SQUIRE PATTON BOGGS

Summary of FDA Statement on Laboratory Developed Tests Released

January 13, 2017

On January 13, 2017, the Food and Drug Administration (FDA) issued a discussion paper on laboratory developed tests (LDT), synthesizing the regulatory dialogue that FDA and stakeholders have had since 2010 and outlining future regulatory possibilities for LDTs. FDA and a majority of stakeholders support a complimentary approach to regulating LDTs that combines FDA's experience in pre- and post-market matters for medical devices themselves with the Centers for Medicare and Medicaid's (CMS) experience in laboratories' processes and procedures.

The discussion paper advances FDA's points on the common topics that have been brought up in the discussion for regulating LDTs and makes proposals for a future program.

- **Focused oversight:** FDA's oversight over LDTs would be focused on new and significantly modified LDTs, "grandfathering" existing LDTs to a certain extent. FDA submits that it would need to retain its enforcement capabilities for all LDTs that are unsafe, clinically invalid or deceptively promoted.
- **Risk-based, phased-in oversight:** FDA proposes a four-year phase-in for regulating LDTs, focusing first on the LDTs for which the consequences of a false result have the highest risk to the patient. FDA recognizes that applying the Quality System Regulation could be new for many laboratories and forwards an additional two years for laboratories to comply with the applicable quality system requirements.
- **Evidence standards:** FDA asserts that its validation and evidence requirements for clinical validity would complement, instead of duplicate, CMS's validation and evidence requirements for clinical utility. While the CMS's requirements do not confirm whether an LDT's results are sufficient to confirm its claimed intended use, "laboratories that already conduct proper validation should not experience new costs for validating their test to support marketing authorization."
- **Third-party review:** FDA proposes to expand its third-party premarket review program to accredit clinical laboratories to review eligible LDTs.
- **Clinical collaboratives:** FDA will expand its collaborative work with the clinical community to develop measurement, review and clinical validity standards to ensure the quality and consistency of LDTs.
- **Transparency:** FDA proposes to make public the analytical and clinical validity evidence of all LDTs so that the public can understand the test performance and how it is derived.
- **Modifications:** FDA submits that laboratories should submit prospective change protocols in premarket submissions that outline specific anticipated significant changes, the procedures that will be followed to implement those changes and the criteria that will be met prior to implementation.
- **CLIA Quality System Requirements:** Acknowledging that many laboratories already operate a quality system, FDA proposes to leverage laboratories' already-existing certification requirements, augmenting them with three FDA-specific quality system requirements that are not duplicated by other programs: design controls, acceptance activities and procedures for corrective and preventive actions.
- **Postmarket surveillance:** FDA proposes comprehensive postmarket surveillance steps for LDTs in light of the phases for pre-market clearance and approval for many LDTs. FDA states that, initially, laboratories would report serious adverse events for almost all LDTs, gradually stepping down surveillance as more evidence becomes available.

If you would like to discuss the implications of the recent FDA Statement on Laboratory Developed Tests, please speak to one of the individuals listed in this publication or your firm contact.

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