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EUAs for LDTs no Longer Required, but at the Expense of PREP Act Immunity

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On August 20, 2020, the Department of Health & Human Services (HHS) released a statement, *Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests*, which announced that the Food and Drug Administration (FDA) will no longer require premarket review of laboratory developed tests (LDTs), such as those currently being used to test for the presence of COVID-19, absent traditional notice-and-comment rulemaking. The notice-and-comment rulemaking now required contrasts with the current practice adopted by FDA that communicates agency policy applicable to LDTs through guidance documents, compliance manuals, website statements, or other informal issuances.

Clinical laboratories opting to use LDTs without FDA premarket review or authorization remain subject to regulation by the Centers for Medicare & Medicaid Services under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a, and its implementing regulations at 42 C.F.R. Part 493. Bringing an LDT to market without securing FDA premarket approval or clearance of, or an emergency use authorization (EUA), comes at a steep cost to clinical laboratories. Public Health and Emergency Preparedness Act (PREP Act) protection is not available to clinical laboratories opting to use LDTs without FDA premarket review or authorization. By way of background, the PREP Act provides immunity "from suit and liability under federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure if a Declaration has been issued with respect to such countermeasure." As discussed in a previous post, HHS issued a Declaration defining covered countermeasures as, *inter alia*, any diagnostic or other device used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.

Clinical laboratories that have already obtained an EUA or other form of marketing authorization for an LDT are not affected by HHS' announcement, and will still enjoy the immunity afforded under the PREP Act. Additionally, clinical laboratory developers seeking approval or clearance of, or an EUA for an LDT may still voluntarily submit a premarket approval application, premarket notification or an EUA request, but are not required to do so, and FDA will adjudicate those submissions.

Because FDA will still issue EUAs for COVID-19 LDTs and because such LDTs will still enjoy

immunity under the PREP Act, it is hard to imagine that a clinical laboratory developing a COVID-19 LDT would not seek such FDA review or authorization. That said, one would not expect developers of LDTs that are not subject to PREP Act immunity to seek FDA regulatory review or authorization for such LDTs. The universe of LDTs that will be wholly without FDA oversight may prompt FDA to articulate a cohesive regulatory framework for LDTs and subject that framework to the traditional rule-and-comment rulemaking process.

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