Laboratory Developed Tests Should Be Carefully Regulated

Position:
The American Society for Clinical Laboratory Science (ASCLS) believes laboratory developed tests (LDTs) must be regulated to ensure their accuracy and overall patient safety. Patients and health care providers need accurate, reliable, and clinically valid tests to make good health care decisions. Inaccurate or false test results, or accurate measurements with an invalid claim regarding the test results' relationship to a disease, can lead to substantial patient harm.

LDTs play an increasingly important role in the provision of high-quality health care, and many laboratories perform proper validation of their LDTs and provide high-quality, professional management of their operations. However, currently, patients and providers cannot uniformly rely on all tests offered for clinical use as some are not subject to active premarket oversight to ensure they provide accurate measurements and valid claims.

Background:
Congress continues work that began in the 115th Congress to address this issue. In early 2019, ASCLS provided input on a proposal known as the **Verifying Accurate Leading-edge IVCT Development Act of 2018 (VALID Act)** and looks forward to additional dialogue on the issue with key members of Congress.

LDTs are defined by the FDA as in vitro diagnostic tests that are designed, manufactured, and used within a single laboratory. In 2014, the FDA released draft guidance to provide enhanced oversight of LDTs. FDA proposed a three-tier risk-based framework for this oversight. On January 13, 2017, the FDA released a discussion paper on LDTs and announced that it would not issue a final guidance on the oversight of LDTs at the request of various stakeholders to allow for further public discussion on an appropriate oversight approach, and to give congressional authorizing committees the opportunity to develop a legislative solution.

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