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Client Alert

FDA & Life Sciences Practice Group

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FDA Issues Discussion Paper on LDTs

Following its recent announcement that it would not finalize its 2014 draft guidance on laboratory developed tests ("LDTs"), the U.S. Food and Drug Administration ("FDA") issued a Discussion Paper on Laboratory Developed Tests ("Discussion Paper") on January 13, 2017, detailing the agency's views on a future approach to LDT regulation. The Discussion Paper synthesizes stakeholder feedback on the 2014 draft guidance, issued in order to "advance public discussion on future LDT oversight." Though not a binding document and not representative of final agency guidance, the Discussion Paper nevertheless offers insight into potential aspects of a future oversight program and serves as a prompt for legislative action.

The Discussion Paper appears to be FDA's attempt to signal the agency's willingness to step away from the contentious regulatory approach set forth in the 2014 draft guidance. Instead, the Discussion Paper proposes a path forward that adopts elements of stakeholder proposals and suggests a more collaborative approach to oversight by spelling out potential roles for each stakeholder. Citing to several oversight proposals prepared by industry organizations, the Discussion Paper points to a growing consensus that more active oversight over LDTs is necessary and highlights common features of each proposal. In addition, the Discussion Paper displays a willingness by FDA to share oversight with the Clinical Laboratory Improvement Amendments ("CLIA") program, which is overseen by the Centers for Medicare and Medicaid Services ("CMS").

In the Discussion Paper, FDA offers an alternative oversight framework, drawing on stakeholder feedback. Key elements of the proposed program include:

Focused Oversight. Subject to certain limitations, the proposed framework would mostly exempt a wide-range of LDTs from FDA oversight, including:

1. LDTs already on the market (though such LDTs would not be exempt from adverse event reporting or Medical Device Reporting ("MDR") requirements);

2. Traditional LDTs;

3. LDTs for public health surveillance;

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4. Low risk LDTs;

5. LDTs for rare diseases,

6. LDTs intended solely for forensic use; and

7. LDTs used in CLIA-certified, high-complexity histocompatibility laboratories for certain organ, stem cell, and tissue transplantation screenings.

According to FDA, the focus of the oversight framework would rest on new and significantly modified high and moderate risk LDTs.

Risk-Based, Phased-In Oversight. FDA further proposes that premarket review of new and significantly modified LDTs be phased in over four years, rather than the nine years originally proposed in the 2014 draft guidance. The Discussion Paper lays out a year-by-year timeline of the phase-in.

Evidence Standards. FDA also provides assurances that the premarket review would not be duplicative of CMS's postmarket oversight of laboratory operations or clinical utility determinations, but would rather be a complementary program. The agency also proposes to reduce premarket review burdens by limiting the scope of post-clearance modifications that would require additional FDA review.

Limited Quality System Requirements. FDA proposes to leverage existing CMS/CLIA requirements relevant to quality systems. For LDTs developed in CLIA-certified laboratories, the agency proposes to focus narrowly on assessing three Quality System Regulation requirements only: design controls, acceptance activities, and corrective and preventive actions ("CAPA").

Third-Party Review. As a further signal of deference to stakeholders, the proposed framework includes an expanded third-party premarket review, including coordination with a range of programs including New York's Clinical Laboratory Evaluation Program, and programs run by CLIA-approved laboratory accreditation organizations.

Transparency. The proposed program also emphasizes transparency. The Discussion Paper proposes that evidence of analytical and clinical validity of LDTs should become publicly available via publication. For FDA-reviewed LDTs, the agency proposes to publish a review memorandum containing the validity evidence.

The Discussion Paper marks a shift in FDA's tone and approach surrounding its regulatory oversight of LDTs. Whether this more collaborative approach will be adopted by the new Trump Administration or extend into other areas, such as oversight of traditional IVDs, remains to be seen.

King & Spalding will continue to monitor the issues raised by the Discussion Paper and other developments affecting LDTs in general. If you have any questions about the Discussion Paper or its proposed oversight framework, we would be pleased to assist.