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ONE HUNDRED THIRTEENTH 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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October 15, 2014

Mr. Allan Coukell
Senior Director
Drugs and Medical Devices
The Pew Charitable Trusts
901 E Street, N.W.
Washington, D.C. 20004

Dear Mr. Coukell:

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. What are other countries or the European Union doing to help spur research and development for anti-infectives? Which initiatives are working well and which will likely have the most significant impact to draw more companies to anti-infective product development moving forward?

The Honorable Marsha Blackburn

1. Our committee has enacted important reforms like the GAIN Act to stimulate development of new antibiotics, but realize more work needs to be done. It is my hope that as part of the 21st Century Cures effort we'll put additional incentives in place for antibiotics that are designated as Qualified Infectious Disease Products (or QIDPs). What other specific incentives do you recommend Congress consider for FDA designated QIDPs?

2. Congress via GAIN gave FDA a very important tool, to designate certain anti-infectives as Qualified Infectious Disease Products (QIDP); and the agency has made good progress on QIDP guidance, as well as designating over 30 developmental antibiotics as QIDPs. If we create other incentives as we should — real incentives are needed –- we must avoid a situation where there's confusion and differences over what qualifies for which type of incentive across different agencies of HHS. Will you respond to this statement?