REGULATORY FOCUS

The Proposed VALID Act: A Possible Next Step in FDA's Goal of Regulating LDTs

By Allyson B. Mullen and Jeffrey N. Gibbs

This article discusses a Congressional draft proposal, *The Verifying Accurate Leading-Edge IVCT Development (VALID) Act* of 2018, aimed at making regulatory changes for Laboratory Developed Tests (LDTs). The authors identify a number of important points about the draft and offer analysis and commentary on proposed changes to classification and premarket review, pre-certification, registration and notification and appeals. They suggest that if the draft *VALID Act* became law, it would have far-reaching and potentially negative consequences for physicians and their patients.

Introduction

In November 2018, *Regulatory Focus* posted an article discussing the past, present and future of Laboratory Developed Test (LDT) regulation.[1] While the future of LDT regulation is still very uncertain, Congress has floated a new draft proposal for regulating LDTs, *The Verifying Accurate Leading-Edge IVCT Development (VALID) Act* of 2018.[2]

Since the 2016 election and the US Food and Drug Administration's (FDA's) subsequent announcement that it would not finalize its 2014 draft Laboratory Developed Test (LDT) guidances, it has become clear that any change to the

diagnostic test regulatory framework (at least in the near term) will need to come via Congressional action. Accordingly, it did not take long for Congress to issue its first proposal in early 2017 with the release of the *Diagnostic Accuracy and Innovation Act (DAIA)*.[3] This document reflected input from various stakeholders over a multi-year period. FDA provided a Technical Assistance (TA) document on the DAIA in the summer of 2018. FDA's TA was essentially a complete rewrite of the DAIA and the changes were viewed very negatively by many in the industry.[4]

However, Congress appeared to view the TA more positively than did industry and, in early December 2018, Chairman Walden, Ranking Member Pallone, Representative Bucshon and Representative DeGette, released a discussion draft of the VALID Act of 2018. This proposal looks very similar to FDA's TA, and contains many problems needing to be addressed. In addition, multiple sources have indicated that it is unlikely the VALID Act will be passed in its current form. Nonetheless, given the increasing likelihood that there will be some potentially significant changes to the diagnostic testing regulatory framework at some point—or at least proposed legislation that will receive significant investor, customer and media attention—it is important for manufacturers and laboratories to keep abreast of these proposals.

Defining IVCTs

The draft *VALID Act* defines *In Vitro* Clinical Tests (IVCTs) very broadly to include any test intended for "identifying, diagnosing, screening, measuring, detecting, predicting, prognosing, analyzing or monitoring a disease or condition, including by making a determination of an individual's state of health; or selecting, monitoring, or informing therapy or treatment for a disease or condition." IVCTs also include all parts and components of such tests, with certain limited exclusions (e.g., general laboratory equipment). The regulated components and parts will include test protocols, test platforms, collection devices, sample preparation devices and software. Thus, the IVCT definition encompasses both traditional in vitro diagnostic devices (IVDs) as regulated by FDA as well as LDTs. Under the discussion draft, IVCTs will be subject to the new FDA regulatory framework with regard to design, development, premarket review and approval, precertification (for select tests), quality system regulations and so on. In many cases, this framework also will apply to laboratories because they will have designed or developed an IVCT. However, these labs will still be required to comply with the Clinical Laboratory Improvement Amendments (CLIA) with regard to lab operations.[5] Thus, for labs, the draft bill will result in some duplicative regulation as it is not always clear precisely where test development ends and laboratory operations begin.

Superficially, this framework looks much like the current medical device regulatory framework, including a classification scheme, premarket review, a breakthrough test program, postapproval requirements, adverse event and recall reporting and quality system and labeling requirements. But, a closer look reveals several material changes.

Classification and Premarket Review

Under the *VALID Act* there would be two classes of IVCTs—high-risk and low-risk—as compared to FDA's current three classes of devices. In terms of premarket review, all high-risk IVCTs would require premarket review and approval unless an exemption applies. The proposed premarket review is onerous and appears to be modeled on FDA's Premarket Approval (PMA) process and it includes, among other things, requirements for demonstrating clinical and analytical validity of a proposed IVCT.

Precertification

One exemption to premarket review is to obtain precertification for a test group. FDA is currently piloting a precertification program for certain software products, but the IVCT precertification program would be a new concept for diagnostic products. Precertification would require an application and possible facility inspection. Precertification would apply to a "test group," which the draft defines as a group of IVCTs with the same analyte of interest, specimen, method, purpose, disease/condition, intended patient population and context of use. This is an incredibly narrow definition, one which will sharply limit the utility of precertification. The definition is also bound to lead to uncertainty as to what falls within a "test group." In addition, precertification would be unavailable for many products, such as test platforms, collection devices, software, certain blood tests, first-of-a-kind tests, tests for home use, high-risk tests, cross-referenced tests (e.g., companion and complementary diagnostics) and direct-to-consumer tests. Precertification also would be limited in duration and require periodic renewal. While there has been much discussion of the precertification program on the software side, it is still unclear how well the concept will work in practice.

Registration and Notification

As suggested in FDA's 2014 LDT guidances, the proposed *VALID Act* would require all IVCT test developers (along with other entities, including contract manufacturers) to register with FDA and notify FDA of their tests. The establishment registration process appears administrative—much like the device establishment registration process. However, the IVCT notification process will be much more burdensome than the current device listing process as it is far more comprehensive than the current device listing form. For example, test developers will be required to submit to FDA, among other things, a description of the test, analytes, specimen type, test method, intended patient population, summary of analytical and clinical performance data and labeling. All of this information would be public.

Appeals

Many of the administrative and postmarket provisions look just like the device provisions, but with small nuances to make them more applicable to IVCTs. The *FDA Safety and Innovation Act of 2012 (FDASIA)* added Section 517A of the

Federal Food, Drug, and Cosmetic Act, which sets specific timelines for medical device appeals, including timing for FDA's decisions on appeals.[6] This statutory change has greatly improved the device appeals process by making timing of appeals more predictable. The proposed appeals provision would require IVCT appeals to be submitted within 30 days of FDA's issuing certain decisions, such as decisions on premarket applications, precertification, investigational IVCT exemptions or emergency use authorizations, which is consistent with 517A. However, unlike the current device appeals process, there is no required timeline for FDA to respond to IVCT appeals. If this provision is passed as written, it would undo the predictability of the current device appeal process and potentially leave some appeals in prolonged "limbo." That is what happens, for example, with appeals relating to product jurisdictional decisions because FDA faces no deadlines for deciding those appeals and it has rendered that appeal process unsatisfactory.

Grandfathering

Finally, much like pre-amendments devices, "grandfathered" tests would be exempt from the new regulatory framework. The proposed *VALID Act* limits grandfathered tests to IVCTs that:

1. were on the market 90 days prior to enactment of the law,
2. were developed by a laboratory with a high complexity CLIA certificate,
3. are performed in the same lab in which it was developed or by another lab "within the same corporate organization and having common ownership" so long as the other lab has a valid CLIA certificate,
4. have not received FDA clearance or approval, and
5. have not been modified such that it would be a new IVCT.

This, too, is a narrow definition, one which will limit the utility of grandfathering and create difficult questions as to whether tests on the market prior to enactment of any new law can qualify for the exemption.

Conclusion

If the draft *VALID Act* became law, it would have far-reaching consequences in terms of patient and physician access to diagnostic tests, including increased cost and development burdens and slowing or preventing the introduction of important new tests. Many of those consequences would be adverse. Enactment also would disrupt the regulation of traditional IVDs because it would replace a well-established system with a system laden with ambiguities and complexity. In our view, as drafted, the *VALID Act* would cause confusion and delays. Once more, the increased costs of the legislation would come without adequate, offsetting benefits. To summarize, the *VALID Act's* passage would be misguided because it would impose substantial regulatory burdens on an entire industry without ensuring that there would be commensurate benefits.

References

1. Gibbs JN and Mullen AB. "LDT Regulation: Past, Present and Future." Regulatory Focus. November 2018. Regulatory Affairs Professionals Society.
2. The Verifying Accurate Leading-Edge IVCT Development (VALID) Act of 2018. http://www.fdalawblog.net/wp-content/uploads/2019/01/VALID-Act-6Dec2018.docx. Accessed 26 February 2018.
3. Diagnostic Accuracy and Innovation Act (DAIA). https://bucshon.house.gov/sites/bucshon.house.gov/files/documents/daia%20summary.pdf. Accessed 26 February 2018.
4. FDA's Views on the Diagnostic Accuracy and Innovation Act (DAIA). http://www.fdalawblog.net/wp-content/uploads/2018/08/FDA-LDT-Draft-Leg.pdf. Accessed 26 February 2018.
5. Clinical Laboratory Improvement Amendments (CLIA). FDA website. https://www.fda.gov/medicaldevices/deviceregulationandguidance/ivdregulatoryassistance/ucm124105.htm. Accessed 26 February 2019.
6. Food and Drug Administration Safety and Innovation Act (FDASIA). FDA website. https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDASIA/default.htm. Accessed 26 February 2019.

About the Authors

Allyson B. Mullen, JD, is a director at Hyman, Phelps & McNamara, P.C., Washington, DC, specializing in FDA regulation of devices and diagnostics. She counsels medical device and in vitro diagnostic manufacturers on pre and postmarket regulatory matters. She was previously in-house counsel at an in vitro diagnostic device company. She can be reached at amullen@hpm.com.

Jeffrey N. Gibbs, JD, is a director at Hyman, Phelps & McNamara, P.C., Washington, DC, specializing in FDA regulation of devices and diagnostics. He has written and spoken extensively on these topics. He was previously an associate chief counsel for Enforcement at FDA. He was the chairman of the Food and Drug Law Institute for 2017-2018. He can be reached at jgibbs@hpm.com.

Cite as: Mullen AB and Gibbs JN. "The Proposed VALID Act: A Possible Next Step in FDA's Goal of Regulating LDTs." Regulatory Focus. February 2019. Regulatory Affairs Professionals Society.