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Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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July 29, 2014

Dr. Janet Woodcock
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Woodcock:

Thank you for appearing before the Subcommittee on Health on Friday, July 11, 2014, to testify at the hearing entitled "21st Century Cures: Incorporating the Patient Perspective."

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 Tuesday, August 12, 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. I asked about this in early April, but I do not believe I have received a response. Do you have any update on the status of the FDA's guidance on biosimilars naming? When will this guidance become final?

2. Has anyone outside of FDA provided the agency with substantive suggestions or recommendations with respect to this guidance? If so, please provide the name of the person or persons who provided those suggestions or recommendations, and any action FDA took in response to those suggestions or recommendations.

The Honorable Gus Bilirakis

1. How many treatments were approved with novel biomarkers used for the first time?

2. How many were for indications other than cancer and HIV?

3. Have any accelerated approvals occurred with a novel marker and a never before treated disease?

4. How many new biomarkers did the FDA accept for a first time use in the last five years?

The Honorable Kathy Castor

1. I want to bring up an issue I sometimes hear from my patients on the Central Coast. As you know, a number of states have passed legislation known as right-to-try laws. In general, they allow drug companies to provide unapproved drugs to patients whose doctors request them, so long as the drugs have passed some level of safety testing. The laws eliminate the need for patients to get a compassionate use exemption from FDA. These laws appear to be based on a misperception that FDA either routinely denies such requests, or that such requests entail lengthy and complex paperwork. I know this is a complicated and often heart-rending issue.

   However, it seems that when patients have difficulty getting access to experimental drugs, it is because the drug company does not wish to provide it, not because FDA has prevented access. Could you describe for us the process FDA has for providing patients with compassionate use access to experimental drugs, including how long it takes and how cumbersome the process is? Why might companies not want to provide their experimental drugs to patients in desperate need? I would also like to know what types of concerns these right-to-try laws raise for FDA. Thank you.