FDA Issues Draft Guidance Relating to Social Media Promotion by Drug and Biologics Manufacturers

On January 13, 2014, the Food and Drug Administration ("FDA") issued a draft guidance document outlining the circumstances under which a manufacturer of a prescription drug or biological product may be accountable for content conveyed through "interactive promotional media." The draft guidance also describes how manufacturers can fulfill regulatory requirements for postmarketing submissions of such promotional content to FDA (*e.g.*, on Form 2253). The draft guidance is limited in scope and represents only a small piece of the social media guidance that the Agency has been promising for years, leaving key industry questions unanswered.

Regulation of "Interactive Promotional Media"

The draft guidance defines "interactive promotional media" as "modern tools and technologies that often allow for real-time communications and interactions (*e.g.*, blogs,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." In the draft guidance, FDA explains that in determining whether a manufacturer is responsible for content on interactive promotional media, it will consider whether the company or anyone acting on its behalf is influencing the communication in whole or in part. If a manufacturer is ultimately responsible for the promotional content, it will be required to submit the content to FDA in connection with the postmarketing reporting requirements.

Because manufacturers may exercise control or influence over interactive promotional media in a variety of ways, the draft guidance addresses the responsibilities that may attach to each:

Responsibility for Promotional Content on Sites Owned or Influenced by the Manufacturer. The draft guidance provides that a manufacturer "is responsible for product promotional communications on sites that are owned, controlled, created, influenced, or operated by, or on behalf of, the firm." Included in this category are not only company-sponsored websites, blogs, and the like, but also pages created, maintained, or otherwise influenced by the company on other interactive platforms (*e.g.*, Facebook pages or Twitter feeds).

Responsibility for Promotional Content on Third-Party Sites. The draft guidance provides that a manufacturer is responsible for product promotion on a third-party site over which it has control or influence, even if that influence is limited in scope. For example, the Agency states that editorial or review privileges associated with a third-party site would be sufficient to result in manufacturer responsibility, as would the manufacturer's right to direct where its promotional content was placed on the site. The provision of financial support alone (*e.g.*, through an unrestricted educational grant), however, would be insufficient to trigger an obligation to submit promotional content on the site to FDA.

Responsibility for User-Generated Content ("UGC"). The draft guidance notes that if UGC (*e.g.*, a Tweet, a blog post) is created by an employee or agent acting on behalf of the manufacturer—such as a sales representative or key opinion leader consulting for the company—the manufacturer is responsible for that content. For transparency purposes, the draft guidance recommends that manufacturers clearly disclose their involvement on a site and identify whether any UGC has been generated by an employee or agent acting on the manufacturer's behalf. The draft guidance also states that a manufacturer is not responsible for UGC that it cannot control; more specifically, UGC will be considered "truly independent" of the manufacturer unless it is produced or prompted by the manufacturer in any way.

Recommendations for Postmarketing Submissions

FDA regulations require that manufacturers submit promotional labeling and advertising pieces at the time of first use. Due to the real-time nature of interactive promotional media and the potentially high volume of posts, however, FDA recognizes that compliance with the postmarketing submission requirements may present a challenge to manufacturers. As a result, the draft guidance offers recommendations for compliance that vary according to the type of interactive promotional media site on which the promotional content is housed and the entity responsible for the site. For example, the draft guidance provides recommendations for open-access versus restricted-access (*i.e.*, password-protected) sites, sites that contain interactive or real-time components versus those that are static, and sites for which manufacturers have responsibility versus those that are controlled by third parties. Importantly, rather than expecting manufacturers to file postmarketing submissions each time the manufacturer posts on an open-access site (*e.g.*, on a public Twitter feed), the draft guidance permits companies to update the Agency with relevant URLs on a monthly basis. For open-access sites, the monthly submission does not need to include screenshots or representations of interactive or real-time communications. For restricted-access sites, the draft guidance recommends that the monthly submission include "all content related to the discussion," including "all UGC about the topic," regardless of whether the UGC is independent or not.

Implications for FDA Regulation of Interactive Promotional Media Generally

The draft guidance represents FDA's continuing effort to grapple with the complex issues presented by interactive promotional media. While the draft guidance rightfully recognizes that manufacturers are not responsible for interactive promotional media that they do not control, more elaboration is required to determine what manufacturer practices may be viewed by FDA as "prompting" or "influencing" UGC or other third-party content. For example, if a manufacturer posts a promotional statement on its Facebook page about an approved use for one of its products, and other users reply to that post by stating that the product is also beneficial for an unapproved use, the draft guidance does not clearly foreclose FDA from taking the view that the manufacturer's initial post "prompted" the off-label UGC. Likewise, because many of the recommendations in the draft guidance apply broadly to interactive promotional media, platform-specific examples would be helpful in interpreting the Agency's expectations.

Additionally, the draft guidance document does not address many other significant issues surrounding interactive promotional media. In particular, the draft guidance does not cover (1) how manufacturers should fulfill regulatory obligations related to adverse events encountered through social media; (2) how to satisfy fair balance and other regulatory requirements on space-limited platforms; and (3) when manufacturers should correct false, misleading, or off-label information posted on social media by third parties. FDA is expected to address these issues and others through separate guidance documents later this year.

FDA will be accepting comments on the draft guidance until April 14, 2014. If you would like to discuss the foregoing or any related matter, please contact any member of Ropes & Gray's FDA regulatory practice or your usual Ropes & Gray advisor.