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RANKING MEMBER

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. Jeff Allen, Ph.D.
President and CEO
Friends of Cancer Research
800 M Street, NW. Suite 1050 South
Washington, DC 20036

Dear Dr. Allen:

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. How do you believe this rule could negatively impact the development and production of LDT screening solutions for cancer patients?

The Honorable Frank Pallone, Jr.

1. FDA previously used enforcement discretion, meaning that the agency generally has not enforced applicable requirements with respect to most LDTs. Can you explain why that approach was appropriate at that time and why this is no longer the appropriate approach?
    a. What consequences do you think patients will face if the status quo remains?

The Honorable Nanette Barragán

1. Dr. Allen, inaccurate test results can lead to delays in necessary treatments or a misdiagnosis and unnecessary treatment. How have the use and volume of laboratory developed tests changed over time such that the regulation of these tests also needs to change?
    a. What are the gaps in CMS's current regulatory ability to evaluate laboratory developed tests and how would FDA regulation fill in these gaps?

2. Dr. Allen, you noted in your testimony that there has been an increase in the use of biomarker testing in clinical trials. These biomarkers help predict which patients are most likely to benefit from a particular treatment. Can you explain why there are wide differences between certain biomarker tests, and therefore differences in research results?
    a. How can FDA regulation of laboratory developed tests help improve standardization of biomarker tests and improve healthcare research?

3. Dr. Allen, there are concerns that the current system actually disincentivizes innovation. A developer can develop and validate a test and face immediate competition from an LDT that makes the same claims, or even claims superior performance, without having to demonstrate that these claims are true. In the case of CellMax, a diagnostics company, they were forced to discontinue tests for colon cancer screening because it faced competition from a flood of LDTs. What incentive do developers have to develop tests given the non-level playing field that CalMac and others are experiencing?