

Center for Biosecurity

UPMC | University of Pittsburgh
Medical Center

March 31, 2008

Senator Richard Burr
217 Russell Senate Office Building
Washington, DC 20510

Dear Senator Burr,

To begin, the leadership and staff of the Center for Biosecurity of the University of Pittsburgh Medical Center (UPMC) would like to thank you and your colleagues in the Congress for your leadership on biodefense issues. This letter is in response to your recent request for the Center for Biosecurity's input regarding the levels of funding necessary for success in 2009 and beyond for the Biomedical Advanced Research and Development Authority (BARDA) within the Department of Health and Human Services (HHS).

For FY2009, we recommend that \$1.7 billion be appropriated in the Public Health and Social Services Emergency Fund (PHSSEF) for BARDA's Advanced Research and Development Fund.

Bioterrorism has been highlighted by the National Intelligence Council, which said: "Our greatest concern is that terrorists might acquire biological agents, or less likely, a nuclear device, either of which could cause mass casualties."¹ Terrorist use of biological weapons against civilian populations is a significant threat to America's national security. As such, it deserves significant federal government investment in the full spectrum of preparedness activities, including the development of new medical countermeasures (MCMs) against biological and other threats to the nation.

As you know, BARDA was established by the Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA; P.L. 109-417) to support the advanced research and development of critically needed MCMs. The Congress authorized \$1.07 billion for Fiscal Years (FY) 2006-2008 in PAHPA for this mission. However, since BARDA's creation in December 2006, only \$201 million has been provided, and the \$250 million requested in the President's FY2009 budget is insufficient given the scale of the challenge facing us.

We do not currently have MCMs for many of the top threats facing the nation, and the BARDA office holds great potential to encourage and facilitate the advanced research and development that will lead to new MCMs and related technologies. The small amount of funding provided to BARDA to date has allowed HHS to establish an infrastructure with the potential to support a robust advanced research and development portfolio. Now we are asking Congress to adequately fund the office so that it may successfully carry out its critical national security mission.

¹ "Mapping the Global Future" – Report of the National Intelligence Council's 2020 Project; January 2005.

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To establish the level of funding necessary for BARDA to be successful, we recently conducted a detailed analysis, the results of which indicate that \$817 million is required in FY2009 to support one year of advanced development for the candidate medical countermeasures against biological threats that are currently in development.² But unfortunately, \$817 million will not support a pipeline of candidate MCMs sufficiently large to guarantee the successful development of new products, given the historically high failure rates for the development of therapeutics and vaccines.

In fact, \$3.39 billion in FY2009 is the level of funding BARDA would need to have a 90% chance of ultimately developing successful MCMs for each biodefense requirement set forth in HHS's Public Health Emergency Countermeasures Enterprise (PHEMCE) Implementation Plan. This level of annual appropriations would have to be sustained for many years, because developing MCMs, as with all biomedical products, is an expensive, high-risk, and lengthy undertaking. BARDA's funding must reflect this reality.

BARDA was created in December 2006, and HHS issued the PHEMCE Implementation Plan in mid-2007. Given that this is a relatively new office, we are making a conservative recommendation that, in FY2009, \$1.7 billion be appropriated for BARDA's Advanced Development Fund. BARDA needs at least this much to begin making a concerted effort to support the development of critically needed MCMs. These funds could potentially be made available in a FY2008 supplemental appropriation given the urgent national security need for new MCMs.

Regardless of the source, this funding should be considered a down payment on fulfilling the larger countermeasure development goals of HHS's PHEMCE Implementation Plan. As already noted, this scale of annual appropriations will have to be sustained for many years. The nation faces grave threats from catastrophic terrorism, and biological weapons are especially serious. It is time for the nation to begin funding BARDA and related preparedness and response activities in an equally serious manner.

Sincerely,



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

² BARDA FY09 Advanced Development Cost Estimates for Medical Countermeasures Against Biological Threats. Center for Biosecurity of UPMC. January 29, 2008. (http://www.upmc-biosecurity.org/website/resources/commentary/2008-01-31-barda_fy09.html)

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cc:

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

Senator Tom Harkin
Senator Daniel Inouye
Senator Herb Kohl
Senator Patty Murray
Senator Mary Landrieu
Senator Richard Durbin
Senator Jack Reed
Senator Frank Lautenberg
Senator Arlen Specter
Senator Thad Cochran
Senator Judd Gregg
Senator Larry Craig
Senator Kay Bailey Hutchison
Senator Ted Stevens
Senator Richard Shelby

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

Representative Dave Obey
Representative Nita Lowey
Representative Rosa L. DeLauro
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Representative Patrick Kennedy
Representative Lucille Roybal-Allard
Representative Barbara Lee
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Representative Michael K. Simpson
Representative Dennis R. Rehberg
Representative Jerry Lewis

Senator Edward Kennedy
Senator Joseph Lieberman
Secretary Mike Leavitt, HHS

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W. Craig Vanderwagen, HHS Assistant Secretary for Preparedness and Response
Gerald Parker, Principal Deputy Assistant Secretary, Office of the Assistant Secretary for
Preparedness and Response, HHS

Carol Linden, Acting Director, BARDA Office, HHS

Robert Kadlec, Special Assistant to President for Homeland Security and Senior Director for
Biological Defense Policy

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