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ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
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Minority (202) 225–3641

September 30, 2014

Dr. Kathleen Behrens Wilsey
Co-Founder
KEW Group
840 Memorial Drive
Cambridge, MA 02139

Dear Dr. Behrens Wilsey:

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. The FDA has cleared a few LDTs with labeling statements that include limitations against use of the tests for treatment selection or even to make a diagnosis. With a manufacturer-distributed kit, a laboratory can use the kit "off label" in practice of laboratory medicine, without running afoul of FDA's promotional rules. With an LDT, however, if FDA considers the laboratory to be a "manufacturer" and considers the LDT service to be a "device" subject to FDA's labeling rules, this could raise concerns that the laboratory is "promoting" off-label use if it performs a test with labeling restricting use for treatment or diagnostic purposes when the laboratory knows that the treating physician does not intend to use the test for such purposes. From your perspective as an investor in laboratories performing LDTs, how would this risk impact your decision to invest in these innovative companies?