Preserving Access to Lab Developed Testing

AACC
Better health through laboratory medicine.

Laboratory developed tests (LDTs) are proprietary tests that clinical labs create for in-house use when a commercial test does not exist or is not appropriate for a particular application or patient population. For example, a lab may develop an LDT to monitor a rare disease or screen for a new designer drug.

LDTs are regulated by the Centers for Medicare and Medicaid Services (CMS) through the Clinical Laboratory Improvement Amendments (CLIA).

Under CLIA, laboratories are required to validate LDTs and adhere to strict quality control and proficiency standards.

LDTs are at the cutting edge of clinical laboratory science and play a vital role in providing quality healthcare in the face of patients' changing medical needs.

CLIA provides robust safeguards; nonetheless, there have been recent efforts to supersede CMS authority and create a duplicative regulatory structure for LDTs within the Food and Drug Administration (FDA).

The Verifying Accurate, Leading-edge IVCT Diagnostics (VALID) Act, introduced in the 117th Congress by Representatives Larry Bucshon and Dianne DeGette, and Senators Richard Burr and Michael Bennet, **would increase the administrative burden and costs on labs performing LDTs without improving patient care.**

The implications of FDA regulation have been demonstrated by the agency's involvement in LDT oversight during the early days of the COVID-19 pandemic. The slow rollout of COVID-19 tests that resulted from FDA inserting itself into the process underscores the fact that imposing additional federal requirements on clinical laboratories can stifle innovation and limit patient access to testing.

There is an ongoing effort to enact the VALID Act by including it in the Medical Device User Fee Amendments (MDUFA) agreement.

Congress should thoroughly evaluate the impact of VALID on innovation and patient care before taking action on this measure. To date, no public hearing has been held on this important, and potentially harmful legislation.

MFUDA is an inappropriate vehicle for enacting major changes to regulatory oversight of LDTs

Our Position:

- CLIA should remain the mechanism for regulating LDTs.
- Duplicative federal regulation will hinder the development of new tests.
- Expanded oversight will force some labs to stop performing LDTs thereby limiting patient access to testing services.

For more Information, please contact:

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