

August 11, 2014

Ms. Mary Greal
President
Healthcare Leadership Council
750 9th Street, N.W.; Suite 500
Washington, D.C. 20001

Dear Ms. Greal:

Thank you for appearing before the Subcommittee on Health on July 22, 2014, to testify at the hearing entitled "21st Century Cures: Examining Barriers to Ongoing Evidence Development and Communication."

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 August 25, 2014. Your responses should be mailed to Jessica Wilkerson, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Jessica.wilkerson@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 1—Additional Questions for the Record

The Honorable Joseph R. Pitts

1. Ms. Grealy, you mention in your testimony that HIPAA was created at a time when policymakers were not thinking about the knowledge that could be gained by accessing data residing in large databases. How does HIPAA need to change in order to ensure that data can be used effectively for this vital research?
2. You stated that in most research environments, patient data must be de-identified before it can be utilized but note that there are circumstances in which de-identified data is not sufficiently useful to achieve particular objectives. Would you expound upon this a little further and explain how we should take this into account in any policy changes we consider as part of this initiative?
3. You note that there are 50 separate sets of state privacy laws and regulations that can be incredibly difficult to navigate. You believe strongly that a national privacy framework should replace this patchwork of current state laws. Would you explain what you mean by a national privacy framework and why you think it is necessary?
4. You state in your testimony that federal health data should no longer be denied to entities perceived to have a commercial interest. What is preventing agencies from making this data available now?
 - a. How would clarifying and modernizing any such laws and policies benefit federal public health agencies?
 - b. Are there operational or organizational changes that could help enhance collaboration within and between federal public health agencies?
5. Would you explain what is current federal policy with respect to allowing innovative companies to access such data and why is this an impediment to additional discovery and development?
6. Are there more collaborative data sharing policies or initiatives in place in other countries that we could learn from?
7. You attach a number of examples in your testimony about lifesaving and life-transforming innovations that are the direct result of collaboration between physicians and drug and device companies. How could misinterpretation of the Sunshine Act impact this critical type of interaction and how can we proactively avoid any such unintended consequences?
8. Data analytics of huge bodies of data holds the potential to spur innovation and development in disease areas that haven't seen a new drug in 50 years. In your testimony, you state that "we are now in an era where researchers can harness vast amounts of data to learn at a rapid pace unlike we have ever seen." We all support the need to protect patient data: is the potential you see in big data spurring development of new treatments limited by HIPAA?
9. (FOLLOW UP): We are entering an age where technological innovation and data have the potential to reinvigorate cures discovery and development in this country, but only so far as the regulation of these technologies allow us to go. In your opinion, do we need to review the current HIPAA and privacy paradigm in this country to ensure it is truly protecting patients – both from a privacy but also accessibility perspective?

The Honorable Renee Ellmers

1. Ms. Grealy, in North Carolina we have academic medical centers like Duke and UNC, and joint-partnerships between the individual physicians, the bio-pharma companies and the teaching hospitals are crucial for innovation. Therefore, I'd like to know, what is the role that academic medical centers play in supporting innovation?