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The Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2020

Section 1. Short Title and Table of Contents

- Title of the bill is the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2020

Section 2. Definitions

- Provides definitions of relevant terms, including for an in vitro clinical test (IVCT). Clarifies that IVCT components - including blood, blood components, or human cells or tissues, laboratory equipment and personal protection equipment - do not qualify as IVCTs.

Section 3. Regulation of In Vitro Clinical Tests

- Amends the Federal Food, Drug, and Cosmetic Act (FDCA) to include the new subchapter for in vitro clinical tests, subchapter J.

VALID Sections under Subchapter J of the FDCA

Section 587. Definitions

- Defines relevant terms used throughout the remainder of the Act, including the definitions for analytical and clinical validity of an IVCT, instruments, developer, technology, high-risk, and low-risk.

Section 587A. Applicability

- Outlines the types of tests that may be exempt under the newly established regulatory framework for in vitro clinical tests.
- Stipulates that the bill will not restrict a provider's ability to administer or prescribe an approved IVCT, or otherwise limit the practice of medicine.
- Determines conditions for emergency use and exemptions from FDA review, such as for grandfathered tests, low-risk tests, and tests for rare diseases.
- Clarifies the types of modifications to premarket tests that can be made with and without additional FDA review (e.g., changes that do not affect the analytical or clinical validity of the test).

Section 587B. Premarket Review

- Provides details for the premarket review and approval process, including the processes for amendments, supplements, appeals, and withdrawals of approvals.
- Clarifies that a premarket application can also be used as a representative test for a technology certification.
- Outlines the information required in a premarket application for an IVCT in order to ensure the test meets the standards of analytical and clinical validity to come to market.
- Provides the pathway to market for test instruments. Includes details related to an application for special pre-market approval for eligible tests, including test instruments, specimen receptacles, and tests that would otherwise be eligible for review under a technology certification order.
- Requires developers of approved IVCTs to submit an annual report to FDA on their IVCT and any modifications.

Section 587C. Breakthrough In Vitro Clinical Tests

- Establishes a program to expedite the development of IVCTs that address unmet need for patients.
- Calls for the Secretary to issue guidance on the implementation of establishing the process for requesting breakthrough status and the criteria for review under the breakthrough designation.

Section 587D. Technology Certification

- Details the process for technology certification review. Technology certification allows for the developer of IVCTs to submit a representative test to be reviewed by FDA. FDA reviews the processes and procedures that are 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 approved, a developer can use that certification to develop tests within the same scope of approval without going back through FDA review each time. For example, the developer can submit one liver enzyme assay as a technology certification, and develop multiple liver enzyme assays that do not require FDA submission, as long as they are within the scope of the technology certification application.
- Outlines the parameters of a technology certification application and requirements for eligible developers.
- Requires that a technology certification be based on a single technology, as defined in section 587 of the VALID Act.
- Calls for the Secretary to establish a public meeting for input and recommendations on implementation of technology certification process within 6 months of enactment.
- The Secretary shall also issue draft guidance two years after enactment and to submit annual reports to Congress for a five-year period to provide updates on the status of the technology certification process.

Section 587E. Mitigating Measures
• Permits FDA to set mitigating measures for IVCTs with the same indications for use. These measures allow FDA to best categorize the risk of an IVCT for providers and patients. Mitigating measures will be publicly available. • Clarifies that mitigating measures required for IVCTs regulated as devices before the enactment of this Act will remain in effect unless FDA changes or withdraws them.
Section 587F. Regulatory Pathway Redesignation
• Allows FDA to change the regulatory designation of a test or tests with the same indication for use in response to new information (such as new mitigating measures) or revoke any exemption of such tests if there is a reasonable probability of severe adverse health consequences.
Section 587G. Advisory Committees
• Allows FDA to establish advisory committees or use previously established committees to rely on their scientific expertise to make recommendations regarding the review and approval of IVCT applications. • Details the criteria for appointing members to advisory committees. • Calls for the Secretary to educate and train each new member of the committee on the requirements of VALID and ensure that the advisory panels meet regularly.
Section 587H. Request for Informal Feedback
• Encourages developers to request informal FDA feedback under this Act for an efficient review process. The informal feedback can be about the submission process, type and amount of evidence needed, or the appropriate regulatory pathway or exemption for the test or tests. • Requires FDA to meet with or respond to the developer's request within 60 days and provide written response to the developer within 30 days of the meeting.
Section 587I. Registration and Listing
• Establishes the process required to register with FDA under the VALID Act. • Requires that developers of IVCTs provide FDA with listing information related to their IVCTs and annually submit relevant information to a publicly available electronic database managed by FDA. • Requires that developers of grandfathered IVCTs provide FDA with a certain information related to their IVCTs.
Section 587J. Test Design and Quality Requirements
• Requires all persons registered under Section 587I to maintain quality requirements tailored to the type of test offered and where it is developed. • Clarifies that FDA-regulated quality requirements apply only to the design and manufacturing of IVCTs and that laboratory operations will continue to be regulated by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA).

- Establishes different quality requirements for labs that are and are not CLIA certified for high-complexity testing and labs that are distributing IVCTs or test protocols within organizations or public health networks.

Section 587K. Labeling Requirements

- Specifies which types of tests should meet labeling requirements and outlines the information that must be contained in an IVCT's label, such as instructions for reporting adverse events, intended use of the IVCT, and warnings and limitations of the test.
- Test instruments, analyte-specific reagents, and IVCTs for research or investigational use are generally exempt from this bill's labeling requirements.

Section 587L. Adverse Event Reporting

- Establishes the processes for IVCT developer adverse event reporting.

Section 587M: Corrections and Removals

- In certain cases, IVCT developers voluntarily report to FDA that they are making corrections to their tests or removing their tests from the market. For example, a developer may implement a new measure to reduce the risk posed by the IVCT. The VALID Act would require a notification of such change within 15 business days of initiating the correction or removal.
- Reporting a correction or removal of an IVCT is not required if the report was submitted as a part of adverse event reporting.
- Outlines the timelines for when the Secretary must classify the correction or removal after receiving the report from the developer and when the Secretary must provide the developer with a written statement confirming completion of the correction and removal activities after notification by the developer of completing the action.

Section 587N. Restricted In Vitro Clinical Tests

- Describes the circumstances under which FDA can add certain requirements to the approval of an IVCT to minimize patient risk and ensure analytical and clinical validity of the test.

Section 587O. Appeals

- Similar to the medical device requirements under the FDCA, this section directs the Secretary to provide a substantive summary of the scientific and regulatory reasoning for any significant decision made by FDA regarding submission or review of an IVCT or for any exemption.
- Outlines the process by which any person may request a supervisory review of any significant decision made by Center for Devices and Radiological Health by the next supervisory level or higher above that person within 30 days of a decision. A decision must be made within 45 days of the initial request for review.
- An individual may also request a review by an advisory committee.

Section 587P. Accredited Persons
• Provides the authority for FDA to accredit qualified entities to review test applications for both premarket approval and technology certification, and to conduct inspections of IVCT developers and other registrants. • FDA will issue guidance on eligibility for accreditation and the processes for accrediting these entities.
Section 587Q. Recognized Standards
• Authorizes FDA to establish performance standards that IVCTs can use to demonstrate clinical validity, analytical validity, and safety as applicable. • Allows FDA to rely on standard setting organizations to utilize recognized standards (including international standards) in the review of an IVCT.
Section 587R. Investigational Use
• Authorizes FDA to implement regulations for IVCTs used for research purposes, also called "investigational use." • Investigational use IVCTs are generally exempt from this bill's requirements; however, researchers must keep records documenting their use of the investigational IVCTs and provide research plans for the development of their IVCT to FDA. • The level of information a researcher is required to provide to FDA is dependent upon the level of risk and benefit to the patients receiving the investigational test. • Allows the Secretary to impose a clinical hold on unsafe investigational use IVCTs in certain circumstances.
Section 587S. Collaborative Communities for In Vitro Clinical Tests
• Allows FDA to participate in collaborative communities composed of a diverse set of stakeholders to obtain ideas regarding the efficient regulation of IVCTs.
Section 587T. Comprehensive Test Information System
• Directs FDA to create and maintain a website to house information about IVCTs available on the market, making certain information available to providers and consumers. • The website will also serve as a secure portal for the submission of premarket applications and technology certification applications.
Section 587U. Preemption
• Prohibits State, tribal, or local governments from establishing or continuing any IVCT regulations that are different or in addition to those established by the VALID Act.
Section 587V. Adulteration
• Lists criteria used to determine whether an IVCT would be deemed to be adulterated.

Section 587W. Misbranding

- Lists criteria used to determine whether an IVCT would be deemed to be misbranded.

Section 587X. Postmarket Surveillance

- Allows the Secretary to require, by order, developers to conduct postmarket surveillance of IVCTs as a condition of approval for such tests or as a mitigating measure.
- Provides information on the process of properly conducting and submitting surveillance to FDA.

Section 587Y. Electronic Format for Submissions

- Requires all IVCT submissions completed under this Act to include an electronic copy, and states that upon a date of the Secretary's choosing, ongoing presubmissions and submissions must be submitted solely through the electronic format specific by the Secretary.
- Specifies that the Secretary should issue guidance implementing this section.

Section 587Z. Postmarket Remedies

- Allows the Secretary to order the developer to submit a plan to repair, replace, or refund the IVCT if a premarket-approved IVCT is found to present an unreasonable risk of substantial harm to public health, after affording opportunity for an informal hearing for the developer.
- Allows the FDA to direct the test developer to immediately cease distribution of the IVCT and notify entities or individuals that use the test if a premarket-approved IVCT is found to cause serious adverse health consequences or death.

Implementing Sections Outside of Subchapter J

Section 4. Enforcement and Other Provisions

- Details the circumstances under which IVCTs would be subject to existing relevant penalties of the Food, Drug, and Cosmetic Act.

Section 5. Transition

- Requires FDA to hold all public meetings listed under VALID within 2 years of enactment and issue certain regulations and guidance within 3 years of enactment.
- Implements the provisions of the VALID Act at the beginning the 4th fiscal year after the date of enactment.
- Allows IVCTs on the market before the enactment to continue to comply with existing laws.
- Determines that IVCTs introduced into the market after enactment, but before its effective date will be deemed 'transitional tests' and will be required to comply with certain interim requirements while remaining on the market.
- Transitional IVCTs are used only in high-complexity testing and are first used on or after the date of enactment of VALID. After the implementation of this Act, they must

comply with its regulations. Transitional IVCTs undergoing review at the time of this Act's effective date may remain on the market until FDA completes its review. • IVCTs that are undergoing FDA review on the effective date of this Act will be regulated according to the pathway through which they were submitted. • Five years after this Act's enactment, test instruments or a member of the same instrument family must be reviewed by FDA.
Section 6. Emergency Use Authorization
• Permits IVCTs to be developed and used under an emergency use authorization.
Section 7. Antimicrobial Susceptibility Tests
• Amends a section of the Federal Food, Drug, and Cosmetic Act addressing breakpoints for antimicrobial resistance tests to adequately address issues pertaining to IVCTs that are developed to help direct the treatment of infectious diseases and maintain the policies established under the 21st Century Cures Act.
Section 8. Combination Products
• Amends a section of the Federal Food, Drug, and Cosmetic Act addressing combination product regulation to clarify the combination product process for products that include an IVCT.
Section 9. Resources
• Provides requirements for the collection of user fees to review IVCT submissions. • Authorizes the Secretary to collect user fees under the VALID Act framework under certain conditions.