

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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July 29, 2014

Mr. Robert J. Beall
President and CEO
Cystic Fibrosis Foundation
6931 Arlington Road, 2nd Floor
Bethesda, MD 20814

Dear Mr. Beall:

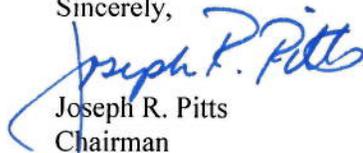
Thank you for appearing before the Subcommittee on Health on Friday, July 11, 2014, to testify at the hearing entitled "21st Century Cures: Incorporating the Patient Perspective."

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 Leonard Lance

1. In the first panel I questioned Dr. Woodcock on the effectiveness of ClinicalTrials.gov. I would like to get your thoughts on the effectiveness of ClinicalTrials.gov. Is it something any of you use as a resource? What can be done to improve the site and what role can it play in modernizing clinical trials?
2. It was clear from our discussion that more needs to be done to increase patient engagement in the clinical trial process. Will you walk me through the process for recruiting and selecting patients for clinical trials? What information is provided to patients? How can researchers and physicians make patients more comfortable with participating in clinical trials?

The Honorable Gus Bilirakis

1. The CF Foundation operates and fully funds the CF registry and seems to have captured the entire CF population in their registry. How can other groups successfully establish their own registry and how can they successfully grow it?
2. Section 903 of FDASIA was the Expert Act, which encourages FDA to proactively engage with specific rare disease experts on an individualized, case by case basis. This is an important provision because many times FDA may lack the expertise on a disease, especially a rare disease. How is the Expert Act being implemented by FDA? How can FDA take advantage of the Expert Act to move treatments to patients quickly?