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ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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July 29, 2014

Dr. Sundeep Khosla
Director
Center for Clinical and Translational Science
Mayo Clinic
200 First Street, S.W.
Rochester, MN 55905

Dear Dr. Khosla:

Thank you for appearing before the Subcommittee on Health on Wednesday, July 9, 2014, to testify at the hearing entitled "21st Century Cures: Modernizing Clinical Trials."

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 John Shimkus

1. You state in your testimony that "the current clinical trial model of placebo-controlled, randomized, double-blinded clinical trial may not be the most effective model, particularly for early phase studies." In the case of antibiotics, for instance, a placebo-controlled randomized, double-blinded trial would require a patient in an emergency room seeking treatment for a deadly disease to be unaware that they are not receiving treatment. Is that a fairly accurate statement?

   From an ethical standpoint, I have trouble squaring that placebo-controlled double blinds are always the best method of study—especially when a patient is suffering life of death consequences from such requirements. Have such FDA requirements forced researchers and developers overseas to conduct such trials and do you believe reforms in this area might help encourage greater research opportunities in the U.S.?