

COVER PAGE

Written Testimony Submitted to the House of Representatives Labor, Health and Human Services, and Education Appropriations Subcommittee Regarding FY 2010 Funding for BARDA Advanced Research and Development

Submitted by:

David P. Wright, Co-Chair of the Alliance for Biosecurity
Washington, DC
david.wright@pharmathene.com
410 269-2500

**March 18, 2009
2 pm**

Summary

The Alliance for Biosecurity respectfully requests that the Subcommittee provide \$1.7 billion in FY 2010 in the Public Health and Social Services Emergency Fund for medical countermeasure advanced research and development. This would allow the Biomedical Advanced Research and Development Authority (BARDA) within the Department of Health and Human Services (HHS) to effectively support development of drugs, vaccines and other medical countermeasures needed to protect Americans from bioterrorism and other catastrophic health emergencies.

Bioterrorism and emerging infectious diseases present an extraordinary and potentially grave threat to public health and national security. One of the most effective ways to improve our national preparedness for these threats is through the development of medical countermeasures that can be distributed in the event of an emergency. The federal government has a central role to play in developing these medical countermeasures, and in BARDA it has an effective tool for doing so. We very much appreciate the Subcommittee's consideration of our views, and we stand ready to work with Subcommittee members and staff on this and other biosecurity matters.

Investing in Innovation to Strengthen Biosecurity, Create Jobs, & Advance Drug Development

Biosecurity is a Critical National Security Challenge

The Alliance for Biosecurity appreciates the opportunity to submit written testimony to the House Labor, Health and Human Services, and Education Appropriations Subcommittee. The Alliance is a collaboration between the Center for Biosecurity of the University of Pittsburgh Medical Center (UPMC) and biopharmaceutical companies working to develop vaccines and medicines for our nation's civilian Strategic National Stockpile (SNS) and the US military. 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 chemical, biological, radiological, and nuclear (CBRN) threats as well as infectious diseases that present security challenges in the 21st Century. To ensure that we have the funds necessary to develop safe and effective countermeasures, the Alliance requests that the Subcommittee consider providing \$1.7 billion in 2010 for the Biomedical Advanced Research and Development Authority (BARDA).

The United States is engaged in an important national security effort to support the development and manufacture of new drugs, vaccines, and diagnostic tests needed to protect Americans from CBRN and emerging infectious disease threats. Currently, medical countermeasures for many of the agents of greatest concern do not exist. Until these medical countermeasures are developed, manufactured and stockpiled, our country will remain vulnerable to terrorist attacks.

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."ⁱ

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. Medical countermeasures must be created in order to reduce our vulnerability to this very real threat. For now, however, the United States remains vulnerable to biological threats, both because (1) many of the medical countermeasures that the US has identified as essential to procure have not yet completed development; and (2) the potential list of biological threats is growing, driven by the ongoing revolution in the life-sciences that opens doors to the development of new and potent bioengineered threats. Addressing threats posed by known and unknown bioterror pathogens, pandemic

influenza, and other destabilizing emerging infectious diseases requires sustained investment and creative partnerships between government, industry, and other stakeholders. Already, there have been extraordinary advances achieved through government investment and partnership with industry with respect to preparedness for pandemic influenza. A similar collective endeavor is not only critical to biosecurity, but it also presents opportunities to leverage cutting edge innovation in the biodefense space to advance and rapidly accelerate drug development for a broad range of emerging infectious diseases in the US and around the world.

Government Resources

New drug development is an extraordinarily time and resource-intensive process that, on average, requires 10-15 years and approximately \$800 million from start to finish for one productⁱⁱ. Development is also high-risk: 80% of all candidates that enter clinical trail fail to attain FDA approval. This process is especially complicated in the case of medical countermeasures, due to a number of factors including the ethical impossibility of human efficacy trials in many cases, the lack of established animal models, and the uncertainty surrounding the FDA animal efficacy rule. Most importantly, because many of these products have either a limited commercial market or no commercial market whatsoever, raising private capital for product research and development is extremely difficult, and often impossible.

Congress has recognized some of these challenges and addressed them by creating effective tools to meet the nation's biosecurity needs, including Project BioShield and BARDA within HHS. Project BioShield is a federal program established in 2004, which provided special authorities to HHS to allow the *procurement and stockpiling* of medical countermeasures against the CBRN agents. Congress provided Project BioShield with a \$5.6 billion appropriation through FY 2013 for this purpose, an adequate initial level given current medical countermeasure availability. However, fully furnishing the SNS will eventually require additional funds, particularly if the existing appropriation is drawn down to fund other priorities. Several critical medical countermeasures, including those for use against anthrax, radiological and nuclear agents, and botulinum toxin, have already been acquired with Project BioShield funds. But as of the midway point of FY 2009, \$3.7 billion of the BioShield appropriation remains unobligated. This is because only a few countermeasures are advanced enough for procurement. Many of those that are in the later stages of development are stalled due to lack of government funding. Developing countermeasures requires a partnership with the government, because in most cases the government is the only customer and the markets are small. Consequently, it is often not possible for companies to attract and sustain the private investments required to fund a company's R&D for the many years of work required before BioShield procurement becomes possible. This is, unfortunately, not simply an academic problem: the development risk attached to creating medical countermeasures has already begun to undermine the goals of Project BioShield.

BARDA was established in 2006 through the Pandemic and All-Hazards Preparedness Act (PAHPA) to address this problem. BARDA leads and coordinates MCM initiatives across the federal government and was set up to provide advanced development

funding for promising medical countermeasures. Specifically, BARDA bridges the funding gap between early-stage research and the ultimate procurement of products for the national stockpile under Project BioShield. Early-stage research is often supported by the National Institutes of Health (NIH), and for this reason the Alliance supports robust funding for NIH and the National Institute for Allergy and Infectious Diseases, which perform much of the basic biomedical research critical to the development of medical countermeasures. The gap between this early-stage research and BioShield procurement – often referred to as the “Valley of Death” – is where many promising technologies and products have languished as the result of scarce resources. By partnering with private industry and providing financial support, BARDA can reduce the development risk entailed in medical countermeasure research, thereby helping to mitigate the disincentives associated with countermeasure development, and ultimately improving our national readiness posture with regard to a chemical, biological, radiological or nuclear attack.

BARDA is ready to effectively deploy the \$1.7 billion we are recommending for FY 2010. It has already made significant advances despite more limited funding, particularly since coming under the successful leadership of Director Robin Robinson in the spring of 2008. Dr. Robinson previously ran HHS’s highly successful pandemic influenza medical countermeasure program and exhibited a superb ability to partner with the private sector and manage complex drug development programs. The Alliance views Dr. Robinson as an able administrator and manager, and a strong leader in the field of public health preparedness and drug development. As Director, Dr. Robinson has described a vision of using BARDA’s investments in medical countermeasures for CBRN threats to improve overall development of drugs and vaccines for influenza and emerging infectious diseases. After an initial ramp-up period, BARDA has begun to move aggressively to fulfill its mandate. BARDA has brought in over 200 expert personnel, and in September of 2008 alone it awarded seven contracts to advance the development of products to treat patients with heavy radiation exposure. In the period since its creation in December of 2006, BARDA has awarded contracts to support the advanced development of vaccines for Ebola and Marburg hemorrhagic fevers, antibiotics for plague and tularemia, and an immunoglobulin and a range of antitoxins for the treatment of anthrax.

BARDA is an effective, agile organization that appreciates the urgency of the challenge it confronts, and is making significant contributions to the development of new medical countermeasures against CBRN threats, pandemic influenza, and emerging infectious diseases. There is now an enormous opportunity to leverage BARDA’s largely untapped potential. A level of BARDA funding more reflective of the magnitude of the threat of CBRN terrorism and emerging infectious disease would improve our nation’s security against weapons of mass destruction, stimulate the biotech sector, drive biomedical science forward, and ensure our country’s continued global leadership in this critical field. Increased funding would also take advantage of BARDA’s potential as an engine of innovation to support development of new science, technology platforms, and accelerated development processes that could be applied to a range of medicines and vaccines against infectious diseases.

Requested BARDA funding level

BARDA was initially authorized at \$1.07 billion over three years, and Congress has provided \$476 million for BARDA since its creation in December 2006. The Subcommittee is to be commended for its efforts to improve our nation's preparedness by dedicating resources to this critical program, and the Alliance is deeply appreciative of the Subcommittee's support for this national security priority. We also thank the Subcommittee for its efforts to include substantial funding for BARDA in the American Recovery and Reinvestment Act of 2009.

However, available data suggests that increased BARDA funding could significantly expedite medical countermeasure development. A recent independent analysis by the Center for Biosecurityⁱⁱⁱ 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^{iv}. Increased funding would advance the day when our nation has access to these countermeasures; until that day arrives, the American people remain vulnerable.

Furthermore, we note that a funding increase would have an immediate and significant stimulative impact on the biodefense industry, as well as on the US economy. Biotech firms, were they to receive increased BARDA funds in FY 2010, could immediately begin putting these resources to work. The U.S. Bureau of Economic Analysis estimates that each new biotech job results in the creation of 5.8 additional jobs in other industries. For every dollar of labor earnings or output in the biotech sector, another \$2.90 or \$1.70, respectively, are produced in other parts of the economy.

Finally, it is important to understand that a sustained effort by industry and government to produce vaccines and therapeutics for the strategic national stockpile will only be possible with a long-term commitment to funding by the federal government. The nation's biodefense procurement goals will not be achieved with a one-year appropriation. A sustained level of funding is necessary for the US to have a reasonable chance of meeting its stated commitment to national biosecurity.

To address our nation's ongoing vulnerability and to provide needed economic stimulus, we urge you to consider funding BARDA at \$1.7 billion in FY 2010. We recognize that FY 2010 may prove to be an austere fiscal environment given the current economic situation and associated federal spending. But developing new medical countermeasures, while expensive in health budget terms, is dwarfed by traditional national security budgets. Investment in BARDA will enable it to improve our national security and benefit research and development with broader application to emerging infectious diseases. Without sufficient funds, promising products will languish and the nation will remain vulnerable.

We thank you for your consideration, and we look forward to working with you and the Subcommittee to increase our country's preparedness against biological weapons.

ⁱ *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.

ⁱⁱ DiMasi, J.A. et al, 2003. The Price of Innovation: New Estimates of Drug Development Costs. *Journal of Health Economics* 22, 151–185.

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

^{iv} PHEMCE is the Department of Health and Human Services' Public Health Emergency Medical Countermeasure Enterprise Implementation Plan for Chemical, Radiological and Nuclear Threats.