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Bylined Article

Social Media and the In-House Counsel

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Social media plays an increasingly significant role in the US healthcare system. According to a recent poll, the average American spends more than 52 hours per year on the Internet looking for health information, but only visits the doctor three times per year. While 53% of users rely on the health information hub WebMD, others rely on more general social media sites like YouTube (12%) and Facebook (10%). Only 9% of Internet users rely on pharmaceutical companies' sites for information.

In light of the growing influence of social media, pharmaceutical companies may be considering their options when it comes to such interactions. But for these organizations, entering the social media scene is not as simple as just creating a Facebook page or learning how to tweet in 140 characters or less. Rather, social media poses a regulatory and litigation maze that must be carefully navigated. Here, we provide some insight into the most pressing questions companies are, or should be, asking about social media.

1. Should my company increase its social media presence?
Most pharmaceutical companies have only a limited presence on social media sites. In fact, according to a study released by the IMS Institute for Healthcare Informatics, "among the 50 largest [pharmaceutical] companies, half still do not use social media to engage consumers or patients." And "only 10 of the top drugmakers have availed themselves of all three of the most widely used social media channels—Twitter, Facebook, and YouTube." Some companies have Facebook pages but include no product information on them, and many explicitly inform visitors to their Facebook pages that any comments mentioning products may be deleted.

Yet, pharmaceutical companies are the logical source for the most current information about a particular product. The lack of clear regulatory guidelines may be part of the reason companies have been reticent to broaden social media interactions with patients.

Companies may want to increase their social media presence for many reasons beyond marketing, not the least of which is to provide the public with clear, unified information on the company and its products. In the absence of information directly from the company on an official or authorized social media page, companies may be able to do little to counteract potential misinformation arising out of the growing amount of anecdotal information available through mainstream social media sites. This could give rise to reputational harm that companies can do little to address after the fact.

2. Does my company's Facebook and other social media presence provide fair balance?

Recent FDA activity, including the agency's letters to Institut Biochimique (IBSA) and Akrimax Pharmaceuticals and to Amarc Enterprises teach us that the FDA is indeed watching what pharmaceutical companies post on social media sites and is continuing to enforce existing advertising guidelines, including fair balance. Companies have struggled with finding ways to meet those requirements on these new platforms, and FDA has provided only limited regulatory guidance thus far. While it is still very unclear what makes for best practices in this space, once can safely assume that until there is new guidance, companies will need to provide the same fair balance information about potential risks and side effects in every posting as they would in any other marketing context.

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FDA has not yet provided any indication that the fundamental fair balance rules will change as social media changes. However, guidelines are expected this year to provide guidance on "Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices" on social media platforms "with Character Space Limitations."

3. What is out there on the Internet about off-label use of my company's products, and what should I do about it?

Despite a US Court of Appeals' ruling in the case of *United States v. Caronia* in 2012, which overturned the conviction of a sales representative for promoting off-label uses for an FDA-approved drug, there does not appear to have been a sea change in the way companies defend claims of misbranding and off-label promotion. Nor does the government appear to be backing off enforcement efforts. Indeed, FDA publicly announced that the decision would not change its enforcement in this area.

FDA's recent draft guidance on "Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices" continues to limit a company's ability to provide

truthful information about its product beyond the four corners of the approved label. In its first foray into social media guidance, the FDA significantly inhibits the use of these opportunities to provide information to patients.

The document limits actions a company may take in responding to "requests" for off-label information about its products, including requiring any response be made only privately to the requesting person, yet provides no guidance as to what a company should do about third-party postings on various social media and interactive sites about unapproved uses of its products but which do not specifically ask for information.

4. Do I need to correct incorrect information posted about my company's products?

Current FDA guidelines do not address what obligation a company has to monitor public statements about its products and provide corrections to misinformation. The number of interactive consumer sites—from Facebook to WebMD to comments on news articles to blogs—provides a nearly infinite range of possibilities for unrelated—and unregulated—third parties to post information about a given product on the Internet. However, all guidance to date has focused on sites or postings under the "control" of a particular company, and has not imposed any obligation for manufacturers to search the entire web.

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Such a limited obligation is consistent with the March 2001 draft guidance on adverse-event reporting, that provides that a company must "review any Internet sites sponsored by them" for potential adverse-event reports, but are not required to review "any Internet site it does not sponsor." Companies have been hesitant to correct or respond to these comments for fear of being viewed as having "control" over the third-party website for both FDA and liability purposes. The agency has stated that the development of guidelines for social media "are among [its] highest priorities" and has indicated its intent to provide draft guidance on "Correcting Independent-Third Party Misinformation About Prescription Drugs and Medical Devices" this year.

5. How does social media impact my company's product liability risk?

Under traditional product liability law, a manufacturer is required to provide warnings about known and knowable risks associated with the use of its products. In the case of pharmaceutical products, most states interpret that obligation as one to provide adequate information about the safe use of the product to a patient's treating physician because the doctor "is a learned intermediary between the purchaser and the manufacturer" who is in the best "position to understand the significance of the risks involved and to assess the relative advantages and

disadvantages" of a particular medication. But in the age of social media, it is reasonable to ask how the increased availability of information directly by patients will affect the application of the learned intermediary doctrine.

Thus far, few states have created exceptions to the learned intermediary doctrine despite the existence of more traditional direct-to-consumer advertising. Only West Virginia has done away with the doctrine completely, and New Jersey and perhaps Texas have limited their availability in the face of consumer advertising. How will increased availability of information—and increased use of that information by patients—change courts going forward?

The second important question to be addressed is how much of the vast information available on the Internet is chargeable to a company? Product liability law requires a company to warn about known and knowable risks, and generally holds a manufacturer to the skill and knowledge of an expert in the field. Pharmaceutical manufacturers are expected to keep abreast of scientific discoveries and advances affecting their products. Manufacturers cannot avoid liability because they chose not to review relevant scientific literature and, as a result, did not provide warnings about potential harm. But manufacturers are "*not* under a duty to warn of every report of a possible risk, no matter how speculative, conjectural, or tentative."

So, how does publication anywhere on the Internet affect a company's state of knowledge under this requirement? In other words, is a posting of a an event something a company "knew or should have known" to put it on notice? The answer is probably not.

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Lori Leskin serves as Co-Leader of Kaye Scholer's Product Liability Litigation Practice and Leader of its Food, Beverage & Supplements team, and recently completed a term as Co-Head of the Products Liability Committee of the American Bar Association's Section of Litigation. She handles all aspects of litigation strategy for complex nationwide and multidistrict litigations involving a variety of products.

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