# May Advocacy Recap - Examining the VALID Act with Dr. Volk

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**Alec Bose:**

Hello, and welcome to the CAP Advocacy Recap, a monthly podcast dedicated to catching you up on the top news for pathologists. I'm Alec Bose from the CAP's Advocacy Communications Team, here with your May recap. This month, we'll be focusing on the VALID Act and its impact on laboratory developed tests. We sat down for an exclusive interview with CAP President Dr. Emily Volk to get some background on the legislation and what to expect from it moving forward.

Dr. Volk, thank you so much for your time today. We really appreciate it.

**Dr. Emily Volk:**

It's my pleasure.

**Alec Bose:**

So to start us off, can you give us some background on the VALID Act and its impact on laboratory developed tests?

**Dr. Emily Volk:**

The VALID Act has actually been in discussion for several years now. And on May 17th, the Senate Health Committee released its latest draft version of the VALID Act. The VALID Act stands for Verifying Accurate Leading-dge In Vitro Clinical Test Development. IVCT is the abbreviation that is used in the Act rather than the term laboratory developed test or LDT. If enacted into law, the VALID Act would establish a new oversight framework for what we refer to as laboratory developed tests, but again what is referred to in the document, as IVCTs.

The CAP has been involved in discussions around the proposed regulatory framework for laboratory developed tests for many years, as have other organizations. We know that the FDA has asserted its authority in this space. Despite the fact that CMS has some oversight over laboratories in general, the FDA has asserted its authority, especially as it pertains to tests that may have high risk to patients.

The VALID Act in its current form does contain provisions that are similar to policy the CAP has advocated for on the regulation of laboratory developed tests since 2009. Our letter to Congress does state that the CAP supports many provisions in the bill, but also advocates for additional improvements. We certainly acknowledge that many of the folks listening to this podcast have heard from other associations representing the laboratory perspective on the bill. Some of these organizations have urged their members to oppose the VALID Act and have asked the CAP to oppose the VALID Act. These organizations are taking the position that blocking this legislation is the best approach. The CAP does not agree with this approach.

We have a difference of opinion on the bill based on our understanding of political realities in Washington around this issue. We understand that support for FDA oversight of laboratory developed tests or IVCTs is present on both sides of the aisle and in both houses of Congress. And in fact, it enjoys wide support among very influential patient advocacy groups. There are patient advocacy groups that are very sophisticated in their understanding of the issues with laboratory developed tests and they do have the ear of Congress. There are many in the laboratory community that believe the VALID Act goes too far. But I can tell you that many of these patient groups don't believe it goes far enough and are actively pushing for even more restrictive paradigms.

Our approach at the CAP is to continue to be at the table and acknowledge and work with the broader group of stakeholders to make sure that the pathologist's voice is heard. What the VALID Act does is it creates a risk-based system of oversight utilizing three tiers, low, moderate, and high risk, in order to target the attention of the FDA oversight. The Act in its current form exempts all existing IVCTs from FDA pre-market review. So any laboratory developed tests you are using today will not be subject to FDA review unless there is a safety concern for patients.

It's also important to understand the FDA actually has asserted its right to come into any laboratory regarding any test currently if there is a perceived safety concern for patients. The Act utilizes mitigating measures to shift laboratory developed tests into lower tiers of risk and regulation. And we think this is incredibly important and reassuring. These measures include such practices as appropriate labeling, performance testing, submission of clinical data, clinical studies, and posting information on a website available to patients.

The Act also offers exemptions from the FDA pre-market review process. These exemptions include LDTs in the low risk category, low volume tests, certain modified tests, tests that have a manual interpretation component, and humanitarian tests. We do understand that some pathologists consider the involvement in the development of laboratory tests to be part of their scope of practice. And we have to keep in mind that the scope of practice is regulated by the states and not the federal government.

The VALID Act requires documentation of clinical validation activities. The VALID Act also outlines how those creating LDTs can demonstrate their clinical validity. It does not, however, define which professionals can or cannot perform those activities. To assert that the development of laboratory tests is a pathologist scope of practice issue would mean only physicians can perform these clinical validation activities, which we know to be currently performed by other laboratory professionals. And this is acknowledged by the VALID Act. The VALID Act stipulates that provisions in the bill will not affect a physician's ability to administer or prescribe an approved IVCT or otherwise limit the practice of medicine.

**Alec Bose:**

What has the CAP stance been on the VALID Act and why did the college come to that position?

**Dr. Emily Volk:**

The CAP has been monitoring the development of this Act in its current form over the past several years, and we've been actively involved with conversations with stakeholders around its various components. Our position is that we understand that the FDA has asserted its right to have oversight over laboratory developed tests. And we want to make sure that as they exercise their oversight for laboratory developed tests, that they do it in the most appropriate way possible. We believe their attention should be primarily in the high risk areas, and that the majority of laboratory developed tests require less intensive oversight may be able to take advantage of the mitigating factors that are outlined in the VALID Act.

I think the other thing is we really do appreciate the patient safety perspective and the perspective of patient advocacy groups, especially as it pertains to tests such as the OvaSure test. This was a test that was developed by a highly esteemed academic laboratory at Yale and marketed by LabCorp, and it was misapplied to patients who had a lower risk of ovarian cancer than was originally intended for it to be applied to. As a result, there is a fair number of false positive tests that led patients to have mutilating surgery. We don't think we can ignore this history. And there are other concerning examples out there. Probably the OvaSure example is the most dramatic. Again, that happened in the late 2000s.

So this conversation around oversight beyond CLIA for laboratory developed tests is not a new conversation and in fact has been underway for well over a decade. The CAP again considers it a priority to be at the table during all of these conversations so we can guide the outcome and make sure that whatever the final rule making process creates is something that does not interfere with innovation, does not interfere with the ability of pathologist to practice medicine and does more good than harm to patients.

**Alec Bose:**

As this legislation continues to move forward, what are some key points that pathologists should know about this?

**Dr. Emily Volk:**

I think pathologists need to understand that the FDA has declared that they have jurisdiction in this space. What the VALID Act does is it provides a framework for that jurisdiction to occur with as much sensibility and reason as possible. To ask Congress to remove FDA's jurisdiction, we just don't see as a viable ask. So we see this oversight from the FDA as something that is already been established as inevitable. So our goal at the CAP is to make sure, again, that their oversight is done in such a way that it maximizes the upside and minimizes the downside.

I also think it's important for pathologists to realize that the CAP will continue to be engaged if this legislation is passed over the next five years in the very important rulemaking process. So all of the details that pathologists are very interested in and how this is going to affect their particular laboratory and their particular practice will really unfold over the next few years. And so having the CAP at the table during those discussions will be critical. Having the laboratory community come together during those discussions also will be critical. And the CAP look forward to those conversations and that engagement.

**Alec Bose:**

Thank you, Dr. Volk. I really appreciate you taking the time out. It's been great.

**Dr. Emily Volk:**

My pleasure. Thank you for all you're doing for the College, Alec.

**Alec Bose:**

That's all for this edition of the CAP Advocacy Recap. Thank you so much for listening. For more information on the VALID Act and LDTs, be sure to read our Weekly Advocacy Newsletter and follow us on Twitter @CAPDCAdvocacy. Once again for CAP Advocacy, I'm Alec Bose, and we'll see you next month.