The Verifying Accurate, Leading-edge IVCT Development (VALID) Act

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Better health through laboratory medicine.

The Verifying Accurate, Leading-edge IVCT Diagnostics (VALID) Act was introduced in the 117th Congress by Reps. Larry Bucshon (R-IN) and Diana DeGette (D-CO), and Sens. Richard Burr (R-NC) and Michael Bennet (D-CO). VALID would eliminate the current pre-market approval and 510(k) processes regulating in vitro diagnostic (IVD) test kits and replace it with a streamlined process for IVD manufacturers. The VALID Act additionally extends Food and Drug Administration oversight to laboratory developed tests (LDTs).

LDTs are tests developed by hospitals and commercial laboratories when there is no test available for a medical condition or the existing test requires modification to provide the information needed by the physician. Unfortunately, there is much confusion in the media and among policymakers about LDTs.

An unfounded yet oft-repeated mischaracterization is that LDTs are unregulated. This is false. Congress already created a mechanism to oversee LDTs – the Clinical Laboratory Improvement Amendments (CLIA). This law, administered by the Centers for Medicare and Medicaid Services (CMS), sets stringent and specific quality, accuracy, and reporting requirements for laboratories approved to develop LDTs.

While VALID would introduce a more simplified and less costly regulatory process for IVD manufacturers, it would introduce unnecessary, duplicative, and costly administrative requirements for laboratories performing LDTs. If enacted, VALID would require laboratories conducting LDTs to:

- register and notify the FDA of the LDTs it performs;
- meet FDA quality system requirements;
- report to the FDA adverse events;
- be inspected by the FDA;
- comply with FDA post-market surveillance requirements; and
- pay a user fee to the FDA to fund its oversight activities.

Many of these requirements are already met by labs under CLIA.

The primary and fundamental misconception about LDTs is that they are equivalent to IVDs in application and scope. IVD manufacturers develop standardized machines and test kits that are marketed and sold to any healthcare provider. Clinical laboratories develop and perform LDTs only for their patients, in the provision of testing services.

The creation of a one size fits all regulatory approach for IVD tests and LDTs would significantly hinder the ability of laboratories to meet the healthcare needs of their patients. While the FDA regulatory structure governing IVDs needs reform, it is important to note that the FDA review process is designed for medical device manufacturers, not clinical laboratories.

A dual regulatory structure, which places laboratory services under both FDA and CMS oversight, will force hospitals and other healthcare providers to discontinue these tests, thereby delaying physician access to timely, often vital patient information.

AACC supports streamlining the FDA review process for IVD manufacturers; however, it strongly objects to extending agency oversight to LDTs. While increases in the number and complexity of LDTs may warrant regulatory review, the regulation of LDTs should be discussed and acted upon within the Clinical Laboratory Improvement Advisory Committee (CLIAC), the federal advisory body that guides CMS on changes to the CLIA standards.

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