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ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

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October 15, 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, September 19, 2014, to testify at the hearing entitled "21st Century Cures: Examining Ways to Combat Antibiotic Resistance and Foster New Drug Development."

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 29, 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 Joseph R. Pitts

1. When considering the importance of antibiotic breakpoints, what barriers do you face when attempting to keep them up to date? Does the FDA need new authority to ensure that antibiotic breakpoints are updated regularly? Do the breakpoint provisions of H.R. 3742, the Antibiotic Development to Advance Patient Treatment Act of 2013 (ADAPT Act) address this matter sufficiently?

2. What are the challenges the FDA believe exist with regard to clinical studies for serious and life threatening antibiotics and how does this situation impact the setting of antibiotic breakpoints at the time of approval?

The Honorable Michael C. Burgess

1. You and the agency are leading champions of replenishing our antibiotic pipeline, but the economics are broken and HHS' own study on antibiotic incentives (*Incentives for the Development of New Drugs, Vaccines, and Rapid Diagnostics for Bacterial Diseases)* demonstrates that moving the needle in monetary terms for companies would take a reduction in clinical trials times by two to three years. Is that really possible? Can the ADAPT Act accomplish such? How else can FDA support bolstering the marketplace for antibiotics?

2. Even with the accelerated approval, sponsors are still required to manufacture product batches on a large scale and perform long stability runs. To what extent has there been discussion at FDA to allow sponsors to build this over time, including after licensure, as this can be a rate limiting step to approval?

The Honorable Phil Gingrey

1. Congressman Green and I have been working on the ADAPT Act, which gives FDA greater flexibility to consider all forms of evidence, in addition to data from clinical trials, when setting breakpoints for new antibiotics at the time of approval. It is critical to ensure FDA has the tools required to incorporate the latest advances in science and modeling into its decision making process, especially when setting an antibiotic breakpoint at the time of approval. Does FDA agree with this statement?

2. This Subcommittee has been a true leader in Congress to enact important reforms like the GAIN Act to stimulate development of important new antibiotics. We have also enacted mandates for FDA to update breakpoints for existing antibiotics in a timelier manner. For new antibiotics, the ADAPT Act would give FDA flexibility to consider all forms of evidence when setting their breakpoints —a parameter that guides the use of these drugs. Do you agree this would be an important reform to follow in the footsteps of what we have already done?

The Honorable Gus Bilirakis

1. How many treatments were approved with novel biomarkers used for the first time within the last five years? How many were for indications other than cancer and HIV? Have any accelerated approvals occurred with a novel marker and a never before treated disease? How many new biomarkers did the FDA accept for a first time use in the last five years?

2. This committee led passage of the Pandemic and All-Hazards Preparedness Reauthorization Act last year. PAHPRA required FDA to establish a new process for frequent scientific feedback between the agency and developers of medical countermeasures under Project BioShield. These Regulatory Management Plans (RMPs) are critical to accelerating the review and approval of critical medical countermeasures against threats like anthrax, smallpox and Ebola. Will you describe FDA's efforts over the last year to implement RMPs with countermeasure developers?

3. PAHPRA strengthened FDA's Emergency Use Authority (EUA), and provided the agency more flexibility to get products to the public in an emergency. I am glad to see that FDA recently issued an EUA for a diagnostic test related to the on-going Ebola epidemic. Will you provide more details on the agency's use of these new authorities for Ebola? Are there more tests or therapies that may become available soon to health care workers on the front lines of Ebola?

4. One of the challenges we have heard from countermeasure developers who are partnering with the federal government is that communication between FDA and the Biomedical Advanced Research and Development Authority (BARDA) has been severely lacking. This makes it difficult for developers to be confident that these high-risk projects, including drugs to combat antimicrobial resistance, can ultimately be successful? What is FDA doing to improve communication with BARDA as it relates to countermeasure development?