RECENT FDA STEPS TO ADVANCE MEDICAL DEVICE ACCESS AND INNOVATION

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On November 6, 2017, U.S. Food and Drug Administration ("FDA" or "the Agency") Commissioner Dr. Scott Gottlieb reiterated the Agency's commitment to advancing medical device access and innovation by stating, "[o]ur goal is to streamline the regulatory pathway to get innovative medical products to people more efficiently, while providing the FDA assurances that consumers seek."[1] Consistent with these efforts, FDA recently issued a notice of intent and request for comments regarding its proposed exemption of direct-to-consumer ("DTC") Genetic Health Risk ("GHR") tests from premarket review under certain conditions. FDA also issued a final order exempting genetic carrier screening tests from premarket review subject to certain limitations. In addition, FDA "qualified" its first medical device development tool under its Medical Device Development Tool ("MDDT") Program. Further, the Agency released one draft guidance document related to the Agency's Breakthrough Devices Program and two final guidance documents related to the submission of new 510(k)s pursuant to changes, including a software change, to a legally marketed medical device.

FDA REGULATION OF DTC GHR TESTS

On November 7, 2017, FDA announced a final order classifying DTC GHR tests as class II devices, subject to special controls.[2] The final order clarifies requirements for assuring accuracy, reliability, and clinical relevance along with a description for the types of studies and data needed to demonstrate performance of such tests.

On this date, FDA also issued a notice of intent and request for comments regarding its proposed exemption of DTC GHR tests from premarket review under certain conditions.[3] FDA's notice proposes to limit the exemption to such tests that have received a first-time marketing authorization. In practical terms, if finalized, this proposal would allow manufacturers with an authorized DTC GHR test to add new capabilities to such tests without further regulatory submission. Stakeholders can submit comments to FDA on this notice by January 8, 2018.

FDA REGULATION OF GENETIC CARRIER SCREENING TESTS FINAL ORDER

On November 7, 2017, FDA also issued a final order, effective immediately, exempting genetic carrier screening tests from premarket review under certain conditions.[4] FDA originally issued a notice of intent to exempt such tests on October 27, 2015.[5]

FDA QUALIFIES ITS FIRST MDDT

On October 24, 2017, FDA qualified its first MDDT, the 23-item Kansas City Cardiomyopathy Questionnaire ("KCCQ") cardiovascular tool that utilizes the Clinical Outcome Assessment that measures patient-reported outcomes.[6] The KCCQ is used to measure a cardiovascular patient's health status, symptoms, and social limitations caused by heart failure.

FDA established the MDDT Program, which is a voluntary process, to increase regulatory efficiencies in the development and review of medical devices. An MDDT is a method, material, or measurement used to assess effectiveness, safety, or performance of a medical device. Qualification means that FDA has reviewed the tool and concluded that it produces scientifically plausible measurements as intended within a specific context of use. The FDA MDDT Final Guidance, published on August 27, 2017, provides process and framework information for qualifying an MDDT. [7]

MDDT tool types eligible for FDA review include: (1) clinical outcome assessments, (2) biomarker tests, and (3) nonclinical assessment models. Once qualified, FDA publicly discloses a summary of evidence and basis of qualification for stakeholders to rely upon as part of their own device development plans. While not required, FDA also encourages developers to make their qualified MDDTs public.

FDA DRAFT GUIDANCE REGARDING THE BREAKTHROUGH DEVICES PROGRAM

On October 25, 2017, the FDA issued draft guidance, clarifying key features of the Breakthrough Devices Program to assist stakeholders in determining whether a medical device meets the criteria of a breakthrough device designation. The voluntary program is for certain medical devices that demonstrate more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Pursuant to the 21st Century Cures Act[8] signed into law on December 13, 2016, FDA implemented the program to foster more timely access to such devices by expediting their development and review.[9]

Under the Breakthrough Devices Program, which supersedes the Expedited Access Pathway[10] and the Priority Review Program,[11] FDA will route each breakthrough device submission to an appropriate organizational unit comprised of personnel experienced with analyzing and reviewing a device's innovative approaches. Additionally, all devices designated as Breakthrough Devices will receive priority review as well as expedited review of manufacturing facilities and quality systems for those submissions requiring a pre-approval inspection. More importantly, FDA intends to provide interactive and timely communication with stakeholders during device development and throughout the review process. The Breakthrough Devices Program applies to devices as well as device-led combination products.

FDA FINAL GUIDANCE DOCUMENTS REGARDING CHANGES TO AN EXISTING LEGALLY-MARKETED DEVICE

On October 25, 2017, FDA also finalized two additional guidance documents related to the submission of a new 510(k) for any changes, including a software change, to an existing legally marketed device.[12] The purpose of the guidance documents is to assist stakeholders in determining when they are required to submit a new 510(k)

pursuant to such changes. Notably, these two guidance documents do not change FDA's review standard, but, instead clarify the Agency's regulatory framework to enhance consistency in a stakeholder's decision-making process.

As FDA continues its efforts to advance medical device access and innovation, K&L Gates will continue to monitor and provide updates on further developments. Given our substantive experience in and knowledge of FDA-regulated industries, we are well positioned to facilitate stakeholder engagement with the Agency in this area.

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[1] *Statement from FDA Commissioner Scott Gottlieb, M.D., on Implementation of Agency's Streamlined Development and Review Pathway for Consumer Tests that Evaluate Genetic Health Risks*, (November 6, 2017).

[2] 82 FR 51560 (November 7, 2017).

[3] 82 FR 51633 (November 7, 2017).

[4] 82 FR 51567 (November 7, 2017).

[5] 80 FR 65774 (October 27, 2015).

[6] *FDA Medical Device Development Tool (MDDT) Qualification Decision Summary for Kansas City Cardiomyopathy Questionnaire (KCCQ)* and *Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps to Advance Medical Device Innovation and Help Patients Gain Faster Access to Beneficial Technologies*, (October 24, 2017).

[7] *Qualification of Medical Device Development Tools Guidance for Industry, Tool Developers, and Food and Drug Administration Staff,* (August 10, 2107).

[8] 21st Century Cures Act, Pub. L. No. 114-255, (December 13, 2016).

[9] *Breakthrough Devices Program Draft Guidance for Industry and Food and Drug Administration Staff*, (October 25, 2017).

[10] *FDA Expedited Access Pathway Program*, (Last updated on October 24, 2017).

[11] *Priority Review of Premarket Submissions for Devices Guidance for Industry and Food and Drug Administration Staff*, (May 17, 2013; withdrawn on August 3, 2017).

[12] *Deciding When to Submit a 510(k) for a Software Change to an Existing Device Guidance for Industry and Food and Drug Administration Staff*, (October 25, 2017) and *Deciding When to Submit a 510(k) for a Change to an Existing Device Guidance for Industry and Food and Drug Administration Staff,* (October 25, 2017).

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