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FDA's Draft Guidance on Addressing Misinformation About Medical Devices and Prescription Drugs

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On July 8, 2024, the Food and Drug Administration (FDA) released updated draft guidance, "Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers," that replaces similar guidance from 2014 on the same topic, "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices." The new guidance document sets out FDA's enforcement policy for internet-based communications used to address internet-based misinformation about or related to a company's approved or cleared medical product when that misinformation is created or disseminated by an independent third party.

The draft guidance applies when a company voluntarily responds to internet-based misinformation and explicitly excludes TV and radio advertisements, even when disseminated by firms via the internet (such as during streamed TV shows). The new draft guidance takes an expansive view of misinformation, defining it as "positive or negative incorrect representations or implications about a firm's product created or disseminated by independent third parties," which does not need to be specific to a company's product in order for a company to respond. FDA allows companies to respond to misinformation about an entire class of drugs or category of medical product if a company has a product in the referenced class.

When a company identifies misinformation about or related to its approved or cleared medical product in an internet-based communication that is created or disseminated by an independent third party, it may respond with a tailored responsive communication. A tailored responsive communication must clearly identify the specific misinformation and communication in which the misinformation appears. Notably, the tailored responsive communication is not limited to the same internet-based setting or settings where the misinformation was posted. Companies that decide to share their tailored responsive communication in a different internet-based setting may also fall within the enforcement discretion policy outlined in the guidance. Further, the tailored responsive communication must be truthful and accurate, scientifically sound, directly relevant and responsive to the identified misinformation, and limited to the information necessary to address the identified misinformation. Finally, the tailored responsive communication must provide a mechanism for obtaining a copy of the current FDA-required labeling and the date the responsive communication is posted, along with disclosing that the communication is shared by the company. If the tailored responsive communication addresses misinformation regarding an unapproved use, the communication also must note that such use or uses of the medical product have not been approved.

If companies follow the guidelines outlined in this draft guidance, FDA has stated that it does not intend to enforce applicable requirements related to promotional labeling and advertising, as well as postmarketing submission of promotional communications – including, for example, postmarketing submissions of promotional communications for drugs and biologics for human use using Form FDA 2253[1] and submissions of promotional communications for accelerated approval products,[2] among others.[3]

Prior to this guidance, in their calculus of balancing brand reputation with regulatory risk, some sponsors of FDA-regulated products steered clear of responding to misinformation on the internet to avoid the appearance of endorsing, for example, unapproved uses. However, FDA requires that drug sponsors submit to the agency promotional communications before disseminating such communications.[4] Some companies have taken an expansive approach when determining what needs to be submitted to FDA through this process, known as a 2253 submission. Before this new draft guidance, responses to misinformation may have been submitted to FDA out of an abundance of caution, necessarily causing a delay in responding to the misinformation, and sometimes negating the response given how quickly and broadly misinformation can be disseminated through social media. We expect that the updated draft guidance will help alleviate these concerns and hopefully allow companies to feel more empowered to respond to internet-based misinformation in a timely manner.

Companies should carefully review the guidance in connection with their crafting of any tailored responsive communication to ensure the communication falls within FDA's enforcement discretion policy. Companies

should consider incorporating the principles outlined in the guidance into their medical, legal and regulatory (MLR) review process (also referred to as the promotional review committee), as well as updating their policies and procedures regarding how companies handle social media communications.

If you have any questions about how this guidance may affect your company's practices, please do not hesitate to reach out to a member of the Cooley life sciences and healthcare regulatory team.

[1] See 21 CFR §314.81(b)(3)(i).

[2] See 21 CFR §314.550.

[3] See, e.g., 21 USC §356(h)(3)(B) (submissions of promotional communications for limited population antibacterial and antifungal drugs); 21 CFR §314.640 and §601.94 (submission of promotional communications for products where human efficacy studies are not ethical or feasible); and 21 CFR §514.80(b)(5)(ii) (submission of promotional communications for animal drugs).

[4] 21 CFR §314.81(b)(3)(i). See also, FDA, "Guidance for Industry: Providing Regulatory Submissions in Electronic and Non-Electronic Format – Promotional Labeling and Advertising Materials for Human Prescription Drugs," April 2022.

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