

Center for Biosecurity

UPMC | University of Pittsburgh
Medical Center

March 9, 2009

President Barack Obama
The White House
1600 Pennsylvania Avenue N.W.
Washington, DC 20500

Dear Mr. President,

The Center for Biosecurity of the University of Pittsburgh Medical Center (UPMC) is a non-profit, non-partisan university think-tank dedicated to reducing the risks and consequences of destabilizing epidemics of infectious disease resulting from natural causes or a bioterrorist attack. **We are writing to recommend that the Department of Health and Human Services' (HHS) Biomedical Advanced Research and Development Authority (BARDA) FY 2010 budget include \$1.7 billion in the Public Health and Social Services Emergency Fund (PHSSEF) for BARDA's advanced research and development mission.**

Biological weapons pose grave threats to our nation. In November 2008, the National Intelligence Council reported that, "one of [its] greatest concerns continues to be that terrorist or other malevolent groups might acquire and employ biological agents, or less likely, a nuclear device, to create mass casualties."¹ In December 2008, the Commission on the Prevention of Weapons of Mass Destruction (WMD) Proliferation and Terrorism reported that "unless the world community acts decisively and with great urgency, it is more likely than not that a [WMD] 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."² Yet, we lack most of the medicines and vaccines required to respond to these threats – and it is BARDA's mission to develop them.

BARDA is the linchpin in the government's program to develop and acquire medicines and vaccines to protect American civilians against CBRN attacks. It was created by Congress in 2006 – with unanimous consent in both chambers – at the urging of HHS and the private sector. Developing a single new drug or vaccine can take ten years and cost \$800 million or more, and over 80% of candidates fail to attain FDA approval even after this significant investment. Before BARDA, the government did not have an effective mechanism to support early stage candidates through this long and costly advanced development process. Companies have few incentives to do so themselves; so there is a limited selection of FDA approved medicines and vaccines for the government to procure for the national stockpile – leaving many gaps in our defenses.

BARDA has the tools to fill these gaps, but it has been underfunded since its inception. We have estimated that BARDA would require \$14 billion through FY 2015 to have a 90% chance of successfully developing all 8 of the current biodefense medicine and vaccine requirements that have been identified by HHS.³ It received only a total of \$201 million in FYs 2007 and 2008.

While \$14 billion may be a large sum in the context of health budgets, it is quite small when considered in the context of national security expenditures. In spite of limited funding to date, BARDA has developed the infrastructure, workforce, and expertise to manage the necessary portfolio of new MCMs. All that remains now is for the program to be fully funded. The projects that BARDA would support would be in the biopharma sector where the U.S. is the global leader, but current trends are moving critical expertise and capacity abroad, taking top-tier jobs with them. If fully funded, BARDA would be supporting national security and economic strength.

Preparedness for catastrophic health events requires stable, continuous funding, planning, and oversight to build the capacity to prevent and mitigate the effects of an attack with a bioweapon. If you do not act to fully fund BARDA, the organization will wither, the private sector will turn away from biodefense, and the American people could ultimately pay a horrible price in the wake of a terrorist attack with a biological weapon.

Sincerely,



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Director and CEO
Center for Biosecurity of UPMC



Thomas V. Inglesby, MD
Deputy Director and COO
Center for Biosecurity of UPMC

cc:

Avital Bar-Shalom, Office of Management and Budget, Executive Office of the President
John Brennan, National Security Council, Executive Office of the President
Peter Emanuel, Office of Science and Technology Policy, Executive Office of the President
Keith J. Fontenot, Office of Management and Budget, Executive Office of the President
Michael Kurilla, Director, Office of Biodefense Research Activities, NIH/NIAID
Carol Linden, BARDA Office, HHS
Gerald Parker, Principal Deputy Assistant Secretary, Office of the Assistant Secretary for
Preparedness and Response, HHS
Robin Robinson, Director, BARDA Office, HHS
Governor Kathleen Sebelius, HHS Secretary-designate
W. Craig Vanderwagen, HHS Assistant Secretary for Preparedness and Response

Senator Richard Burr
Senator Susan Collins
Senator Tom Harkin
Senator Edward Kennedy
Senator Joseph Lieberman
Senator Arlen Specter

Representative Anna Eshoo
Representative Peter King
Representative David Obey
Representative Mike Rogers (MI)
Representative Bennie Thompson
Representative Todd Tiahrt

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¹ *Global Trends 2025: A Transformed World* (NIC 2008-003). Washington, DC: National Intelligence Council. November 2008 http://www.dni.gov/nic/PDF_2025/2025_Global_Trends_Final_Report.pdf. Accessed February 10, 2009.

² *World at Risk*. Washington, DC: Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. December 2008. <http://documents.scribd.com/docs/15bq1nr19aerfu0yu9qd.pdf>. Accessed February 10, 2009.

³ Matheny, J., Mair, M., and Smith, B. T. 2008. Cost/Success Projections for US Biodefense Countermeasure Development. *Nature Biotechnology*. **26**:981-983.