March 11, 2014

Draft FDA Guidance on Real-Time Promotional Statements Made Via Social Media

In January 2014, the US Food and Drug Administration (FDA) gave the pharmaceutical industry another glimpse of its thinking on social media marketing. The agency's draft guidance, titled "Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics," sheds some light on circumstances where a manufacturer of a prescription drug or biologic should submit to the FDA content generated through "interactive promotional media." Despite this small peek behind the curtain, numerous questions and issues remain unaddressed for companies regulated by the FDA. This advisory provides a brief overview of the current landscape.

What the FDA Considers to Be "Interactive Promotional Media"

In what is likely an effort to stay relevant in the exceptionally dynamic field of social media, the FDA does not employ the term "social media," but instead describes tools such as Twitter and Facebook as "interactive promotional media." The draft guidance states broadly that this term encompasses "modern tools and technologies that often allow for real-time communications and interactions (e.g., blogs, microblogs, social networking sites, online communities and live podcasts) that firms use to promote their drugs." While Facebook, Instagram, Twitter and Wikipedia certainly fall within this definition, the definition is broad enough to provide room for future innovation in online marketing platforms.

What "Interactive Promotional Media" Should Be Submitted to the FDA

One key concern for pharmaceutical companies is the degree to which they are responsible for content generated and posted outside of their own websites, Facebook pages, Twitter feeds, blogs or other social media. In its draft guidance, the FDA outlines three broad categories of interactive promotional media where pharmaceutical companies are responsible for content and accordingly should file submissions with the FDA.

First, and most obviously, a pharmaceutical company is responsible for submitting its own interactive promotional media. This encompasses responsibility for "product promotional communications on sites that are owned, *controlled*, *created*, *influenced*, or operated by, or *on behalf of*, the firm [emphasis added]." Accordingly, this category is broader than the company's own website and any sponsored blogs. A company's Facebook page, Twitter feed, Pinterest board and other social media accounts fall within this category because they are "influenced" or "operated" "on behalf of" the company.

Second, under certain circumstances, a manufacturer is responsible for the content on third-party sites. There is some commonality between this category and the first—the touchstone is the influence of the company. While the draft guidance provides that even limited influence is enough, it must be more than mere financial support. Rather, where a company

For more information, or if you have any questions, please contact your Katten Muchin Rosenman LLP attorney or any of the following members of Katten's **Intellectual Property Practice**.

Brian J. Winterfeldt
+1.202.625.3562
brian.winterfeldt@kattenlaw.com

Elese E. Hanson
+1.312.902.5390
elese.hanson@kattenlaw.com

Phillip V. Marano
+1.202.625.3583
phillip.marano@kattenlaw.com

"collaborates, or has editorial, preview, or review privilege, then it is responsible for its promotion on the site and, as such, that site is subject to submission to the FDA to meet postmarketing submission requirements."

Third, a pharmaceutical company is responsible for content created by an employee or agent acting on its behalf to promote its product. For example, a company is responsible for submitting content generated by a "medical science liaison or paid speaker (e.g., a key opinion leader) acting on the firm's behalf," including those comments made on a third-party site. "Astroturfing"—the practice of making sponsored endorsements via social media appear as genuine grassroots sentiments—is one obvious example where speakers are acting on behalf of a company. In any event, Federal Trade Commission guidelines governing endorsements in advertising already require disclosure of any such material connections shared with the company. With user-generated content, the FDA draft guidance highlights the importance of transparency in that companies should disclose any "involvement on a site by clearly identifying the [user-generated content] and communications of its employees or third parties acting on behalf of the firm."

How and When "Interactive Promotional Media" Should Be Submitted to the FDA

The FDA draft guidance addresses two other key issues, namely timing and practicality. Current FDA regulations mandate that pharmaceutical companies submit promotional labeling and advertising at the time of its initial display. This presents a significant practical hurdle when it is applied to social media, which can change in real time, literally by the second. Accordingly, the FDA attempts to provide recommendations as to how companies should comply with promotional statement submission requirements.

Specifically, the FDA draft guidance provides differing recommendations based on the type of social media platform. It differentiates between open and restricted access websites, as well as websites that contain static versus real-time components. Companies should continue to submit their own static websites at the time of initial display and upon amendment, including annotations to describe any real-time components. The FDA does not intend to object to mere updated listings—absent screenshots or the like—where such websites are publicly accessible and the only changes reflect real-time interaction. In addition, companies interacting on third-party social media websites should submit the home page and the first communication posted by the company at the time of initial display. Once per month, a company should also submit to the FDA an updated list covering all open access websites on which the company remains an active participant. Finally, companies should submit all related content—whether user generated or otherwise—to facilitate FDA review regarding websites with restricted access.

What Key Issues Remain Unanswered?

While the FDA draft guidance provides some insight into the agency's thinking on the disclosure of social media marketing, several key issues remain unresolved. For example, the draft guidance does not address adverse event reporting or circumstances when a pharmaceutical company is required to correct off-label promotion posted by third parties. In and of itself, the key inquiry—whether a company has "influence" over a site or a user—is not well defined outside of a few discrete examples. Finally, while the FDA draft guidance was prepared by the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Veterinary Medicine, it may be adopted by the centers within the agency, therefore applying to a broader spectrum of products.

The deadline for comments on the draft guidance is April 14, 2014. Attorneys in Katten's Internet practice and Pharmaceutical and Life Sciences Litigation practice have extensive experience in counseling clients with regard to social media and regulation of promotional statements by the FDA. If you would like to discuss the FDA draft guidance, or would like assistance in drafting a public comment, please contact Brian Winterfeldt at **brian.winterfeldt@kattenlaw.com**.