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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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July 12, 2018

Dr. Rick A. Bright
Director, Biomedical Advanced Research and Development Authority
Deputy Assistant Secretary, Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. Bright:

Thank you for appearing before the Subcommittee on Oversight and Investigations on June 15, 2018, to testify at the hearing entitled "The State of U.S. Public Health Biopreparedness: Responding to Biological Attacks, Pandemics, and Emerging Disease Outbreaks."

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. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, July 26, 2018. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

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

Sincerely,

Gregg Harper

Gregg Harper
Chairman
Subcommittee on Oversight and Investigations

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

Attachment

Attachment—Additional Questions for the Record

The Honorable Gregg Harper

1. In the 2017 update to HHS' Pandemic Influenza Plan, HHS provided benchmarks for manufacturing and distributing vaccines during declared influenza pandemics. HHS stated that it aims to ensure that limited vaccine distribution occurs within 12 weeks of a pandemic being declared, with distribution sufficient to meet overall public demand occurring within 16 weeks. Could you tell us why this process seemingly takes so long, and provide any recommendations for improving it? If the 12 and 16-week benchmarks are HHS's goals, what are our current capabilities?

2. In general, what is the shelf-life for the H7N9 influenza strain vaccine that is in BARDA's pre-pandemic stockpile that will protect against the 2013 H7N9 strain? When was the last time BARDA performed a potency test on these vaccines?

3. How serious of a pandemic threat does the BARDA view the 5th wave H7N9 influenza strain, currently circulating in China? If a pandemic were to occur, how severely would it impact public health? Is BARDA currently overseeing the manufacturing of a vaccine for storage in its pre-pandemic stockpile which will match this H7N9 influenza strain?

4. How much is BARDA currently spending on CARB-X? Does the agency anticipate maintaining this level of spending over the next five years?

5. What is the PHEMCE's role in making a material threat determination, and how can the length of time it takes for such a determination be reduced?

6. After ASPR assumes operational control of the Strategic National Stockpile on October 1, 2018, what role will CDC play in support of the stockpile's mission?

7. How prepared are the nation's hospitals to respond to biological threats or infectious diseases? What are the most pressing challenges facing non-governmental health systems and what could we do to improve their response capabilities?

The Honorable Michael C. Burgess

1. Dr. Bright, in 2010, BARDA established three centers to develop and manufacture medical countermeasures, such as vaccines and therapeutics, to protect our citizens during public health emergencies. Texas A&M's Center for Innovation in Advanced Development and Manufacturing is one of these centers, and was intended to focus on surge capacity for flu vaccines. I understand that the initial contract period with the Texas facility expires at the end of this month. How does BARDA plan to utilize these centers in the future? Will BARDA maintain and grow existing partnerships that have the infrastructure to deploy capabilities in the wake of a crisis?

2. How do you communicate with centers such as Texas A&M about what medical countermeasures they should develop? How involved is BARDA in helping these "Centers" identify additional partners with whom they can work?

The Honorable Frank Pallone, Jr.

1. With respect to the three types of threats we often hear about—natural, intentional, and accidental—to what extent do preparedness efforts for the different types of threats overlap?

2. How can we plan long-term for therapeutics and vaccines in order to respond to outbreaks that we cannot yet anticipate?

3. BARDA's CARB-X program is developing many nontraditional products at the preclinical stage. Can you briefly explain why you have supported these products, and what BARDA is doing to make sure that enough products move on to clinical trials?

4. Can you explain what BARDA is doing to foster public-private partnerships, and why this is important?

5. ASPR has a number of programs in place, including the Hospital Preparedness Program and the Medical Reserve Corps, which are designed to help ensure readiness at the state and local level. How do these programs ensure that our front-line responders are able to respond effectively in a public health emergency situation?

6. CDC recently concluded an operational readiness review to assess whether state and local governments and public health services will be able to effectively get medical countermeasures to the appropriate person at the appropriate time. How does BARDA work with CDC and health departments to ensure that we develop countermeasures with this "last mile" of delivery in mind?