

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

COMMITTEE ON ENERGY AND COMMERCE

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July 1, 2014

Dr. Samuel E. Gandy
Chair
Alzheimer's Disease Research Center
Mount Sinai Health System
One Gustave L. Levy Place
New York, NY 10029

Dear Dr. Gandy:

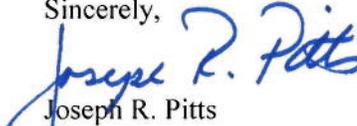
Thank you for appearing before the Subcommittee on Health on Wednesday, June 11, 2014, to testify at the hearing entitled "21st Century Cures: Examining the Role of Incentives in Advancing Treatments and Cures for Patients."

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, July 16, 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. Would you comment on some of the barriers that Class III medical device manufacturers face when seeking coverage and payment from CMS for innovative and cutting edge technology that improves the lives of patients?
2. When innovative therapies are FDA approved, there is a significant lag time between FDA approval and Medicare coverage decisions leaving these products to be reviewed and paid on a case by case basis. Many of these initial claims will be adjudicated through the Medicare appeals process. The three year back log at the Office of Medicare Hearings and Appeals (OMHA) for Administrative Law Judge (ALJ) hearings creates a financial disincentive for hospitals and providers to use these therapies given the uncertainty regarding timely reimbursement. Would you explain how this severe backlog would impact your hospital's ability to use cutting edge therapies when the reimbursement landscape for Medicare patients is uncertain?

The Honorable Cathy McMorris Rodgers

1. In your testimony, you recommend that Congress develop legislation which provides market exclusivity for orally administered compounds which is independent of their patent life. You put this forward as a solution to one side of the coin—the post-market life of approved therapies. I am certainly open to a discussion on incentives like exclusivity—particularly for therapies where there is a public health need.

But I am also curious about what we can do on the other side of the coin—the pre-market time period—that uses innovation and new science to streamline the approval process and cuts down on the time it takes drugs to get to market.

I know you have focused your research on Alzheimer's. Do you have any specific ideas on how we could improve the way we do clinical trials that could help get a breakthrough Alzheimer's drug to market? I am aware of ongoing efforts to develop standing Alzheimer's trial sites and robust patient registries as well as efforts to facilitate access to data from unsuccessful trials in a precompetitive manner. What are your thoughts about reforms like these and others? What can we learn from innovative trials in the oncology space to translate into the chronic disease space like Alzheimer's and diabetes?

2. How can we improve our existing research structure in a way which incentivizes more investment? What is the possibility for clinical trials networks? Or more partnerships with NIH? How about the interaction of the SBIR/STTR program with NIH?