



IDS



Trust for
America's Health
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March 21, 2008

The Honorable Tom Harkin
Chair
Subcommittee on Labor, Health and
Human Services, Education and Related
Agencies Appropriations
Room 131 HSOB
United States Senate
Washington, DC 20510

Dear Chairman Harkin:

The Infectious Diseases Society of America (IDSA) and Trust for America's Health (TFAH) were strong advocates for the creation of the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response at the Department of Health and Human Services (HHS), as enacted in the Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA; P.L. 109-417). BARDA is intended to support the advanced research and development (R&D) of critically needed medical countermeasures against biological, chemical, nuclear, and radiological threats to the nation as well as naturally-occurring threats such as pandemic influenza. 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. For FY 2009, we request \$850 million for biological countermeasures and diagnostics, which should be made available over multiple years in the Public Health and Social Services Emergency Fund (PHSSEF) for BARDA's Advanced Research and Development Fund. In addition, we support \$1.29 billion to be made available over multiple years for BARDA's Pandemic and Emerging Disease Program.

BARDA holds great potential to encourage and facilitate R&D of new biomedical countermeasures, diagnostics, and related technologies; however, the intentions of the Congress and the Administration in creating BARDA are far from being realized. The small amount of funding provided to BARDA to date only has allowed HHS to establish an infrastructure to support a yet-to-be-seen robust advanced R&D portfolio for many innovative biomedical products. We urge Congress to provide adequate funding for BARDA in order for it to function as a leader in civilian advanced R&D. BARDA's budget must be substantial to allow for flexible decision-making and risk-taking and its portfolio diverse to encompass a range of conventional "one bug, one drug" approaches to more novel, high-risk projects. The \$250 million requested for BARDA and the \$507 million requested for pandemic influenza in the President's FY 2009 budget is insufficient given the scale of the challenge.

As evidence of what level of funding is necessary for this office for biological threats alone, an analysis conducted by the Center for Biosecurity indicates that \$817 million in FY 2009 would be required to support one year of advanced development for the candidate medical countermeasures currently in development against biological threats.¹ Unfortunately, even \$817 million will not support a pipeline of candidate biological countermeasures sufficiently large to guarantee the successful development of new products given the historically high failure rates for the development of therapeutics and vaccines. For BARDA to have a 90% chance of ultimately developing successful medical biological countermeasures for each requirement set forth in the Public Health Emergency Countermeasures Enterprise (PHEMCE) Implementation Plan, the Center's analysis indicates \$3,390 million in FY 2009 for advanced R&D would be required.

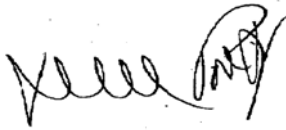
This \$850 million request for FY 2009 should come with multiple years of fiscal availability, which will enable BARDA to be flexible and partner effectively with product developers. This level of annual appropriations will need to be sustained for many years and should be considered a down payment towards fulfilling the larger countermeasure development goals of the PHEMCE Implementation Plan.

Within BARDA, the Pandemic and Emerging Disease Program covers naturally-occurring infections that threaten national security, specifically pandemic influenza. We commend the BARDA Influenza and Emerging Infections Program for making great strides to advance our knowledge and ability to produce a safe and efficacious pre-pandemic vaccine. Still, the office has a long road ahead as it must navigate through vaccine manufacturing and surge capacity complexities with the ultimate goal of executing the timely, grand scale production of a closely-matched pandemic strain vaccine to support the entire U.S. population.

Last year, the President proposed \$790 million for BARDA for the advanced development of pandemic influenza vaccine and pre-pandemic vaccine and antiviral stockpiles. Our organizations were greatly disappointed that last year's omnibus appropriations bill did not fund the President's request. This year's budget request of \$507 million takes steps to fund pre-pandemic vaccine and medical countermeasure stockpiling as well as vaccine manufacturing capacity; however, it does not replace the original \$790 million request. Given the remaining challenges associated with the development and stockpile of pandemic vaccines, therapeutics, and diagnostics, IDSA and TFAH strongly encourage Congress to provide \$1.29 billion for FY 2009 for pandemic influenza, which includes the \$507 million indicated in the President's FY 2009 proposal and the \$790 million requested in FY 2008.

¹ 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)

Sincerely,



Donald M. Poretz, MD
President
Infectious Diseases Society of America



Jeffrey Levi, PhD
Executive Director
Trust for America's Health

cc:

Senator Edward Kennedy, Chair, Senate Health, Education, Labor, and Pensions
Senator Michael Enzi, Ranking Member, Senate Health, Education, Labor, and Pensions
Senator Richard Burr, Senate Health, Education, Labor, and Pensions
Representative John Dingell, Chair, House Energy and Commerce
Representative Joe Barton, Ranking Member, House Energy and Commerce
Representative Frank Pallone, Chair, House Energy and Commerce Subcommittee on Health
Representative Nathan Deal, Ranking Chair, House Energy and Commerce Subcommittee on Health
Senator Joe Lieberman, Chair, Senate Homeland Security and Government Affairs
Senator Susan Collins, Ranking Member, Senate Homeland Security and Government Affairs
Secretary Michael Leavitt, Department of Health and Human Services
RADM W. Craig Vanderwagen, MD, HHS Assistant Secretary for Preparedness and Response
Carol Linden, PhD, Acting Director, BARDA Office
Robert Kadlec, MD, Special Assistant to President for Homeland Security and Senior Director for Biological Defense Policy
Bruce Gellin, MD, MPH, Director, National Vaccine Program Office, HHS
William Raub, Science Advisor to the Secretary of Health and Human Services