

May 4, 2018

Dear Chairman Alexander, Ranking Member Murray, Senator Isakson and Senator Casey,

Thank you for the opportunity to comment on the discussion draft of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 (PAHPAI), and your continued efforts to respond to the ongoing threat of antibiotic resistance. The [recent spread of mcr-1](#), a gene that makes bacteria resistant to colistin, the antibiotic of last resort, serves as an alarming reminder of what the actual implications of antibiotic resistance are. [Mcr-1](#) is particularly concerning because of the relative ease with which it can move from one bacterium to another, spreading colistin resistance to a wide variety of bacterial species leaving patients without any treatment options.

Antibiotic resistance does not refer to a specific disease or infection. But rather, effective antibacterials are central to the nation's ability to respond to public health emergencies, including those resulting from chemical, biological, radiological, and nuclear attacks, pandemic influenza, and emerging infectious disease. Antibiotics underpin modern medicine and antibiotic resistance renders the entire health system vulnerable.

The Biomedical Advanced Research and Development Authority (BARDA) safeguards our nation's health infrastructure by revitalizing and encouraging antibacterial innovation. BARDA's Broad Spectrum Antimicrobials (BSA) program and ongoing support for the CARB-X accelerator fill critical gaps along the antibacterial pipeline, advancing development of products to address highly resistant infections and fostering breakthrough approaches to respond to resistance threats yet to emerge.

We very much appreciate the reference to antimicrobial resistance in section 404 of the discussion draft. We have attached proposed changes to the language in order to strengthen this provision. Below is an explanation of our recommendations.

- BARDA must be able to anticipate and respond to all chemical, biological, radiological, and nuclear threats (CBRN), both intentional and naturally occurring. Because of this we suggest including "public health threats" among the priority threats for which the Secretary, acting through the Director of BARDA, may implement strategic initiatives. Because the threat of antibiotic resistance – which transcends individual pathogens and can undermine the practice of medicine -- will inevitably emerge naturally, and could be introduced through advances in genetic engineering, we recommend that it be specifically mentioned.
- BARDA must be able to cultivate a diverse array of approaches to meet the challenge of antimicrobial resistance by supporting a robust pool of candidate products entering and progressing through the clinical development pipeline. BARDA's unique experience working closely with industry to drive targeted, milestone-driven research is particularly important to advance novel therapeutic and preventive approaches and to bridge the "valley of death" from basic science to clinical development.
- Without effective antibiotics, the nation's medical response capabilities will be severely hampered. Therefore, we suggest that this work should receive a dedicated authorization of appropriations.



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Thank you for your consideration of this issue.

Sincerely,

Kathy Talkington  
Antibiotic Resistance Project Director