

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
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WASHINGTON, DC 20515-6115  
Majority (202) 225-2927  
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June 17, 2016

Dr. Richard Hatchett MD  
Acting Director  
Biomedical Advanced Research and  
Development Authority  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

Dear Dr. Hatchett:

Thank you for appearing before the Subcommittee on Health on May 19, 2016 to testify at the hearing entitled "Examining H.R. 3299, Strengthening Public Health Emergency Response 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. 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 July 1, 2016. Your responses should be mailed to Graham Pittman, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to [graham.pittman@mail.house.gov](mailto:graham.pittman@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 Gene Green, Ranking Member, Subcommittee on Health

Attachment

## Attachment — Additional Questions for the Record

### The Honorable Marsha Blackburn

One of the mechanisms proposed by the Federal Government to offset development costs for essential medical countermeasures is the support of so-called “Dual Use Compounds.” These medical interventions are designed to address a specific bioterror threat, but are simultaneously being developed for the treatment of specific patient populations. In the setting of these parallel development programs, safety concerns may emerge which are specific to a limited patient population or are related to an extended duration of treatment.

1. Are there mechanisms in place to prevent a safety concern which is relevant to a specific patient population from negatively impacting the development or procurement of a medical countermeasure, particularly when the safety concern is not applicable to the general population in the event of a bioweapon attack?

### The Honorable Michael C. Burgess

1. The Ebola crisis exposed weaknesses in our healthcare system’s ability to identify and respond to biological public health threats. In what specific ways does H.R. 3299 address gaps in our national biological preparedness? Additionally, how will the bill improve HHS’s ability to both proactively identify biological pathogens, such as Ebola or Zika, and make available medical countermeasures in a timely and effective manner?
2. When BARDA was created in 2006, Congress provided the agency with authority to negotiate its own contracts. In 2009, ASPR moved all of BARDA’s authority to negotiate contracts to ASPR’s Office of Acquisitions Management, Contracts, and Grants. While this move was intended to simplify the contracting process it created confusion and unnecessary delays. There is a consensus among industry that sole contracting authority should return to BARDA. H.R. 3299 would direct the Secretary of HHS to delegate contracting authority for negotiating and entering into any contracts, grants, or cooperative agreements back to BARDA. Please describe the specific ways this authority would improve BARDA’s ability to execute its mission.

### The Honorable Billy Long

On January 20, 2004, the Secretary of Homeland Security determined that anthrax is a material threat to the U.S. population sufficient to affect national security. Since that time, the U.S. Department of Health and Human Services (HHS) has been pursuing a comprehensive strategy to address this threat. This approach has included acquisition of vaccines, antibiotics, and therapeutics to meet immediate public health needs in the event of an anthrax attack. While progress has been made in preparing against anthrax, I would like to learn more about BARDA’s plans for the future of its anthrax vaccine program.

1. Can you please provide an update on the next-generation anthrax vaccine candidates currently being supported by BARDA?

I also understand that BARDA continues to pursue multiple next-generation Recombinant Protective Antigen (rPA) anthrax vaccines. The president's FY17 budget reinforced the support and need for an rPA anthrax vaccine, and indicated that in the next three years BARDA anticipates new procurements of an rPA anthrax vaccine for the U.S. Strategic National Stockpile. Additionally, in the PHEMCE Multi-Year Budget submitted to Congress, BARDA says it intends to procure \$300 million of an rPA anthrax vaccine in FY18. The budget includes timelines indicating BARDA's plans to transition from development to procurement of an rPA anthrax vaccine in FY2017–FY2018.

2. Can you please describe the potential benefits associated with an rPA anthrax vaccine, as compared to traditional anthrax vaccines?
3. Can you please provide a detailed summary of the developmental status and projected timelines for each of the rPA anthrax vaccine programs?