video drug ads run on third-party websites during purchased time slots, similar to television ads. Ms. Davis agreed that the major statement used in DTC broadcast ads would likely be appropriate for these types of online ads. While this represented Ms. Davis' own perspective on the subject, and not necessarily that of FDA, it is significant since the major statement is generally a shorter, more concise version of the important safety information included in the majority of drug product promotional materials. Ms. Davis did say, however, that DDMAC would expect consumers to have the ability to access a product's full prescribing information directly from the ad, by means of a hypertext link, for example. This differs from broadcast ads run on TV and radio, where immediate provision of the prescribing information is not feasible.

## Regulatory Pitfalls of Engaging in Social Media

The pharmaceutical industry has been hesitant to participate in social media due to concerns regarding AE reporting obligations and perceived off-label promotion.

## Adverse Events

Companies are justifiably concerned with how AE reports posted on pharmaceutical company-

sponsored or third-party sites should be handled. However, the main question is not how reports should be handled but rather what triggers reporting. FDA has four criteria that must be met for a pharmaceutical company to report an adverse event: an identifiable patient, an identifiable reporter, a specific medication and an adverse experience. A recent analysis of online messages by Nielsen Online suggests that online mentions of potential AEs are rare, with one out of 500 healthcare-related messages meeting all four reporting criteria.<sup>6</sup>

The key here appears to be the difference between the terms “identified” and “identifiable.” While almost no one posting on message boards or blogs is clearly identified by actual name, many of them are nonetheless “identified” by log-in name. Thus, when an AE is reported, it is not clear what will be considered sufficient follow-up for purposes of determining if the source is identifiable. In the court of public opinion where hindsight is 20/20, ignorance will likely be a poor excuse. The bottom line is: What will be considered sufficient follow-up in cases where log-in names may have no relation to an actual name and may be the only available identifier?

### **Off-label Discussions: How far is too far?**

According to 21 CFR 202.1(e)(6)(i), an advertisement for a prescription drug is false, lacking in fair balance or otherwise misleading, or otherwise violative of section 502(n) of the act, among other reasons, if it, “...contains a representation or suggestion, not approved or permitted for use in the labeling...whether or not such a representation or suggestion is made directly or [through] other references.” Based on this, would the mention of an unapproved use, dose, etc. by a visitor to a pharmaceutical company-sponsored community be considered off-label promotion by the company? What about an off-label use comment posted to a third-party community discussion in which a company is participating, assuming the company did not prompt the comment?

### **Regulatory Roadmap for Engaging More Broadly in Social Media**

Content that is sponsored or created by a manufacturer and promotes a specific product or products is required to comply with all applicable regulations pertaining to advertising and promotional labeling. This compliance includes, but is not limited, to the communication of approved indications, presentation of an appropriate balance of benefit and risk information and fulfillment of the adequate provision requirement (prescribing information or brief summary). The authors offer for consideration the following approaches as possible methods of overcoming the regulatory obstacles created

by AE reporting and off-label promotion concerns. Since there is no specific FDA guidance on industry engagement in online social media and the media themselves are evolving rapidly, companies are encouraged to obtain DDMAC’s advisory comments on specific initiatives before they are implemented.

Based on current regulations and available guidance, or the lack thereof, the authors believe it is appropriate for pharmaceutical company-sponsored sites to contain “rules of engagement” or terms of use that must be agreed to by site visitors prior to participation. These rules should address the discussion of AEs and off-label product uses. In addition, we recommend that companies determine in advance how frequently such sites will be monitored, for purposes of gauging compliance with the site’s terms of use, and what action will be taken if they are violated.

The site rules typically provide that users comply with the terms of use. There are various terms of use that a company should consider, such as notifying participants that comments on the site are subject to review and removal if the company deems that they violate the terms of use. In this case, the company should establish a process for removing such posts, notifying individuals who have submitted violative comments and determining when, and for how long, violators will be barred from further participation in discussions on the site (and how this will be enforced from a technical perspective). It is important to inform the community that the company is imposing these restrictions because it is a highly regulated entity.

If the site is not intended for the reporting of adverse events, it is recommended that it be clearly stated that the site is not intended for that purpose and that if visitors, or people they know, have possibly experienced side effects while taking the company’s product(s), they should contact the company (typically its pharmacovigilance department), and may also report side effects to FDA. Appropriate contact information should be provided.

The company should consider when and how it will react in the event a participant posts what might be considered an AE. For example, what attempt will be made to obtain additional information from the reporter to determine if the four criteria for reporting can be met? If direct communication with an individual is not possible, the company could consider posting a general comment advising the visitor that the comment might constitute an AE report and requesting additional information. The comment should provide a hypertext link and/or toll-free telephone number to the company’s pharmacovigilance department.

Regarding off-label discussions, the terms of use could note that the site is intended for discussions of FDA-approved product uses only, and list those approved indications. Posts containing discussions that are inconsistent with

FDA-approved prescribing information may be subject to removal as stated in the terms of use. There should be an internal process established for handling product-related questions, including those pertaining to off-label uses, so that they are directed to appropriate company personnel trained to respond to the types of questions that may be received.

In the event that a participant posts an off-label product use comment on a company site, the company may specify that it will remove the comment and attempt to contact the individual. Alternatively, the company might consider posting a comment to the community that corrects the off-label information and includes a hypertext link to the product's full prescribing information, or that notifies the community that the visitor's comment includes off-label information and includes a hypertext link and/or toll-free telephone number by which the visitor can contact the company's medical information department with any questions. A company may consider whether or not comments should be deleted when a visitor's post is being corrected based upon possible community reaction to perceived "censorship."

### **Regulatory Considerations are not the Only Concerns**

Beyond regulatory considerations, companies will have to answer important questions regarding their commitment to social media:

- Is the company's culture social media-friendly and willing to accept negative comments and criticism?
- How liberal or conservative are the company's compliance standards regarding FDA regulations?
- What is the company's appetite for the unpredictability and uncertainty of an ever-changing social media landscape where performance cannot always be easily measured?<sup>5</sup>
- Is the company prepared to pursue initiatives that put it at the leading edge among its peers?

Once the decision is made to engage in social media, companies should proactively consider how they will engage. For example:

- How will the company handle negative commentary when engaging in open discussions?
- How will new initiatives (i.e., monitoring) be supported?
- The digital space is a platform and recruiting ground for company/industry opponents. How will they be managed?
- Competitors and/or detractors may use social media to spread false information about a company and its products. How will the company counteract this?
- If a company restricts postings (e.g., off-label comments, AEs) it may lead to accusations of censorship and silencing detractors. How will this be addressed?



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## Conclusion

In recognition of the need to comply with existing FDA regulations related to prescription drug advertising and promotion, the authors have outlined potential approaches to enable the pharmaceutical industry's engagement in online social media. Because industry participation has been extremely limited to date, companies are missing opportunities to join meaningful discussions with members of online social networks, which are increasingly a source of health information. We hope this discussion can foster new ways for companies to sponsor and participate in online communities in a compliant yet unrestrictive manner. The recent announcement of an FDA-sponsored public hearing on regulated product promotion using the Internet and social media provides the perfect opportunity to present these and other reasonable approaches to the agency, which is clearly open to suggestions for appropriately applying, or possibly amending, its regulations. It is an opportunity that should not be missed.

## References

1. Manhattan Research. (2009). *ePharma Physician*® v9.0
2. Manhattan Research. (2009). *Cybercitizen Health*® v9.0
3. Kunst H, Groot D, Lathe PM, Lathe M, Khan KS. (2002). "Accuracy of information on apparently credible websites: Survey of five common health topics." *BMJ*, 324, 581-582.
4. Food and Drug Administration. *Guidance for industry: Consumer-directed broadcast advertisements* (August 1999). Accessed 1 October 2009, at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070065.pdf>
5. TNS Media Intelligence/Cymfony. "Connecting with patients, overcoming uncertainty." September 2007. Accessed 18 September 2009, at [www.seyfarth.com/index.cfm/fuseaction/publications.publications\\_detail/object\\_id/1d21aaf1-4ad5-4e22-af28-af3f6ea533e6/ConnectingwithPatientsOvercomingUncertainty.cfm](http://www.seyfarth.com/index.cfm/fuseaction/publications.publications_detail/object_id/1d21aaf1-4ad5-4e22-af28-af3f6ea533e6/ConnectingwithPatientsOvercomingUncertainty.cfm)
6. Nielsen Online. "Listening to consumers in a highly regulated environment: How pharmaceutical manufacturers can leverage consumer-generated media." August 2008.

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