

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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July 1, 2014

Mr. Mike Carusi
General Partner
Advanced Technology Ventures
485 Ramona Street
Palo Alto, CA 94301

Dear Mr. Carusi:

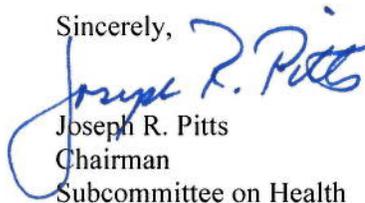
Thank you for appearing before the Subcommittee on Health on Wednesday, June 11, 2014, to testify at the hearing entitled "21st Century Cures: Examining the Role of Incentives in Advancing Treatments and Cures for Patients."

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 Joseph R. Pitts

1. The size and cost of clinical trials is an impediment to investment and innovation, particularly for products treating diseases that impact large patient populations. How can advances in technology make trials more efficient?
2. Understanding that lengthy clinical trials with a large number of participants are currently the norm for drugs treating chronic diseases such as heart disease and stroke, what processes does FDA have in place to provide the necessary certainty to sponsors up front so that, when resources are devoted to drug development in these areas, investors and companies can plan accordingly?
3. To date, CMS has declined to provide guidance regarding the extent to which changes may be made to a durable medical equipment (DME) product such that it remains a “modified” or “upgraded” product subject to the grandfathering provision of the three-year minimum lifetime requirement (MLR) for DME, and not a “new” product that may no longer be eligible for reimbursement as DME. What is the impact of this lack of guidance on Medicare beneficiary access to innovative medical devices?
4. What are your recommendations for DME reimbursement policy regarding the application of the grandfathering provision of the three-year MLR that continues to promote and foster innovation of medical devices?

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 cutting edge technology that improves the lives of patients?

The Honorable Cathy McMorris Rodgers

1. Would you explain the evaluation that a VC does of a medical device start-up? Are you looking at how promising the idea is, what the outlook is for FDA approval, whether or not CMS will cover the device, or a combination of factors? How has this continuum changed over the last 10-15 years?

The Honorable Gus Bilirakis

1. Your testimony mentioned that FDA allows for the use of novel endpoints, biomarkers and non-traditional clinical trial designs, but lacks transparency and consistency in their approach. How can we improve the process and encourage regulators to use every tool in their proverbial toolbox?
2. One mechanism drug companies have to improve certainty about the agency’s acceptance of certain trial designs is to enter into a Special Protocol Assessment (SPA) agreement, which was first authorized in 2007 for that very purpose. Have these agreements generally brought the intended certainty to companies and has the agency always held up its end of the binding contract?

3. What barriers are currently in place that limit the potential of using clinical and outcomes data to learn about how therapies are working on patients in the real world? How should we address them?
4. In your testimony, you touch on the need for certainty after approval and the challenge of ensuring that there is coverage of a new drug or device by Medicare, Medicaid or private insurance. Typically, commercial insurers cover something that Medicare covers. Would you talk about some of the challenges that are faced getting covered and reimbursed under Medicare?