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ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-3641
Minority (202) 225-2927

May 8, 2024

Ms. Susan Van Meter
President
American Clinical Laboratory Association (ACLA)
1201 Pennsylvania Avenue, NW. Suite 810
Washington, DC 20004

Dear Ms. Van Meter:

Thank you for appearing before the Subcommittee on Health on Thursday, March 21, 2024, to testify at the hearing entitled "Evaluating Approaches to Diagnostic Test Regulation and the Impact of the FDA's Proposed Rule."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Tuesday, May 21, 2024. Your responses should be mailed to Emma Schultheis, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Emma.Schultheis@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Brett Guthrie
Chair
Subcommittee on Health

cc: Anna Eshoo, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

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?

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?

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?

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

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?

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?

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?

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?