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ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States
House of Representatives
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May 8, 2024

Dr. Dara Aisner, M.D., Ph.D.
Medical Director, Colorado Molecular Correlates Laboratory
Professor of Pathology, University of Colorado School of Medicine
Representative, Academic Coalition for Effective Laboratory Developed Tests
12705 East Montview Boulevard, Suite 400
Aurora, CO 80045

Dear Dr. Aisner:

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. We've heard concerns about the FDA Rule's potential effect on the C.W. Bill Young Transplantation Program (Nation's Registry), which began over 30 years ago and was most recently reauthorized through legislation I co-led, the TRANSPLANT Act (P.L. 117-15). Since its inception, more than one hundred thousand blood cancer patients have been able to undergo stem cell transplantation, maintaining a single point of access for patients to matched volunteer donors and cord blood units. The process heavily relies on LDTs, through the use of human leukocyte antigen (HLA) testing, to determine compatibility. The LDT Rule allows enforcement discretion for HLA testing, but my colleagues and I are concerned this definition is too narrow, and that we should use the term "histocompatibility tests" which covers both donor and recipient matching. It is vital for the sake of blood cancer patients that any testing connected to organ, blood cell, and tissue transplantation be allowed to continue under the existing program. As a pathologist yourself, can you describe the importance of histocompatibility LDTs for transplantation?

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 Angie Craig

1. The Minnesota-based National Marrow Donor Program (NMDP) operates the federally authorized bone marrow transplantation program, called the CW Bill Young Transplantation Program, that matches living unrelated adult donors with patients in need of a life-saving cell transplant. NMDP provides blood-forming cells collected from volunteer adult donors on the registry to unrelated patients for cell transplants to treat blood cancer related diseases.

   This process utilizes LDTs to determine donor and recipient compatibility matching and to reduce the possibility of rejection – this is broadly known as histocompatibility testing. One type of histocompatibility testing is known as human leukocyte antigen (HLA) testing. In the current proposed rule, HLA testing will continue under discretionary enforcement.

   Given the proposal's specific reference to HLA testing, it is unclear to me what the rule means for the broader scope of discretionary enforcement of histocompatibility testing in connection with organ, blood cell, and tissue transplantation and all donor and patient testing related to the transplant process. Do you believe FDA's rule should continue enforcement discretion of all necessary histocompatibility testing for transplantation?