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FDA Issues Two Additional Draft Guidance Documents on Social Media

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On June 17, 2014, the US Food and Drug Administration (FDA) released two additional draft guidance documents relating to the pharmaceutical industry's use of social media. One of the guidance documents addresses how pharmaceutical and medical device companies should deal with independent third-party misinformation, including user-generated content (UGC). The other addresses how the industries may be able to use platforms with character space limitations, such as Twitter. Although addressing two different topics, the draft guidance documents do have one common theme according to Thomas Abrams, the Director of the FDA's Office of Prescription Drug Promotion: they both aim to "ensure that the information provided by drug and device companies is accurate and will help patients to make well-informed decisions in consultation with their health care providers."[1] With that goal in mind, this advisory outlines key points from both of the draft guidance documents.

FDA June 2014 Draft Guidance #1: Internet/Social Media Platforms—Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices

What Is Covered

This draft guidance applies to: (1) misinformation that is (2) posted by independent third parties. In order for the guidance to apply, the subject content must satisfy both criteria. The draft guidance defines "misinformation" as both "positive or negative incorrect representations or implications about a firm's product . . ." In order to come within the purview of the draft guidance, the misinformation must also be within content generated by an independent third party, regardless of where it appears: "the draft guidance applies when a firm is not responsible for a product-related communication that appears on the firm's own forum, an independent third-party website, or through social media. . . ." In other words, comments on the company's own website (including UGC), if made by an independent third party, are covered by the draft guidance.

Content generated by the company directly or indirectly is not covered. This includes any content made by the company's employees or agents and any content that a company "writes, collaborates on, or exerts control or influence over."

What the FDA Suggests: Voluntary Correction of Misinformation

The draft guidance encourages, but does not require, companies to voluntarily correct misinformation. If a firm does so in a "truthful and non-misleading manner" as suggested in the guidance, the FDA intends not to object to the corrective information—even if it "does not satisfy otherwise applicable regulatory requirements regarding labeling or advertising, if any."

[1] http://Blogs.fda.gov/fdavoice/ (entry from June 17, 2014).

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

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The "How" and "What" of Corrective Information

The draft guidance suggests two ways of providing corrective information: a firm may directly provide appropriate truthful and nonmisleading corrective information or it may provide a reputable source where correct information can be obtained. In addition to providing corrective information, a company may also choose to remove (or request removal of) the misinformation.

The draft guidance also sheds light into the FDA's view of what an appropriate correction would be. Corrective information must be relevant and responsive to the misinformation, as well as specifically tailored. It must be nonpromotional in nature, tone, and presentation; consistent with the FDA-required product labeling; and supported by sufficient evidence. In other words, providing corrective information is not a sales or advertisement opportunity. Transparency is also key. It should be clear that the corrective information is provided by the company affiliated with the product.

The draft guidance recognizes that a company's actions will differ if the misinformation appears on the company's own website in the form of UGC or if it appears on a third party's website. If the correction is posted by the company on its own site, it should be posted directly with the misinformation. If the company is providing the corrective information to a third party for posting on the third party's site, it should reference the misinformation and indicate that the correction should be posted in conjunction with the misinformation.

Limitations on Correcting Misinformation

The draft guidance does provide some limitations on correction of misinformation. For example, it specifies that a company is not expected to correct each piece of misinformation in a forum. However, corrections should clearly identify the misinformation and define the portion of the forum it is referencing. In addition, companies should be careful to correct all types of misinformation, regardless of whether the misinformation overstates a benefit from using the product or is negative in tone.

The draft guidance also provides limitations as to when a company will be held accountable for misinformation, recognizing that companies do not have control over the actions of independent third parties. While a company may submit corrective information, a third party may choose not to post that information in the forum. Or, even if a company requests that misinformation be removed, a third party may choose to leave that information posted. In these situations, the FDA will not hold the company responsible. The key, though, will be documenting all efforts made to correct misinformation. Accordingly, the draft guidance suggests that records be kept regarding a company's efforts. Such records should include the content of the misinformation, the date it was posted or located, the forum to which it was posted, the corrective information provided, and the date that the corrective information was provided.

FDA June 2014 Draft Guidance #2: Internet/Social Media Platforms With Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices

What Is Covered

The draft guidance sets forth the FDA's current thinking on how pharmaceutical and medical device companies may use character-space-limited social media platforms. The draft guidance relates to current platforms such as Twitter and sponsored links, but it also seeks to cover any future platforms that may impose similar restrictions on the amount of information that may be communicated at one time.

The key takeaway is that any communication should convey both benefit and risk information in a balanced fashion. This can be accomplished by including a link to the complete risk profile for a product within a communication.

Regulation of social media posts by pharmaceutical and medical device companies is within the FDA's purview as part of the agency's power to regulate "labeling"—which has been broadly defined and need not be affixed to a product—or "advertising." Thus, a post on a Twitter account (or other social media platform) can, in fact, result in misbranding if the communication makes a representation about a product's use without disclosing the product's risks.

What the FDA Suggests: Fair Balance

The touchstone of the FDA's suggested actions for character-space-limited social media is "fair balance." The draft guidance sets out several broad considerations in this regard. Aside from being truthful and nonmisleading, the communication should also include both the indicated use of the product and the risks associated with its use. Any required information should be prominent and able to be understood by the product's consumer. The content of risk information should include the most serious risks, generally including all risks from a boxed warning, all fatal risks, and all contraindications. That said, risk information may be concise if supplemented by a prominent reference to the presence and location elsewhere in the advertisement of a more complete discussion. In other words, risk information can be supplemented by a direct link to a dedicated webpage providing complete risk and side effects information. The draft guidance also clarifies that this fair balance must be achieved within a single communication.

Guidance Specific to Character Space Limitations

The FDA provides a few suggestions specific to character space limitations. For both clarity and length, the FDA suggests that a communication separate risk and benefit information by a dash. Also, a communication may use abbreviations such as the "&" symbol and shortened chemical names (e.g., HCl for hydrochloride). While the draft guidance does not prohibit the use of tiny uniform resource locators (URLs), the FDA prefers that a descriptive website be used for the risk information and provided the structural example of "www.product.com/risks."

If Fair Balance Cannot Be Obtained, Use an Alternative Platform

Companies with products that have "complex indications or extensive serious risks" may find that platforms which impose character space limitations do not "enable meaningful presentations of both benefit and risk." In these situations, companies should opt to use a different platform. However, "reminder promotions"—communications that contain the name of the drug or medical device but do not include indications, dosage recommendations, or other information—may still be made via a character-space-limited platform.

The deadline for comments on these draft guidance documents is September 15, 2014. Also, the FDA will host a Social Media Guidance Webinar and question and answer session on the draft guidance on July 10, 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 either of the FDA draft guidance documents and their impact on your organization, or would like assistance in drafting a public comment, please contact Brian J. Winterfeldt.