From the President's Desk

Contextualizing the VALID Act

September 2022—Like so many pathologists, I have been keeping a close eye on the VALID Act, which would create a new framework for FDA oversight of laboratory-developed tests (LDTs). As I write this, the VALID Act has been voted out of a Senate committee and now awaits further action by the full Senate.

I have heard from some pathologists and laboratorians who are concerned about this legislation and about the CAP position on it since the Senate HELP Committee released a draft on May 17, 2022. If you have not followed this bill and the issues of LDT oversight, allow me to offer some context.

Regulatory oversight of LDTs has been in active discussion since 2008 when the FDA intervened with a national reference laboratory that was selling a test that had been developed at a prestigious university to identify high-risk women who might have ovarian cancer. Patient advocacy groups had raised a concern because several women had undergone unnecessary prophylactic bilateral oophorectomy based on this LDT. In response, the FDA expressed concern about the public harm, and the reference laboratory pulled the test from the market.

Since then, patient advocacy groups have been calling for tougher safeguards on LDTs, demanding government oversight. In 2014, the FDA published a draft guidance for oversight of LDTs. In 2017, the Diagnostic Accuracy and Innovation Act was circulated. The CAP opposed this legislation, as it was overly complex and included extraneous provisions unrelated to LDTs.

Dr. Volk

For the past four years, Congress has been working on the VALID Act to address consumer group and laboratory industry concerns in an attempt to clarify the FDA's role in regulating LDTs. This legislation is bipartisan and bicameral with significant congressional support.

A number of pathology and laboratory organizations are opposed to the VALID Act, objecting to any involvement of the FDA in the regulation of LDTs. This has been described as a CLIA-centric approach. The CAP has taken a different position in light of two important observations. First, the FDA has already made clear that it believes it has authority in regard to the safety of LDTs through the Federal Food, Drug, and Cosmetic Act. Second, the CAP advocacy team believes that VALID's momentum, fueled by significant patient and consumer support, indicates a high likelihood of passage. Therefore, the CAP chose to work as a trusted stakeholder with Congress to advocate for important revisions in the bill.

The big difference between those in support of the VALID Act versus those opposing is the belief that Congress will reaffirm FDA's jurisdiction. The CAP sees the FDA role as a political reality and thus has remained at the table lobbying for guardrails for FDA and flexibility for laboratories. As support for VALID has grown, some of the other laboratory groups responded with another bill (VITAL) that amplified their anti-FDA stance. This bill has a single congressional sponsor who is also one of the most virulent critics of the FDA.

In contrast, the bipartisan authors of VALID worked to develop a framework that establishes guardrails around the FDA role in the oversight of LDTs, including prohibitions against the infringement on the practice of medicine, duplication of CLIA requirements, or insertion into laboratory operations.

While it may have felt more gratifying to merely oppose this legislation, I think the most responsible way to represent pathologists—whose laboratories may soon need to coexist with the FDA—is to engage actively in influencing the terms of this relationship.

Based on the latest version of the VALID Act, the CAP's efforts have gotten results. This is the third major version of the bill, and each revision has included positive steps that reflect feedback from the CAP. We have lobbied for very specific provisions to increase flexibility and lessen the burden on laboratories while still maintaining protections for patients. At every step, our goal has been to strike the right balance so that laboratories may continue to foster innovation as they ensure patient safety.

The current bill includes many provisions the CAP supports, such as:

- a three-tiered, risk-based system.
- a five-year delay to allow for rulemaking, public hearings, and study after the bill becomes law.
- a grandfather clause to protect all currently available LDTs in any given laboratory.
- a stipulation that there should be no duplication of current CLIA regulations.
- specific language prohibiting infringement on pathologists' practice of medicine.
- allowance for modifications of LDTs in cases where performance characteristics are not significantly changed.
- exemptions for low-volume testing and humanitarian testing.

Based on this bill, new LDTs would be assessed individually, and the level of regulatory oversight would depend on the risk classification of that specific test. We believe the FDA's focus will be on the highest-risk testing—testing that runs the risk of doing irreparable harm to a patient. CLIA regulations do not require establishing clinical validity for high-risk, "black box" LDTs; there are no reporting requirements for high-risk LDTs that may not work as expected and might have led to patient harm. Allowing focused regulatory oversight of these tests through the FDA fits into the overall movement of health care to a more transparent, patient-centric delivery model and away from the traditional paternalistic model of medicine. This is a direction the CAP fundamentally supports.

I understand that this change seems daunting for many in our community. But it is coming. There will be many opportunities for the pathology and laboratory community to engage in shaping how this legislation becomes operationalized through rulemaking, and I strongly encourage everyone to engage with a solution-based mindset. It is so important for us to have a seat at that table and to bring our expertise to influence those discussions.

Of course, the CAP will continue to lobby on behalf of our profession. It has lobbied elected officials for years to lessen the regulatory burden on laboratories and will continue to do so long after the VALID Act gets its vote. I believe this is core to the CAP's mission of fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

Dr. Volk welcomes communication from CAP members. Write to her at president@cap.org.