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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
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
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December 9, 2015

Dr. Jeffrey Shuren
Director
Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Shuren:

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, D.C. 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.

1. Lab developed tests play an important role in how we detect and treat diseases, medical conditions, and infections. These tests also play a large role in our delivery of health care with one analysis finding that results from clinical laboratory tests influence around 70 percent of health-care decision-making. Yet despite this, publicly available information about lab developed tests continues to be limited. Some have said that the number of tests that have been cleared or approved by FDA is a fraction of the tests estimated to be available. How can we address this gap in knowledge of the number of LDTs that are available today? Is additional authority needed by FDA?

2. One of the criticisms the Committee has heard about FDA's proposed framework regulating LDTs is that FDA is attempting to redefine lab developed tests as a device rather than recognizing that LDTs is a service performed by health care providers. Some have even claimed that FDA is trying to regulate the practice of medicine through the agency's proposed framework. Please explain further on when the development, use, or modification of a test becomes a service.

The LDT report FDA released includes a number of examples of faulty or unproven lab developed tests being marketed to patients and providers. It is especially concerning that the tests outlined as problematic in the report all came from laboratories that met the minimum requirements of CLIA. A number of the problematic tests included in the report have been developed to identify genetic markers for specific cancer risks, such as the OvaSure test. Unfortunately, OvaSure was not a reliable indicator detecting early stage ovarian cancer and produced a high number of false-positives and false-negatives

3. The Committee has often heard repeatedly that tests used to identify genetic markers will be critical to the advancement of precision medicine. However, this advancement is dependent on these tests providing accurate and reliable diagnoses. Will you please explain further how FDA will appropriately balance and support the development of tests for genetic markers, while also ensuring that these tests can be clinically validated?