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ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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May 8, 2024

Dr. Donald S. Karcher, M.D., F.C.A.P.
President
College of American Pathologists (C.A.P.)
1001 G Street, Suite 425 West
Washington, DC 20001

Dear Dr. Karcher:

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 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.

    Dr. Karcher, your organization administers a third-party accreditation program for CLIA certified labs. What have been some successes of that program?
    a. What can we learn from leveraging third party review?

2. Dr. Karcher, can you speak to how adding a bunch of these labs to a medical device framework might create burdens, both at FDA and for industry?

3. Are you able to quantify what some of these burdens might actually be?

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 Raul Ruiz

1. The VALID Act carves out exemptions for grandfathered LDTs that are already in use. What should the FDA's role be in regulating high-risk LDTs that are already out there?