

Alliance for Biosecurity

Office of the Secretary and Legal Counsel

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April 4, 2008

The Honorable David Obey
Chairman
House LHHS Appropriations Subcommittee
2314 Rayburn House Office Building
Washington, D.C. 20515

The Honorable James Walsh
Ranking Member
House LHHS Appropriations Subcommittee
2372 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Obey and Ranking Member Walsh:

We are writing on behalf of the Alliance for Biosecurity to respectfully request that you provide adequate funding in Fiscal Year (FY) 2009 for the Biomedical Advanced Research and Development Authority (BARDA). BARDA is one of our nation's first lines of defense against biological, chemical, radiological or nuclear (CBRN) threats. The Alliance recommends a \$1.7 billion appropriation for BARDA's Advanced Development Fund in FY 2009. This amount is an appropriate first installment in a long-term investment in this important national security program. Adequate funding is critical to ensure that America is better prepared in the event of a CBRN terrorist attack or public health emergency.

In response to the threat of catastrophic terrorism against Americans using CBRN agents, the Congress established the Strategic National Stockpile in 1999 with the intent to stockpile needed vaccines and therapeutics (medical countermeasures) to protect against CBRN agents. Unfortunately, nearly 10 years later, we do not have all the medical countermeasures needed to protect the nation against key CBRN threats. Further, the supplies of countermeasures we do have are insufficient. There are many reasons for our lack of preparedness. Developing new drugs and vaccines is an extraordinarily resource-intensive, time consuming, and risky process. The majority of private companies engaged in drug and vaccine development make the investment only because a successful product might eventually be sold in the marketplace and thereby recoup costs and realize a profit. Most medical countermeasures to CBRN threats, however, will have little to no commercial market potential. Recognizing this, the BioShield special reserve fund was created in 2004 to procure medical countermeasures for the Strategic National Stockpile.

However, even with BioShield, the non-commercial nature of medical countermeasure development means that companies in the CBRN arena have less access to market capital to fund countermeasure development. Without shared risk with and consistent funding from the government many companies were unable to move promising CBRN medical countermeasure candidates forward. As a result, many products stalled in the so-called "Valley of Death" (i.e. advanced development) between basic research supported by NIH and procurement of final products by BioShield.

**Acambis, Inc. • Bavarian-Nordic • Cangene Corporation • Center for Biosecurity of UPMC • DOR BioPharma, Inc.
Dynport Vaccine Company LLC, a CSC Company • Elusys Therapeutics • Emergent BioSolutions
Hematech, Inc., a subsidiary of Kirin Pharma Company, Ltd. • Human Genome Sciences, Inc. • Iomai Vaccines, Inc.
NanoViricides, Inc. • Pfizer Inc. • PharmAthene • Siga Technologies**

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To address this challenge, Congress created BARDA in late 2006 as a means by which to provide support for advanced development of medical countermeasures. BARDA was initially authorized at \$1.07 billion over three years, but appropriated levels have fallen far short of this mark: only \$201 million has been appropriated by Congress through FY08, approximately one-fifth of the authorized level. A report by the non-profit Center for Biosecurity of UPMC, *BARDA FY09 Advanced Development Cost Estimates for Medical Countermeasures Against Biological Threats*, notes that "FY09 advanced development funding required for BARDA to have a 90% chance of ultimately developing one successful medical countermeasure (MCM) for each requirement set forth in the Public Health Emergency Countermeasures Enterprise (PHEMCE) Implementation Plan" would need to be \$3.39 billion. This level of annual funding would need to be maintained for many years. Clearly, there must be a substantial investment made in FY 2009 in BARDA's Advanced Development Fund in order to ensure that the country makes progress in its preparedness for a terrorist attack or public health emergency.

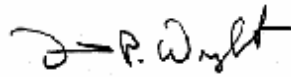
We recognize that this is a significant outlay, and that FY 2009 may prove to be an especially austere fiscal environment. But developing new medical countermeasures, while expensive, is an endeavor critical to national security. If BARDA is given \$1.7 billion for FY 2009, it can support important work on advanced research and development of needed countermeasures. Without sufficient funds, promising products will languish and the nation will remain vulnerable.

As you may know, the Alliance for Biosecurity is a collaboration between the Center for Biosecurity of UPMC, pharmaceutical companies, and biotechnology companies working to develop vaccines and medicines for our nation's Strategic National Stockpile. The Alliance mission is to work in the public interest to promote a robust and sustainable research and development infrastructure necessary to prevent and treat the infectious disease threats that present security challenges in the 21st Century.

Respectfully submitted on behalf of the Alliance,



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Senior Director of Operations and Communications
Pfizer Inc.
Co-Chair, Alliance for Biosecurity



David P. Wright
President & CEO
PharmAthene
Co-Chair, Alliance for Biosecurity



Tara O'Toole, MD
CEO & Director, Center for Biosecurity
University of Pittsburgh Medical Center
Strategic Director, Alliance for Biosecurity

cc: Members of the House Labor, Health and Human Services, and Education Appropriations Subcommittee