

Center for Biosecurity

UPMC | University of Pittsburgh
Medical Center

March 3, 2009

Senator Tom Harkin
Chairman
Senate LHHS Appropriations Subcommittee
731 Hart Senate Office Building
Washington, DC 20510

Senator Arlen Specter
Ranking Member
Senate LHHS Appropriations Subcommittee
711 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Harkin and Ranking Member Specter,

The Center for Biosecurity of UPMC is writing to express its concern over the deletion of funding for the Department of Health and Human Services' (HHS) Biomedical Advanced Research and Development Authority (BARDA) in the American Recovery and Reinvestment Act. **We recommend that \$1.7 billion be appropriated for FY 2010 in the Public Health and Social Services Emergency Fund (PHSSEF) for BARDA's advanced research and development mission.** We also recommend that the FY 2010 funding be a new appropriation and not transferred from the BioShield Special Reserve Fund (SRF), which cannot support annual redirection of its funds and remain viable. We also urge you to reaffirm Congress' commitment to development of new medicines and vaccines (*i.e.* medical countermeasures or "MCMs") to counter bioterrorism and other threats.

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 MCMs 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/or acquire MCMs to protect American civilians. It was created by Congress in 2006 – with unanimous consent in both chambers – at the urging of HHS and the private sector. Before BARDA, the government could not support early stage MCMs through the long and costly advanced development process. As a result, there was a limited selection of MCMs for the government to procure for the national stockpile – leaving many gaps in our defenses. However, BARDA has been underfunded since its inception; it has received only \$201 million to date. 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 MCM requirements that have been identified by HHS.³ 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, though, BARDA has developed the infrastructure, workforce, and expertise to manage the necessary portfolio of new MCMs. All that remains now is for Congress to fully fund the program.

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 Congress does not act to fully fund BARDA, the organization will wither, the private sector will turn away from biodefense, and the American people will ultimately pay a horrible price in the wake of a terrorist attack with a biological weapon.

The \$1.7 billion we recommend for BARDA's advanced research and development mission in FY 2010 is an urgently needed down payment on the organization's long-term funding needs. BARDA holds great potential to encourage and facilitate development of new medical countermeasures, diagnostics, and related technologies; however, the intentions of Congress in creating BARDA are far from being realized.

Sincerely,



Tara O'Toole, MPH, MD
Director and CEO
Center for Biosecurity of UPMC



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

cc:

Members of the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies:

Senator Daniel Inouye
Senator Herb Kohl
Senator Patty Murray
Senator Mary Landrieu
Senator Richard Durbin
Senator Jack Reed
Senator Frank Lautenberg

Senator Thad Cochran
Senator Judd Gregg
Senator Kay Bailey Hutchison
Senator Richard Shelby

Senator Richard Burr
Senator Susan Collins
Senator Edward Kennedy
Senator Joseph Lieberman

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
Michael Kurilla, Director, Office of Biodefense Research Activities, NIH/NIAID
Gerald Parker, Principal Deputy Assistant Secretary, Office of the Assistant Secretary for Preparedness and Response, HHS
Robin Robinson, Director, BARDA Office, HHS
W. Craig Vanderwagen, HHS Assistant Secretary for Preparedness and Response

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/15bq1nrl9aerfu0yu9qd.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.