Health Industry Alert

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Diagnostics Reform Heats Back Up with Introduction of the Verifying Accurate Leading-edge IVCT Development Act of 2021

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In vitro diagnostics (IVD) reform re-entered the legislative fray this week. The Verifying Accurate Leading-edge IVCT Development Act of 2021 (the "VALID Act of 2021," the "VALID Act" or the "Act") was introduced in both the House and Senate on June 24, 2021 by U.S. Reps. Diana DeGette (D-CO) and Larry Bucshon (R-IN) and U.S. Sens. Michael Bennet (D-CO) and Richard Burr (R-NC).

The bipartisan Act seeks to modernize regulatory oversight of IVDs, including laboratory developed tests (LDTs), by creating a single, diagnostics-specific, regulatory framework under the authority of the Food and Drug Administration (FDA) aimed at promoting innovation and improving patient and public health. Introduction of this legislation coincides with the introduction of numerous bills and other initiatives to provide coverage and reimbursement for diagnostics or therapies that have obtained FDA marketing authorization.[1] The COVID-19 public health emergency confirmed the importance of IVDs, but also highlighted uncertainties as to the regulatory requirements applicable to clinical testing. The VALID Act would address these regulatory uncertainties, while developing a legal framework for diagnostics that is distinct from medical devices.

A version of VALID was first introduced by the same four members of Congress on March 5, 2020, and reflected several years of collaboration between the sponsors and key stakeholders. The VALID Act of 2021 incorporates additional stakeholder input and positions the VALID Act to be considered in this Congress, including as part of the much anticipated User Fee Reauthorization in 2022. However, several key policy points are likely to be considered further before the bill is readied for passage.

Regulatory Overview

The impetus for the VALID Act is multifold. Advances in diagnostics have posed challenges for the existing medical device regulatory framework. Many diagnostic technologies, including software, are conducive to rapid changes and modifications. Moreover, at home and point-of-care testing has become increasingly common—a trend accelerated by the COVID-19 public health emergency. Finally, the longstanding

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uncertainty as to the legal status of laboratory developed tests (LDTs) also became more acute during the public health emergency. While FDA has asserted jurisdiction over these tests, the agency has generally exercised enforcement discretion for such tests as long as they were developed and used within an individual, high-complexity laboratory. In certain instances, however, FDA has asserted regulatory oversight over these tests, such as in the area of pharmacogenomics.[2] In certain cases, laboratories have opted to seek, and have received, marketing authorization for their LDTs.

FDA has also taken the position, notwithstanding its overall approach of enforcement discretion towards LDTs, that these tests required Emergency Use Authorization (EUA) in order to be used during a public health emergency. FDA took the same position at the beginning of the COVID-19 public health emergency. In August 2020, however, the Department of Health and Human Services (HHS) announced in the *Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests* that FDA would no longer require premarket review for LDTs, but that labs could voluntarily seek an EUA for their LDTs. HHS further opined that FDA's authority to subject LDTs to premarket review as medical devices was unclear and required rulemaking. In response, FDA announced that the agency would not review EUA submissions for LDTs in order to prioritize other EUA applications. HHS subsequently directed FDA to resume its review of EUA applications for COVID-19 LDTs.

While the August 2020 policy has not been formally withdrawn, it was removed from the HHS website in the spring of 2021. The current Administration has not articulated an interpretation of FDA's authority with respect to LDTs, but the reintroduction of the VALID Act, as well as the competing Verified Innovative Testing in American Laboratories (VITAL) Act, have provided the Administration an opportunity to provide input to Congress.

Overview of Provisions in the VALID Act of 2021

The VALID Act of 2021 shares the same construct and many of the same standards and requirements as the 2020 bill. In the following section, we provide an overview of these fundamental provisions of the bill.

The VALID Act would remove in vitro clinical tests (IVCTs) from the scope of medical device regulation and create a separate paradigm specific to IVCTs. IVCTs are defined to include traditional IVDs and LDTs. IVCTs include diagnostic software (except software excluded from the definition of a medical device), an instrument and a test protocol or laboratory test protocol. IVCTs do not include certain IVCT components, such as blood, blood components or human cells or tissues.

Under the bill, the regulatory framework for IVCTs would parallel the medical device framework in many respects, subject to important differences reflecting how tests, and their use and evaluation, differ from non-diagnostic medical devices. For example, the VALID Act sets an "applicable standard" for IVCT defined generally as "a reasonable assurance of analytical and clinical validity." This would replace, for IVCTs, the prevailing device standard of a reasonable assurance of safety and effectiveness. Notably, the Act applies different standards for instruments as well as articles for taking or deriving specimens—generally focused on analytical validity (and explicitly safety, with regard to articles for taking or deriving specimens).

The VALID Act would also subject IVCTs to a tailored premarket review process. As is the case with the current process for medical devices, the nature of review for IVCTs would be tiered based generally (but not entirely) on risk. In general, high risk IVCTs would be subject to the most exacting review. Most IVCTs that are low risk would be required to list with FDA but would not be subject to premarket review. IVCTs that are neither high risk nor low risk would be subject to a more tailored application process. Unlike the medical device review process, however, these "moderate" risk IVCTs would obtain an approval, rather than a clearance, and review would not be based on a showing of substantial equivalence as is the case for devices under the current 510(k) process. Notably, IVCT developers could include a proposed change protocol with their applications, which would allow the developer to make certain changes to their approved test based on validation.

Of the premarket review processes detailed in the VALID Act, perhaps the most significant is the Technology Certification program. For IVCTs that are not high risk, instead of using the traditional application process, the developer could obtain marketing authorization by submitting to FDA information concerning a representative test, along with an assessment of the developer's methods and procedures for test development, validation and maintenance. FDA will then review the processes and procedures related to the design of the test, as well as the clinical and non-clinical data utilized in designing the test. If the technology certification is granted, a developer may modify the IVCT or develop related versions of the IVCT within the scope of that approval. Importantly, the technology certifications must be based on a single technology as defined in the VALID Act, and is subject to additional limitations detailed in the Act. FDA would maintain the ability to withdraw the certification prior to its timeline for renewal, or seek additional information about IVCTs covered by the certification.

In addition to these premarket pathways, the VALID Act also establishes a breakthrough designation, which allows for priority review of IVCTs meeting specific eligibility requirements. This section of the Act is based on the medical device breakthrough designation.

In addition to the low-risk IVCTs that are exempt from premarket review, certain types of IVCTs are specifically exempted from a premarket submission and other specified requirements of the VALID Act, including tests for humanitarian use that meet certain requirements and tests intended solely for public health surveillance activities.

Other important elements of the VALID Act of 2021 include:

- **Tests for Emergency Use**: The Act would authorize the use of validated tests for emergency purposes for a period of time pending the review of an EUA authorization—somewhat analogous to the notification process that FDA employed for certain COVID-19 tests during the current public health emergency.
- **Grandfathered Tests**: The Act provides for "grandfathered" status for qualifying LDTs that were offered for clinical use prior to enactment of the legislation; such tests will not require premarket review after the Act's effective date provided that they carry a labeling disclaimer, that the test is generally not modified, and that FDA does not identify a particular concern about the test (see "Special Rule" below).

- **Transitional Tests**: IVCTs first offered between the date of enactment of the VALID Act and the date that is 90 days after the effective date, referred to as "transitional" IVCTs, are permitted to remain on the market after the effective date of the Act as long as their developer submits a timely marketing application.
- **Special Rule**: The Act includes a process whereby FDA can request information from the developer of an otherwise exempt IVCT, such as a grandfathered IVCT, under certain circumstances.
- **Test Design and Quality Requirements**: The Act establishes quality requirements applicable to IVCTs, akin to Quality Systems requirements applicable to medical devices.
- **Collaborative Communities for IVCTs**: Under the legislation, FDA may participate in collaborative communities composed of a diverse set of stakeholders, for the purpose of "facilitating community solutions and decision-making with respect to" IVCTs.
- **Comprehensive Test Information Systems (CTIS)**: Directs FDA to create and maintain a database about IVCTs available on the market that is more extensive than the current device registration and listing database.
- **Adulteration, Misbranding, and Postmarket Surveillance**: These provisions largely mirror the Food, Drug, and Cosmetic Act provisions currently applied to devices.

Notable Changes and Open Questions

One of the more significant changes between the 2020 and 2021 versions of the VALID Act is the alignment of the Technology Certification program with a more risk-based framework. Unlike the 2020 version, the VALID Act of 2021 applies the Technology Certification program to IVCTs that are not high risk (but which still require premarket review), without making distinctions base on particular types or uses of the tests. The updated bill makes other minor changes to the Technology Certification program, and also provides more clarity and direction for the development of implementing rules and guidance during the transition period.

Drafters of the Act also sought to provide additional clarity to the definitions of high- and low-risk devices. With respect to high-risk devices, the VALID Act of 2021 altered the definition to exclude IVCTs from the definition if mitigating measures are established to "prevent, detect, or otherwise mitigate the risk of inaccurate results…" or if another specified exemption applies. The Act includes a broader definition of low-risk devices, including, among other things, a wider variety of factors regarding risks to patient health in the ultimate designation of a test as low-risk.

Many elements of the VALID Act of 2021 will require further deliberation. The sponsors of this bill and their staffs have spent considerable time obtaining input from stakeholders. However, much of that input occurred before the public health emergency and prior to the change in administrations. These discussions are now expected to advance, with the potential target of passage either this year or as part of next year's user fee reauthorization.

[1] These include H.R. 5333, Ensuring Patient Access to Critical Breakthrough Products Act of 2019; H.R. 1946, the Medicare Multi-Cancer Early Detection Screening Coverage Act; Sections 305 and 404 of the newly introduced Cures 2.0 Act; and the Medicare Coverage of Innovative Technology (MCIT) final rule.

[2] More information on this topic can be found here.