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FDA Offers Draft Guidance Concerning the Presentation and Correction of Information on Internet/Social Media Platforms Regarding Prescription Drugs and Medical Devices

The U.S. Food and Drug Administration ("FDA") has released draft guidance for industry on two separate but related topics concerning online creation and dissemination of information regarding prescription drugs and medical devices. In its draft guidance, FDA addressed how manufacturers, packers, and distributors of prescription drugs and medical devices (collectively, "firms") should go about: (1) promoting their FDA-regulated products on internet and social media platforms associated with character space limitations (e.g., Twitter and sponsored links appearing on Google and Yahoo); and (2) correcting misinformation about their FDA-regulated products that may be disseminated online by independent third-parties (e.g., bloggers and participants in web-based discussion forums). (Click here and here to access FDA's draft guidance documents in their entirety.)

With respect to the promotion of products on internet and social media platforms with character space limitations, FDA enumerated various factors that firms should take into consideration when presenting benefit information, disclosing risk information, and communicating other required information about their products on such platforms.[1] In particular, within each character-space-limited communication (e.g., a 140-character Twitter "tweet"), benefit information promoted should be accurate and non-misleading, include material facts about the indications and usage of the product, and be accompanied by risk information disclosing, at a minimum, the most serious risks associated with the product. Moreover, the prominence of the risk information within each character-space-limited communication should be comparable to that of the benefit information, and each character-space-limited communication also should include a hyperlink or other mechanism providing direct access to a "landing page" with more complete discussion of risk information (e.g., a website, webpage, or PDF file "devoted exclusively" to providing comprehensive risk information about the product) — a general hyperlink to a company or product website that also encompasses other products, claims, or information would not suffice. In addition, firms should include both the established name of the drug or medical device and the trade or brand name within each character-space-limited communication and on each hyperlinked landing page, along with certain other information.[2]

[1] FDA's draft guidance is not intended to apply to or "address promotion via product websites, webpages on social media networking platforms (e.g., individual product pages on websites such as Facebook, Twitter, Youtube), and online web banners" that "do not impose the same character space constraints as online microblog messaging and online paid search" platforms. In addition, the draft guidance does not concern so-called "'reminder' promotion, which calls attention to the name of a product but does not make any representations or suggestions about the product."

[2] FDA's draft guidance includes hypothetical examples of communications that would comply with its recommendations for product promotion on internet and social media platforms with character space limitations. These examples concern the fictitious and facetious prescription drugs NoFocus (rememberine hydrochloride) for mild to moderate memory loss, and Headhurz (ouchafol) for severe headache from traumatic brain injury.

Recognizing the difficulties that firms may face when trying to fit so much information into each character-space-limited communication on a given internet or social media platform, FDA expressly encourages firms to "reconsider using that platform for the intended promotional message" whenever it appears that "adequate benefit and risk information, as well as other required information, cannot all be communicated within the same character-space-limited communication[.]"[3]

With respect to the correction of misinformation disseminated on internet and social media platforms by third parties (sometimes referred to as user-generated content or "UGC"), FDA's draft guidance does not require firms to police such content, but recommends some steps that a firm may take if it so chooses to voluntarily correct third-party misinformation. For example, a firm may choose to provide appropriate truthful and non-misleading corrective information that is relevant, responsive, and narrowly-tailored to the misinformation, and also consistent with or mirroring FDA-required labeling, or "alternatively, it may provide a reputable source from which to obtain the correct information, such as the firm's contact information." Moreover, a firm may publish the corrective information directly on the forum itself, when feasible, or provide the corrective information to the independent author and request that the author or site administrator modify or remove the misinformation.

FDA's guidance on this subject recognizes the practical challenges faced by firms trying to correct misinformation disseminated by third parties. For example, because firms cannot control whether third-parties will correct some or all of the misinformation even after appropriate corrective information has been provided, "FDA will not hold a firm accountable for an independent third-party's subsequent actions or lack thereof." Nor does FDA "expect the firm to continue to monitor the website or communication that previously included UGC containing misinformation" — although firms should try to keep records of their corrective efforts. Similarly, because "[i]t may be difficult for a firm to correct all misinformation about its products in one forum depending on the nature of the forum, the quantity of the forum, the quantity of information, and the length of time the forum encompasses", FDA does not expect firms to correct all misinformation that exists in a given forum. Nonetheless, a firm that chooses to correct misinformation should clearly identify what portion of a forum it is addressing and correct *all* misinformation within that defined portion of the forum. In other words, the firm should correct "misinformation that overstates the benefits of its product" and not just "misinformation that portrays its product in a negative light[.]"

Importantly, FDA also recognized that firms that voluntary choose to correct positive or negative misinformation about their products often perform a valuable service, particularly when the misinformation may be dangerous or harmful to the public health. Accordingly, firms are free to deviate from the recommendations set forth in FDA's draft guidance so long as their corrective information is truthful, non-misleading, and consistent with other applicable regulatory requirements.

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FDA's draft guidance documents presently are subject to a comment and suggestion period. Any firm with a view on the best practices proposed in the draft guidance should consider working with counsel

[3] Notably, while FDA indicated that "common abbreviations (including scientific and medical abbreviations), punctuation marks, and other symbols may, in many cases, reasonably be used to help address character space constraints[,]" and that shortening services may be used to create a URL or web address for the risk disclosure hyperlink with fewer character spaces, it also recommended that "the URL or web address itself denote to the user that the landing page consists of risk information" and cautioned that the URL or web address itself may be deemed false or misleading if it is too promotional in content or tone.

on a written submission to FDA. Whether finalized in their current form or not, FDA's draft guidance on internet and social media platforms serves as a reminder to industry that, regardless of the advertising medium at issue, firms should strive to present truthful, accurate, and non-misleading information to the public with an appropriately balanced presentation of product benefits and risks.

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If you have any questions or comments, please feel free to contact the authors below or any one of your Kramer Levin attorney contacts:

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