DORSEY
DORSEY+WHITNEY LLP

FDA Issues Guidance on Drug and Device Manufacturer Communications: Part II – Medical Product Communications that are Consistent with the FDA-Required Labeling

July 10, 2018 – Dorsey Health Law
by Alex Stoflet and Edwin N. McIntosh

On June 12, the FDA issued guidance that clarifies its recommendations for certain product communications made by medical product manufacturers, packers, and distributors (collectively "firms"). The guidance, "Medical Product Communications That Are Consistent With the FDA-Required Labeling" (the "Guidance"), explains the FDA's views on firms' communication of information that is not contained in the FDA-required labeling for their drugs or medical devices, but that is consistent with that labeling.

As explained in a statement by FDA Commissioner Scott Gottlieb introducing the Guidance, FDA-required labeling "is the primary tool that communicates the essential information needed for the safe and effective use of a medical product [and it is] subject to content requirements and limitations." That being said, FDA-required labeling does not address all that is known about a product, such as data from post-market studies and surveillance of a product's approved uses or additional information obtained from pre-market studies. Firms may want to communicate this information to help inform decision-making regarding patient care, and payors want this information to inform their purchasing decisions or negotiation of value-based contracts. However, firms may be wary of communicating such information for fear of being deemed to have communicated information that is inconsistent with FDA-approved labeling, that is false or misleading, and/or that establishes a new intended use.

In response to a number of questions from firms on these issues, the Guidance seeks to clarify what types of information are considered consistent with FDA-required labeling. It also provides general recommendations for conveying that information in a truthful and

Related Capabilities

- Healthcare & Life Sciences
- Healthcare Transactions & Regulations
- Healthcare Litigation
- Medical Devices

non-misleading way, along with examples to illustrate these concepts. The Guidance makes clear that the FDA does not view communications consistent with required labeling alone as evidence of a new intended use, though it does caution that such communications will not necessarily be excluded altogether from assessing a firm's conduct if there is other evidence of a new intended use.

When determining whether a communication is consistent with the required labeling for the product, the FDA considers three factors. A communication must satisfy all three factors in order to be consistent with the required labeling:

- Comparing to Conditions of Use: First, the FDA considers how the information in the product communication compares to the information about the conditions of use in the product's required labeling. More specifically, a product communication is not consistent with the FDA-required labeling if the representations/suggestions in the communication relate to a different indication than the ones reflected in the product's required labeling, if the patient population represented/suggested in the communication is outside of the approved/cleared patient population in the required labeling, if the representations/suggestions in the communication conflict with the use limitations or directions for handling, preparing, and/or using the product reflected in the required labeling, or if the representations/suggestions about the product conflict with the recommended dosage or use regimen, route of administration, or strengths set forth in the required labeling.

- Evaluating Effect on Potential for Harm: Second, the FDA considers whether the product communication increases the potential for harm to health relative to the labeling. If a communication alters the risk-benefit profile of a product in a way that may result in increased harm to health, this indicates the communication is not consistent with the required labeling. For example, if the representations/suggestions in a communication may introduce new risks not included in FDA-required labeling or increase the rate of occurrence or severity of existing risks, the communication may fail this test.

- Evaluating Effect on Safe and Effective Use: Finally, the FDA considers whether the directions for use in the labeling enable the product to be used safely and effectively under the conditions represented/suggested in the product communication under consideration. Here, firms should examine any unique considerations associated with the use suggested by a product communication and whether the FDA-required labeling furnishes appropriate context.

The Guidance acknowledges the potential for overlap in these three factors, but emphasizes that all must be satisfied for a communication to be consistent with the required labeling. It also gives examples of communications that may satisfy one factor but fail others.

The Guidance also outlines recommendations for truthful and non-misleading promotional communications of information consistent with required labeling, including recommendations regarding evidentiary support. To be truthful and non-misleading, representations or suggestions made by firms about their products need to be grounded in fact and science and presented with appropriate context. Any data, studies, or analyses relied on should be scientifically appropriate and statistically sound to support the representations or suggestions made. While sufficient evidentiary support must be presented, the FDA will not consider representations or suggestions in a communication consistent with required labeling to be false or misleading based only on the lack of evidence sufficient to satisfy the applicable approval/clearance standard.

In the same statement introducing the Guidance, Commissioner Gottlieb also introduced accompanying guidance, "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities - Questions and Answers," which we covered in more detail in a previous post. Commissioner Gottlieb explained that the ultimate goal of the two guidances "is to help facilitate a market that is more competitive, based on the outcomes that matter most –the benefit to patients."

Authors' Note: Summer Associate Margaret Fitzpatrick provided substantial assistance with the drafting of this blog post.