

The Honorable Tom Harkin
Chairman
Senate Appropriations Subcommittee on
Labor, HHS and Education
131 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Richard Shelby
Ranking Member
Senate Appropriations Subcommittee on
Labor, HHS and Education
131 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Denny Rehberg
Chairman
House Appropriations Subcommittee on
Labor, HHS and Education
2358B Rayburn House Office Building
Washington, DC 20515

The Honorable Rosa DeLauro
Ranking Member
House Appropriations Subcommittee on
Labor, HHS and Education
2358B Rayburn House Office Building
Washington, DC 20515

June 8, 2012

Dear Chairmen Harkin and Rehberg and Ranking Members Shelby and DeLauro:

We, the undersigned organizations, are committed to public health emergency preparedness, and for this reason are writing in support of an appropriation for the Biomedical Advanced Research and Development Authority (BARDA) of at least \$547 million for Fiscal Year (FY) 2013, the level requested by the Administration. BARDA provides an integrated, systematic approach to the advanced development and purchase of necessary medical countermeasures (MCMs), including vaccines, biological and small molecule therapeutics, antiviral drugs, antifungal drugs, and antibiotics, diagnostics, respiratory devices, and other medical supplies. BARDA's work is critical for the nation's ability to respond to biological, chemical, nuclear, and radiological threats as well as naturally occurring threats, such as antimicrobial resistance, pandemic influenza and other emerging infectious diseases. Despite being underfunded since its inception, investments by BARDA have resulted in the development of new drugs, biologics and vaccines for many of the most important biological threats. BARDA's successes include the development of a new smallpox antiviral and vaccine for at-risk individuals such as those living with HIV, anthrax treatments including antitoxins, as well as important milestones toward developing new anthrax recombinant vaccines. These successes exemplify how industry and the U.S. Government are able to work together to address public health emergency needs.

BARDA has become a critical source of funding for industry research and development (R&D) efforts to develop novel antibiotics to treat infections caused by multi-drug resistant pathogens. Such support is crucial because, despite the growing number of patients with resistant infections, private investment in antibiotic R&D has plummeted. While antimicrobial resistant pathogens are a very serious and immediate threat in health care settings and communities, they also could be used in a bioterror attack leading to devastating consequences. An October 2011 report card issued by the Bipartisan WMD Terrorism Research Center, co-chaired by former Senators Bob Graham and Jim Talent, found that the nation has failed to meet expectations in terms of the availability of MCMs to respond to a large-scale attack involving drug-resistant pathogens.

Their report highlights the need for strong funding to allow BARDA to continue to strengthen its support for antimicrobial R&D.

BARDA also has made significant progress towards increasing and securing domestic manufacturing capacity for pandemic influenza vaccine development. While only one manufacturing site existed in the U.S. during the influenza vaccine shortage of 2004, now there are three, with more on the way. However, the 2009 response to H1N1 shows that our ability to respond rapidly is still hampered by the limits of current technology. BARDA is working with several partners to develop modern platforms for manufacturing influenza vaccines more efficiently and effectively. BARDA is also working to ensure that safe and effective antivirals are available for the treatment of influenza by supporting the advanced development of new drugs. These investments are beginning to pay off. Strong and sustained funding is needed to ensure that BARDA's efforts continue to significantly increase the availability of treatment options and the flexibility, surge capacity, and reliability of influenza vaccine production.

BARDA funding also is critically needed to support the development of new diagnostics. Better diagnostic tests can improve both clinical and public health responses to outbreaks, pandemics and bioterror attacks. For each unique threat, it is important to have diagnostic tools available for rapid detection and identification purposes and to help health care providers determine the most appropriate countermeasures to use to prevent illness and treat those who become infected. By helping to determine the most appropriate treatment, diagnostics for bacterial and viral pathogens help limit the development of drug resistance. Lastly, diagnostics can help identify patients eligible for clinical trials of new antimicrobials, reducing the cost of bringing these desperately needed drugs to market and enhancing their judicious use in the clinic.

While BARDA has made important gains in the advanced development of MCM needed to respond to bioterror attacks, naturally occurring pandemics, and other emerging diseases, BARDA's appropriation has been insufficient to support making these and many other critically needed MCMs ready for deployment. Very few companies have the resources or are willing to take the risk and expend the resources necessary to research and develop MCMs, as the market is limited and difficult to predict. That is why we join the Administration in urging Congress to provide at least \$547 million for BARDA for FY13. These funds would support R&D for additional countermeasures in the high priority areas of anthrax, broad-spectrum antimicrobials, various antivirals, versatile platform technologies, diagnostics, next-generation influenza vaccines, and countermeasures for radiological and chemical weapons. MCMs will save lives during a public health crisis or weapons of mass destruction attack. Ensuring the availability of MCMs is the responsibility of the U.S. Government. Providing sufficient funding for BARDA is a key component of this duty. Thank you for your consideration.

Sincerely,

Alliance for Biosecurity
American Academy of Neurology
American Academy of Orthopaedic Surgeons
American College of Medical Quality
American College of Rheumatology

American Public Health Association
American Society for Microbiology
American Thoracic Society
Antibiotics and Innovation Project of the Pew Health Group
Association of State and Territorial Health Officials
Bavarian Nordic, Inc.
Biotechnology Industry Organization
Center for Biosecurity of UPMC
Center for Infectious Diseases Research and Policy at the University of Minnesota
Elusys Therapeutics, Inc.
Emergent BioSolutions
Food Animal Concerns Trust
Immunization Action Coalition
Infectious Diseases Society of America
International Association of EMS Chiefs
National Association of County and City Health Officials
National Association of Nurse Practitioners in Women's Health
National Association of Pediatric Nurse Practitioners
National Coalition of STD Directors
National Foundation for Infectious Diseases
National Hispanic Medical Association
National Viral Hepatitis Roundtable
Pediatric Infectious Diseases Society
PharmAthene, Inc.
Planet Biotechnology Inc.
Premier, Inc.
RetireSafe
SIGA Technologies
Society for Healthcare Epidemiology of America
Treatment Action Group
Trust for America's Health