

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115  
Majority (202) 225-2927  
Minority (202) 225-3641

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:

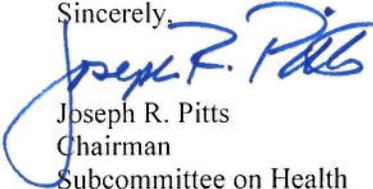
Thank you for appearing before the Subcommittee on Health on November 17, 2015, to testify at the hearing entitled "Examining the Regulation of Diagnostic Tests and Laboratory Operations."

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](mailto: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?