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Client Alert

The FDA Releases New Draft Guidance on Considering Health Care Disparities When Reviewing Proposed Devices

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On October 21st, the U.S. Food and Drug Administration (FDA) released a draft guidance that, if finalized, will update the agency's 2018 guidance on its Breakthrough Devices Program (the "Program"). In the draft guidance, the FDA announced that when reviewing the eligibility of medical devices for the Program, the agency will also consider whether a device will help address health care disparities and promote health equity. In other words, FDA intends to specifically consider whether a device may provide for more effective treatment or diagnosis in populations impacted by health and/or health care disparities when determining eligibility for breakthrough status.

The Breakthrough Devices Program was launched in 2018 to provide patients and health care workers with faster and easier access to medical devices that effectively diagnose and treat life-threatening or irreversibly debilitating diseases or conditions. This program allows the FDA to speed up the development, assessment and review of products all while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization. If this latest draft guidance is finalized after a period of public comment, the agency will incorporate the proposed language into the 2018 guidance.

To address health disparities, FDA proposes adding new section III.B.3.d to the 2018 guidance in which it acknowledges the urgent public health need for innovative technologies that help to reduce barriers to achieving health equity and help to improve health outcomes across diverse populations. . The new section would acknowledge that "[a]ddressing health and health care disparities is not only important for achieving health equity, but also for improving the overall quality of life and health outcomes for all patients." It thus proposes to take into account whether a device "is designed to address a pathophysiological or clinical characteristic associated with certain populations that could have a clinically meaningful impact for the treatment or diagnosis of the condition in those populations." If so, the device may "be considered as reasonably expected to offer a more effective treatment or diagnosis" and thus could be eligible for breakthrough status. FDA asserts that the proposed changes "may expedite the availability of certain devices that meet the statutory designation criteria and benefit populations impacted by health and/or health care disparities, thereby promoting and advancing health equity."

In addition to the considerations for health care disparities, FDA proposed the following other changes to the 2018 guidance:

- In the **Introduction**, certain non-addictive medical products to treat pain or addiction may not be eligible for the Breakthrough Devices program.

- **Section III.B.1 Designation Considerations** will have added language stating that the FDA will "review all information on a proposed device including its function, potential for technical success, the potential for clinical success, potential for a clinically meaningful impact, and its potential benefits and risks when evaluating whether a device is reasonably expected to provide for more effective treatment or diagnosis"
- The last section receiving updates is **Section III.C Designation Review Process** which will describe when the FDA may publicly disclose designation requests that have been "previously publicly disclosed or acknowledged by the sponsor of the Breakthrough Device designation request" and will publicly disclose its Breakthrough Device designation status for its intended use.

FDA will accept comments on the draft guidance through December 18, 2022.

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