AMERICAN CLINICAL LABORATORY ASSOCIATION

May 20, 2024

Chair Brett Guthrie
Subcommittee on Health
House of Representatives Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Ranking Member Anna Eshoo
Subcommittee on Health
House of Representatives Energy & Commerce Committee
2322A Rayburn House Office Building
Washington, DC 20515

By Email: Emma.Schultheis@mail.house.gov, Lydia.Abma@mail.house.gov

Re: Questions for the Record for 3/21/2024 HE Hearing, "Evaluating Approaches to Diagnostic Test Regulation and the Impact of the FDA's Proposed Rule"

Dear Chair Guthrie and Ranking Member Eshoo,

On behalf of the American Clinical Laboratory Association (ACLA), I appreciate the opportunity to provide these responses to the questions for the record following the March 21, 2024, hearing of the Health Subcommittee of the House of Representatives Energy & Commerce Committee, "Evaluating Approaches to Diagnostic Test Regulation and the Impact of the FDA's Proposed Rule." As I explained in my testimony, laboratory developed testing services are an indispensable pillar of our health care system. Ensuring continued access to testing services is of paramount importance to the public health.

However, FDA's final rule will limit access to scores of critical tests, increase healthcare costs, and undermine innovation in new diagnostics. The rule also exceeds FDA's statutory authority, as Congress has never granted the agency authority to regulate laboratory developed testing services offered by laboratory professionals. ACLA maintains that legislation is the right—and only—approach for FDA to regulate the professional testing services provided by laboratories. We would be pleased to continue working with this committee to create a regulatory framework tailored to the dynamic nature of laboratory diagnostics.

Below are answers to the specific questions that I received:

The Honorable Gus Bilirakis

1. Considering that laboratories are once again facing cuts to reimbursement because of the Protecting Access to Medicare Act (PAMA) of 2017, I believe we must make every effort ensure that our nation's laboratories have the resources they need to serve patients. We should protect our laboratory infrastructure and preserve patient access to essential diagnostic tests such as through the bipartisan Saving Access to Laboratory Services Act (SALSA). Without these reforms, I am concerned that this FDA rule only will further exacerbate and hamper laboratories from investing in innovation. Could you elaborate on the expected economic impact of the FDA's proposal on laboratories, including small-and mid-sized laboratories?

FDA's final rule to regulate laboratory developed testing services as medical devices will impose significant burdens and costs on an industry that already operates on thin margins. At the same time, the costs of labor, equipment, and supplies are escalating, and a systemic workforce shortage for laboratory personnel persists. Combined with the anticipated PAMA cuts, there is a significant danger that a number of laboratories will be driven out of business, and others will be forced to significantly reduce their offerings, including removal of certain testing services. These challenges will affect all laboratories, including small, mid-sized, and large laboratories, alike.

2. Since Congress has been debating these issues for many years, would you agree that the best path forward is for Congress to legislate any issues related to LDTs, especially due to the anticipated compliance costs and new infrastructure required to implement this rule?
    a. And if so, what objectives should we pursue to ensure safety without hampering the current pipeline for innovation in the space?

ACLA steadfastly maintains that legislation is the right – and only – approach for FDA to have a role in the regulation of laboratory developed testing services. FDA's unilateral imposition of device law is misguided.

Over the past several years, ACLA worked collaboratively with FDA, Congress, and patient, provider, and diagnostic manufacturer stakeholders on legislation that could have established a role for FDA in an appropriate regulatory system for all diagnostics, complimentary to the already robust oversight of laboratory developed testing services. ACLA's goal throughout that process was to develop a regulatory approach that would account for the unique attributes of laboratory diagnostics and which would strike the right balance between encouraging diagnostic innovation, maintaining access to important tests, and regulatory oversight.

3. What are the estimated annual costs required to implement this rule, both in terms of costs to U.S. taxpayers and also higher patient healthcare costs for lab tests?

FDA has estimated the annualized costs of the final rule to be between $1.29 billion and $1.37 billion, but this likely is a dramatic underestimation. Indeed, in the final regulatory impact analysis, FDA acknowledged that if the proposed rule had been finalized without modification,

the annualized costs would have exceeded the benefits by approximately $440 million to $1.62 billion. *See* Final Regulatory Impact Analysis, page 137 (alternative 4). This is essentially an inversion of FDA's original estimate that the proposed rule would have had annualized net benefits of approximately $16.7 to $25.53 billion per year. *See* Preliminary Regulatory Impact Analysis, page 97. The change in the cost-benefit analysis for the proposed rule appears to be driven by a reduction in the estimated benefit of the proposed rule (from an estimated benefit of $22.3 to $31.4 billion to a revised estimated benefit of only $4.21 to $5.14 billion). Accordingly, although FDA appears to have revised its economic analysis of the benefits of the proposed rule following public comment, it does not appear to have incorporated feedback regarding the Agency's flawed costs analysis. Therefore, we continue to believe that FDA has underestimated the costs of the proposed rule, and likely has underestimated the costs of the final rule.

However, it is difficult to accurately estimate the annual costs of the final rule because, as FDA acknowledges, there is incomplete information regarding the number of high-complexity CLIA laboratories or laboratory developed testing services that would be subject to regulation. Even in the final rule, FDA states that it "do[es] not have exact numbers" for the number of laboratories and laboratory developed testing services on the market. 89 Fed. Reg. 37286, 37384.

In our comments, ACLA explained that FDA could have coordinated with other HHS agencies, CMS and CDC, to collect information from CLIA-certified laboratories regarding the number of laboratories that are high-complexity laboratories and the number of laboratory developed testing services offered by each such laboratory. FDA also could have issued a request for information seeking this information. ACLA continues to believe that implementing this regulation without complete information on the impacts to laboratories and patients is irresponsible.

4. How would this new rule affect smaller labs and university labs?

The final rule imposes significantly greater costs on laboratories seeking to offer laboratory developed testing services to meet patient needs. These burdens will make it difficult for many small laboratories to continue developing and offering tests for patients, including tests for rare diseases and other tests with small patient populations. However, the rule does not apply differently depending on the size of the laboratory, and these same challenges will be faced by all clinical laboratories, including mid-size and large commercial laboratories.

5. How will the FDA's proposed rule impact the availability of laboratory tests for the millions of Americans that rely on these diagnostic solutions?

We are greatly concerned that the final rule will reduce the availability of laboratory developed testing services for the millions of Americans that rely on these services. As explained in response to question 1, the final rule imposes significant new costs and burdens on laboratories that are already operating on thin margins, and there is a significant danger that a number of laboratories will be driven out of business or forced to reduce their testing services.

Moreover, under the final rule, surviving laboratories will have to shift resources away from the development of the next generation of diagnostics for various diseases and conditions, including rare diseases and diagnostics specifically for pediatric patients. This drain on innovation will be driven not just by the direct costs of FDA regulation (which are significant), but

also because the device framework is ill-suited and was never intended for laboratory developed testing services.

The Honorable Troy Balderson

1. Nationwide Children's Hospital (NCH) in Columbus is not only one of the largest Children's Hospitals, but they are also a leading research institution. In a recent comment letter, Nationwide Children's raised concerns that "the proposed rules to classify LDTs as medical devices will essentially curtail all advanced laboratory developed tests (LDT) access at NCH… effectively arrogating our ability to deliver high-quality care for the patient who come to our medical center." Further, the letter highlights that, in 2022 alone, Nationwide Children's Hospital used 528 LDTs to provide more than 75,000 laboratory tests for more than 58,000 patients.

   I spoke with staff at Nationwide Children's because I wanted to know what kind of tests we are talking about – these are assays to diagnose [e.g. genetic testing and immune system testing]. I'm concerned that the FDA's proposal to apply LDT regulations to academic medical centers, such as Nationwide Children's, would not only restrict access to the best treatment options available today, but would also hinder innovation. From my perspective, clinicians, researchers, and most concerning, sick children will lose timely access to life saving diagnostics. Can you assure the American people that the FDA LDT proposal will not interrupt access to LDTs already proven effective in diagnosing rare genetic disorders, immune dysregulation, immunodeficiencies and other complex disorders affecting more than one organ system?

ACLA's member laboratories are committed to patient care and will strive to ensure that there will be continued patient access to important tests, including those mentioned in the question. However, the economic reality is that FDA's new requirements are burdensome and costly, and this runs the significant danger of driving certain laboratories out of business, having certain tests removed from test menus, and patients resultingly losing access to such tests.

The Honorable Debbie Dingell

1. While these LDTs fill important gaps in commercial testing, these diagnostic tests for rare diseases are viewed as unprofitable by manufacturers. So, the FDA oversight process proposed in the rule might affect patient access to available LDTs. But it's also clear that as these tests are impacting decision-making, we also want to ensure they are reliable and can be trusted. Mrs. Van Meter, can you speak about the ways that the new proposed rule might affect patients who need testing for rare diseases?

Given the economics of commercial test development, rare diseases frequently lack a commercialized, FDA-cleared or -approved test. Laboratories have filled this gap by developing tests for a very small group of people, thereby meeting unmet clinical needs. However, under FDA's final rule, laboratories are less likely to develop these tests as they will face the same commercial pressures as device manufacturers. In turn, failure to obtain a timely diagnosis will

likely lead to increased morbidity and mortality, along with associated costs to our healthcare system and society more broadly.

For example, a September 2023 study by EveryLife Foundation concluded that, on average, rare disease patients spend more than 6 years searching for a diagnosis, but an earlier diagnosis can avoid costs between $86,000 and $517,000 per patient cumulatively, in terms of medical costs and productivity loss in the pre-diagnosis years, during such period.[1] That earlier diagnosis is often available only with laboratory developed testing services, but those specialized services may not be available under device regulation.

Moreover, FDA's humanitarian device exemption (HDE) under FDCA section 520(m) is inadequate to address this issue. First, the HDE for diagnostics is limited to tests where "not more than 8,000 patients per year would be subjected to diagnosis by the device in the United States." 21 CFR § 814.102(a)(5). Although a diagnostic may be intended to identify patients with a disease that affects no more than 8,000 patients, screening more than 8,000 patients would almost always be necessary. Indeed, even if a disease affects only 100 people in the United States, it may be necessary to test more than 8,000 patients per year to identify them. However, pursuing marketing approval for such a use would be cost prohibitive. Second, such exemption prohibits manufacturers from commercializing their assay except under narrow conditions.

The Honorable Angie Craig

1. You provided very helpful testimony and mentioned your interest in working on legislation, particularly the VALID Act. What specific changes would need to be made for your organization to endorse the bill?

ACLA steadfastly maintains that legislation is the right – and only – approach for FDA to have a role in the regulation of laboratory developed testing services. FDA's unilateral imposition of device law is misguided.

Over the past several years, ACLA worked collaboratively with FDA, Congress, and patient, provider, and diagnostic manufacturer stakeholders on legislation that could have established a role for FDA in an appropriate regulatory system for all diagnostics, complimentary to the already robust oversight of laboratory developed testing services. ACLA's goal throughout that process was to develop a regulatory approach that would account for the unique attributes of laboratory diagnostics and which would strike the right balance between encouraging diagnostic innovation, maintaining access to important tests, and regulatory oversight.

Our goal in continuing to work on legislation to create a diagnostics-specific framework would be the same. For example, such legislation could include many key concepts reflected in the VALID Act that would be critical to the success of a diagnostic framework, such as the technology certification program that would aim to keep pace with the dynamic nature of diagnostic innovation.

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[1] EVERYLIFE FOUND. FOR RARE DISEASES, THE COST OF DELAYED DIAGNOSIS IN RARE DISEASE: A HEALTH ECONOMIC STUDY (2023), https://everylifefoundation.org/wp-content/uploads/2023/09/EveryLife-Cost-ofDelayed-Diagnosis-in-Rare-Disease_Final-Full-Study-Report_0914223.pdf.

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If you have follow-up questions, please reach out to Mary Lee Watts, Vice President of Government Affairs and Policy, at [redacted].

Sincerely,

Susan Van Meter
President
American Clinical Laboratory Association