ROPES & GRAY ALERT

FDA Regulatory ▪ Health Care

November 23, 2016

FDA Indefinitely Delays Action on Regulating Laboratory Developed Tests

Attorneys
Gregory H. Levine
Mark Barnes
Abram S. Barth
David Peloquin

On November 18, 2016, the Food and Drug Administration (FDA) notified industry groups that it no longer plans to finalize its draft guidance on laboratory developed tests (LDTs) this year. FDA stated that it intends to work with the new administration and Congress, as well as stakeholders, to update the LDT framework. This alert briefly reviews the context for FDA's announcement and discusses what the future may hold for the regulation of LDTs.

Draft LDT Framework Guidance

On October 3, 2014, FDA issued draft guidance on a proposed framework for regulatory oversight of LDTs. FDA announced that it would end its historical policy of not applying the medical device regulations to LDTs at all, and instead set forth a risk-based approach for regulating moderate- and high-risk LDTs. A previous Ropes & Gray alert describes the draft guidance in detail.

Congress has shown a keen interest in the future direction of LDT regulation. Even before FDA published its draft guidance, Congress enacted section 1143 of the Food and Drug Administration Safety and Innovation Act, which prohibited FDA from issuing any draft or final guidance on the regulation of LDTs without providing at least 60 days prior notice to the Energy and Commerce Committee of the House of Representatives and the Senate Health, Education, Labor, and Pensions (HELP) Committee.[1] FDA provided that notice to Congress on July 31, 2014, and subsequently published its draft guidance on October 3, 2014.

Many Proposals, No Consensus

Following FDA's notice to Congress, the Health Subcommittee of the House Energy and Commerce Committee held a hearing on FDA's proposal in September 2014, and solicited feedback from stakeholders on how LDTs should be regulated. Since then, a variety of stakeholders have weighed in on the issue, including *in vitro* diagnostic (IVD) test manufacturers, clinical laboratories, medical associations, patient advocacy groups, and universities. For example, AdvaMedDx, a trade association representing manufacturers of clinical diagnostic tests, has expressed its support for FDA's jurisdiction over LDTs, whereas the American Clinical Laboratories Association (ACLA) is staunchly opposed to heightened FDA regulation of LDTs and even threatened to sue the agency if it proceeded with its framework guidance. Medical societies, universities, and trade associations such as the Association for Molecular Pathology (AMP) and the College of American Pathologists (CAP) have argued for modernizing Clinical Laboratory Improvement Amendments (CLIA) requirements while limiting FDA regulation of LDTs to only high-risk tests, or even precluding FDA oversight altogether.

By October 2015, the Energy and Commerce Committee had circulated draft legislation that would, among other things, remove *in vitro* clinical tests from FDA's medical device regulatory authority and relocate them under a new center within the agency; create an abridged regulatory pathway for tests for rare diseases and unmet needs, as well as tests that offer a clinically significant advantage over currently approved *in vitro* clinical tests; require FDA review of all high-risk *in vitro* clinical tests using a single standard for approval; and authorize joint FDA-Centers for

[1] Pub. L. 112-144, 126 Stat. 993 (2012).

Medicare & Medicaid Services (CMS) inspections of laboratories to assess compliance with both FDA requirements and CMS-administered requirements under the CLIA. No consensus formed around the Energy and Commerce Committee approach, however, and varying proposals continued to be floated by stakeholders. This past fall, Lamar Alexander (R-TN), Chairman of the Senate HELP Committee, proposed the creation of an entirely new regulatory agency to oversee laboratory developed tests, with a goal of supplanting duplicative regulation by CMS, FDA, and state authorities. Senator Alexander will retain the Senate HELP Committee chairmanship following the 2016 congressional elections.

What Now?

With an incoming Republican president and majorities in both houses of Congress, one might expect the appetite to be low for increasing FDA oversight of LDTs or creating an entirely new bureaucracy to regulate such tests. As outlined above, however, the politics of this issue are complex, with some industry players traditionally allied with pro-business Republicans advocating increased regulation of LDTs, others arguing that FDA regulation would be undesirable and that the focus should be on improving regulation under CLIA, and yet others calling for hybrid or entirely new approaches. We expect that medical and public interest organizations, patient groups, universities, and other interested stakeholders will continue to follow the issue closely and weigh in with their views. In this environment, the only certainty is that the question of how LDTs should be regulated in the future will not go away. FDA's latest announcement may, however, have the effect of preserving the status quo for longer than might have otherwise been the case. With the next round of Medical Device User Fee Amendments (MDUFA IV) set to be enacted in 2017, it is possible that Congress could use that legislative vehicle to establish a new LDT scheme if consensus can be reached by then.

While the debate over LDT regulation goes on, FDA should be expected to continue its historical hands-off approach for tests that are either traditional LDTs or for which there is a colorable argument that they are LDTs. Conversely, FDA staff can be expected to continue threatening or taking enforcement action with respect to laboratory tests promoted directly to consumers (DTC), unless ordered to stop doing so by new FDA or HHS department management under the incoming administration. FDA has stated repeatedly in recent years that it considers DTC tests to fall outside its historical enforcement discretion policy for LDTs,[2] and has taken several highly publicized actions to address the marketing of such tests without FDA approval or clearance.[3] Similarly, FDA staff may continue to issue safety alerts seeking to dissuade use of particular tests marketed as LDTs that the agency considers to present a public health risk.[4]

Ropes & Gray will continue to monitor developments in this area. If you would like to discuss the implications of FDA's announcement, please contact any member of Ropes & Gray's FDA regulatory or health care practices or your usual Ropes & Gray advisor.

[2] *See, e.g.*, LDT framework draft guidance, footnote 4 ("FDA generally does not exercise enforcement discretion for direct-to-consumer (DTC) tests regardless of whether they meet the definition of an LDT provided in this guidance. Therefore, the enforcement policies in this guidance do not apply to DTC tests, and FDA's usual enforcement policies apply to DTC tests.").
[3] *See, e.g.*, "It Has Come to Our Attention" Letters issued to Sure Genomics, Inc. (Feb. 16, 2016), Pathway Genomics (Sept. 21, 2015), and Interleukin Genetics, Inc. (Nov. 4, 2015).
[4] *See, e.g.*, FDA's safety alert for ovarian cancer screening tests issued on September 7, 2016.