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FDA Issues New Draft Guidance for Unapproved Use Communications

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On Monday, October 24, the Food and Drug Administration (FDA) issued a new draft guidance titled, "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products." The draft guidance supersedes FDA's 2014 draft guidance titled, "Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices." Comments on the draft guidance should be submitted by December 26.

When finalized, the draft guidance will provide FDA's current thinking on the dissemination of what FDA is now referring to as SIUU, or scientific information on unapproved uses. This draft guidance continues FDA's ongoing effort to provide policies and recommendations relating to communications regarding unapproved uses of approved/cleared medical products. This effort began in 2009 with FDA's final guidance for industry titled "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices." It continued in 2014 with the revised draft guidance titled "Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices," which, among other things, addressed the dissemination of reference texts and clinical practice guidelines.

New Requirements

The SIUU guidance does not change FDA's overall position on disseminating scientific or medical publications in any significant way, including with respect to the types of information that need to be disseminated or disclosed when companies proactively provide health care providers with SIUU materials. What the guidance adds, however, is significant. Specifically, the guidance expands beyond scientific and medical publications by allowing companies to proactively share "firm-generated presentations of scientific information from an accompanying published reprint" and "independent clinical practice resources."

The guidance also provides a new standard for scientific evidence, referring to "scientifically sound and clinically relevant" evidence. In this regard, the guidance provides additional clarity regarding what FDA would consider clinically relevant. In some cases, the new standard expands the types of studies that can be shared. For example, the guidance indicates that real world data and associated real world evidence might meet this standard under some circumstances. In other cases, the guidance narrows the types of studies that can be shared. For example, medical device nonclinical studies, which could previously be disseminated under some circumstances, would not meet the new standard. The guidance also makes clear that, to be clinically relevant, studies or analyses used in SIUU communications to health care providers should provide information "to inform clinical

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practice decisions for the care of an individual patient." The emphasis on "individual patient" is notable and may further limit the dissemination of information that is too general to provide meaningful information relevant to the care of individual patients.

The guidance further indicates that SIUU communications should not use "persuasive marketing techniques," and should be separate and distinct from promotional communications about approved uses. Notably, FDA also requested that companies consider the use of "plain language" in the content they develop for SIUU communications "to facilitate comprehension." FDA defines plain language as language that "is clear, concise, well-organized, and where possible, avoids complexities such as technical jargon, passive voice, and long sentences and paragraphs."

As in the past, if companies share information on unapproved new uses for an approved/cleared product in a manner that is consistent with the guidance, FDA does not intend to use that "standing alone" as evidence of a new intended use.

Key Takeaways

By expanding the types of information regarding unapproved new uses for approved products that companies can disseminate, while also providing more concrete limitations around the source data of the communications, FDA has taken another step toward balancing the competing interests behind constitutionally protected free speech and FDA's premarket requirements. The guidance reiterates the government's interest in ensuring that companies do not circumvent FDA's approval or clearance processes by leveraging this guidance to "promote" unapproved new uses. It also acknowledges that health care providers may have a legitimate interest in scientific information regarding unapproved new uses to the extent that information is relevant to their care of a specific patient.

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