

# Alliance for Biosecurity

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## **Written Testimony Submitted to the Senate Labor, Health and Human Services, and Education Appropriations Subcommittee Hearing**

“Defending Against Public Health Threats”

Regarding the Department of Health and Human Services’ August 19, 2010 Report - Public  
Health Emergency Medical Countermeasures Enterprise Review: Transforming the Enterprise to  
Meet Long-Range National Needs

Submitted by:

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The Alliance for Biosecurity

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### Summary

The Alliance for Biosecurity respectfully submits testimony to the Senate Labor, Health and Human Services, and Education Appropriations Subcommittee regarding the Department of Health and Human Services’ (HHS) Report - Public Health Emergency Medical Countermeasures Enterprise Review: Transforming the Enterprise to Meet Long-Range National Needs (Countermeasure Enterprise Review) for the “Defending Against Public Health Threats” hearing on September 29, 2010.

We very much appreciate being invited to appear today before the Subcommittee to discuss this important Report and thank you for the consideration of our views. The Alliance for Biosecurity is a collaboration among 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.

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 drugs, vaccines, and diagnostics, called medical countermeasures (MCMs), 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 the Alliance stands ready to work with the Administration, Congress, industry, and other stakeholders in our shared mission to identify, create, and obtain MCMs to protect citizens against bioterrorist attacks and potentially destabilizing emerging infectious diseases.

### **Positive Elements of the Countermeasure Enterprise Review**

We share and support the goal of the Countermeasure Enterprise Review, which is “a modernized countermeasure production process where we have more promising discoveries, more advanced development, more robust manufacturing, better stockpiling, and more advanced distribution practices.” We support the intention of the Review and look forward to working with the Subcommittee and the Administration to further evaluate some of the initiatives included in the Report as well as other ideas that will help to sustain and further develop the biodefense enterprise.

The Alliance is thankful to have been consulted by the Assistant Secretary for Preparedness and Response, Nicole Lurie, throughout the course of this important review. In addition to in-person meetings, we submitted a White Paper on March 2, 2010 that incorporated a number of core recommendations, including the need to (i) improve the procurement and contracting process to more effectively promote development of MCMs, (ii) improve the speed and efficiency of regulatory interactions between private industry and the US government, and (iii) improve coordination among the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Biomedical Advanced Research and Development Authority (BARDA), and other relevant agencies around the development and approval of MCMs.

Therefore, the Alliance was particularly pleased to see the Countermeasure Enterprise Review include plans for HHS to increase transparency, communication, and predictability within the contracting and procurement processes and across agencies. We hope that this includes transparency regarding setting requirements and specific information such as a target product profile as early as possible and is publicly disclosing allowable requirement and population threat analyses information..

Further, we were encouraged that the Review included a commitment to develop a five-year budget plan for the entire MCM enterprise, expand the advanced development program, and increase staff levels. We welcome these enhancements and feel strongly that the MCM enterprise and our nation’s preparedness will benefit from increased communication, development of a five-year budget, continuity, and transparency. We hope the Administration will include such a coordinated long range budget plan as part of the 2012 President’s budget.

The Alliance was also pleased with the emphasis placed on enhancing FDA regulatory innovation, science, and capacity in the Review, as well as the recognition of the importance of optimizing the legal and policy framework for MCM oversight and approval. Therefore, we support the Administration’s August 20<sup>th</sup> budget amendment request to make available balances from prior pandemic influenza appropriations to modernize FDA “regulatory science.” We believe that this new approach to regulatory science must focus on the agency’s “animal rule” in

order to make it an effective mechanism for the approval of needed countermeasures in the numerous instances where human testing of drugs and vaccines is unfeasible and/or unethical. This focus requires the addition of substantial manpower to the agency to meet the complex needs of this space, and the training of regulatory personnel to facilitate their understanding of the unique national security and public health issues that chemical, biological, and nuclear threats represent.

### **Elements of Concern Regarding the Countermeasure Enterprise Review**

The Alliance's March White Paper also included a core recommendation to "improve predictability and ensure the availability of consistent, robust funding for the development of MCMs." Indeed, this is essential to ensuring that the MCM enterprise is successful. We were disappointed that the Countermeasure Enterprise Review did not propose fully funding the advanced development program at BARDA, nor outline a process for restoring funding to the Special Reserve Fund (SRF) beyond 2013 or otherwise providing long-term and stable funding for the procurement of MCMs. We support plans for the sustainability of the Enterprise but caution that investments must be made upfront in order to guarantee success over the long term.

As you know, in 2004, Congress – recognizing that the country was relatively unprepared for the aftermath of an attack with CBRN agents – passed the Project BioShield Act (P.L. 108-276), which established the SRF. In the Project BioShield Act, Congress described the purpose of the SRF as procuring products to "treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security." Congress appropriated \$5.6 billion for this purpose in 2004 to remain available until 2013. Since that time several critical medical countermeasures have been purchased and stored in the Strategic National Stockpile with SRF funds.

Predictability and availability of robust funding for the advanced development and procurement of MCMs is one of the most important signs to industry and to private investors that the government is serious about moving the MCM initiative forward. Although there are a number of initiatives listed in the Review that may help the MCM enterprise in the long-term, there was little mentioned about immediate funding. Since advanced development is the most expensive part of MCM development, it must be funded at a higher level. In addition, the SRF should not be depleted for other uses, including proposals put forth in the Countermeasure Enterprise Review.

Private sector firms cannot invest in product development, which requires 10 to 15 years and hundreds of millions of dollars, unless they are reasonably certain that a market will exist for their product when it is finished. The SRF serves as a concrete demonstration of the federal government's commitment to procuring medical countermeasures. Diminishing or eliminating the SRF would call into question the credibility of that commitment, and by doing so make it difficult for the private sector to remain in the countermeasure business. While this would significantly affect these companies and their employees, it would be a much larger setback for the country as a whole.

For this reason, we are concerned that the Administration's August 20th budget amendment request included the transfer of (i) \$200 million from the SRF to the Department of Defense (DoD) in order to establish a Technical Center of Excellence for Advanced Development and Manufacturing; and (ii) \$200 million from the SRF to establish a new medical countermeasure strategic investment firm.

Establishment of a "Technical Center of Excellence" for advanced development and manufacturing of MCMs is a laudable goal. However, DoD intends to dedicate significant funding to the development of platform technologies and the advanced development and manufacturing of novel countermeasures. We support this initiative but oppose transferring SRF funds to support it. As previously stated, depleting the SRF now raises a number of concerns. Any flexible manufacturing initiative should be funded apart from the SRF with new resources, which do not compete with funding for advanced development at BARDA. Lastly, it is important to ensure that all existing manufacturing capacity is being effectively and efficiently deployed before investing in the creation of new capacity.

Likewise an independent strategic investment firm for innovation in MCM, "to provide necessary support for small innovators and increase the odds of moving innovation into successful development" may have some merit although little concrete information has been provided to evaluate the value of this initiative. It seems somewhat paradoxical, however, to deplete the SRF – the primary signal of a government market for MCMs – in order to create a strategic investment firm to promote innovation of MCMs. Such an action would send, at best, a confusing signal to industry and private investors, and could have the impact of discouraging further investment in MCMs under development. Additionally, it is premature to transfer funds to create a new investment firm when the Administration has not decided on the model, structure, or objectives of such a firm.

The Alliance urges the Subcommittee to work closely with the Administration to clarify, execute an adequately fund the programs needed to sustain the PHEMCE enterprise as the initiatives included in the Countermeasure Enterprise Report are further developed and implemented. The Alliance is committed to working with Congress, the Administration, and others to make the countermeasure enterprise a success. We thank you for your attention and consideration.