FDA Issues Draft Guidance Addressing Aspect of Social Media Use in Prescription Drug Product Promotion

On January 13, 2014, the Food and Drug Administration's Office of Prescription Drug Promotion (OPDP) issued Draft Guidance on "Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics." Despite its title and ostensible focus on postmarketing submissions, the guidance also sheds light on other critical issues – including the extent of a pharmaceutical manufacturer's responsibility for content on third-party websites and user generated content on a company's own website – that help open the door to greater use of interactive social media by pharmaceutical companies.

With just six months left until its deadline under the Food and Drug Administration Safety and Innovation Act (FDASIA) to issue guidance describing FDA policy regarding internet promotion of medical products, FDA issued what is hopefully the first of several much-anticipated guidance documents on the topic.

Postmarketing Submission Relief

In recognition of the challenge companies would face in submitting promotional materials displaying real-time information "at the time of initial dissemination," the draft guidance creates an exception to this general rule for "interactive promotional media." Interactive promotional media, as defined by FDA, includes "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)." For such media, the draft guidance provides a two-step submission process: (1) at the time of initial display of the interactive component, the company should make a submission on Form 2253; (2) thereafter, the company should submit an updated listing on Form 2253 once a month. Changes to static components of the promotional media still require an updated Form 2253 contemporaneous with initial dissemination.

Extent of Responsibility for Communications on Third-Party Websites

In addition to providing a potential path for the use of more dynamic online promotional venues by relaxing the submission requirements for interactive promotional media, the new draft guidance also recognizes distinctions among various forms of interactive promotional media and the extent to which a company is responsible. The draft guidance places responsibility on a company for (1) product promotional communications on sites that are owned, controlled, created, influenced or operated by or on behalf of the company; (2) content generated by an employee or agent (such as a paid speaker) who is acting on behalf of the company to promote the company's product regardless of where it is posted; and (3) promotion on a third-party site if the company has any control or influence on that site, including determining the placement of its promotional message or review privileges of materials posted on the site. In contrast, if a company has no control or influence over a site (even if the company provides financial support, such as through an unrestricted educational grant), the company is not responsible for information on the third-party site. A company's level of involvement and ownership of a site or

comments made on a third-party site determine what must be submitted to FDA: the entire website, only the comments made by the company or its representative, or the promotional messages plus surrounding pages for context.

Responsibility for User Generated Content

The draft guidance addresses a third issue that pharmaceutical manufacturers have wrestled with: how to maintain a presence on social media venues that include opportunities for user generated content, such as "likes," "favorites," "sharing" and "comments." Notably, the draft guidance establishes that a manufacturer is generally not responsible for user generated content (UGC) that is truly independent from the manufacturer. Content is considered independent if it is not "produced by, or on behalf of, or prompted by" the manufacturer. Notably, the draft guidance provides that FDA will not ordinarily consider UGC on company-owned or controlled venues to be promotional content on behalf of the company provided there is no affiliation with the company and the company had no influence on the UGC. To that end, the draft guidance recommends that companies be transparent about identifying UGC of its employees and others acting on behalf of the company.

Conclusion

In contrast to prior pronouncements from FDA about social media, the draft guidance reflects a greater recognition by FDA of the unique aspects of social media that necessitate modifications to the traditional rules. This is hopefully the first of several steps in this direction. Although the draft guidance should provide a level of comfort to pharmaceutical manufacturers wanting to engage in promotion involving user generated content, this guidance does not address all of the unique aspects of social media (e.g., use of venues with space limitations). It also leaves room for interpretation. For example, when will social media use by a key opinion leader who also serves as a consultant be deemed to be on behalf of the company? Or when will a company's posts be found to have "prompted" or had influence on another party's UGC so as to impute liability back to the company? It remains to be seen to what extent these outstanding issues will be addressed in future guidance documents versus through regulatory actions, such as warning and untitled letters, against companies who wade into the still relatively uncharted waters of interactive promotional media for prescription drugs.

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