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SIDLEY UPDATE

U.S. Food and Drug Administration Proposes Changes to the Premarket Pathway for Genetic Health Risk Tests

On Nov. 8, 2017, the Food and Drug Administration (FDA) published two final orders and a notice related to direct-to-consumer (DTC) genetic tests with potentially important implications for developers of such tests. One of the orders, issued under new authority provided by the 21st Century Cures Act, finalizes the exemption from Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FDCA) Autosomal Recessive Carrier Screening Gene Mutation Detection Systems; FDA had proposed to exempt these tests after its landmark de novo authorization of 23andMe's Personal Genome Service. The other order codifies FDA de novo authorization concerning 23andMe's Genetic Health Risk (GHR) Assessment Systems (GHR Order). The notice, *Exemptions from Premarket Notification for Class II Devices*, proposes and seeks comments on a simplified path to market for Genetic Health Risk (GHR) genetic tests under which, according to an FDA statement, manufacturers of these tests "would have to come to FDA for a one-time review to ensure that they meet the FDA's requirements, after which they may enter the market with new [genetic health risk] tests without further review." The notice also proposes to exempt four other class II devices from 510(k).

This approach would be limited to GHR tests that rely on qualitative detection of indicated variants and do not provide an overall risk assessment of a person's likelihood of developing disease. It is unclear whether a test that provides a risk profile for certain diseases based on the presence of several variants associated with disease risk would fall within the relevant device classification regulation. In addition, to qualify for the new approach, the test could not be indicated for (i) prenatal testing, (ii) determining predisposition for cancer where the result of the test may lead to additional testing or treatment that may incur morbidity or mortality, (iii) certain pharmacogenomics indications or (iv) assessing the presence of deterministic autosomal dominant variants. *See* 21 C.F.R. § 866.5950(b)(4).

Under the proposal discussed in the notice, GHR tests must comply with these limitations on indications for use and other special controls to be partially exempt from 510(k). Other special controls in 21 C.F.R. § 866.5950 include extensive requirements for labeling, public disclosure of information about test performance, use of FDA reviewed or exempt sample collection kits and requirements to establish analytical and clinical validity. Partial exemption means developers of GHR tests would still have to submit a 510(k) before marketing a GHR test for the first time but could offer the test to detect additional variants or market new GHR tests without seeking FDA review. FDA's press statement compares the proposed policy for GHR tests to the precertification policy FDA is piloting for digital health products in that FDA is seeking a "firm-

based" rather than product-based oversight model that focuses on the product developer's capabilities to consistently design and develop high-quality products.

By allowing test developers to market tests for the detection of additional variants following initial FDA clearance, the proposed policy, if finalized, potentially reduces burden on GHR test developers in two ways. First, premarket burden would be reduced because test developers would likely submit information concerning only their test's detection of a single or a small subset — as opposed to dozens or hundreds — of variants. Second, test developers would be able to expand the indications of their marketed test without further FDA review.

Importantly, however, the exemption from 510(k) remains subject to FDA's standard limitations on exemption, which describe certain changes to a 510(k) exempt device that trigger the need for a 510(k). The notice states that the proposal to exempt GHR devices from 510(k) applies only to GHR tests "for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality." It is unclear how — or whether — this language would apply to genetic health information that is not being marketed for diagnostic purposes; if the language somehow applies, it is also unclear whether this language tracks the exclusion from the GHR classification of certain indications for use or expands the exclusion, potentially excluding indications other than those associated with prenatal testing, cancer, pharmacogenomics and autosomal dominant variants. Additional clarity from FDA in its final notice on these points is needed to ensure that genetic test developers reap the full benefit of the partial exemption from premarket review.

Interested persons can file comments on the notice by Jan. 8, 2018. Under section 510(m)(2) as amended by the 21st Century Cures Act, FDA must publish its final notice concerning the exemption of the five devices within 120 days or by Feb. 5, 2018.

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work or

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