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ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States
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May 8, 2024

Mr. Zach Rothstein, J.D.
Executive Director
AdvaMedDx
1301 Pennsylvania Avenue, NW. Suite 400
Washington, DC 20004

Dear Mr. Rothstein:

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. As we consider possible legislative approaches, such as the VALID Act, to address the issues raised in this hearing, what are the key objectives we should pursue, and what should we avoid?

2. I have raised concerns about the impact of the FDA's rule or any new regulatory framework on patients with rare diseases, given their challenging diagnostic odyssey. Do these same concerns about access to accurate diagnostic tests for rare diseases exist under the VALID Act's framework?
    a. How does the legislation seek to address those concerns?

3. How can we ensure that any legislative proposal would ensure safety while maintaining a strong innovative pipeline for LDTs?

The Honorable Dan Crenshaw

1. In a year, the FDA's own estimates show they would have to review and approve between **forty thousand** (40,000) to **one hundred and sixty thousand** (160,000) diagnostic tests currently on the market and between nearly **four thousand** (4,000) to **fifteen thousand** (15,000) new lab diagnostic tests per year.
    - *See Reference 34 – PRIA for LDTs Re: Medical Devices; Laboratory Developed Tests*:
      https://www.regulations.gov/document/FDA-2023-N-2177-0077 | FDA

    Now, the FDA mentions third-party review in their rule. Basically, having someone outside FDA assist with review to decrease workload. But the current 510K Third-Party Review Program only reviews **three thousand** (3,000) submissions a year. You can just do the math.

    Mr. Rothstein, given the current program, is it realistic for FDA to estimate that at least 50 percent of LDTs would seek review by a third-party organization?
    a. Do your member companies utilize third party review at that rate? We're talking about THOUSANDS of new applications at FDA.

2. Mr. Rothstein, would you say the third-party review program needs reform generally? Just as good FDA policy?

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 Frank Pallone, Jr.

1. New York State conducted premarket review for thousands of LDTs, and in their comments on FDA's proposed rule, they said that over half of the LDTs they have received for review (54 percent) could not be approved based on their initial submissions because they had a range of problems including "design flaws, inadequate validation data, and process problems that call into question the reliability of the test."

   These are the types of problems FDA has said have been occurring for years, and FDA included numerous examples in their Notice of Proposed Rule Making, such as problems in prenatal screening tests.

   In the case of New York State, do you agree that the consequences for patients could have been severe if these tests were not evaluated and their problems addressed first?
   a. Doesn't this evidence from New York State tell us that it is important for FDA to make sure these tests are actually working, regardless of who makes them?
   b. Do you agree that FDA has the authority to regulate these tests, or do you believe these are services as some have argued?

The Honorable Nanette Barragán

1. Mr. Rothstein, some groups have argued that FDA regulation will hurt innovation and limit patient access to laboratory developed tests, particularly those for rare diseases. Can FDA regulation of these tests be carried out in a way that will encourage innovation and promote access to effective tests?

2. Mr. Rothstein, early detection of diseases is beneficial to maximize patients' quality of life and save costs. If people who will get Alzheimer's disease in the U.S. were diagnosed early, it would save $7 *trillion* in health and long-term care costs. Yet the FDA has found cases of laboratory developed test results that led to inaccurate diagnoses for several health conditions, including Alzheimer's disease. This is unacceptable. Can you share how FDA regulation of laboratory developed tests will improve the reliability of these tests, which can save time and money for both patients and the health care system?

The Honorable Angie Craig

1. There are approximately 330,000 CLIA laboratories in the United States, all likely having some laboratory developed tests (LDTs) and many with tens or hundreds of unique LDTs subject to proposed FDA oversight. Can you explain how FDA will ensure that requests are processed in a timely fashion to not negatively impact immediate patient care?

2. What are the specific current test development gaps by clinical laboratories that the Administration's proposal aims to resolve to make health care safer?