



Analysis of the VALID Act

On May 26, 2022, the Senate Committee on Health, Education, Labor and Pensions (HELP) introduced the FDA user fee program reauthorization package, known as, [the FDA Safety and Landmark Advancements Act \(FDASLA\) of 2022 \(S.4348\)](#). The bill is scheduled to move through the Senate HELP Committee the week of June 13.

One section of the Senate bill is **The Verifying Accurate Leading-edge IVCT Development (VALID) Act**, which would establish a new framework for the FDA to regulate in vitro clinical tests (IVCTs). The bill would create a variety of requirements for IVCTs, such as a pre-market review approval program, a technology certification program for developers of certain IVCTs, risk-based classifications, expedited development and priority review for breakthrough tests, registration requirements, labeling requirements, an appeals process, and postmarket surveillance requirements. It also creates a third-party reviewer program. As with the regulatory systems for biologics, drugs and medical devices, the FDA would be charged with promulgating regulations and developing guidance that interprets, implements, and operationalizes the new regulatory framework.

- **Definition of IVCT:** An IVCT would be defined as “an article...intended... to be used in the collection, preparation, analysis, or in vitro clinical examination of specimens taken or derived from the human body” to diagnose or identify a disease or condition; provide information for diagnosing, screening, measuring, detecting, predicting, prognosing, analyzing or monitoring a disease or condition; or to selecting, monitoring or informing therapy or treatment for a disease or condition. An “article” would include a test kit, test system, test protocol or laboratory test protocol, an instrument, a specimen receptacle, certain software, and some components or parts of tests, test protocols, instruments, articles or software, such as reagents, calibrators and controls. In vitro diagnostics (IVDs) and laboratory developed tests (LDTs) would be regulated as IVCTs.
- **Blood, blood components, human cells and tissues intended to be used as part of an IVCT are excluded from the definition of an IVCT.** If intended to be used as a component or part of an IVCT, “blood, blood components, human cells or tissues, from the time of acquisition, donation, or recovery of such article, including determination of donor eligibility,... until such time as the article is released as a component or part of an in vitro clinical test by the establishment that collected such article” are excluded from the definition of an IVCT. A “component or part” of an IVCT includes “a substance, piece, part, raw material, software, firmware, labeling, or assembly, including reagents, that is intended by the developer to be included as an aspect of” an IVCT.
- **The VALID Act is not intended to modify the authority of FDA “with respect to laboratories, establishments, or other facilities to the extent they are engaged in the propagation, manufacture, or preparation, including filling, labeling, packaging, and storage, of blood, blood components, human cells, tissues, or tissue products pursuant to any requirements under [the Federal Food, Drug and Cosmetic Act] or section 351 or 361 of the Public Health**

Service Act.” Additionally, the Secretary is to avoid duplicating requirements under CLIA. The bill specifically prohibits FDA from infringing on the practice of medicine.

- **The VALID Act would regulate IVCTs that are “introduced or delivered for introduction into interstate commerce.”** Any IVCT “that is offered, including by making available for clinical use in the United States” would be deemed to be introduced into interstate commerce for the purposes of the Act.
- **LDTs performed by AABB members may be included in the definition of an IVCT and subject to the new regulatory framework.** Once blood, blood components, human cells and tissues are released as a component or part of an IVCT, the test would likely be captured by the new statutory framework. Therefore, LDTs and other tests that satisfy the definition of IVCTs performed by AABB members, such as IRLs, may be covered by the new regulatory requirements governing IVCTs. IVCTs would not be considered biological products.
- **There are three general premarket pathways under the bill: full premarket review; abbreviated premarket review; and technology certification.**
 - The full premarket review pathway would represent the highest bar to market. Under this pathway, the FDA would review comprehensive data on the product’s safety and efficacy, proposed labeling, a bibliography of studies related to the test, information to demonstrate compliance with quality requirements and standards, and a “proposed change protocol” for any modifications to the test that fall within the scope of approval, and documentation on quality systems.
 - Under the abbreviated premarket review pathway, certain individual IVCTs for which full review is not required could be reviewed in a more streamlined fashion, based on FDA’s review of their proposed labeling and summary data. Sponsors would not necessarily need to include quality requirement information or “raw data, unless explicitly requested” or data on software validation, electromagnetic compatibility and electrical safety.
 - The technology certification pathway would allow developers to submit a “representative test” to the agency and seek certification for marketing that type of technology without needing regulatory review for each individual product within the technology type. IVCTs intended for use for testing donors, donations, and recipients of blood, blood components, human cells, tissues, cellular-based products, or tissue-based products would not be eligible for technology certification.
- **The bill includes three risk categories for IVCTs, which determine the level of regulatory review that applies.** As with medical devices, the FDA would have authority to determine risk classification of IVCTs. FDA would be permitted to establish “mitigating measures” to help inform the risk category of a product.
 - High-risk IVCTs would be required to undergo full premarket review. They include IVCTs (or categories of IVCTs) where (1) an undetected inaccurate result from such a test (or category of tests) has the substantial likelihood to result in serious or irreversible harm or death to patients or serious harm to the public health or is likely to result in the absence, significant delay, or discontinuation of life-supporting or life-sustaining medical treatment; and (2) sufficient mitigating measures have not been established or applied

to prevent, mitigate or detect the inaccurate result, or otherwise mitigate the risk resulting from an undetected inaccurate result.

- Moderate-risk IVCTs would be subject to an abbreviated premarket review and would include tests that would otherwise meet the high-risk classification but to which mitigating measures have been applied or would be expected to produce non-life-threatening injuries or present a reasonable risk for users or public health.
 - Low-risk IVCTs, which would be exempt from pre-market review, would be IVCTs for which an inaccurate result would cause minimum or immediately reversible harm, or a higher risk product to which mitigating measure have been applied.
 - “Mitigating measures,” would be defined to include controls, standards and other requirements that FDA determines are necessary for an IVCT to meet the applicable standard or to mitigate the risk of harm ensuing from an undetected inaccurate result or misinterpretation of a result. They may include applicable requirements regarding labeling, conformance to performance standards and consensus standards, performance testing, submission of clinical data, advertising, website posting of information, clinical studies, postmarket surveillance, user comprehension studies, training, and confirmatory laboratory, clinical findings, or testing. Additionally, special controls established for IVCTs cleared or exempt as devices prior to October 1, 2027 would be deemed to be mitigating measures for the purposes of IVCT regulation.
- **Several IVCTs would be exempt from premarket review.**
 - Examples of tests that would be exempt from premarket review by FDA would include low risk IVCTs, an IVCT under a technology certification order; IVCTs that were 510(k) exempt prior to the enactment of the VALID Act, certain point of care tests, custom and low-volume tests, those used for public health surveillance, IVCTs intended solely for use in forensic analysis or law enforcement activity, and tests that meet criteria to qualify as humanitarian tests (tests intended for use by fewer than 10,000 individuals per year that meet certain criteria).
 - Manual IVCTs meeting certain criteria would be exempt from premarket review, although manual tests “intended for testing donors, donations, or recipients of blood, blood components, human cells, tissues, cellular-based products, or tissue-based products” would not qualify for this exemption.
 - An IVCT “intended to inform the use of a specific individual or specific type of biological product, drug, or device” would be exempt from premarket review if the developer “submits a request... for informal feedback and the Secretary determines that” the IVCT is eligible for an exemption.
 - Certain IVCTs offered for clinical use before the date of enactment of the VALID Act and developed by laboratories with CLIA certificates that meet the requirements for performing high complexity tests would be grandfathered and would be exempt from the premarket approval, labeling requirements, test design requirements and quality requirements in the Act.

- **The bill would establish additional regulatory requirements for developers of IVCTs.** Such requirements would be related to registration and listing, labeling, test design and quality, adverse event reporting, and corrections and removals. The bill specifies that “labeling for an [IVCT] used for immunohematology testing shall meet the applicable requirements set forth in part 660 of title 21, Code of Federal Regulations (or any successor regulations), related to the labeling of blood grouping reagents, reagent red blood cells, and anti-human globulin.”
- **The bill would give FDA the authority to accredit eligible persons to review and make recommendations on IVCT applications for both premarket approval and technology certification, and to conduct inspections of IVCT developers that that are not duplicative of CLIA inspections.** The Secretary would be permitted to “provide for accreditation... through programs administered by the [FDA], by other non-Federal government agencies, or by qualified nongovernmental organizations.” A person may be accredited to review premarket approval applications, technology certification applications and to conduct inspections, or for a subset of these activities. Within 180 days of enactment, the Secretary would be required to issue draft guidance specifying the process for submitting a request for accreditation and reaccreditation under the VALID Act. Initial accreditations may be for up to 3 years, after which accredited persons may be reaccredited for unlimited additional 35-year periods.
- **The bill would allow FDA to recognize appropriate standards established by nationally and internationally recognized standards development organizations, and a person may submit a declaration of conformity in order to meet a requirement to which the standard is applicable.** FDA would be permitted to consider previously recognized device standards as recognized standards for IVCTs. FDA would be required to issue regulations establishing the criteria and process for the recognition and adoption of standards.
- **There would be a five-year transition period, with an effective date of October 1, 2027.** However, the FDA may implement the registration requirements as early as October 1, 2024. FDA would be required to hold public meetings within one year of enactment, promulgate final regulations within 3 years of enactment, and issue final guidance within 30 months of enactment. The bill includes a process for transitional IVCTs, which are first offered for clinical use beginning on the date of enactment through the effective date and meets certain criteria.
- **The bill would require FDA, in consultation with regulated industry, to present recommendations to Congress on a user fee program to support the IVCT regulatory framework.** FDA would be permitted to collect user fees beginning on October 1, 2027.

If you have any questions or would like additional information, please contact us at advocacy@aabb.org.