FDA Issues Two Draft Guidance Documents Relating to Internet and Social Media Use by Drug and Device Manufacturers

On June 17, 2014, the Food and Drug Administration ("FDA") released two draft guidance documents related to manufacturer communications on the Internet and social media platforms. The two documents are (1) "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices" (*Draft Guidance on Correcting Misinformation*); and (2) "Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices" (*Draft Guidance on Character Space Limitations*).

The *Draft Guidance on Correcting Misinformation* indicates as a threshold matter that drug and device manufacturers have no obligation to correct misinformation about their products provided on the Internet or social media by an independent third party and also addresses how manufacturers should correct misinformation if they so choose. The *Draft Guidance on Character Space Limitations* provides FDA's recommendations for drug and device product promotion on electronic platforms with character space limitations, such as Twitter, which limits messages to 140 character spaces, and sponsored links, which have their own character space limitations and other constraints depending on the platform. This alert summarizes the key aspects of each document.

Draft Guidance for Correcting Third-Party Misinformation Communicated on Internet and Social Media Platforms

The *Draft Guidance on Correcting Misinformation* provides recommendations for companies that wish to correct misinformation about their prescription drugs and medical devices posted by independent parties on the Internet or through social media and indicates that so long as the correction occurs in a manner consistent with the recommendations, FDA will not expect it to comply with otherwise applicable advertising and labeling requirements (e.g., comparable presentation of benefits and risks).

Fundamental Principles. The *Draft Guidance on Correcting Misinformation* applies only to misinformation for which a drug or device manufacturer is not responsible. When content is "owned, controlled, created, [] influenced, or affirmatively adopted or endorsed by, or on behalf of, the firm," the firm is obligated to correct the misinformation, and those corrective communications are subject to regulatory requirements for advertising and labeling. By contrast, when content is "truly independent" of the company (e.g., found on a third-party site that is "not produced by, or on behalf of, or prompted by the firm in any particular"), the company may attempt to correct the misinformation but is not required to do so.

Appropriate Corrective Information. If a company decides voluntarily to correct misinformation on a third-party site, FDA recommends that the communication disclose the affiliation of the person providing the information and be:

- Relevant and responsive to the misinformation;
- Limited and tailored to the misinformation;
- Non-promotional in nature, tone, and presentation;
- Accurate;
- Consistent with FDA-required labeling for the product;

- Supported by sufficient evidence; and
- Posted in conjunction with the misinformation.

Scope of the Correction. The *Draft Guidance on Correcting Misinformation* clarifies that if a company corrects one piece of information on a site, such as a single comment to a news article, it is not obligated to correct each piece of information in the entire forum; moreover, FDA does not expect companies to continually monitor and correct misinformation on an ongoing basis. The *Draft Guidance on Correcting Misinformation* does indicate, however, that companies should not "cherry pick" the misinformation to correct (e.g., by correcting information that overstates a product's risks but allowing information that overstates the benefits to remain).

How to Correct Misinformation. Companies may attempt to remedy misinformation by:

- Correcting misinformation directly on the site;
- Providing the corrective information to the independent author for incorporation;
- Requesting that the author or site administrator remove the misinformation or allow corrective comments to be posted.

When correcting misinformation, the *Draft Guidance* recommends that companies clearly define the portion that is corrected, provide the correction date, and keep records related to the content of the information, where it appeared, and how it was corrected. Additionally, the *Draft Guidance on Correcting Misinformation* explains that the correction should be tailored specifically to address the information that was incorrect; if, for example, a company submitted corrective information regarding a contraindication but also provided comparative safety information to a competitor's product unrelated to the contraindication, the communication would fall outside the scope of the *Draft Guidance on Correcting Misinformation*.

Implications for Industry. The *Draft Guidance on Correcting Misinformation* provides drug and device manufacturers with significant discretion to determine when to correct misinformation posted on the Internet or social media by a third party. Importantly, the agency has clarified that companies are not obligated to correct such misinformation and that even if they choose to do so, a decision to correct a single incorrect user comment does not translate into an obligation to comb through an entire site in search of all instances of misinformation or the obligation to monitor the site on an ongoing basis. As with FDA's January 2014 *Draft Guidance on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media*, however, the *Draft Guidance on Correcting Misinformation* advances a broad interpretation of when a company may be responsible for content on the web or social media, and more elaboration is needed to determine what communications may be viewed by the agency as "truly independent" of a manufacturer and thereby covered by the *Draft Guidance*.

Draft Guidance for Promotional Material on Platforms with Character Space Limitations

The *Draft Guidance on Character Space Limitations* provides recommendations for drug and device companies that promote their products on platforms with character space limitations. At bottom, the *Draft Guidance on Character Space Limitations* makes clear that FDA expects product messaging to comply with all applicable regulations related to advertising and labeling—regardless of the constraints associated with the social media platform—and indicates that Twitter and similar forms of media may not be appropriate for promotion of products with complex indications or serious risks.

Presenting Benefit Information

The *Draft Guidance on Character Space Limitations* provides three recommendations for the communication of benefit information:

- *Benefit information should be accurate and non-misleading and should reveal material facts, such as limitations to an indication or the relevant patient population, within each individual message or tweet.*
- *Benefit information should be accompanied by risk information within each individual message or tweet.*
- *If a firm concludes that adequate benefit and risk information, as well as other required information, cannot be communicated within the same message or tweet, the firm should reconsider using that platform for the intended promotional message.*

Presenting Risk Information

FDA recommends that communication of risk information adhere to the following principles:

- *Risk information should be presented together with benefit information in the same message or tweet.*
- *The content of risk information should, at a minimum, include the most serious risks associated with the product.* For prescription drugs, FDA expects a message to include all risk concepts from a boxed warning, all risks that are known to be fatal or life-threatening, and all contraindications from the approved product labeling; if a product does not have a boxed warning and is not associated with fatal or life-threatening risks or any contraindications, FDA recommends that companies communicate "the most significant warnings or precautions about the product." For devices, the agency recommends that the message include information about each risk associated with a particular identifiable use or population.
- *A hyperlink should be provided to allow direct access to a more complete discussion of risk information.* The *Draft Guidance on Character Space Limitations* recommends that companies include a direct link to a landing page exclusively devoted to the communication of risk information about the product; the link may not, in other words, direct users to the PI or a product's promotional home page.
- *The prominence of risk information should be comparable to the benefit information, taking into account any formatting capabilities available on the specific platform.* FDA recommends that companies use similar techniques to emphasize both benefit information and risk information for the product. Additionally, the guidance recommends that companies utilize any formatting capabilities (e.g., bolded text) to highlight significant risk information.

Presenting Other Product Information

In addition to benefit and risk information, the *Draft Guidance on Character Space Limitations* recommends that:

- *Companies include both the proprietary name and the established (i.e., generic) name of the product in a single message or tweet; and*
- *For prescription drugs, quantitative ingredient information and at least one dosage form should be prominently displayed on the landing page.*

Implications for FDA Regulation of Platforms with Character Space Limitations

While the *Draft Guidance on Character Space Limitations* does provide some clarity on how FDA intends to regulate promotional messaging on space-limited platforms, it is fairly limited in scope and does not cover promotion via other types of social media such as product pages on Facebook and YouTube, Twitter profiles, and online web banners. As a practical matter, it may be difficult to craft tweets and similar messages for many drugs and devices because 140 characters may not be sufficient to include the established and proprietary names, product benefits, detailed risk information, and hyperlink to a separate page devoted to product safety information. That said, the *Draft Guidance on Character Space Limitations* does provide a clear path forward for the promotion of low-risk drugs and devices with benefit and risk information that can be succinctly communicated, and it permits companies to use space-limited platforms in other ways, such as for reminder advertisements, disease-awareness communications, and other messaging.

FDA will be accepting comments on both drafts until September 16, 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.