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Device Modernization Series: In Vitro Clinical Tests

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In our first two Device Modernization series posts, we discussed **FDA's 510(k) modernization efforts** and the **proposed De Novo regulation**. FDA has also had a heavy hand in legislative efforts to retool oversight of laboratory developed tests (LDTs) and other in vitro diagnostics (IVDs). The proposed approach would create an entirely new category of medical product separate from medical devices known as in vitro clinical tests (IVCTs).

The rebranding is an outcome of the dialogue around LDTs that began when FDA in 2014 released a draft guidance proposing to stop exercising enforcement discretion and phase in a risk-based premarket review system for LDTs. The term IVCT was introduced in the Diagnostic Accuracy and Innovation Act (DAIA) **discussion draft**, released in 2017 by Reps. Larry Buchson (R-IN) and Diana DeGette (D-CO). Those Members of Congress asked the public, including FDA, for feedback on DAIA.

FDA's extensive feedback was, for the most part and in addition to feedback from other interested stakeholders, integrated into a new discussion draft with a new name—the Verifying Accurate and Leading-edge IVCT Development Act, or **VALID Act**. FDA's feedback included suggestions that Congress provide authority for the agency to use new regulatory approaches for overseeing the unknown but presumably large volume of currently marketed tests. One such approach is pre-certification, a concept borrowed from FDA's efforts to create a more modern regulatory framework for **software**. Pre-certification would allow a test developer to enjoy streamlined FDA review if they demonstrate they meet certain criteria. While FDA has spent more than a year publicly thinking through how pre-certification will work for software developers, the agency seems to be waiting for Congressional authorization before developing a model for IVCT pre-certification and is also likely planning to borrow heavily from a final software pre-certification framework. That's good news for IVCT developers (*i.e.*, labs—primarily), who should want, like the **nine companies** working with FDA on creating a software pre-certification model, to have a say in how pre-certification would work for them.

In addition to pre-certification, other features of the VALID Act that should be of interest to IVCT developers include:

- Grandfathered and Transitional Tests. Grandfathered tests are currently marketed tests allowed to continue being marketed under the new oversight model without further action needed (like submitting a premarket application) if they meet very specific criteria. Transitional tests are currently marketed tests that would be required to meet the new requirements but could stay on the market while undergoing FDA premarket review. How these terms are defined and understood will have significant consequences for products currently marketed.
- Effective date of the law and other time frames. The discussion draft provides for an effective date later than the date of the law's enactment. Having a later effective date will allow companies more time to adjust business plans and take steps to comply with new requirements. There are also timelines suggested for length of pre-certification, how long transitional tests would be able to be marketed before being required to comply with new requirements, and how long FDA should have to conduct premarket review.
- User fees. Once enacted, the VALID Act requires FDA and IVCT developers to negotiate a user fee agreement. IVCT developers would be required to pay a fee to FDA to review their tests, become pre-certified, or take other actions. The amount of those fees, what they pay for, performance metrics tied to fees, and other related items will be the subject of the negotiations. As a former user fee negotiator for FDA, I can say with certainty those discussions will be complex and challenging.

Some trade associations and other interested stakeholders have shared feedback on the VALID Act discussion draft with Congressional staff, who are now considering whether and how to incorporate such feedback into the next version. The goal of having multiple discussion drafts is so that when the bill is officially introduced minimal changes will be needed because the rough edges will have been ironed out and placeholders filled in.

IVCTs play an integral role in delivering healthcare, so IVCT developers and patients alike deserve a regulatory model that is predictable, risk-based, and appropriately flexible. The VALID Act enjoys bipartisan and bicameral support and, after years of discussion between Congress, FDA, labs, patients, and other interested stakeholders, seems poised to be enacted before the end of the current Congress.

Conclusion

In our Device Modernization series, we discussed modernizing the 510(k) program, the De Novo proposed regulation, and a new oversight model for diagnostics. The common theme is that the regulatory schemes that have become familiar over the past few decades are changing, whether through FDA action, Congressional action, or both. Medical device manufacturers and IVCT developers should understand how these proposals will affect their business models.

FDA and Congress continue to be open to hearing from stakeholders about these proposals and we'll be following action at the agency and on Capitol Hill to see where they go and what the implications will be on each player in the healthcare ecosystem.

Authors