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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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June 4, 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 Thursday, April 30, 2015, to testify at the hearing entitled "Legislative Hearing on 21st Century Cures."

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 Thursday, June 18, 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

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 Joseph R. Pitts

1. Recently, we have heard from individuals and companies about a growing concern with counterfeit medical devices being used by certain physicians and practices. In some cases, patients have been harmed. Awareness of this illegal activity surfaced via FDA's MDR system. Upon further examination, it was concluded that the legal products were never purchased by the identified physician/facility and that counterfeit products were used on patients.

2. Please explain if you are aware of these types of situations. If so, what steps are you taking to address? How long does it take for FDA to close out an investigation once it begins?

The Honorable Leonard Lance

1. Are FDA-approved tests safer or more effective than LDTs approved under the current process, and what data do you have that supports an answer either way?

2. Initiating an entirely new regulatory regime for LDTs will likely take significant time and resources. The FDA guidance requires nine years to fully implement. It has been suggested by the Diagnostic Test Working Group that FDA tackling this job will require creating a whole new division in FDA.

3. Do you have an estimate of how much this will cost and how it will be paid for?