KAYE | SCHOLER

Walking the Social Media Tightrope

Recent advancements in technology pose a host of opportunities for pharmaceutical manufacturers, but also a potential quagmire for regulatory or liability compliance. FDA's recent draft guidelines for companies on responding to requests for off-label information, were updated specifically to address requests made through social media. But the draft guidelines address only one small part of the complex issues surrounding social media, leaving companies to walk a fine line between regulatory compliance and litigation liability.

Pharmaceutical marketing — from a purely legal perspective — used to be simple and the rules relatively straightforward. When marketing to doctors and other healthcare providers, drug companies were bound by the FDA-approved label as to what they could say about the safety and efficacy of their product. Courts applied the "learned intermediary" doctrine, holding that a company's duty to warn was directed to the doctor, not to the ultimate patient.

But then things changed: direct-to-consumer advertising added a new twist to the way consumers viewed pharmaceuticals; new regulations were put in place; and courts began questioning the way the learned intermediary doctrine was applied. Technology advanced beyond television, radio and print. Internet websites introduced banner advertisements. Instant messaging and chat rooms led to commenting on articles, and to Facebook, MySpace, Twitter and other social media sites. As Dan Bryant of Red Dog Communications recognized in *Pharma*, social media and the Internet represent a unique and evolving platform for both communicating important health information to the public, and providing a means for people to discuss and seek out important information about their health, diseases and treatments.[1] Yet, as these advances in technology move into the mainstream, FDA regulations and the law have lagged behind. Companies are now hungry for guidance on critical issues unaddressed by the draft guidance: what obligation does the company have for monitoring third-party sites and correcting information?

> ***"As these advances in technology move into the mainstream, FDA regulations and the law have lagged behind."***

According to Google's presentation to FDA at its November 2009 public hearing, 111 million individuals searched on Google using health-related keywords between October and December 2007. A September 2010 survey by Pew Research Center found that 80% of Internet users — or 59% of US adults — look

About the Author

Lori Leskin is Partner and Co-Chair of the Product Liability group at Kaye Scholer. She is valued by her clients for her ability to successfully assess, strategize and implement unique solutions to their unique problems. Lori handles all aspects of litigation strategy for complex nationwide and multidistrict litigations involving a variety of products, including currently, the representation of Pfizer Inc as national counsel in its Hormone Therapy and Viagra® product liability litigations. Viewed as a leader in her field, Lori regularly authors, organizes, speaks and is referenced on a wide range of product liability litigation topics through numerous mediums. She can be reached at ***lori.leskin@kayescholer.com***

This article originally appeared in March-April 2012 issue of *Pharma.*

online for health information.[2] As consumers and healthcare professionals increasingly turn to online resources for information about prescription drugs, manufacturers have waited — and with increasing urgency, advocated — for a comprehensive framework for the disseminationof information via social media. FDA responded with a 2-day public hearing in November 2009, where it solicited input on a broad range of issues, including adverse event reporting, parameters for the use of hyperlinks, and the ability of manufacturers to post corrective information on discussion forums. Following the hearing, the FDA Center for Drug Evaluation and Research (CDER) indicated that it would publish proposed guidelines. The year came and went without publication, and observers took note when the proposed document was omitted from CDER's 2011 Guidance Agenda. Instead, CDER listed a planned guidance on "Responding to Unsolicited Requests for Prescription Drug and Medical Device Information, Including Those Encountered on the Internet."[3]

> ***"Recent advancements in technology pose a host of opportunities for pharmaceutical manufacturers, but also a potential quagmire for regulatory or liability compliance."***

Even that limited document was ultimately scaled back. Published in the Federal Register on the last business day of 2011, the Draft Guidance has been narrowed to address only unsolicited off-label information requests. Far from a comprehensive guide for dealing with social media, the Draft Guidance discusses social media issues solely within the confines of existing policies regarding off-label communications.

FDA's distinction between 'solicited' and 'unsolicited' requests reflects the reality of the distinction between company-created, sponsored or controlled online content versus third-party created and controlled content. For example, in defining the distinction between 'solicited' and 'unsolicited' requests for information, in addition to traditional means of requesting information, FDA considers a scenario where a firm "asks or otherwise encourages users to post videos about their own uses of its product on third-party video-sharing sites."[4] Information requests triggered by such a posting, according to the draft, would be considered 'solicited' requests. Other activities that could lead to 'solicited' requests about off-label use include:

- Encouraging bloggers to write about off-label uses of a product.
- Announcing results of a study via Twitter "suggest[ing] that an off-label use...is safe and effective."[5]
- Maintaining a website that enables users to peruse a ompany's standard responses concerning off-label uses

These guidelines do not, however, cover any disclosure requirements to the public about the company's control concerning these various activities.

Perhaps most interesting — and least satisfying — is FDA's advice regarding information requests posted to public online forums. Although acknowledging that "it can be in the best interest of public health for a firm to respond to unsolicited requests for [off-label] information...that are made in public forums," such interests appear secondary to FDA's reservations about making off-label information "availableto a broad audience and for an indefinite period of time."[6] Accordingly, the Draft Guidance directs that substantive responses to publicly posted off-label information requests —if the manufacturer should choose to respond at all — should be provided only to the specific individual who requested the information as a private, one-on-one communication. (Emphasis added.) A company may issue a public response on the online forum, but it "should be limited to providing the firm's contact information and should not include any off-label information." (Emphasis in original.) Any public response should also disclose the company's involvement, convey that the question pertains to an unapproved use, and refer to the current FDA labeling. The current guidelines make no distinction among the diverse forums where prescription drug products might be discussed, whether on a site targeted specifically to healthcare professionals or a patient- or consumer-oriented website.

> ***"Far from a comprehensive guide for dealing with social media, the Draft Guidance discusses social media issues solely within the confines of existing policies regarding off-label communications."***

Also unanswered by the Draft Guidance is the need for parameters governing public correction of online misinformation. The Draft Guidance governs responses only to 'requests' or 'questions,' not affirmative statements. A company seeking to correct online statements about off-label uses would appear to be left unguided. Faced with online testimonials pertaining to off-label uses of its product, — for example, a Wikipedia entry that has been edited by others to provide information that is not compliant with existing advertising and labeling rules or public social media comments incorrectly attributing off-label use of a product to the manufacturer — a company would be understandably confused, and rightfully concerned about FDA's reaction (possible regulatory enforcement action) to any public response on the one hand, and a potential increase of liability for failure to warn, and so on, on the other. This leaves manufacturers walking a difficult tightrope without a net. Finally, the draft guidance does not address the question of adverse event reporting. A key issue during FDA's public hearing on social media was the obligation of a company to monitor, report and follow up on adverse events posted on the Internet. It is patently unfair to expect a company to monitor the entire Internet for adverse events.

So What's Next?

It is unclear whether FDA still intends to issue a more comprehensive document on social media, or whether the issues under consideration since 2009 will be addressed slowly by piecemeal. If, however, change is possible, the changes that drug and medical device companies would probably like to see include the following:

Although companies cannot police the whole Internet to ensure that third-party statements are correct — making any requirement to monitor unrealistic and impossible to meet — there needs to be freedom and flexibility in a company's ability, where in its judgment it is appropriate, to correct information posted by others without permission on a site they control (for example, on a Facebook page created by the company), whether there is a formal 'request' for information or not. From a liability perspective, the company may indeed be obligated to make such corrections.

Given the real public health dangers and lack of accountability posed by nonregulated advertisers, bloggers and online content creators who provide information about prescription medications on-line, FDA should encourage manufacturers' legitimate, FDA-regulated contributions to the discussion as a source — sometimes the only source — of reliable information.

FDA's draft guidance attempts to create a single set of rules to govern all promotional activity, regardless of the medium. But there is an obvious need to differentiate Internet and social media from traditional forms of promotion and communication. Unlike traditional print or broadcast advertising, Internet and social media users have a great ability to control, alter and respond to the promotional messages and other product information they receive. Manufacturers' primary concern should be that individuals have access to accurate and responsible information.

FDA should acknowledge the additional difficulty in following up on adverse event reports in the online space. Even if a potential adverse event is identified, given the anonymity prevalent on the Internet, and even if the four required elements for reporting are present, there will likely be no reliable means to follow up to obtain additional information — or even to determine the veracity of the posting.

---

[1] D. Bryant, "Pharma Adverse to Social Media?" *Pharma* **7**(6), 6 (2011).

[2] www.pewinternet.org/Commentary/2011/November/Pew-Internet-Health.aspx

[3] www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf

[4] Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices — Draft Guidance (December 2011).

[5] Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices — Draft Guidance (December 2011).

[6] Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices — Draft Guidance (December 2011).