

**House Energy & Commerce Committee’s Health Subcommittee Hearing titled,  
“Evaluating Approaches to Diagnostic Test Regulation and The Impact of The FDA’s  
Proposed Rule”  
March 21, 2024**

**Health Subcommittee Chairman Guthrie (R-KY)**

- Discussed the oversight of LDTs Split between CMS and FDA.
- LDTs are important tools for medical uses—treating cancer, etc.
- FDA repeatedly attempted to completely reform LDT regulations to give them sole jurisdiction.
- FDA 2023 proposed rule would regulate LDTs in FDA’s existing medical device framework-510K or premarket approval. Labs would not be able to make simple modification to LDTs.
  - Problematic; no grandfathering clause for continued use of CLIA certified LDTs. Could lead to unnecessary care or delaying care is why this proposed rule is needed.
  - Guthrie – agrees with FDA Commissioner Califf about patient safety... but concerned whether this will protect patient safety in the most effective way.
  - Unintended consequences of proposed rule...greater consolidation of testing providers, reducing access hurting the high-quality care of patients with life-threatening diseases, especially in the cell and gene therapy space.
  - American Hospital Association (AHA) comment letter mentions one of its systems has 1600 LDTs – could mean that the system could pay up to \$31 million to comply with FDA’s rule.
  - Doesn’t support the FDA’s proposed rule and hope it is withdrawn.

**Ranking Member of the Health Subcommittee Anna Eshoo (D-CA)**

- Supports FDA’s intent; don’t believe the FDA’s proposed rule is the way to go.
- Made positive comments about the Bucshon-DeGette legislation, [the VALID Act, H.R. 2369](#)

**Chair of the full committee Cathy McMorris Rodgers (R-WA)**

- FDA proposed rule is the wrong approach.

**Ranking Member full Committee Frank Pallone (D-NJ)**

- Scary to think that LDTs do not have oversight by FDA.
- Mentioned Theranos.
- Have a responsibility to provide patients with more certainty over tools that provide patients with their medical information.
- That’s why FDA’s proposed rule is an important step.
- Helps eliminate patient harm from over-treatment or not enough treatment.

**Testimony**

**Susan Van Meter, President of the American Clinical Laboratory Association (ACLA)—**

Three concerns regarding the FDA’s proposed rule: patient access, innovation, legal. Legislations is the right way to address this problem.

**Zach Rothstein, Executive Director of AdvaMedDx, division of AdvaMed**

An updated and modernized regulatory framework is essential to foster continued innovation and ensure patients and providers confidence in the test that they rely upon.

Appreciate the work that has gone into the VALID Act.

Supports comprehensive reform of the regulatory system.

**Dr. Donald Karcher, President of the College of American Pathologists**

All LDTs should be safe and effective. Any LDT regulation must allow innovation to continue and must not introduce overly burdensome or costly requirements for the lab. Stifling innovation and overburdening labs would lead to many labs to stop developing LDTs, depriving patients of these lifesaving tests. Have significant concerns regarding FDA's proposed rule – believe that the proposal will delete the number of LDTs available to patients and delay medical innovation and timely patient care. Support the VALID Act because it has a reasonable and balanced regulatory framework.

**Jeff Allen, President and CEO of Friends of Cancer Research**

Supports the VALID Act.

Regarding the FDA proposed rule to address this matter, there's nothing precludes Congress from continuing to work on this issue.

**Dr. Dara Aisner, Medical Director, CO Molecular Correlates Laboratory, Academic Coalition for LDTs**

Opposes the FDA's proposed rule.

No systematic evidence of harm from using LDTs.

She is a cancer patient.

Urges FDA to withdraw the proposed rule.

**Q&A with Witnesses**

**Chairman Guthrie:**

*President of the College of American Pathologists (Karcher)* Is there data to suggest that LDTs perform better or worse in proficiency?

- Do have problems with a number of tests. Yes, there are occasionally inaccurate results in LDTs. But still one of the best ways to confirm accuracy.

*ACLA (Van Meter):* Does the LDT rule eliminates innovation?

- Feel it will have a downward impact on innovation. Not the right approach.

*AdvaMedDx (Rothstein), Friends of Cancer Research (Allen), Academic Coalition for Effective Laboratory Developed Tests (Aisner)* – What in the CLIA framework needs modernizing? Do you believe FDA's proposed rule will help prevent any challenges?

- CAP (Rothstein): Two elements missing in CLIA—pre-market review and comprehensive post-market oversight.
- Friends of Cancer Research (Allen)—CLIA designed to provide oversight of lab operations not the individual performance of tests. CMS has acknowledged that it doesn't have the in-house knowledge to evaluate these tests properly. More effective to give FDA tools to identify underperforming tests before it is used.

- Aisner- CLIA is over 30 years old – needs to be updated. Let's tackle that first.

**Ranking Democratic Member Anna Eshoo (D-CA):**

This is the sixth year that Congress has been grappling with VALID Act. FDA's Director of the Center for Devices and Radiological Health (CDRH) Jeff Shuren has told her that he supports the VALID Act.

Not drawn to revamping CLIA, think it complicates the issue.

Asked each witness if prefer they preferred FDA proposed rule or passage of VALID Act?

- ACLA (Van Meter) -VALID is the right approach.
- AdvaMedDx (Rothstein)-VALID
- CAP (Karcher) -VALID
- Friends of Cancer Research (Allen) —VALID
- Academic Coalition for Effective Laboratory Developed Tests (Aisner) - Do not support VALID or FDA proposed rule – want middle ground.

**Eshoo:** Terrifies her that someone could have a cancer test with false positive results.

- Think there is solid support for VALID Act and Congress needs to pursue that.
- Lack of congressional action forced FDA's hand.
- Fashionable to bash the FDA but up to Congress to act.
- Only two states in country that have passed laws to regulate LDTs – WA and NY.
- NY experience is a broad one where state approves the lab.

**Committee Chair Kathy McMorris Rodgers (R-WA)**

*ACLA (Van Meter)* -- Do you have an economic assessment of the impact of FDA's proposed rule? Can you summarize your findings?

- Believe that the FDA has underestimated the cost and overestimated the benefits. Presumes that LDTs revenue is very high and going through the approval process is lower -- FDA's math doesn't work.

**Committee Ranking Democratic Member Frank Pallone (D-NJ)**

- Anyone who is concerned about the cost of FDA's proposed rule should also be concerned about the cost of using unproven tests.
- FDA's analysis shows the benefits significantly outweigh the costs—the downstream costs of unproven treatments can be staggering.

*AdvaMedDx (Rothstein)* – do you agree that there is potential for significant costs for our health care system if we do not ensure that tests work regardless of where they are made?

- Yes.

*Friends of Cancer Research (Allen)* -what are the consequences of cancer patients who receive the wrong treatment or fail to be treated early on when they need it.

- Depends on the different scenarios, but if there is a patient getting the wrong treatment, they may not respond to subsequent treatment due to detrimental effects.
- That is the biggest concern of having tests not properly identifying the treatment that has been shown to benefit patients.

*AdvaMedDx (Rothstein)*--potential of significant costs if those treatments do not work. Talk about that some more.

- First cost concern is to the patients themselves, associated with the patients having to go back for retreatment or undergoing treatment that are otherwise unnecessary.
- Economic costs incurred by the health care system.
- Other costs are associated with those types of inaccurate tests and how that leads to a lack of confidence in the testing community-very concerned about this.
- Important that patients, providers have confidence in the tests that they receive.
- That these tests have gone through similar review and that there is a public repository for them so patients and providers can understand the context of how they are using these tests.

**Pallone follow up**-At this point we can all agree that the status quo is not tenable, and we have a responsibility to ensure that FDA has the tools it needs to ensure providers and patients can trust the results of these tests.

Problem is that the results of these tests are being used to make treatment decisions regardless of whether they are accurate.

**Dr. Michael Burgess (R-TX), former Chair of the Health Subcommittee**

*ACLA (Van Meter)*—respond to the question just posed by Rep. Pallone – what is the cost of a test that is an error? There is also a cost if the test is not done, correct?

- No question, if access is diminished – it is a problem – that is an enormous factor.

*Academic Coalition for Effective Laboratory Developed Tests (Aisner)*

- Agree. Patient would be on a diagnostic odyssey.

**Burgess follow up:** Will submit a number of questions for the record. We have had this hearing a lot of times. In 2007, I asked Dr. Shuren of FDA what is the problem you are trying to solve and he has been unable to tell me.

*Academic Coalition for Effective Laboratory Developed Tests (Aisner)* -- If you tested a patient for lung cancer, would you recommend a thoracotomy?

- Absolutely not, we would evaluate and ask does everything make sense?

**Burgess follow up:** That is what we forget—most physicians act on our clinical judgment. That is what has been irritating to me, that someone gets a test that is inaccurate, and a body part is removed based on that test – no doctor does that! Get an abnormal test, next thing you do is get subsequent testing. We forget clinical practice in this discussion...If we pass the VALID Act, it will more or less include language that would call on HHS and FDA to do rulemaking. How can we construct the legislation so that we get the desired result and not get an invalid result from the agency? Had multiple hearings on this and I'll bet this is not the last one.

**Rep. John Sarbanes (D-MD)**

Good thing that biomedical research has increased but at the same time, it has increased the urgency that the regulatory approach is keeping pace with innovation. In my former life, did a lot of work with a lot of labs as an attorney.

*Friends of Cancer Research (Allen)*--CDC estimates that LDTs inform 77% of medical decisions these days. Give me a sense of the kinds of decisions based on those results?

- Oncology focus—ranges from initial diagnosis to treatment options to whether the treatment is working –presence of reoccurrence.

Follow up to *Friends of Cancer Research (Allen)*—what are the real-world implications and FDA’s overview of the landscape and why is it so important that the accuracy of these test is sound?

- Needs to be a more transparent system on how different tests relate to one another to ensure that when patients are given the results, no matter which test they receive, they are able to be correctly interpreted.

### **Dr. Larry Bucshon (R-IN), sponsor of the VALID Act**

Been working on the issue for 7 years – complicated topic. Displeased about FDA regulating LDTs as medical devices for many reasons ---1.) unique tools should not be evaluated the same way FDA evaluates machines, implants, and other devices. In vitro devices should be evaluated in a separate category and Congress needs to act. That’s the idea behind the VALID Act. Includes a grandfathering clause, includes a new category for invitro devices and LDTs; high risk tests would be exempted if developed for a specific individual or a group. It is complex and it is a carefully developed and well-vetted bill but needs more work.

All witnesses-would all of you be willing to work with Congress and this committee on the VALID Act?

- All witnesses said yes.

*AdvaMedDx (Rothstein)*-do you believe VALID encourages innovation?

- VALID would bring regulatory confidence.
- Think it has a number of provisions that will help bring innovative products to market. Better provisions on device modifications post-market.
- It also uses mitigation measures to bring test down to a lower risk classification.

### **Rep. Tony Cárdenas (D-CA)**

LDTs are being used to guide medical decisions. Ensuring that they are adequately regulated is important. Finding balance between encouraging innovation and safety is important. —

*AdvaMedDx (Rothstein)*-you mentioned the importance of resources. What are some of the resource constraints you expect FDA to have, if any, and what can Congress do to ensure that FDA is resourced appropriately?

- Two ways to think about it – 1.) how FDA will implement its final rule or 2.) or what VALID would require?
- Look at VALID Act—expect Congress to help FDA increase its capacity to review additional products.
- VALID would also set up a user fee program which is essential to bringing industry and FDA together to ensure that there are clear rules of the road.
- Clear timelines and that FDA would be able to meet those timelines.

*Follow up to AdvaMedDx (Rothstein)*-Can you express concerns about the FDA framework and how it exists currently?

- Currently LDTs not subject to FDA regulation don’t include a public repository of information – how it operates.
- CMS has testified on this – there is no public mechanism to show the variability of the test results. Important to include public repositories.

*Follow up to AdvaMedDx (Rothstein)*-How does oversight delay the development of LDTs?

- As a nation, we need to be in a system that puts test makers in a place where they are competing based on quality and innovation, not gaming out a bifurcated regulatory process.
- VALID Act encourages the development of cutting-edge novel diagnostics.

*Friends of Cancer Research (Allen)*—identify the dangers of not taking a unified approach of diagnostic testing for cancer patients in particular?

- Begins with uncertainty.
- No way of knowing the number of tests out there and how they are performing.
- That is issue number one.
- Could be addressed by additional oversight and bringing all tests in a common construct. Also need to give FDA the opportunity to act if there signs of concern to make sure that they are resolved.

### **Rep. Bob Latta (R-OH)**

Concerned about the FDA's proposed rule and what it would do. Definitely overreach.

*ACLA (Van Meter)*—Diagnostic tools used for pediatric health is sometimes vastly different from adults. LDTs allow pediatric-focused institutions to serve pediatric patients through the use of age appropriate and needed technical modifications. How will this rule impact pediatrics and just by coincidence, this week, I was at a pediatric facility, and would we be discriminating against our children because of this rule?

- We are tremendously concerned about pediatric patients, small patient populations, patients with rare diseases. LDTs are the principal source of diagnostic tools that serve this patient populations. Fear with a one size fits all application of the medical device authorities, we are going to see patients lose access to those necessary services. Example of a tremendous test that you probably heard about during your visit. There is an LDT service that is used on infants in the neonatal intensive unit, rapid hold genomic sequencing, this tremendous test allows for the determinations for what is ailing the patient in 40- 50% of cases. That's an LDT. Worry that patients will lose access to those types of services if this rule is implemented.

*Follow to ACLA (Van Meter)*—Let me follow up. Given that the proposed rule does not contain any exemptions for low volume, custom, or humanitarian tests, how will ACLA members adapt to providing care for rare diseases?

- Think laboratory community across the country, particularly ACLA members, are already doing the work to determine how to implement this rule. That means culling through test menus to make determinations for which tests can submissions be developed and submitted.
- Keep in mind that it is within 3 1/2 years that all high-risk test submissions must be submitted to the agency. In short, we could see some tests come off test menus and I'm worried most about those that serve the small patient population for which revenue is modest.

*Academic Coalition for Effective Laboratory Developed Tests (Aisner)* --What would be the impact to diseases of genetic basis that require more specialized and sophisticated tests such as gene and cell therapy?

- In order to effectuate gene and cell therapy, a number of tests have to be developed on a per patient basis.
- Often times, an individual patient needs to have a test developed just for them.
- It is unclear how a laboratory could establish a paradigm where they have the ability to move forward with this.
- If these tests are determined to be high risk, I believe that the technology certification no longer applies.
- Think there is a real danger that we will cut off the ability to bring about the most cutting edge, the most innovative testing.
- Example – a laboratory at the University of CO is working on cell therapy and they have sought out our assistance in molecular diagnostics to make sure that their product doesn't have any contamination from any of the non-patient cells that are needed to generate the product.
- These are things that we can adapt to on the fly because we are know what we are doing.

*Follow up to AdvaMedDx (Rothstein)*-What would you anticipate your member companies investing in their research and development differently if the final rule is published?

- In terms of the current regulatory uncertainty environment that we deal with today, the final rule would bring about at least some level of certainty potentially long-term, however, litigation is likely to ensue.
- Would prefer regulatory certainty through VALID because it would allow for investments decisions from the investment community and members who have R&D dollars to spend to really understand what the future of diagnostics regulation will look like.

*Follow up to AdvaMedDx (Rothstein)*-Assume that when you are looking at pediatric diagnostic tests, and other small populations, would you say that those would be hard hit then (by the FDA proposed rule being finalized)?

- No patient should lose access to these critically important tests, at the end of the day, if there are concerns in the docket, we would expect FDA to address them in how it implements the final rule.
- We don't think that any patient, particularly those in a vulnerable population, should have a test that has not gone through the same standards of review as any other patients and that's why we think VALID has provisions in it to really bring those types of tests to vulnerable populations, those with unmet needs, rare diseases, and pediatric in a much more equitable fashion.
- It has that technology certification platform that allows for tests to made rapidly without going through the FDA review (there is a low volume exception in the bill as well) plus it includes grandfathering after implementation of the bill which means that all the tests that are on today and potentially those for the next 4-5 years afterwards could remain on the market without going through FDA review.

**Dr. Raul Ruiz (D-CA)**

Need to ensure patient protections for these tests. Am an original cosponsor of the Nancy Garner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act. Bill requires such tests

to receive FDA approval before they would even engage Medicare in the coverage determination process.

*ACLA (Van Meter)*—How can we ensure that patients feel safe and assured of test performance?

- There is significant oversight right now for LDTs included in CLIA. Patient and providers should have confidence now in the accuracy of tests.
- LDTs are not medical devices, they are medical services.

**Ruiz Follow up:** FDA laid out examples of LDTs that had inaccurate results. COVID test –82 showed poor performance.

*AdvaMedDx (Rothstein)*—what are the consequences for patients if FDA is not reviewing tests for public health emergencies?

- Creates regulatory uncertainty in the investment community, not good.

*President of the College of American Pathologists (Karcher)* -- Tiered risk-based approach—how would that help patients?

- Believe that there is a group of high-risk tests that are in need of high-level oversight and believe FDA would be the appropriate agency to do so.
- That would protect patients receiving those tests.
- There should also be flexibility with oversight of lower risk tests.

### **Rep Gus Bilirakis, Co-Chair of the Rare Disease Caucus**

As the co-chair of the Rare Disease Caucus, goal is to improve access to tests for those with rare diseases. Moffitt Cancer Center serves patients with innovative biomarker testing with fast, safe results. Concerned that FDA's proposed rule would limit access to these types of tests.

*ACLA (Van Meter)*—have a tremendous challenge with small patient populations for most rare disease patients. Will the FDA's LDT rule add further challenges to conduct clinical trials for potential cures for rare disease patients and how should Congress think about the economic and patient trade offs for LDT services for rare disease under the FDA's proposed framework?

- We do think there will be downward impact on patient testing generally. Acutely concerned about small patient populations, rare diseases in particular.
- LDTs services is the backbone of diagnostics for those patient populations.
- Very concerned with FDA's unilateral approach in its proposed rule to apply the medical device authorities to LDTs – it is dramatically inflexible and ill suited for LDTs, period.

*AdvaMedDx (Rothstein)*—Impact of the FDA's proposed rule on rare disease patients? Is there a way that Congress could tailor diagnostics regulation to avoid in order to mitigate these concerns. Do you believe FDA's recent announcement of its intent to down classify most high risk, IVDs will provide a less burdensome pathway for most LTDs?

- Proposed rule, no patient should lose access to a test and FDA should respond in the docket to concerns raised regarding this matter.
- Do believe that all patients deserve tests with the same regulatory review and that's why they like the VALID Act.
- It provides a more suitable mechanism particularly for those with rare diseases. Repeated the helpful provisions in the VALID Act (outlined above). Will have to get back to you on IVD question.

*President of the College of American Pathologists (Karcher)* – Based on your organization's perspective of accrediting CLIA labs, do you believe the proposed timeline for ending enforcement discretion is realistic for labs to meet in order to prevent gaps in care.



- Do not believe that laboratories would be able to function and provide the services that are vitally important to patients.
- Think it would take laboratories much longer period of time to adjust to the changes to the rule as written.
- Think most labs would give up and stop developing LDTs, limiting patient access.

**Rep. Debbie Dingell (D-MI), wife of the late John Dingell**

Lack of oversight can lead to devastating consequences for patients and their families. Co-leading the Shandra Eisenga Human Cell and Tissue Product Safety Act to strengthen awareness and accountability of tissue product providers. Introduction of the bill is in response to Shandra fatally contracting TB after she received a tissue donation that was TB infected.

*AdvaMedDx (Rothstein)* – It is my understanding that there is not currently an FDA approved test to detect TB in donor materials. What impact would the LDTs proposed rule have on the testing and screening of TB in donor materials to prevent infection?

- No patient should lose access to critical tests as a result of the FDA proposed rule. The current market dynamics are likely what leads to a lack of an FDA approved test not being on the market today as opposed to innovation within the manufacturing community of IVDs.
- Two-pronged system in terms of how we bring a test to market right now – there are cases documented in the proposed rule that show once an IVD manufacturer brings a product through the FDA program, LDTs are developed and compete with them.
- Right now, manufacturers of IVDs have to consider that as they are considering whether or not to bring a test to market through the agency.
- That’s why comprehensive diagnostics reform is needed – it would put everybody into the same program/system and patients would continue to receive these products and we would be able to understand how to best allocate resources to meet the patients’ needs.

Follow up question to *AdvaMedDx (Rothstein)*: From a public health standpoint, why is it equally important for FDA to have oversight over all diagnostic tests, including conventionally manufactured tests, test kits, those developed and used in laboratories and those used in academic settings?

- At this time, LDTs and IVDs have become more and more complex.
- They also continue to be made by different types of entities -- more than those represented at this table.
- The current framework is very old and VALID Act is the more appropriate approach here, to bring these tests to the market because what it would do is offer a more tailored mechanism for them to come into the fray.
- However, in the current system, all LDTs, right now, do not go through pre-market review and also do not have consistent post-market review or analysis or a comprehensive program to capture any adverse events, malfunctions or recalls.

*Friends of Cancer Research (Allen)*--Some have also raised concerns that prenatal testing has led to false positives that indicate that the fetus has a genetic condition. Women who have been tested for breast or ovarian cancer have received false positives which could impact their decision to get a mastectomy or hysterectomy. Can you speak about inaccurate results from LDTs? How would FDA oversight reduce inaccurate results?

- You've noted the magnitude of the issue at hand. That's the assurance that FDA oversight would provide and would do so before the tests are being utilized. Pre-market review would ensure the performances of the tests.

**Dr. Neal Dunn (R-FL)**

Strongly oppose the proposed rule by FDA. Know FDA is slow. FDA rule would crush innovation, cost a lot of money to labs. Why subject our innovators to this? Ensuring that patients, not bureaucrats, are in the driver's seat is key. Impact on rural areas would be dramatic. Would have an adverse impact on NCI-designated cancer centers, like Moffitt and University of Miami.

*Academic Coalition for Effective Laboratory Developed Tests (Aisner)*--Can you speak to the incentives that would drive work force incentives? Suspect will see a stagnation of innovation and a stall in the pipeline as a result of this proposed rule being implemented.

- Agree completely. I would have to completely restructure who we hire and why we hire them, and it will bring the lab to a grinding halt.

*ACLA (Van Meter)*—Can you elaborate on some of the issues that medical device style regulation/rules would have on toxicology testing for developers and hospitals and the ER?

- When patients are being treated for substance abuse, toxicology tests will drive the right care within our communities. Xylazine with fentanyl – the only test for identifying that substance is an LDT.
- Think that need for toxicology testing would suffer tremendously under the FDA proposed rule.

**Rep. Robin Kelly (D-IL)**

CMS supports FDA's proposed rule on LDTs.

*Friends of Cancer Research (Allen)*--What are the deficiencies with CMS current regulatory structure and how would FDA's proposed structure address those deficiencies?

- They are very different. Think it would be a misguided approach—the expertise and experience lie at the FDA. FDA has been reviewing similar diagnostic tests for years.

*AdvaMedDx (Rothstein)*: How can we ensure that LDTs are used to screen for women and diverse populations?

- Important issue. Simply don't know – that's because LDTs do not have a public repository.
- Believe that the VALID Act would be most appropriate way to bring all the tests under a single framework.
- Would ensure that LDTs and IVDs go through the same regulatory process at FDA to ensure that clinical trials represent diverse populations.

**Rep. Buddy Carter (R-GA)**

Seventy percent of health care decisions are influenced by lab tests.

*ACLA (Van Meter)*—Could you elaborate on the importance of LDTs?

- LDTs are the cutting-edge technology for personalized medicine-COVID tests. Concerned that medical device authority being imposed on LDTs is not the right approach.

*All the witnesses:* Yes or no, is the current medical device framework is the best way to address the regulation of LDTs?

- All said no.

**Dr. Kim Schrier (D-WA) pediatrician**

Need assuring a balance that tests are accurate but also allow access to testing.

*Friends of Cancer Research (Allen)* Could you share the potential harms and benefits of LDTs?

- It is increasing complicated – their availability is hand in hand with their accuracy.
- Need to look at it at a local level – NY regulates these tests.
- NY patients are not having problems accessing tests.

**Schrier follow up:** Have concerns regarding pediatrics, rare diseases–kids require specialized care. Emphasize the importance of early detection even with newborn screening.

*President of the College of American Pathologists (Karcher)* --There doesn't seem to be any specific mention of pediatrics or Children's Hospitals in this proposed rule. Wondering how FDA might make some exceptions.

- We very much worry about pediatric patients being on the losing end if the proposed rule goes forward as is.
- We clearly need to let Children's Hospitals, which develop a large number of LDTs – to find a way in the system that ensures accuracy and flexibility so that they are not prevented from developing those lifesaving tests.

**Schrier follow up:** Agree that we need that flexibility. Children's Hospitals in WA describe the lack of flexibility in this rule as potentially devastating.

**Dr. John Joyce (R-PA)**

Has concerns with the FDA proposed rule.

*AdvaMedDx (Rothstein):* What will happen to LDTs for rare diseases if this rule is allowed to move forward?

- Think the VALID Act provides a mechanism that would allow these tests to come to the market quickly. 1.) Technology certification program 2.) Low-volume exceptions and 3.) Grandfathering of tests that are on the market today.

*Academic Coalition for Effective Laboratory Developed Tests (Aisner)* Do you think that innovation will be stifled if the FDA proposed rule is implemented?

- I am confident that innovation will be stifled.
- The resources of a hospital-based lab are not the same as the resources of a test manufacturer.

*President of the College of American Pathologists (Karcher)*--FDA says that it lacks the evidence to quantify the number of LDTs currently on the market as there is no publicly available source of this data. Would such a central site be of value?

- Absolutely. Helpful to know the scope. The estimate of 80,00 is an underestimate.

Joyce Follow up to *President of the College of American Pathologists (Karcher)*: Would your organization or CLIA be able to provide on all of tests out there?

- Under the current structure of CLIA, that would be difficult to do.
- Don't have a mechanism but would work with you to find a way to make that possible.

### **Rep. Diana Harshbarger (R-TN)**

*President of the College of American Pathologists (Karcher)*:What is the importance of CAP accreditation and what has been CAP's experience in inspecting CLIA labs?

- We do this work through our deemed status at CMS. Believe that our laboratory accreditation upholds CLIA standards.
- Believe that it goes above CLIA standards, and we are the best in the world.

Harshbarger follow up to *President of the College of American Pathologists (Karcher)*: FDA proposed rule references 3rd party review programs and how might CAP's check list be updated to reflect the validation that FDA is looking for in leu of duplicative oversight.

- We are an example of a 3rd party reviewer due to our accreditation program for CLIA. Think an external review accreditation review process, some of the same benefits could very likely be applied to this process as well.

Follow up *President of the College of American Pathologists (Karcher)*: Your organization (CAP) endorsed the VALID ACT but some of your members didn't support it. How did you come to the decision to support it?

- Tough decision for us.
- Endorsed it at the end of the process in 2022 because we worked very hard with Congress so we could endorse it.

### **Diana DeGette (D-CO), Lead Democratic sponsor of the VALID ACT**

*President of the College of American Pathologists (Karcher)*-- Would your members support the VALID Act over the FDA proposed rule?

- Can't read their minds but I think so.

DeGette Follow up to *President of the College of American Pathologists (Karcher)* Would the VALID Act bring your lab to a grinding halt?

- No.

Is there currently pre-market review of LDTs?

- There is none.

*ACLA (Van Meter)*—Haven't heard anyone say they support using medical device regulations for regulating LDTs. Is medical device regulation appropriate for invitro device regulation in general? Could we improve on it and is a comprehensive system needed?

- Think that is the heart of the matter – think the medical device regulation is the wrong approach.

*AdvaMedDx (Rothstein)*--Does CLIA ensure clinical validation?

- There is no pre-market review by a CLIA inspector or analytical validity.

**Rep. Dan Crenshaw (R-TX)**

*Friends of Cancer Research (Allen)*: What is the problem we are trying to solve? Are we in a situation where clinical laboratories are running amuck, and we have to do something?

- Don't think that is the proper characterization.
- In most instances, we don't know.
- Number one issue we are trying to solve is awareness.
- Two, the ability to act if a problem is identified – is there an expert entity that can help mitigate that problem.
- Three, try to avoid errors before they occur.

Crenshaw Follow up to *Friends of Cancer Research (Allen)*--Agree but didn't hear a glaring problem in that response.

*Academic Coalition for Effective Laboratory Developed Tests (Aisner)* was asked the same question.

- Have a different opinion – cited a paper from JAMA oncology which shows LDTs, and FDA assays had an equivalent performance for cancer therapy for melanoma, colorectal cancer, and lung cancer.
- Have lost sight of the fact that the problem is a very narrow constrained concern and as someone who focuses on biology – we are not yet fully studied up on the biology which is very complicated.
- Data from CAP state that laboratories perform at an exceptionally high level.