

ONE HUNDRED FIFTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
Minority (202) 225-3641

June 26, 2018

Ms. Anna Abram  
Deputy Commissioner for Policy, Planning, Legislation, and Analysis  
U.S. Food and Drug Administration  
White Oak Campus  
10903 New Hampshire Avenue  
Building 1, Room 2335  
Silver Spring, MD 20993

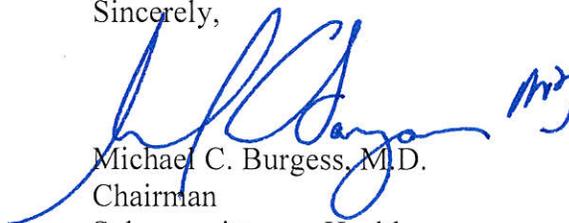
Dear Ms. Abram:

Thank you for appearing before the Subcommittee on Health on June 6, 2018, to testify at the hearing entitled "Reauthorizing the Pandemic and All-Hazards Preparedness Act."

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 July 11, 2018. Your responses should be mailed to Daniel Butler, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to [daniel.butler@mail.house.gov](mailto:daniel.butler@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 Gus M. Bilirakis**

1. Resiliency is vital to preparedness and ultimately response and recovery. The stockpile of drugs, vaccines, and other medical products and supplies, known as the Strategic National Stockpile is critical to our ability to respond and recover from catastrophic events. Reliable storage and delivery of these lifesaving medicines is also important in terms of patient safety and cost.
  - a. In what way is your agency working with industry to extend shelf life and improve resiliency of the Strategic National Stockpile?

### **The Honorable Markwayne Mullin**

1. Do you all believe that current law puts some constraints on how BARDA is able to partner new companies and new technologies?
  - a. Follow up: Can you explain to me the limits of BARDA's authority to work with companies developing non-therapeutic technologies to counter antibiotic and antimicrobial resistance?
  - b. Follow up: Do you believe giving BARDA the flexibility to work with companies more broadly would be beneficial to BARDA as they work to achieve their mission to counter anti-biotic and antimicrobial resistance?

### **The Honorable Frank Pallone, Jr.**

1. The FDA previously expressed concerns about the medical countermeasure (MCM) priority review voucher (PRV) that was created as part of the 21st Century Cures Act in 2016. Now that the PRV has been in effect for two years, can the FDA comment on the challenges of this program?
2. Should the PRV program be made permanent during the reauthorization of PAHPA? Please explain why or why not.
3. How can drug development tools and the qualification process impact national security?
4. If the agency is given authority to limit disclosures that may have national security implications, how will the FDA work with sponsors and other stakeholders to ensure consistent implementation of this authority?

5. HHS has proposed language that would allow for public postings of drug development tool qualification submissions to be modified if there is information that would compromise national security, when and how would the FDA exercise this authority?
6. What actions has FDA taken to address the cybersecurity threats to medical devices?
7. What actions does FDA plan to take in the future to help industry prepare and respond to cybersecurity threats?
8. Under the proposed bill, H.R. \_\_\_\_, the Pandemic and All-Hazards Preparedness Reauthorization Act of 2018, FDA's emergency use authorities (EUA) and the definitions of "eligible product" and "qualified pandemic or epidemic product" would be modified. How would extending FDA's EUA be beneficial? What challenges may result from this expanded authority?
9. Please provide an example of how the FDA may issue and EUA related to a cybersecurity threat or how a medical product could be developed with cybersecurity threats in mind?
10. Please comment on FDA's implementation efforts of H.R. 4374, To amend the Federal Food, Drug, and Cosmetic Act to authorize additional emergency uses for medical products to reduce deaths and severity of injuries caused by agents of war, and for other purposes and any resources the Department of Defense has expended in the implementation of this legislation.