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Client Alert Commentary

Latham & Watkins Healthcare & Life Sciences Practice February 13, 2014 | Number 1649

A Look at the FDA's New Social Media Guidance

Draft guidance provides the medical industry with long-awaited boundaries for marketing in the electronic age.

On January 13, 2014, the Food and Drug Administration (FDA) released a draft guidance document providing industry with long-awaited insight into how the Agency views drug and biologic manufacturer regulatory obligations for social media marketing. The draft guidance defines interactive promotional media as "modern tools and technologies that often allow for real-time communications and interactions (*e.g.*, blogs,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."[1] Arguing that such forums do not fit neatly into the FDA regulatory framework for drug product promotion, industry has long sought guidance from the Agency as to how to comply with the law when taking advantage of new electronic promotional tools.

In the new draft guidance, FDA acknowledges the existing lack of clarity, and addresses one aspect of such compliance: postmarketing submission requirements. Specifically, the draft guidance outlines FDA's approach for how firms can fulfill their postmarketing submission obligations in a practical manner, taking into account the potential volume of real-time information that is continually posted and shared through interactive media platforms. More importantly, the draft guidance also provides insight into the considerations FDA takes into account when determining whether a firm is responsible for product communications facilitated by interactive technologies, including user-generated content. In this regard, although the draft guidance is directed toward drug and biologic compliance issues, it should be useful for medical device companies and other FDA-regulated industries as well.

FDA's Past Actions in the Social Media Space

The Federal Food, Drug, and Cosmetic Act (FDCA) defines labeling as "all labels and other written, printed, or graphic matter" that is "upon any article or any of its containers or wrappers," or "accompanying such article."[2] As discussed in the guidance, the language "accompanying such article" has been interpreted broadly by FDA and the courts to include materials that supplement or explain a regulated product, even if no physical or temporal attachment to the product is present.[3] As a result, FDA generally recognizes two types of labeling: FDA-required product labeling, such as package inserts and medication guides, and promotional labeling, which is pretty much everything else.[4] This dual system, however, does not provide specific guidelines for a firm's promotional activities in the social media space, where consumer interaction can cloud the line between firm-generated and user-generated content.

FDA has held public meetings in the past to discuss the promotion of FDA-regulated medical products using the Internet and social media, and at meetings in both 1996 and 2009, the Agency indicated that it would provide specific guidance on the topic.[5] However, instead of issuing the promised guidance, FDA continued to enforce its labeling regime in the social media space, building precedent through its compliance actions. For example, FDA issued warning letters on the basis of firms' Facebook and Twitter

activities and cited them for issues from failure to communicate required risk information to off-label promotion, and in some cases, failure to submit promotional materials to FDA prior to initial publication pursuant to the Agency's postmarketing submission requirements. Throughout this time, FDA seemed to be clarifying that the Agency's advertising and promotion rules applied regardless of the medium.

In 2011, FDA issued a draft guidance document which touched on social media, though only in the limited context of how firms should respond to unsolicited requests for off-label information.[6] The 2011 draft guidance, which has never been finalized, states that if a firm responds to public unsolicited requests for off-label information — including those encountered through emerging electronic media — in the manner described in the guidance, the Agency will exempt such responses from its risk disclosure requirements for promotional labeling and advertising. However, according to the draft guidance, the requests must be unsolicited (*e.g.*, a consumer posting a question about an off-label use on a firm-controlled website or social media page), and firms may only respond through private, one-on-one communications discussing approved or cleared product uses. The draft guidance appears to assume that all such manufacturer discussions of regulated products based on social media interactions are considered promotional labeling and advertising, though the draft guidance provides no further guidance on firms' additional regulatory obligations in this regard.

Recognizing the continued uncertainty, in July 2012, Congress enacted a provision in the Food and Drug Administration Safety and Innovation Act intended to force FDA into action. The provision specifically requires the Agency to issue guidance on its policy toward Internet and social media promotion no later than July 9, 2014.[7] Since enactment of the statute, however, FDA has issued more warning letters on social media promotion but continued to withhold guidance, until now.

Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media

Under FDA's regulations, firms marketing approved drugs and biologics must submit postmarket reports to FDA, including advertisements and promotional labeling. Specifically, firms are instructed to submit specimens of mailing pieces and any other labeling or advertising devised for promotion of a product, and must do so at the time of initial dissemination or publication.[8] In the new draft guidance, FDA acknowledges the challenges of complying with this requirement as it pertains to promotional materials displaying real-time communications, and the Agency describes its intent to exercise enforcement discretion in certain circumstances. However, in a bigger move, FDA outlines the factors it considers in determining a firm's responsibility for submitting interactive promotional media in the first place, and in doing so, provides insight into how the Agency views social media content as fitting within its broader regulatory framework.

Taking the latter issues first, FDA outlines three basic principles for determining a firm's responsibility for submitting interactive promotional media as required by FDA's postmarketing submission requirements:

1. A firm is responsible for product promotional communications on sites that are owned, controlled, created, influenced, or operated by, or on behalf of, the firm.

A firm is responsible for a site if it, or anyone acting on its behalf, is influencing or controlling the site in whole or in part. This principle applies if the firm exerts influence over a site in any particular, even if the influence is limited in scope, such as editorial or review privileges. For example, if a firm provides an online forum on its website giving users the opportunity to post comments about the use of its product, the firm is responsible for submitting the forum content to FDA. (But see below regarding user-generated content.)

2. Under certain circumstances, a firm is responsible for promotion on third-party sites.

A firm is responsible for promotion on a third-party site if the firm has any control or influence over the third-party site, even if the influence is limited in scope, such as content collaboration or editorial or review privileges. If a firm is merely providing promotional materials to a third-party site but does not direct its placement and has no other control or influence over the site, the firm is only responsible for the specific content it submits. For example, if a firm posts content on a third-party site but has no other control or influence over the site, the firm is only responsible for the firm-generated content posted to the site. However, if the firm has the ability to determine the placement of its content or contribute any other details, the firm is responsible for submitting both the firm-generated content and the surrounding pages of the site that provide the context of the promotional message. In addition, if a firm provides only financial support and has no other control or influence over a site, the firm is not responsible for the site at all.

3. A firm is responsible for the content generated by an employee or agent who is acting on behalf of the firm to promote the firm's product.

The above two principles apply even if the promotion is not carried out directly by the firm but by someone else on the firm's behalf. For example, if a sales representative acting on behalf of a firm posts comments about the firm's product on an independent third-party site, the firm is responsible for that content. Similarly, if a blogger paid by a firm maintains a blog about the firm's product, the firm is responsible for the blog. However, a firm is generally not responsible for user-generated content that is truly independent of the firm, *i.e.*, is not produced on behalf of nor prompted by the firm in any way. This key takeaway of the draft guidance appears to ensure that FDA will not hold a firm responsible for user-generated content even if the firm owns or controls the electronic venue (*e.g.*, firm websites, blogs, message boards, chat rooms), so long as the user has no affiliation with the firm and the firm had no influence on the content.

On the basis of these three principles, FDA outlines its enforcement discretion approach, providing the framework for postmarketing submission compliance with respect to interactive media. In doing so, the Agency distinguishes between restricted and unrestricted sites, where a restricted site is one that is not publicly available or is password-protected such that FDA may not have access to the site or the specific communications at issue.

- With respect to **public/unrestricted sites for which a firm is responsible**, a firm should submit the site in its entirety upon initial display, including visuals of the comprehensive static website and a description of the interactive parts that allow for real-time communications. Subsequently, the firm should submit an updated listing of all such unrestricted sites for which the firm is responsible on a monthly basis. Firms need not submit visuals of the actual communications in these monthly updates.

- With respect to **public/unrestricted third-party sites on which a firm's participation is limited to interactive or real-time communications**, a firm should submit the home page, the interactive page(s), and the firm's first communication upon initial display, including visuals. Subsequently, the firm should submit an updated listing of all such unrestricted sites in which the firm remains an active participant on a monthly basis. Firms need not submit visuals of the actual communications in these monthly updates either, though firms should submit a notification to FDA on the first day the firm ceases to be active on a site.

- With respect to **non-public/restricted sites**, a firm should make the same initial submissions described in the two scenarios above; however, subsequently, the firm should submit visuals of all content related to the product discussion, including all user-generated content. Monthly updates are not permitted, and FDA will not exercise its enforcement discretion for non-public/restricted sites in this regard.

Next Steps and Industry Response

FDA has requested that comments and suggestions regarding the new draft guidance be submitted by April 14, 2014 to ensure the Agency considers them before beginning work on the final guidance.[9] Industry's reaction thus far has been mixed, and the number of comments are expected to be substantial.

On one hand, many industry players are applauding the draft guidance's language that appears to protect a company from regulatory exposure based on user-generated content that appears on company-sponsored media, a move that represents a divergence from FDA's stance in the past. Others caution, however, that the language should not be taken too broadly. For example, the draft guidance does not address the issue of whether a firm has an obligation to correct misleading user-generated content, and leaves considerable room for ambiguity on the types of limited influence or control over website content that can result in regulatory responsibility. Some have noted that Federal Trade Commission requirements for testimonials could still restrict firms' ability to take advantage of FDA's seemingly more laissez faire approach. In sum, most agree that the draft guidance is a step forward, but industry is quick to point out all that FDA has left to be desired. All will be watching closely for FDA's next moves in the ever-evolving and increasingly influential social media space.

If you have questions about this *Client Alert*, please contact one of the authors listed below or the Latham lawyer with whom you normally consult:

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Endnotes

1 FDA, "Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics" (Draft Jan. 2014), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf.

2 21 U.S.C. § 321(m).

3 See Kordel v. United States, 355 U.S. 345, 350 (1948).

[4] See, *e.g.*, 21 C.F.R. § 202.1(l)(2).

[5] For further information from the most recent public meeting, see FDA, Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm184250.htm.

[6] FDA, "Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices" (Draft Dec. 2011), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf.

[7] Pub. L. No. 112-144, § 1121, 126 Stat. 993, 1112 (2012).

[8] 21 C.F.R. §§ 314.81(b)(3)(i), 601.12(f)(4).

[9] 79 Fed. Reg. 2449 (Jan. 14, 2014).