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FDA's Regulation of Laboratory Developed Tests (LDTs) - Changes on Horizon?

By Deborah M. Shelton

For years, the Food and Drug Administration has maintained that it has jurisdiction over laboratory-developed tests ("LDTs") – those *in vitro* tests developed, validated and used for in-house pathology and diagnostic purposes – as medical devices. Yet the Agency has, with some few exceptions (e.g., IVDMIAs), exercised enforcement discretion, reasoning that most LDTs were simple, well-characterized, and reliant upon various FDA-regulated individual components. As LDTs have become increasingly complex and the laboratory setting increasingly large-scale, FDA has begun rethinking its regulatory approach.

To this end, the Agency has announced that it will hold a public meeting on oversight of LDTs on July 19-20, 2010, in Rockville, Maryland. Sessions at the meeting include (1) patient considerations; (2) challenges for laboratories; (3) direct-to-consumer marketing of testing (DTC); and (4) education and outreach. Interested persons can request time to make a brief presentation and/or can submit written comments to the relevant docket.

In its announcement of the meeting, FDA specifically raises concerns about use of LDTs for genetic testing and "personalized medicine," the use of LDTs outside of the physician-patient context, and the development of LDTs by larger corporations. In the Agency's view, the shifting terrain and complexity both increase the risks of misdiagnosis. Questions about FDA's exercise of enforcement discretion have been looming at least since the 1997 report of the NIH-DOE Joint Task Force on Genetic Testing. Moreover, the regulations that once would have been so evidently burdensome if borne by small labs offering simple tests and/or specialized tests for rare disease now meet a marketplace with a new economy of scale. This marketplace and its complexities are, in turn, changing FDA's calculus about enforcement discretion.

From the laboratory perspective, a robust regulatory framework already governs LDTs. Some stakeholders point to the comprehensive regulatory scheme established under the Clinical

Laboratory Improvement Amendments (CLIA) (42 U.S.C. § 263a), which require extensive proficiency and quality-control testing for laboratories. The CLIA applies special scrutiny to LDTs precisely because they have not faced FDA clearance. Furthermore, most of the reagents in use for these tests fall within the FDA's 1997 Analyte Specific Reagents (ASR) rule. And, arguably, those who develop and use LDTs sell only a diagnostic service, not a medical device. Thus, FDA has nothing to regulate.

From the Agency's meeting-notice, a different view emerges. FDA suggests that its hands-off approach may have disincentivized innovation by manufacturers who must seek FDA approval, yet it also acknowledges the dependence of innovation upon an appropriate oversight framework, particularly in areas such as genomics, genetic testing, and diagnostics for rare diseases, areas in which medicine is highly reliant upon LDTs. In the Agency's words, "In these and other categories, it is important that FDA provide a reasonable, predictable, and consistent regulatory policy for ensuring the safety and effectiveness of LDTs and provide sufficient time for implementation. Therefore, this policy should encourage innovation, improve patient outcomes, strengthen patient confidence in the reliability of these products, and help reduce health care costs."

As FDA seeks to create a phased-in, risk-based oversight framework for LDTs, it seeks input from laboratory professionals, clinicians, patients, and industry. After the public meeting, the Agency intends to move quickly toward a draft framework, on which the public is invited to comment.

There is no registration fee to attend the public meeting, but registrations must be submitted to FDA by 5 pm on July 12, 2010, and can be completed online by clicking here, or by telephone at (301) 796-6652. Requests to present at the meeting must be submitted via the FDA contact information provided in the Federal Register announcement of the public workshop, which can be found here. Finally, regardless of attendance at the public meeting, persons are also invited to submit written comments to FDA concerning the FDA's regulation of LDTs. The comment period is scheduled to close August 15, 2010.

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