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Written Testimony Submitted to the House of Representatives
Labor, Health and Human Services, and Education Appropriations Subcommittee
Regarding FY 2011 Funding for BARDA Advanced Research and Development

Submitted by:

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on behalf of

The Alliance for Biosecurity (www.allianceforbiosecurity.org)

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Summary

The Alliance for Biosecurity respectfully submits testimony in support the Biomedical Advanced Research and Development Authority (BARDA) program within the Department of Health and Human Services (HHS) and urges a substantial increase in BARDA funding. These funds are required to close the gap between the FY2010 funding level of \$305 million and the estimated \$3.4 billion needed annually through FY 2015 to give BARDA a 90% chance of developing one successful medical countermeasure for each of the eight key bioterrorism threats facing the U.S. The Alliance also expresses its concern that continued transfers of funds out of the BioShield Special Reserve Fund (SRF) places the sustainability of this program in jeopardy.

Bioterrorism and emerging infectious diseases present an extraordinary and potentially grave threat to public health and national security. The development of medical countermeasures that can treat, mitigate and prevent biological agents are an essential component of national preparedness. Given the catastrophic consequences of a newly emerged infectious disease (e.g. SARS) or the intentional release of bioweapons (e.g. anthrax or smallpox) these medical countermeasures need to be developed, licensed and stockpiled well in advance of an emergency.

The federal government is essential in developing these medical countermeasures. The lack of a commercial market for these products means that without governmental involvement these life-saving products will not be developed. Congressional foresight combined with bipartisan and bicameral support for these efforts led to the establishment of BARDA. BARDA has both the statutory authority and administratively effective tools to meet this challenge. Indeed, initial federal investments during BARDA's start-up phase are beginning to deliver results. Unfortunately, however, thus far the federal investment in BARDA has not been commensurate with either the magnitude of the threat of bioterrorism and emerging infectious diseases, or the high costs associated with drug and vaccine development.

Despite the challenges associated with drug development the civilian population is far better protected today than it was in 2001 following the release of anthrax in the US Capitol and postal system. The Strategic National Stockpile, the repository for medical countermeasures, contains entirely new products to treat anthrax exposure including a first in-class monoclonal antibody, a new immune immunoglobulin that can be used to treat botulism poisoning and numerous other products that can prevent, mitigate or treat exposure to chemical nerve agents; biological agents, including smallpox and anthrax, and radiological agents.

The Alliance for Biosecurity is a collaboration among eleven private and public pharmaceutical and biotechnology companies that are working in the public interest to improve prevention and treatment of severe infectious diseases—particularly those diseases that present global security challenges. The Alliance promotes a stronger, more effective partnership between government, the biopharmaceutical industry, and other stakeholders in order to advance their shared goal of developing critically needed medical countermeasures.

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.

Biosecurity is a Critical National Security Priority

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.

As you know, BARDA is responsible for protecting Americans against chemical, biological, radiological and nuclear (CBRN) agents by supporting the advanced development and procurement of essential medical countermeasures, including medicines, vaccines and medical devices. Congress established two distinct mechanisms to fund these activities; advanced development to be funded by yearly appropriations as authorized in the Pandemic and All-Hazards Preparedness Act of 2006 and procurement to be funded using the Special Reserve Fund established in Project BioShield Act of 2004.

BARDA advanced research and development funding is essential to ensure that promising medicines and vaccines do not languish after early-stage research. The US government is the only purchaser of these products and therefore there is no commercial market for these products; as such, robust and consistent funding of BARDA advanced research and development is needed to ensure that the US has the medical countermeasures necessary to protect Americans. An independent analysis concluded that funding BARDA advanced development at \$3.4 billion annually would be required through FY 2015 to give BARDA a 90% chance of developing one successful medical countermeasure for each of the eight key bioterrorism threats facing the U.S.

The Alliance has consistently supported robust funding for medical countermeasure development and procurement through BARDA and the SRF. The Alliance recognizes the current budget constraints Congress faces; however, we are very concerned about the gap between the needed amount as stated above and the FY2010 funding level of \$305 million for BARDA. We urge your consideration of a substantial increase in funding for FY2011 to close this gap to ensure essential medicines and vaccines are developed.

The Alliance firmly believes that continued transfers of funds out of the BioShield SRF places the sustainability of this program in jeopardy. The original appropriation under Project BioShield was meant to be used over the course of 10 fiscal years. This reflected the length of time it takes to develop a drug or vaccine, as well as the need for a long term biodefense market. The Alliance requests that the committee follow the original legislative intent of Project

BioShield and use SRF monies solely for activities directly related to the advanced development and procurement of medical countermeasures.

Medical Countermeasures are Essential to Preparedness

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.”

On January 26th, 2010, the WMD Commission issued its report card on the federal government’s progress in WMD prevention and preparedness. In the area of bioterrorism, which the Commission has characterized as the most urgent threat, the White House and Congress were given an “F”. In the Commission’s words,

"Especially troubling is the lack of priority given to the development of medical countermeasures—the vaccines and medicines that would be required to mitigate the consequences of an attack. Congress created the Biomedical Advanced Research and Development Authority Advanced Development Fund to promote the development of new vaccines, drugs, and production processes required to meet the modern threats from man-made and naturally occurring epidemics. The estimated cost of developing the medical countermeasures required to meet the threats identified by the Department of Homeland Security is \$3.4 billion a year for the next five years. Appropriation for FY 2010 is less than one tenth of that. In addition, there have been several attempts by the Administration and Congress to “raid” the BioShield Strategic Reserve Fund for programs not associated with national security. In *World at Risk*, the Commission unanimously concluded that bioterrorism was the most likely WMD threat to the world. The capability to deter and respond to bioterrorism depends upon the strength of all links in the biodefense chain. Virtually all links are weak and require the highest priority of attention from the Administration and Congress."

These stark observations reflect the fact that bioterrorism represents one of the direst threats to national security, and that the federal government has not done nearly enough to prepare for it. 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 Funding is Insufficient to Protect American Citizens

New drug development is an extraordinarily time and resource-intensive process, with considerable risk: 80% of all candidates that enter clinical trials fail to attain FDA approval. As a result, on average it requires 10-15 years and approximately \$800 million from start to finish to gain approval for one productⁱ. The development of medical countermeasures is further complicated by limited commercial returns or no commercial market whatsoever. Thus the traditional pharmaceutical model of 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. 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. Funding remains in Project BioShield that is currently unobligated. This is not surprising or unwarranted. Procurement using Project BioShield funds can only occur when medical countermeasures development has progressed sufficiently to warrant procurement.

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. 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 was initially authorized at \$1.07 billion over three years, and Congress has provided \$781 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.

However, available data suggests that increased BARDA funding could significantly expedite medical countermeasure development. An independent analysis by the Center for Biosecurityⁱⁱ 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 Planⁱⁱⁱ.

BARDA is an 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.

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. As you know the Secretary of HHS has requested an end-to-end review of the countermeasure enterprise. We look forward to the results of the review and its recommendations for improving the process and providing feedback to the Subcommittee on the review.

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

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

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