

## ISSUE SUMMARY

Laboratory developed tests (LDTs) are vital elements in providing innovative and tailored treatment options to patients with the assistance of rapidly developing diagnostic tools. Through draft guidance issued in October 2014, the U.S. Food and Drug Administration (FDA) proposed a system of oversight that would begin to regulate LDTs as medical devices. This proposed framework has raised important concerns in the academic medicine community that such regulation has the potential to significantly increase costs, stifle innovation, and ultimately decrease the ability to provide the most effective and appropriate care to patients.

### Issue

In October 2014, the FDA released draft guidance on its proposed oversight of LDTs, which are generally in vitro diagnostic (IVD) tests designed and used by a single laboratory. When LDTs are offered by clinical labs at academic health centers, those labs are subject to regulation under the Clinical Laboratory Improvement Amendments (CLIA) program, which oversees the operations and testing processes. LDTs are not currently regulated by the FDA through the current device regulations, but many would be subject to this regulatory oversight under the proposed guidance. According to the FDA, the purpose of the revised framework is to give the FDA oversight of LDTs “based on risk to patients rather than whether they were made by a conventional manufacturer or a single laboratory.” In this new structure, LDTs designated as higher risk, including companion diagnostics and LDTs used to inform treatment decisions, would be reviewed by the FDA through the existing premarket review process. However, the proposed guidance would exempt very few existing or emerging tests from this new, costly regulatory process, which may unintentionally make it financially and administratively infeasible for academic medical centers to continue developing tests that are tailored for a small number of affected individuals or administered infrequently. Many academic medical centers are concerned that the proposed guidance as initially drafted could suppress innovation in conditions or populations for which there is little incentive for commercial entities to develop tests.

### Background

Immediately after the release of the proposed guidance, academic institutions and other entities raised concerns that the proposed framework would slow down innovation, create a burdensome and expensive process, and potentially jeopardize patient care and advances in personalized medicine. In addition to submitting comments to the FDA on the guidance, several interest groups including physician associations and other health care provider associations, academic entities, and industry each developed alternative proposals to the FDA draft guidance. The alternative proposals address whether the FDA or the Centers for Medicare and Medicaid Services (CMS) should bear primary responsibility for LDT oversight, and they include different approaches for classifying tests based on risk. Those alternative frameworks that propose an expanded role for CMS note that LDTs, while currently not regulated by the FDA, are subject to some level of oversight through CLIA. More “CLIA-centric” proposals suggest that the role of CMS should be expanded by investing additional federal resources in CMS and modernizing CLIA to give greater oversight responsibility and enforcement authority over LDTs. Some have suggested a blended approach, where certain tests, such as those deemed very high risk or those containing proprietary information would be automatically or voluntarily submitted to the FDA for approval, while the vast majority of LDTs would either be regulated through CLIA or not subject to additional regulation. The House Energy and Commerce Subcommittee on Health has also convened hearings on the subject and circulated draft legislation, while the Senate Health, Education, Labor, and Pensions (HELP) Committee held a hearing in September 2016.

The AAMC agrees that LDTs used for diagnostic and treatment decisions should have clinical validity and accuracy. However, we share our members' concerns that the FDA's regulation of LDTs as proposed would interfere with delivering innovative, cutting-edge medical care, negatively impact patients, or mire the development of critical new tests in a costly and laborious process. LDTs are often innovative or low-volume tests whose speed of adoption has outpaced the ability of commercial IVD manufacturers to plan and submit formal clinical trials that would be required for the FDA approval for marketing.

As the AAMC wrote in its comment letter to the FDA, academic medical centers and teaching hospitals that are performing LDTs every day are "on the front line of patient care and are best able to define the impact on their own institutions and their ability to treat patients with important information gleaned from clinically validated, well-proven, and carefully tailored diagnostic tests. In light of the president's initiative on precision medicine, the FDA should be working in concert with academic medicine to encourage innovation in patient care, not stifle it."

### AAMC Policy Recommendations

- Any potential revised regulatory framework must avoid an overly burdensome system that would greatly slow innovation critical to keeping our health care system vital, providing care to patients, and responding quickly to emerging public health risks.
- The breadth of any potential regulation of currently used tests that have demonstrated validity should be limited. Given the cost of guiding even a single test through the FDA premarket approval process, the AAMC is concerned that institutional investment in each currently used LDT would be economically untenable, not only limiting patient access to new innovative and targeted diagnostic tests but potentially making diagnostic tests that are available today unavailable in the future.

- Before finalizing any potential framework, policymakers should determine the current frequency and types of modifications to existing tests to inform which modifications would require a new approval process.
- Any potential regulation of LDTs should include a wide range of situations under which enforcement jurisdiction or grandfathering is applied to facilitate the continued use of current well-known and well-developed tests without undue burden on the system as a whole. A system that recognizes the proven success and validity of certain tests or categories of LDTs is essential to ensure that the nation's resources are targeted to reviewing the subsection of diagnostic tests that present the most potential risk to patients.

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### Web Resources

#### AAMC Comment Letter to FDA on Regulation of LDTs

[www.aamc.org/download/423626/data/aamccommentsonfdaproposedguidanceonldts.pdf](http://www.aamc.org/download/423626/data/aamccommentsonfdaproposedguidanceonldts.pdf)

#### FDA Information on LDTs

[www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm407296.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm407296.htm)