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FDA Gives Companies a New Way to Fight Misinformation

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Misinformation shared by independent third parties presents a significant public health concern because it can lead patients and healthcare providers to forgo treatments that are safe and effective or choose treatments that are not. Such misinformation is especially harmful when it is shared by an internet user with a large following or someone who holds a position of trust, and when the misinformation relates to medical products that treat or prevent serious or life-threatening diseases. However, industry players have been limited in what they can legally say about their medical products, curtailing the ability to address harmful false statements.

On July 8, 2024, the US Food and Drug Administration (FDA) issued draft guidance on how to effectively address the growing problem of online misinformation about medical products, titled Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers. The new draft guidance replaces earlier draft guidance from 10 years ago and proposes to grant leeway to companies when addressing third-party misinformation about or related to their cleared or approved medical products.

Under the new draft guidance, companies may choose to address such misinformation with a "tailored responsive communication," which, if published in line with the FDA's guidance, will not be subject to traditional promotional marketing requirements. For example, if an independent third party posts on their blog that a new prescription drug (Drug X) has been approved to treat non-small cell lung cancer but according to Drug X's Prescribing Information it is a second-line treatment approved for certain patients with non-small cell lung cancer who have unsuccessfully tried a chemotherapy regimen containing platinum, then the blogger's post is false, inaccurate and/or misleading because it omits material facts regarding the full indication for Drug X. Therefore, Drug X's manufacturer may post a response to address the misinformation about Drug X's indication if the company's post

comports with the guidance's requirements (outlined in more detail below).

The revised draft guidance is open for public comment until September 9, 2024.

In Depth

The draft guidance focuses on a firm's voluntary responses to internet-based misinformation created or disseminated by independent third parties about or related to the firm's approved or cleared medical products. For purposes of the guidance, "misinformation" is "implicit or explicit false, inaccurate, or misleading representations of fact about or related to the firm's approved/cleared medical product" and an expansive list of statements meeting this definition is included. "Independent third party" is a person or entity that, in communicating about a firm's approved or cleared medical product, is not acting on behalf of that firm.

The FDA splits its recommendations, presented in Q&A format, into two categories. The first category refers to recommendations for tailored responsive communications, which are a company's voluntary internet-based communications that identify and address online third-party misinformation about the company's approved or cleared medical products. It outlines an enforcement policy for these types of industry communications, explaining that the FDA will not enforce marketing requirements usually applicable to such communications if a company issues them in line with the guidance.

The second category concerns permissible "general medical product communications," which are the existing ways companies may communicate about their approved or cleared medical products. This includes online communications about a product and non-internet communications channels such as sales aids and TV advertisements. Because they are not included in the reduced enforcement policy for tailored responsive communications, these types of communications must comply with all applicable FDA requirements and other relevant regulations. However, a company addressing misinformation in such a communication does not create special considerations regarding the application of FDA enforcement policies as these types of general communications are already permitted.

TAILORED RESPONSIVE COMMUNICATIONS

As stated above, the enforcement policy outlined in the guidance applies to tailored responsive communications that identify and address misinformation that is (1) about or related to the company's approved or cleared medical product, (2) in an internet-based communication, and (3) created or disseminated by an independent third party. Of note, the first criterion does not require that the product be mentioned by name. The misinformation may refer to an entire class of drugs or devices.

The draft enforcement policy provides that if a company issues a tailored responsive communication in accordance with the guidance in this subsection, the FDA does not intend to enforce applicable requirements for promotional labeling and advertising or post-marketing submission of promotional communications. Also, if a company issues a tailored responsive communication addressing misinformation that its product should be used for an unapproved use and the communication follows the guidance in this subsection, the FDA does not intend to use such communication as evidence of a new intended use.

The draft enforcement policy has several limitations. First, it does not extend to a company's responses to statements describing opinions or value statements about an approved or cleared

medical product. Additionally, it does not apply to a company's responses to representations about an individual patient's experience using a company's product, whether made by that individual or others, unless the statements include misinformation as defined in the guidance.

In addressing independent third-party misinformation, the guidance states that the company should clearly identify both the specific post or communication and the misinformation. When a company identifies misinformation that is widespread, it should at least clearly identify one statement that contains the misinformation to be addressed. Overall, a company should ensure that the information in its tailored responsive communication is (1) truthful and accurate, (2) scientifically sound, (3) directly relevant and responsive to the identified misinformation, and (4) limited to the information necessary to address the identified misinformation as well as any recommended disclosures to help the public understand the context of the response.

Additional recommended disclosures include a mechanism for obtaining a copy of the current FDA-required labeling, the date the company's tailored responsive communication is posted (if a date is not automatically generated) and a disclosure that it is being shared by the company. Moreover, if a company wishes to address misinformation that its product should be used for an unapproved use, the FDA recommends that it include a statement identifying the unapproved use(s) and noting that the unapproved use(s) of the product has not been approved by the FDA and that the safety and effectiveness of the product for that use has not been established. Such recommended disclosures should be presented clearly and prominently.

The FDA recommends that companies prioritize addressing misinformation that has current relevance (*e.g.*, it is trending or actively spreading online) and is being spread by independent third parties with large followings or who hold positions of trust. Regardless of where the misinformation first appeared, companies may post tailored responsive communications to different or additional online forums or social media platforms but should ensure that other platforms allow the entirety of the original post to be displayed.

GENERAL MEDICAL PRODUCT COMMUNICATIONS

The guidance also addresses a second category of corrective firm communications: existing avenues companies can utilize to address misinformation other than tailored responsive communications. Such general medical product communications fall outside of the reduced enforcement policy and therefore must comply with applicable FDA regulations.

This includes promotional communications that provide information about an approved or cleared product's safety and effectiveness. In such communications, companies may decide whether to address misinformation implicitly, without directing attention to that misinformation, or call out the misinformation expressly. Companies may also choose to share promotional communications in a variety of settings, internet-based or not, as they retain the flexibility to direct their communication approaches. For example, a company may enlist healthcare providers to help reach that audience, reach the general public via a radio advertising campaign, work with an influencer to convey the company's message in internet-based settings, or any combination of these avenues as long as the promotional communication complies with the pertinent FDA requirements, including promotional labeling, advertising and information on unapproved or uncleared uses.

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