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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
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December 9, 2015

Dr. Patrick Conway
Deputy Administrator for Innovation and Quality
Chief Medical Officer
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Conway:

Thank you for appearing before the Subcommittee on Health on November 17, 2015, to testify at the hearing entitled "Examining the Regulation of Diagnostic Tests and Laboratory Operations."

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 December 23, 2015. Your responses should be mailed to Graham Pittman, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to graham.pittman@mail.house.gov.

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

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Frank Pallone, Jr.

The Clinical Laboratory Improvement Amendments are quality standards that apply to all clinical laboratories to ensure that test results are accurate and reliable. The standards a lab must meet correspond with the complexity of the test – labs performing more complex test must meet higher standards – and are focused on personnel qualifications, laboratory systems, quality control and proficiency testing. Some stakeholders have advocated for a modernized CLIA as a way to address gaps in oversight over LDTs.

To better understand the limitations of CLIA's authority in comparison to the FDA's proposed regulatory framework, please respond to the following questions:

1. Does CMS require labs to provide any evidence that the tests labs are performing are producing accurate results?

2. Does CMS require labs to provide evidence that would support claims they make about their tests?

3. Does CMS collect or report on any adverse events for tests?