

Alliance for Biosecurity

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President Barack Obama
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear President Obama:

We are writing on behalf of the Alliance for Biosecurity to respectfully request that your Fiscal Year (FY) 2011 budget include adequate funding for advanced development at 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 and emerging infectious disease threats. The Alliance recommends a \$1.7 billion budget request for BARDA's Advanced Development Fund in FY 2011. This amount is an appropriate first installment in a long-term investment in this important national security program.

The December, 2008 report of the Congressionally established *Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism* found that "it is more likely than not that a weapon of mass destruction will be used in a terrorist attack somewhere in the world by the end of 2013," and that "terrorists are more likely to be able to obtain and use a biological weapon than a nuclear weapon." Along similar lines, in November of 2008 the National Intelligence Council reported that "one of [its] greatest concerns continues to be that a terrorist might acquire and employ biological agents, or less likely, a nuclear device, to create mass casualties." These findings reflect the fact that bioterrorism represents one of the direst threats to national security. Bioterrorism is on par with nuclear terrorism in terms of lethality, but far more likely given the lower technological thresholds to create and deploy a biological agent. Vaccines, therapeutics, and other medical countermeasures must be created in order to reduce our vulnerability to this very real threat.

In response to the threat of catastrophic terrorism against Americans using CBRN agents, the Strategic National Stockpile was established in 1999 with the intent to stockpile needed medical countermeasures. Unfortunately, 10 years later, we do not have all the medical countermeasures needed to protect the nation against identified CBRN threats. Further, the supplies of countermeasures we do have are insufficient.

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 Kyowa Kirin • Human Genome Sciences, Inc. • NanoViricides, Inc. • Pfizer Inc. • PharmAthene • Siga Technologies • Unither Virology LLC, a subsidiary of United Therapeutics Corporation

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.

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 funding levels have fallen far short of this mark: only \$476 million has been appropriated as of this date, less than half of the authorized level.

The most recent White House budget request for BARDA was \$305 million. This was an improvement over levels that had been appropriated in previous years, but we would respectfully submit that it is still far short of what is appropriate given the magnitude of the threat, and the cost of improving our preparedness for it. If you believe that medical countermeasures are important for national security, and that it is important to have countermeasures that fit each of the eight requirements established by the Department of Homeland Security, then increased funding is required.

A recent independent analysis by the Center for Biosecurity estimated that \$14 billion through FY 2015 in advanced development funding for BARDA would be required to have a 90% chance of ultimately developing just one successful medical countermeasure for each of the eight biodefense requirements set forth in HHS's PHEMCE Implementation Plan. BARDA funding closer to this level would advance the day when our nation has access to these countermeasures; until that day arrives, the American people remain vulnerable.

We recognize that \$1.7 billion is a significant outlay, and that FY 2011 may prove to be an especially austere fiscal environment. But developing new vaccines and therapeutics, while expensive, is an endeavor critical to national security. If BARDA is given \$1.7 billion for FY 2011, it can support important work on advanced research and development of needed countermeasures. Furthermore, BARDA can serve as an innovation engine to support development of new science, technology platforms, and accelerated development processes that could be applied to a range of infectious agents.

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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Eric A. Rose, MD
Chairman & CEO
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cc: Peter Orszag, Office of Management and Budget
John Brennan, Assistant to the President for Homeland Security and Counterterrorism
Peter Emanuel, Office of Science and Technology Policy, Executive Office of the President
Michael Kurilla, Director, Office of Biodefense Research Activities, NIH/NIAID
Nicole Lurie, HHS Assistant Secretary for Preparedness and Response
Gerald Parker, Principal Deputy Assistant Secretary, Office of the Assistant Secretary for Preparedness and Response, HHS
Robin Robinson, Director, BARDA Office, HHS