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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
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Minority (202) 225–3641

December 7, 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 21, 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 Marsha Blackburn

1. To what extent in the ongoing MDUFA IV negotiations have any discussions included projections or proposals taken into account the anticipated increase in workload or resource needs required for regulating laboratory developed tests (LDTs) within the MDUFA program? If so, please provide the Committee with such estimates for workload and resource needs. If not, when does the FDA expect to release such estimates?

2. In the FDA's continuing work on the guidance documents proposing to regulate laboratory developed tests as medical devices, has the FDA conducted an economic impact analysis, including the potential increase in cost in developing new LDTs and the potential impact to small business laboratories? If so, please provide the Committee with such analysis.

3. During the hearing, you indicated that the FDA would move to finalize the guidance documents to regulate LDTs in "2016". Please provide the Committee with the date when the Center for Device and Radiological Health expects to complete the Center's internal work on the final guidance and submit to the FDA Commissioner and/or Health and Human Services and/or the Office of Management and Budget for review and approval.

4. In review of the statutes governing medical devices, are there any updates to statute that the FDA would recommend to ensure that *in vitro* diagnostics are reviewed by an appropriate standard to ensure continued innovation and the availability of safe, accurate, and reliable clinical laboratory tests for patients?

The Honorable Michael C. Burgess

1. For those *in vitro* diagnostics (IVDs) currently approved or cleared by the FDA, please provide the following:
    a. The number of IVD pre-market applications, *de novo* applications, and 510(k) applications approved by the FDA annually;
    b. Of these applications, how many are applications for modifications of IVDs previously approved or cleared by the FDA;
    c. The number of IVD adverse event reports that the FDA receives annually that the agency considers "serious," or the agency found either caused real harm to patients or had a reasonable probability to cause harm to patients;
    d. In the case of such adverse event reports, what types of actions has the agency taken to remediate the adverse event, particular in the case of real patient harm; and
    e. In review of the adverse event reports, what internal actions has the FDA taken to reduce the occurrence of adverse events, once an IVD has received FDA approval or clearance.

2. On April 16, 2015, the FDA and CMS announced the formation of the "Task Force on LDT Quality Requirements." Please provide the following:
    a. The scope of the Task Force's work;

b. When findings or conclusions of the Task Force will be made public and, if not to be made public, the rationale for not making public;
c. The anticipated time period the Task Force is expected to operate; and
d. The extent to which the Task Force is coordinating with industry, and/or provider, and/or patient stakeholders.