

Alliance for Biosecurity

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October 31, 2008

The Honorable Tom Harkin
Chairman
Subcommittee on LHHS
S-131 U.S. Capitol
Washington, D.C. 20510

The Honorable Arlen Specter
Ranking Member
Subcommittee on LHHS
S-131 U.S. Capitol
Washington, D.C. 20510

Dear Chairman Harkin and Ranking Member Specter:

We are writing on behalf of the Alliance for Biosecurity to urge that any economic stimulus package considered and passed by the 110th Congress include \$905,000,000 for the Public Health and Social Services Emergency Fund for the advanced development of medical countermeasures, to be administered by the Biomedical Advanced Research and Development Authority (BARDA). This level was included in S. 3604, the economic stimulus legislation considered on the Senate floor on September 26, 2008. The Alliance for Biosecurity strongly supports this level of funding for this critical national security program.

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, 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. Because the Department of Health and Human Services (HHS) is operating under a continuing resolution until March 2009, it is unclear what level of FY09 funding will ultimately be provided for BARDA as part of the regular appropriations order. While the Alliance understands that \$201 million 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 \$905 million level included in S.3604 is 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 of the eight biodefense requirements in the PHEMCE Plan, it represents an important improvement over previous funding levels.

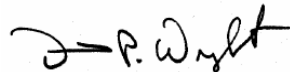
We recognize that \$905 million is a significant outlay, and that FY 2009 may prove to be an especially austere fiscal environment given the current economic situation and associated federal spending. But developing new medical countermeasures, while expensive, is an endeavor critical to national security. 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 Committee on Appropriations
Members of the Senate Labor, Health and Human Services, and Education
Appropriations Subcommittee