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*It's VALID, but Is It Rational?*

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**Guests:** Dr. Patricia Jones is the Clinical Director of the Chemistry and Metabolic Disease Laboratories in Dallas, Texas, and is Professor of Pathology at UT Southwestern Medical Center. Dr. Eric Konnick is an Associate Professor and Associate Director of the Genetics and Solid Tumors Laboratory in the Department of Laboratory Medicine and Pathology at the University of Washington in Seattle.

Randye Kaye:

Hello, and welcome to this edition of *JALM Talk* from *The Journal of Applied Laboratory Medicine*, a publication of the American Association for Clinical Chemistry. I'm your host, Randye Kaye. A laboratory developed test, or LDT, is a type of in vitro diagnostic test that is designed, manufactured, and used within a single laboratory. Clinical laboratories may choose to develop LDTs when there is no FDA approved test available to meet a certain clinical need. Many physicians and patients rely on LDTs. Currently, LDTs are regulated by CMS under Clinical Laboratory Improvement Amendments of 1988. However, Congress is currently considering legislation called the Verifying Accurate Leading-edge IVCT Development Act of 2022, commonly referred to as the VALID Act, that would add FDA oversight to the existing CMS oversight of LDTs.

In an editorial article published in the November 2022 issue of *JALM*, a group of laboratory medical directors from Academic Medical Centers and reference laboratories discuss the current status of VALID and how it will impact clinical laboratories. Today, we're joined by two authors of the article. Dr. Patricia "Patti" Jones is the Clinical Director of the Chemistry and Metabolic Disease Laboratories, at Children's Health System in Dallas, Texas, and is Professor of Pathology at UT Southwestern Medical Center. Dr. Jones has been a member of AACC since 1986, serving in many capacities, including as President in 2016, and she currently serves as Chair of the Policy & External Affairs Core Committee. Dr. Eric Konnick is board-certified in molecular, clinical and anatomic pathology and is an Associate Professor and Associate Director of the Genetics and Solid Tumors Laboratory in the Department of Laboratory Medicine and Pathology at the University of Washington in Seattle. He has been extremely involved in advocacy across multiple organizations and is currently Chair of the Professional Relations Committee for the Association of Molecular Pathology and Vice-president of the Washington State Society

of Pathologists. Drs. Jones and Konnick, welcome. Firstly, what is the current status of VALID?

Patricia Jones: Well, luckily for us, it was not included in the legislation to fund the government through December 15th. That legislation was passed September 30th and VALID was not part of it. The FDA was essentially funded for five years without VALID included. So, we were pretty happy about that. However, there's always a "but." Eric, you want to talk about what our but is?

Eric Konnick: Right. While the FDA was funded for five years, there were some provisions in the temporary funding that was passed. That covers the government from October 1st to December 15th that deal with the FDA. And so more issues are going to come up to fund the government after December 15th, and that's in something called an omnibus legislation. We don't know for sure what's going to be included within that legislation, but we've heard from multiple people that VALID is likely to be included, and so it's going to come back up again in just a few short months. One of the important things to know is that if for some reason, VALID is not included in this upcoming legislation, basically, the end of the congressional session, which is January 20th, all the legislation that wasn't passed basically evaporates and they have to start over from scratch with the new Congress. There are a couple of months where we're not sure what's going to happen, it maybe voted out again, and then another couple of months where if it's not passed, it has to be brought in to legislation again.

Randy Kaye: Okay. And of course, the question always comes up is do they really understand what they're voting on? For everybody, can you summarize why patients and physicians and laboratories, why we should all be concerned about VALID becoming law?

Patricia Jones: I think if I wanted to put it into a bottom line, I think it has a real strong potential to harm patient care. It can directly affect our ability to provide good testing for our patients. And that is the bottom line why people should care about VALID. Tests that patients count on now that are high quality, cutting edge, it's entirely possible, we won't be able to provide those if VALID goes into effect or the ones that we currently provide, we won't be able to update and keep current. It will be excessively difficult to bring in anything new. It could very well impact patient care significantly.

Eric Konnick: From the physician standpoint, most of the physicians that we work with are very accustomed to getting all the tests they want, when they want them, get those results as fast as possible. And under the construct that VALID would create, what would likely happen is, as Dr. Jones mentioned, we'd

have a decreased availability of cutting-edge tests and then the tests that remain would likely be centralized because of the cost prohibitive nature of the VALID legislation and how it would be implemented. And so whenever we have to send out a test, that adds days to weeks to the turnaround time. Things that physicians are really accustomed to getting quick results for care of their patients, they would have to wait much longer. They would probably have to order multiple tests upfront rather than doing things in a stepwise fashion and then have to aggregate the data more distantly from when they actually saw the patient.

Randye Kaye: That covers patients and physicians. What about laboratorians? Why should they be concerned about VALID becoming law?

Eric Konnick: I think there are numerous reasons laboratories need to be concerned. But one of the key things is that VALID, as it's currently proposed, would set up a whole new structure, a regulatory structure that laboratories would have to abide by. In thinking about how we staff our laboratories and the expertise we use and what types of people we hire, this would be totally different because we would need people with much more regulatory experience. These won't necessarily be people that can contribute to generating patient results, but would be necessary to get through the regulatory process so additional people, all the resources needed for that, and then also planning in when we we're developing laboratory develop tests, what additional work we would have to do. Dr. Jones, can you think of other things that laboratories need to worry about?

Patricia Jones: Yes, my laboratory does not have anyone in it who could take a test through the FDA and the regulatory structure at this point. It will require us, if we want to keep developing laboratory developed tests, if we want to keep adjusting our LDTs to keep them current, it will take a significant addition of personnel, and probably resources and money, to put the infrastructure in place to be able to do that.

Eric Konnick: And I think there's no provision in this law that reimbursements would increase to account for that increased cost. And I think anyone who's in the laboratory industry the last several years knows that the pressures are always to make things cheaper and faster, not necessarily increase their cost. We would be -- just again, we'd be expected to do more with less and probably fewer monetary resources. I think it would just be a huge ask for most laboratories.

Randye Kaye: I see. Certainly, there is some controversy surrounding VALID. There are some organizations that support this change in regulatory oversight of lab testing. Why do you think that is? What's that side of the story?

Patricia Jones: From my perspective, I think our colleagues in the in vitro diagnostic industry feel as though VALID would level the playing field. I mean, they have to take their tests through the FDA, so all tests should have to go through the FDA. From their perspective, it would level the playing field. On the other hand, we developed the tests that the in vitro diagnostic industry is not willing to because there's not enough of a market for them or whatever their reason may be. We're providing a service that they're not willing to provide, essentially.

Eric Konnick: In addition to the industry groups that have generally come out in support of VALID, some patient groups have come out in favor of VALID as well. And oftentimes the arguments are made about accuracy and safety of tests. And what's really interesting about that is that we actually have programs already in place to demonstrate the accuracy of testing. We have proficiency testing or other alternative assessments that we have to do, and we have to demonstrate that our results are accurate compared to our peers and compared to standards. So, that's a little unusual that they are saying we need more accuracy when we already have that. In terms of safety, one of the things that really improves safety of laboratory testing is having that testing close to the patient. Why is that important? Because if I have a question about a result that I'm ready to put to the patient chart, I can call that physician. I can call the team and ask the questions and really clarify what's going on. Even before we do the testing, if something's unusual, I can really clarify what it is they're asking, because the test that they ordered may not be what's appropriate for the patient. That aspect of safety is baked into laboratory developed tests that are done within the facility where the patient is being seen.

Patricia Jones: I would also like to add that the vast majority of professional organizations in the laboratory field oppose the VALID Act.

Randy Kaye: Okay, thank you. So, do we need something other than VALID to help improve clinical lab testing?

Patricia Jones: From my perspective, we currently have something other than VALID to improve laboratory and oversight of laboratory developed tests. We have CLIA, and CLIA has been regulating laboratory developed tests since it was instituted. CLIA can stand to be modernized. It could be strengthened with respect to LDT but it's not a completely separate level of regulation, which is what we would have with VALID, and it has worked very well for us up until this point.

Eric Konnick: Yeah. And I will add that CLIA, the way it was constructed, was very flexible, and that's why I think it has served us so well over the decades is that there is that inherent flexibility

in the legislation and regulation. But I think, as Dr. Jones mentioned, updating the regulations is important and in fact that actually happens all the time with CLIA where new regulations are proposed, they're vetted through expert committees, and then eventually put into practice. And so, there's already a process in place for doing this, it's just the core of the regulations and legislation hasn't been updated since essentially the early 1990s.

And so, there are tests that weren't even conceivable at the time the legislation came out that we're now using every single day on our patients. And so, you're really taking the construct that we're already regulated under, we already have a well-established system for laboratory inspections and proficiency testing and all these other things that we do for patient care, and then really just bringing it into the 21st century.

It seems like a much more streamlined approach and much more, probably much more cost-effective than getting a whole other regulatory agency with different requirements involved. And then what we have is a system where potentially laboratories who are serving the patients have to have two sets of regulatory books if you will to meet the two sets of regulatory requirements. And that's different from the manufacturers who basically only have to abide by FDA regulation, so it's putting quite a bit more burden on our laboratories.

Randy Kaye: All right, thank you. So there already is something in place even if it needs a little updating. So if we want regulators to better understand the consequences of over-regulation, how can laboratorians demonstrate the value of LDTs?

Eric Konnick: This is a really hard question because how do you demonstrate value? I mean, we can look at some of the tests that you have gone from laboratory developed tests into manufactured and distributed tests, as an example, where there is obviously enough value where for-profit companies saw that they could be profitable doing a select number of tests and offering those on a widely distributed model.

The hard part is when you have the thousands of thousands of tests that those manufacturers aren't manufacturing because there's obviously a clinical need because the laboratories have brought them up for a very specific purpose and aren't available commercially. And so, how to demonstrate that this is of value, it's hard to wrap your mind around it because a lot of these tests they aren't necessarily profitable. A lot of these tests that we do, these laboratory developed tests, are cost centers where we spend more to get the result than actually we make in reimbursement. But we do it because it necessary for patient care and so, it's hard

to think of how you're going to do a large study to demonstrate the value.

Dr. Jones, do you have ideas on this?

Patricia Jones: Yeah. I actually echo your sentiment here. We very often offer laboratory developed tests because there is an absolute need for it and we operate them at a loss and they're not going to be probably ever produced by the in vitro diagnostics industry or anyone else. So in order to make these tests available, we have to have the infrastructure in place to allow us to do that. Yeah. It's difficult to put a price tag on something.

I guess for instance, I run a laboratory developed test for a drug called antifungals. Before I was providing that service, they waited four days to get a result back so they could change a child's dose. So the child was in the hospital four extra days until they could get a result back to change their dose of this drug. And that obviously is not adding value and costing quite a bit of money. So there probably are some tests that we could show have a monetary value to being able to offer them as laboratory developed tests, as LDTs. But there a lot of tests that it's not a monetary value, it's a patient care value, and that's a little bit harder to demonstrate I think.

Eric Konnick: As Dr. Jones was talking, I was thinking about some of the work that she does, and her laboratory does, in diagnosing metabolic disorders. She can obviously speak to it much better than I can but thinking about that where these tests at one point weren't available to diagnose these children so we could provide treatment. So maybe Dr. Jones, you could talk about some of that testing and how it impacts individual patients and how you use laboratory-developed tests and maybe that's a way of just demonstrating value.

Patricia Jones: Yeah. I mean, that's a clear one because most testing for inborn errors of metabolism, if not all testing, is laboratory developed tests. And diagnosing within days of birth and getting them the proper treatment, there are many of these kids with many of these disorders that lead a normal life because of that diagnosis and treatment, as opposed to being institutionalized their entire life and the cost of that. That's significant.

Randy Kaye: Wow. So how can readers of *JALM* and listeners of this podcast, how can they stay educated and engaged in clinical lab advocacy?

Patricia Jones: AACC has a really strong advocacy program. We do a pretty good job of keeping our membership informed as much as we can. The Lab Advocate, part of the Artery, does that. We

send out grassroots emails to our membership when we've got an issue that concerns them, or should concern them, and we'd like them to contact their congress people. We do Hill visits. We do congressional meetings.

So AACC, I think that from the advocacy efforts, we're strong. I would just say that the readers of *JALM* need to keep reading *JALM* and keep up with what's going on AACC's website. They'll see it. It's there.

Randye Kaye: All right, thank you. Any last words Dr. Konnick or Dr. Jones?

Eric Konnick: I'd really just like to echo what Dr. Jones just said about AACC being a leader in advocacy for laboratory professionals. And unfortunately, this particular piece of legislation and other legislation are still going to impact our patients and our physician colleagues and then our laboratories. And so, really just keeping involved and watching out for those advocacy alerts, watching out for the notifications from AACC will really benefit our community by keeping people engaged and understanding what's going on, because if it's not this particular issue, there are a suite of others that are coming down the pipe that we have to be aware of.

Randye Kaye: All right. Well thank you so much to both of you for joining me today.

Patricia Jones: Yeah, thank you for giving us the opportunity.

Eric Konnick: Yes, thank you very much.

Randye Kaye: That was Drs. Patti Jones and Eric Konnick describing the *JALM* editorial article, "It's VALID, but Is It Rational?" Thanks for tuning in to this episode of *JALM* Talk. See you next time and don't forget to submit something for us to talk about.