FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH 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

September 30, 2014

Mr. Alan Mertz
President
American Clinical Laboratory Association
1100 New York Avenue, N.W., Suite 725 West
Washington, D.C. 20005

Dear Mr. Mertz:

Thank you for appearing before the Subcommittee on Health on Tuesday, September 9, 2014, to testify at the hearing entitled "21st Century Cures: Examining the Regulation of Laboratory Developed Tests."

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 Wednesday, October 15, 2014. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@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 Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

Attachment—Additional Questions for the Record

The Honorable Michael C. Burgess

1. Some advocates in favor of the FDA intervening in LDTs have suggested that laboratory tests are unregulated (or inadequately regulated) because they have not been required to go through FDA review. Is this the case? Have LDTs been unregulated all these decades that FDA claims to have been exercising "enforcement discretion?"

2. Reimbursement for most diagnostic tests is very low. If the anticipated revenue for a test over time is lower than what a company would need to spend for FDA pre-market approval will companies now abandon development of tests that can benefit our healthcare system?

3. How will the FDA proposed LDT regulations impact current CLIA certification process? Will if weaken CLIA or cause duplication, redundancy and excessive administrative burdens on small companies?