Pharmaceutical Promotion and Social Media: FDA Issues A Trial Prescription

While not the panacea for which the pharmaceutical industry has been clamoring for years, on January 13, 2014, the Food and Drug Administration ("FDA") issued a much-anticipated draft guidance document outlining various legal requirements (and recommendations) surrounding the promotion of FDA-approved products communicated through social media.

In particular, the document, entitled "*Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics*," details the circumstances under which a drug manufacturer, packer or distributor ("firm") may be responsible for content submitted on interactive promotional media, and provides recommendations regarding how firms may satisfy postmarketing submission requirements in light of the real-time information flow characteristic of social media platforms.

Background

The Federal Food, Drug, and Cosmetic Act and implementing regulations mandate that all advertisements and promotional labeling for a prescription drug product be submitted to the FDA at the time of their initial publication or dissemination. As traditionally understood, this meant that every promotional piece—be it a print advertisement, TV commercial, or product web page—is required to be submitted by the firm to the FDA at the time of initial display (*e.g.*, when the TV ad first airs).

However, in the context of social media and other forms of "interactive promotional media"—defined in the draft guidance to include blogs, microblogs, social networking sites, online communities, and live podcasts—submission "at the time of initial dissemination" poses unique difficulties for firms, particularly when these media communicate information that is displayed in real time. Indeed, just imagine if a firm were required to submit for FDA review a copy of each promotional tweet it sends out!

The FDA's draft guidance is meant to address these challenges in an effort to help pharmaceutical companies navigate the social media space more confidently, and with less legal and regulatory uncertainty.

Regulation of "Interactive Promotional Media"

In determining whether a firm is responsible for content on interactive promotional media, the FDA states it will consider whether the firm or

anyone acting on its behalf is influencing or controlling the communication, either in whole or in part.

In particular, the draft guidance specifies that a firm is accountable for promotional activities in the following circumstances:

Promotional Content on Sites Owned, Controlled, Created, Influenced or Operated by, or on Behalf of the Firm. 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." This category includes not only company-sponsored websites, blogs, discussion boards, chat rooms, and the like, but also pages created, maintained, or otherwise influenced by the company on other interactive platforms, such as a company's Facebook page.

Promotional Content on Third-Party Sites. The draft guidance provides that a firm is responsible for product promotion on a third-party site if it has any control or influence on the third-party site, *even if that influence is limited in scope.* For example, collaboration on, or editorial, preview or review privileges associated with content on a third-party site—such as influencing the placement of the firm's promotional message—would be sufficient to trigger postmarketing submission requirements. However, if a firm only provides financial support (*e.g.*, through an unrestricted educational grant), with no additional control or influence over the third-party site, then the firm would not be responsible for the site's content.

Promotional Content Created by An Agent or Employee of the Firm. The draft guidance notes that the "FDA's regulation of prescription drug product promotion extends both to promotional activities carried out by the firm itself, and to promotion conducted on the firm's behalf." For example, firms have responsibility for the content of the social media posts created by an employee or agent acting on the firm's behalf—such as bloggers, sales representative or paid professional speakers—, and are subject to the FDA's postmarketing submission requirements in these circumstances.

Representing perhaps the most notable (and welcome) statement of the FDA's "current thinking" regarding social media, as it relates to user-generated content ("UGC"), including "comments," "shares," and "likes," that is posted on the firm's own Facebook page, blog, or forum, the draft guidance clarifies that a firm is "generally" NOT responsible for such content "that is truly independent of the firm (*i.e.*, is not produced by, or on behalf of, or prompted by the firm in any particular)." Further, the "FDA will not ordinarily view UGC on firm-owned or firm-controlled venues such as blogs, message boards, and chat rooms as promotional content on behalf of the firm as long as the user

has no affiliation with the firm and the firm had no influence on the UGC." To that end, the FDA recommends that a firm be transparent in disclosing its involvement on a site by clearly identifying any communications of its employees or third parties acting on behalf of the firm.

Recommendations for Postmarketing Submissions

The draft guidance also provides detailed recommendations on how firms can fulfill regulatory requirements for postmarketing submissions relating to branded, promotional content on social media. Recommendations of special note include:

1. *For all sites for which it is responsible*, a firm should submit in its entirety all such sites on Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) or Form FDA 2301 (Transmittal of Periodic Reports and Promotional Material for New Animal Drugs) at the time of initial dissemination, including the static product website with the addition of interactive or real-time components (*e.g.*, comments sections, live chat, *etc*.).

2. *For third-party sites on which a firm's participation is limited to interactive or real-time communications*, a firm should provide the home page of the third-party site, along with the interactive page within the third-party site and the firm's first communication on Form FDA 2253 (or 2301, as applicable) at the time of initial display.

3. *For restricted (i.e., password-protected or subscription-based) sites*, once every month firms should submit on Form FDA 2253 (or 2301, as applicable) all content related to the discussions, including all UGC about the topic regardless of whether the UGC is independent or not, together with screenshots or other visual representations of the actual site, including the interactive or real time communications. Formatting factors (such as appearance, layout, and visual impression) should also be taken into consideration when submitting communications to the FDA to enable the FDA to view the communications as a whole.

4. *For non-restricted sites* for which it is responsible or in which it remains an active participant and that include interactive or real-time communications, firms should submit a completed Form FDA 2253 (or 2301, as applicable) once every month, together with an updated listing of all

such sites, which includes the site name, URL, and date range, as well as a cross-reference to the date of the most recent site submission. Screen shots or other visual representations of the interactive or real-time communications are NOT required for publicly accessible sites.

Looking Ahead

The draft guidance represents only a small (albeit, significant) step forward towards achieving a more comprehensive statement of the social media regulatory guidelines the FDA has been promising pharmaceutical companies for years.

While the draft guidance may help allay some concerns of pharmaceutical companies leery of engaging in social media, many questions (and therefore uncertainties) remain, including issues arising out of character space limitations (as it relates to risk-related and warning information), adverse event reporting, and the obligation, if any, to correct false, misleading, or off-label information about a firm's product posted on third-party websites.

Fortunately, the FDA is expected to release additional guidance documents addressing these and other related issues in the upcoming months.

In the meantime, the FDA will be accepting comments on the draft guidance until April 14, 2014. Industry stakeholders should be sure to weigh in and join the conversation.

A copy of the draft guidance can be found here.

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