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BLOG

FDA Premarket Review/Authorization No Longer Needed for COVID-19 Laboratory Developed Tests

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On August 19, 2020, the Department of Health and Human Services (HHS) rescinded prior guidance and "other informal issuances" concerning premarket review and authorization of laboratory developed tests "LDTs) for COVID-19 and "future pandemics." Citing its "ongoing department-wide review of regulatory flexibilities enacted since the start of COVID-19," HHS determined that FDA will not require premarket review of COVID-19 or "future pandemic" LDTs absent notice-and-comment rulemaking. Any statements or requirements made in "guidance documents, compliance manuals, website statements, or other informal issuances" can no longer serve as the basis for requiring FDA premarket review for such LDTs. This also means, in essence, that an emergency use authorization (EUA) is no longer required to market COVID-19 tests.

Importantly, while "[t]hose opting to use LDTs in their laboratories without FDA premarket review or authorization may do so," HHS clarified that such usage would not be eligible for PREP Act coverage and its associated immunity (as discussed in prior alerts, available here, here and here). Only use of LDTs that have been subject to FDA approval or clearance, or have obtained an EUA, would be provided immunity under the PREP Act. However, regardless of whether LDTs have been approved or received an EUA, they remain subject to regulation under the Clinical Laboratory Improvement Amendments of 1988 (codified at 42 U.S.C. § 263a).

While the HHS Announcement expressly allows the use of COVID-19 LDTs without FDA premarket review or authorization, companies should carefully consider the risks and benefits of using such tests, including the lack of any of the broad protections afforded by the PREP Act absent FDA approval, clearance, or an EUA.

For any questions regarding the HHS Announcement, please contact Sandra Edwards, Rand Brothers, or your Winston relationship attorney. The HHS Announcement can be found here.

View all of our COVID-19 perspectives here. Contact a member of our COVID-19 Legal Task Force here.

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