

Alliance for Biosecurity

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September 8, 2008

The Honorable Tom Harkin
Chairman
Senate LHHS Appropriations Subcommittee
131 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Arlen Specter
Ranking Member
Senate LHHS Appropriations Subcommittee
711 Hart Senate Office Building
Washington, D.C. 20510

Dear Chairman Harkin and Ranking Member Specter:

We are writing on behalf of the Alliance for Biosecurity to express our strong support for the administration's revised Fiscal Year (FY) 2009 budget request for "advanced research and development" in the Public Health and Social Services Emergency Fund which is administered by the HHS Biomedical Advanced Research and Development Authority (BARDA). In an August 1, 2008 communication to Congress, the White House amended its previous FY2009 budget request for this critical national security program from \$275,000,000 to \$748,000,000. This funding level more closely reflects the magnitude of the threat Congress designed BARDA to address, and we strongly encourage the Subcommittee to fund BARDA at this level for Fiscal Year FY2009.

BARDA is one of our nation's first lines of defense against biological, chemical, radiological or nuclear (CBRN) threats. Its mission to develop and then procure new drugs and vaccines, and other medical countermeasures, is an extraordinarily resource-intensive, time consuming, and risky process. Since these medical products have essentially no commercial market – the government is the sole customer - finding private investors willing to support development of medical countermeasures against CBRN threats is nearly impossible. To address this investment shortfall, Congress created BARDA in late 2006 as a means by which to provide support for advanced development of medical countermeasures needed for the nation's Strategic National Stockpile (SNS).

BARDA was initially authorized at \$1.07 billion over three years, but funding levels have fallen far short of this mark: only \$201 million has been provided by Congress in FY07 and 08, approximately one-fifth of the authorized level. While the Alliance understands that this is not an inconsiderable sum, it is important to note that drug development is a very resource-intensive process, and that developing drugs to protect the nation against CBRN threats will require much greater support. Unless BARDA funding is significantly increased, it is highly unlikely that medical countermeasures for each of the threats set forth in HHS's Public Health Emergency Countermeasures Enterprise (PHEMCE) Implementation Plan for inclusion in the SNS will be successfully developed. Although the amount requested by the administration for FY2009 BARDA funding is far below the level of \$3.39 billion per year that the Center for Biosecurity has estimated would be required to achieve a 90% chance of developing a countermeasure for each

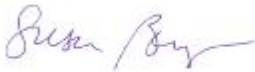
[Bavarian-Nordic](#) • [Cangene Corporation](#) • [Center for Biosecurity of UPMC](#) • [DOR BioPharma, Inc.](#) [Dynport Vaccine Company LLC, a CSC Company](#) • [Elusys Therapeutics](#) • [Emergent BioSolutions](#)
[Hematech, Inc., a subsidiary of Kirin Pharma Company, Ltd.](#) • [Human Genome Sciences, Inc.](#) • [Intercell USA, Inc.](#)
[NanoViricides, Inc.](#) • [Pfizer Inc.](#) • [PharmAthene](#) • [Siga Technologies](#)

of the eight biodefense requirements in the PHEMCE Plan, it represents an important improvement over previous funding levels.

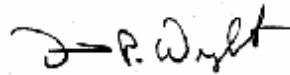
We recognize that the administration's request is a significant outlay, and that FY 2009 may prove to be an especially austere fiscal environment. But developing new medical countermeasures, while expensive, is an endeavor critical to national security. Without sufficient funds, promising products will languish and the nation will remain vulnerable.

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,



Susan Berger, Ph.D.
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 Senate Labor, Health and Human Services, and Educations Appropriations Subcommittee