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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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December 18, 2017

The Honorable Francis Collins
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins:

Thank you for appearing before the Subcommittee on Health on November 30, 2017, to testify at the hearing entitled "Implementing the 21st Century Cures Act: An Update from FDA and NIH."

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 January 8, 2017. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Michael Burgess

1. A goal of 21st Century Cures was to help the transition between research generated by NIH and regulated by FDA. Are there areas where this could be improved? One challenge is that NIH funds new clinical trials that may become difficult to complete because a new drug is approved mid-way through the trial for the condition being researched. Could a "memorandum of understanding" allow for pre-approval data to be shared from FDA to NIH earlier in the process to improve coordination of research and regulation?

2. As you know, the NIH has made some changes to the definition and requirements regarding clinical trials in order to improve thoroughness and transparency. Can you walk through those changes and the impact on both the patient and the research community? What is the NIH doing to address any concerns and confusion from those in the grantee community who will be impacted by these changes?

3. We've heard a lot about how the 21st Century Cures Act has helped eliminate red tape for extramural researchers, so they can spend less time on paperwork and more time on science. Can you tell us about how these provisions have helped your researchers over the last year?

4. The 21st Century Cures Act included language addressing medical rehabilitation research at the NIH. The language changed the requirements for this research, including revise the purpose of the National Center for Medical Rehabilitation Research, or NCMRR, and transfer responsibility for developing a comprehensive research plan to NCMRR from the Eunice Kennedy Shriver National Institute of Child Health and Human Development. What steps has the Office of the Director, in coordination with NCMRR, taken to implement the rehabilitation research provisions in Cures?

5. Part of the intent of 21st Century Cures was to support better collaboration in research and further trans-NIH initiatives. One opportunity for such an initiative would be in better understanding how individuals with three copies of chromosome 21, which causes Down syndrome, are protected from certain cancers and heart attacks, but are more likely to succumb to Alzheimer's disease, childhood leukemia, and certain autoimmune disorders. It is my understanding that Trisomy 21 is unique in that it is the only genetic condition with these co-morbid condition connections. Do you see any opportunities for enhanced coordination among NIH Institutes to better unlock the secrets of Down syndrome, and in turn identify ways to prevent and treat Alzheimer's? How can precision medicine advance this goal?

The Honorable Cathy McMorris Rodgers

The 21st Century Cures Act improved upon the National Pediatric Research Network Act, which was initially crafted in 2013 with the intent to address the shortfall in pediatric biomedical research using the well-proven network model to foster greater collaboration, coordination, and sharing of resources. As an author of the underlying statute, I can tell you that our vision was that each consortium would be investigator-initiated, consist of multiple institutions in a "hub and spoke" arrangement and be competitively selected through a rigorous review process. My understanding is that the NIH maintains it has implemented the NPRNA by establishing the IDeA States Pediatric Clinical Trials Network. I support your current efforts, but am concerned about the geographical limitations on the network as well as precluding funding for all phases of scientific research other than clinical trials.

1. Do you have plans to further implement the full scope of the NPRNA, and if not, why?

The Honorable Marsha Blackburn

2. Children sometimes fail to benefit from NIH's research because there is no existing mechanism to collect and report the ages of patients enrolled in trials, meaning we have no idea how many children participate in NIH studies. That is why I worked with Rep. Capps to include our bill, the Children Count Act, in the Cures Act to require NIH to collect this critical information. Can you please update us on how NIH plans to implement this provision and when NIH will require the information to be collected for all studies?

The Honorable John Sarbanes

The 21st Century Cures Act seeks to accelerate the development of new antibiotics as part of our national effort to address the increasing threat of antibiotic resistant organisms. This threat, combined with the dwindling pipeline of novel antibiotic research, requires policies that prevent inappropriate use of antibiotics.

One potential way to do that is to increase the use of penicillin allergy testing. While about 10 percent of the population reports a history of penicillin allergy, studies show that approximately 90 percent or more of these patients are actually not allergic to penicillin and are able to take these antibiotics safely. If these individuals are tested to verify they are truly allergic, they may be able to prevent the unnecessary use of broader spectrum antibiotics.

1. Has the NIH initiated research in this area with the goal of changing the behavior of patients and providers?

2. What initiatives has the NIH undertaken to implement the research agenda developed by a workshop on drug allergy held in 2013?