

# Alliance for Biosecurity

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July 22, 2009

The Honorable David Obey  
Chairman, House Committee on Appropriations  
2314 Rayburn House Office Building  
Washington, D.C. 20515

Dear Chairman Obey:

On behalf of the Alliance for Biosecurity, we want to thank you for your leadership on biodefense issues. We are grateful for the time and attention that you and your staff invest in this important national security area. We appreciated the opportunity to provide testimony before you during the Labor, Health and Human Services, and Education (LHHS) Appropriations Subcommittee's public witness hearings earlier this year. We know that you share our concern with the country's current state of biosecurity preparedness, and we would therefore like to bring to your attention a specific provision in the fiscal year (FY) 2010 House LHHS bill that we believe is problematic.

The FY 2010 LHHS appropriations bill includes a provision that would transfer \$500 million from the Project BioShield Special Reserve Fund (SRF) to the National Institute of Allergy and Infectious Diseases (NIAID). The Alliance for Biosecurity strongly opposes this provision, and believes its enactment would weaken national efforts to protect Americans from chemical, biological, radiological, and nuclear (CBRN) threats. Transferring funds out of the SRF would dramatically reduce incentives for industry participation, stall the purchase of additional countermeasures and increase the chances that this relatively new program might fail. The Alliance agrees that robust funding of basic research at NIAID is critical to the success of our nation's biosecurity preparedness efforts and does not oppose increases to the NIAID budget. But this funding must not come at the expense of Project BioShield, which is a critical component to create a viable market for biodefense countermeasures.

The FY 2010 House LHHS committee report argues that Project BioShield is "failing," and that one of the primary causes of this failure is a shortage of basic research at NIAID. We respectfully disagree with this argument. Specifically, we believe evidence does not support the contention that Project BioShield is failing. Project Bioshield was created in 2004 and provided \$5.6 billion to remain available through 2013. The LHHS committee report states that "due to the lack of medical countermeasure procurements, there are still significant carryover balances in the Project BioShield SRF. As of June 2009, approximately \$2,881,000,000, or more than 50 percent, of the \$5,593,000,000 provided in 2004 for the Project BioShield SRF remains unobligated." Assuming these figures are accurate, Project Bioshield is roughly halfway through its period of authorization, and it has obligated slightly less than 50 percent of its funds. We

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DOR BioPharma, Inc. • Dynport Vaccine Company LLC, a CSC Company • Elusys Therapeutics  
Emergent BioSolutions • Hematech, Inc., a subsidiary of Kyowa Kirin  
Human Genome Sciences, Inc. • Pfizer Inc. • PharmAthene • Siga Technologies  
Unither Virology LLC, a subsidiary of United Therapeutics Corporation

believe that this does not represent an inappropriate expenditure rate. On the contrary, it would be problematic if a fund intended to last through FY 2013 had no significant carryover balances by the summer of 2009.

More importantly, we would point to the procurements already made under Project BioShield. As of today, eight contracts have been awarded for the following products under Project BioShield:

- Anthrax Vaccines: 28,750,000 doses
- Anthrax Therapeutics: 30,000 doses
- Botulinum antitoxin: 200,000 doses
- Smallpox Vaccine: 20,000,000 doses
- Rad/Nuclear therapeutics: 5,273,810 doses

Under Project BioShield, contracts have been awarded to procure enough countermeasures to protect millions of Americans from a range of CBRN threats. We would argue that although this achievement must be expanded on, it nonetheless represents initial success for this young program. In fact, the biggest funding gap in medical countermeasure research and development is in the later stages of development, where most products fail. That is why Congress created BARDA and why we support robust funding for advanced research and development.

The committee report also argues that an example of Project BioShield's shortcomings is that "Project BioShield has been unable to procure the next generation vaccine for anthrax." The report then states that there is the need for "significant increased investment in discovery and pre-clinical development through NIAID..." It is true that Project BioShield has not yet procured a second generation anthrax vaccine. However, it is important to note that the Biomedical Advanced Research and Development Authority (BARDA) is well into a process of reviewing product proposals that have been deemed to be within the competitive range for a second generation anthrax vaccine. Although it would obviously be preferable for national security purposes if this contracting process were completed sooner rather than later, it is not the case that transferring funds from the SRF to NIAID to pay for discovery and pre-clinical development would accelerate anthrax vaccine procurement, and by doing so address Congressional concerns.

In establishing the SRF, Congress recognized that without the guaranteed government commitment to countermeasure procurement that a long-term reserve fund represents, private sector companies with the expertise needed to develop drugs and vaccines would be unable to assume the risks inherent in drug development. Private sector firms cannot engage in product development processes that require 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. Until now, the SRF has served this function effectively. Although funds have recently been transferred out of the SRF for purposes unrelated to CBRN countermeasure procurement, the majority of the SRF has remained intact and available for the purchase of countermeasures, providing the market incentive needed by companies working to develop these medicines. Depleting the SRF to support NIH would call into serious question the credibility of the government's commitment to countermeasure procurement, and by doing so make it difficult for the private sector to remain in the countermeasure business. While this would affect these companies and their employees, it would be a much larger setback for the country as a whole.

Finally, it should be noted that the Alliance does not oppose the roughly \$157 million increase over the FY 2009 level that the committee has provided to NIAID in its FY 2010 bill. Nor does

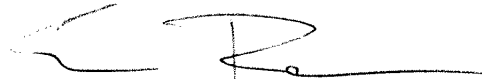
the Alliance oppose the increases provided to NIH institutes and centers that, cumulatively, account for a \$500 million increase to NIH above the White House request level. However, we oppose this or other provisions that would fund this increase by depleting the SRF.

The Alliance for Biosecurity is a collaboration between the Center for Biosecurity of UPMC, pharmaceutical companies, and biotechnology companies working to develop vaccines and medicines for our nation's Strategic National Stockpile. 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 the infectious disease threats that present security challenges in the 21st Century. We thank you for your consideration of our views. If you have any questions or if we can otherwise be of any assistance, please do not hesitate to contact us, or Anita Cicero of the Alliance Secretariat at ([anita.cicero@dbi.com](mailto:anita.cicero@dbi.com) 202-230-5163).

Respectfully submitted on behalf of the Alliance,



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cc:

Members of the House LHHS Appropriations Committee

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