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The VALID Act, Aiming to Reform the Regulation of Diagnostic Products, Is Finally Introduced in Congress

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Following years of discussion, on March 5, 2020, U.S. Representatives Larry Buchson (R-IN) and Diana DeGette (D-CO) and U.S. Senators Richard Burr (R-NC) and Michael Bennet (D-CO) introduced identical versions of the Verifying Accurate and Leading-edge IVCT Development (VALID) Act in both chambers of Congress. The bipartisan legislation closely tracks existing medical device laws with some notable exceptions, as discussed below and in a **prior post**. If enacted, many regulatory elements familiar to in vitro diagnostic (IVD) and other medical device manufacturers would be applied to clinical laboratories that develop their own tests, commonly known as laboratory developed tests (LDTs). The bill also includes elements that are priorities for the Food and Drug Administration (FDA), including a program conceptually similar to pre-certification, third-party review, and Collaborative Communities. Unlike previously-circulated discussion drafts, the introduced bills include specific language designed to address public health emergencies, including **COVID-19**.

Background on LDTs

In 1976, when FDA began regulating medical devices, including IVDs, it elected not to impose the medical device requirements on LDTs. The agency has said that, back then, LDTs were typically manufactured in a single lab for use with a small group of patients, often for a low-risk disease or condition. Therefore, LDTs required less oversight than higher-risk and more widely-distributed diagnostic devices.

Since the 1970s, the laboratory industry has grown significantly and laboratories have been developing LDTs, including genetic tests, that diagnose more serious diseases and provide highly complex information to both physicians and patients. As a result, about a decade ago, FDA revisited its approach to LDT oversight, and in 2014, FDA issued draft guidance which proposed the phase-in of greater oversight over LDTs. That proposal was met with resistance from the laboratory community and Congress, which collectively urged FDA to work with them on a legislative solution.

The primary argument that clinical laboratories made for not supporting FDA's proposed oversight model was the comprehensive regulation of all laboratory testing pursuant to the Clinical Laboratory Improvement Amendments (CLIA). CLIA governs laboratory accreditation, inspection, and certification, as well as the analytical validity of a test (which refers to whether the test be conducted accurately and reliably). FDA's counterargument was that CLIA is not a complete solution because it does not include provisions to assure that a test is clinically valid (which refers to the accuracy with which the test identifies, measures, or predicts the presence or absence of a clinical condition or predisposition in a patient). Moreover, from a public health standpoint, the agency added that it had seen examples of patients harmed by LDTs that were later demonstrated to be clinically invalid.

Although FDA argued that it had authority to regulate LDTs as a subset of IVDs under existing law, certain stakeholders and legal scholars rejected that position, which put the agency at risk of a legal challenge if it finalized its LDT policy as proposed in the 2014 draft guidance. Ultimately, the agency decided not to vigorously defend its interpretation to the public, the industry, Congress, or in the courts, and instead it worked with the public health community to develop a new regulatory framework designed specifically for these types of products. Together, and as defined in the VALID Act, these products have become known as in vitro clinical tests (IVCTs), which includes both LDTs that FDA has not regulated and IVDs that FDA has regulated as medical devices.

Notable Provisions in the VALID Act

During the past several years and prior to the introduction of the VALID Act, various industry, patient, and other groups in the health care community reviewed and commented on multiple discussion drafts of possible legislation. The VALID Act, as introduced in both the House and the Senate, represents the culmination of those discussions. The following elements from the VALID Act are notable either for their alignment with existing medical device authorities enforced by the FDA or for their novelty when compared with how the agency has historically regulated medical products.

Technology Certification

Perhaps most novel and the biggest win for FDA is the proposed creation of a technology certification program. This concept had been included in earlier VALID Act drafts, referred to as a pre-certification program and pitched as similar to the **pre-certification proposal for software** (regularly referred to as "pre-cert"). However, the provisions in the introduced bill appear to propose a program that is more similar to the over-the-counter (OTC) drug monograph program.

As contemplated in the legislation, through technology certification, an IVCT developer would submit a representative test to FDA for review. FDA would review the test, including the processes and procedures related to the design of the test and the clinical and non-clinical data used in designing the test. If FDA approves, the IVCT developer could then use the technology certification to develop tests that are within the scope of that approval without submitting a test for FDA review each time.

This is different and arguably narrower in scope than the FDA's pre-certification model for software because, as proposed, pre-cert for software certifies a developer, not a product or technology.

Third-Party Review

FDA leadership has long said that it wants to actively regulate the highest risk IVCTs, at one point suggesting that only **10% of tests** would require intensive review by FDA. In addition to technology certification to streamline the process, meeting the goal of regulating the highest risk IVCTs would require having a robust third-party review program in place to handle the significant volume of low- and moderate-risk IVCTs. Similar to existing third-party review programs for traditional medical devices, this program would allow people or organizations accredited by FDA to review IVCTs, which would then only need a quick check by FDA. The bill also would allow third parties to review technology certifications and conduct inspections.

Collaborative Communities

A strategic priority for FDA's device center is to have established 10 **Collaborative Communities** by the end of 2020. FDA's website currently lists two. Language in the VALID Act supports the establishment of a Collaborative Community to assist in "facilitating community solutions and decision-making with respect to [IVCTs]" and should help FDA add one more Collaborative Community to the list. If the VALID Act is enacted, it would authorize (but not require) FDA to consult with a community of private and public-sector stakeholders that will make recommendations and provide other strategic input with regard to the establishment of the new IVCT regulatory program.

User Fees

The VALID Act would require FDA and regulated IVCT developers to negotiate a **user fee agreement** the same way the agency negotiates **user fees** with other industries. In particular, IVCT developers would be required to pay a fee to FDA for various activities, likely including review of tests and technology certifications. The amount of those fees, what specifically they would pay for, performance metrics tied to fees, and other related items would be the subject of negotiations with industry. While an IVCT user fee program would be new, FDA has relevant, related experience in establishing and operating other user fee programs and has data about IVD review times and knowledge about performance goals from the existing device user fee program.

Other Elements

The VALID Act includes language about mitigating measures, which appear to be identical in concept to special controls for medical devices. The bill would also allow FDA to establish or recognize performance standards for IVCTs in much the same way standards are presently used for medical devices. Finally, the bill includes a grandfather clause exempting from its requirements any IVCT marketed prior to the law's enactment if certain criteria are met.

Impact on IVD Manufacturers & Clinical Labs

We expect that, if enacted, the impact of the VALID Act will be minimal for IVD manufacturers because of the alignment between the VALID Act and existing medical device statutory and regulatory requirements and the fact that such requirements have been enforced for IVD manufacturers for decades.

However, if the VALID Act is enacted, it will have a significant impact on clinical laboratories as they will need to comply with many new requirements, including:

- Registration and listing with FDA;
- Quality requirements;
- Investigational studies;
- Premarket review and approval;
- Adverse event reporting; and
- Corrections and removals (recalls).

While the VALID Act outlines a framework for these elements (among others), the law, if enacted, would direct FDA to promulgate regulations and issue guidance documents, giving clinical laboratories and others ample opportunity to participate in shaping the new IVCT regulatory program.

Coronavirus

The VALID Act is sure to draw attention because of the public health crisis that the country is facing regarding COVID-19, the illness caused by the novel coronavirus, and the need to expand the nation's ability to test for the virus. Unlike discussion drafts, the introduced bill includes language exempting from its requirements an IVCT developed under certain emergency conditions, including a public health emergency as declared by the Secretary of Health and Human Services. This language was likely inserted as the bill neared formal introduction to ameliorate concerns that the regulatory reforms proposed in the bill could delay or otherwise limit access to novel tests during an emergency.

What's Next for Stakeholders?

Laboratories and IVD manufacturers should closely study the VALID Act and consider how it could impact them and their future business plans. Congressional committees with jurisdiction over FDA and health care will likely hold hearings on this bill in late spring or early summer 2020, giving stakeholders an opportunity to voice support or concern about the legislation's many provisions. The bill could be incorporated into a broader **health care legislative package** widely expected to be enacted in 2020. Get in touch with any questions or concerns and stay tuned for additional updates.

Authors