FDA Proposes Updates to Breakthrough Devices Guidance with a Focus on Reducing Disparities in Health and Health Care

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While 2018 guidance on the U.S. "Breakthrough Devices Program Guidance for Industry and Food and Drug Administration Staff" is still in force, FDA has drafted a new proposal for the program. Titled "Select Updates for the Breakthrough Devices Program Guidance: Reducing Disparities in Health and Health Care," the draft guidance outlines how the U.S. agency's voluntary Breakthrough Devices Program may be updated for devices that specifically provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases.

Specifically, the draft guidance, issued October 20, 2022, proposes updates for clarifying how its Breakthrough Devices Program may be applicable to certain medical devices that promote health equity for those impacted by disparities in health and health care.

"The FDA is committed to advancing the development of safe and effective technologies to meet the needs of all patients and consumers," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "This draft guidance, once finalized, can help FDA and our stakeholders leverage the interactive nature of the Breakthrough Devices Program to move us closer to achieving our new Strategic Priority to Advance Health Equity, where technologies, including digital health technologies, can help advance better health care, quality of life, and wellness for all communities, and meet the needs of diverse populations."

The draft guidance specifies updates to **Section III Designation Request** by updating a subset of recommendations adding to **Section III**: *When submitting a request for Breakthrough Device designation, sponsors should clearly indicate the proposed indications for use for which they are seeking designation, as illustrated in Appendix 1. The proposed indication(s) may target a subset of a broader disease population.*

An update to **Section III.B3** requires a statement on whether a device provides for "more effective" treatment or diagnosis and includes the level and type of evidence needed to determine increased effectiveness.

Additional considerations for a Section.III.B.3 update include a new subsection regarding reducing disparities in health and health care. FDA points out that variables such as race, ethnicity, socioeconomic status, age, sex, disability status, sexual orientation, gender identity, language, and location, have been identified with health and healthcare disparities. The agency intends to consider technologies and devices that can address disparities and promote health equity.

FDA also seeks to update the Breakthrough Devices Program's efforts in treating rare diseases or conditions for which there are limited diagnostic and treatment options.

In updating **Section III.C Designation Review Process**, FDA is proposing adding language regarding confidentiality provisions and information disclosure as contained in the Freedom of Information Act. When Breakthrough Device designation and marketing authorization has been obtained, FDA intends to publicly disclose Breakthrough Device status as well as indications for use.

Stakeholders can submit comments regarding this Draft Guidance under docket number FDA-2022-D-1061 at www.Regulations.gov to ensure the FDA considers comments before it begins work on the final version of the guidance.