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ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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December 10, 2015

Dr. Robin Robinson
Director, Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response
200 Independence Avenue, S.W.
Washington, DC 20001

Dear Dr. Robinson:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, November 19, 2015, to testify at the hearing entitled "U.S. Public Health Preparedness for Seasonal Influenza: Has the Response Improved?"

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 Thursday, December 24, 2015. Your responses should be mailed to Greg Watson, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Greg.Watson@mail.house.gov.

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

Sincerely,



Tim Murphy
Chairman

Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

Attachment 1—Additional Questions for the Record

The Honorable Marsha Blackburn

Dr. Robinson, as you know, the Public Readiness and Emergency Preparedness Act, or “PREP Act”, authorizes the HHS Secretary to issue a declaration that provides liability immunity to organizations that manufacture countermeasures to diseases such as influenza. In fact, there currently is a PREP Act declaration in effect for pandemic influenza vaccines, which has been extended multiple times. The current declaration is set to expire at the end of the year.

1. In light of the ongoing public health challenges associated with pandemic influenza do you expect this PREP Act declaration to be extended and, if so, when will it be extended?

The Honorable Paul Tonko

Dr. Robinson, I appreciate BARDA’s role in increasing the availability of all medical countermeasures, including vaccines. I also have appreciated our working relationship to ensure that there are no delays in bringing these countermeasures to market. With recent biotechnology developments, I understand there is increased domestic capacity for discovery and development of fully human antibodies.

1. How is BARDA assessing its current investments to ensure that you are fully leveraging the capacity we have here in the United States for delivering these cutting edge technologies as quickly and effectively as possible? And what can we in Congress do to enhance your ability to meet these goals?

The Honorable Gene Green

BARDA clearly plays a critical role in protecting public health and we applaud you for executing contracts that can be leveraged to secure the vaccine, drug delivery devices and other products necessary to effectively address a pandemic event.

That said, I am concerned that while the mechanisms are in place to secure needed products, some steps have yet to be taken to produce the products contemplated under BARDA’s existing contracts.

1. With the understanding that it takes a realistic amount of lead time to produce and deliver the products necessary to administer vaccines and address an outbreak on a large scale, do you believe we are in a position to respond today to the needs of 300 million Americans in the event of a pandemic?
2. What has BARDA learned from the H1N1 outbreak of 2009? Specifically, what steps have been taken as a result of lessons learned to ensure that we now have the appropriate

number of drug delivery devices needed to either vaccinate or administer therapies in response to a large scale outbreak of influenza?

We have heard a lot today about how poor a match the 2014-2015 vaccines were at addressing the strains of flu that were prevalent that season. While many of my colleagues have hit upon how we must do a better job at producing a vaccine, I'd like to address another problem with poor vaccines.

Every year during flu season my office hosts health fairs throughout my district where we do a drive in the community in an effort to get people vaccinated. Due to how poor the vaccine was, we're now having trouble getting people to come out to these events because they all believe the vaccine doesn't work.

3. After such a poor vaccine in the 2014-2015 season, what are each of your agencies doing in terms of outreach to combat the perception that the flu vaccine doesn't work? What efforts are being made to inform people on the importance of vaccination and the utility of the vaccine itself?