

Alliance for Biosecurity

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The Honorable Kathleen Sebelius
Secretary of the Department of Health & Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

June 1, 2009

Dear Secretary Sebelius:

The Alliance for Biosecurity urges in the strongest possible terms that funds in the Project BioShield Special Reserve Fund (SRF) be used only for their intended purpose: the procurement of medical countermeasures against chemical, biological, radiological and nuclear (CBRN) threats to national security. The Project BioShield SRF was created by Congress to procure medical countermeasures such as drugs and vaccines against CBRN threats. It now appears that the administration is considering significantly depleting the SRF to fund the development and/or procurement of H1N1 influenza vaccine. Depleting the SRF for this purpose will severely diminish US efforts to improve preparedness for CBRN events, thereby undermining the President's commitment to a strong national biodefense program.

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, and since that time several critical medical countermeasures have been purchased and stored in the strategic national stockpile with SRF funds.

In addition to its role in procuring countermeasures, the existence of the SRF has enabled private biotech companies to develop new countermeasures against threats for which drugs and vaccines do not currently exist. In establishing the SRF, Congress recognized that without the guaranteed government commitment to countermeasure procurement that a long-term reserve fund represents, private 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 fund has remained intact and available for the purchase of countermeasures, providing the certainty needed by companies working to develop these medicines.

Bavarian-Nordic • Cangene Corporation • Center for Biosecurity of UPMC • 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. • NanoViricides, Inc. • Pfizer
Inc. • PharmAthene • Siga Technologies • Unither Virology LLC, a subsidiary of United Therapeutics
Corporation

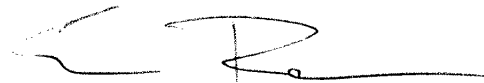
Depleting the SRF to fund H1N1 vaccines, or to fund any other program unrelated to the mission of the SRF, would have a devastating impact on efforts to develop countermeasures for CBRN threats. Without confidence that the government is committed to procuring countermeasures, companies would have to consider abandoning, or significantly scaling back, efforts to produce biosecurity products, especially if their private investors conclude that a long term investment in product development is untenable without government funds available to purchase the products. 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 if not impossible 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.

Pandemic influenza preparedness is an important national priority, and the Alliance believes that the robust funding historically provided to pandemic influenza programs should continue. However, we believe that if H1N1 poses a new and significant threat to public health, then it merits new funding. The Alliance understands why transferring existing appropriations to fund spending increases on separate programs is attractive from a budgetary prospective. But to be clear: strengthening H1N1 preparedness by depleting the SRF will profoundly weaken biosecurity preparedness. The short term, expedient use of SRF funds for H1N1 preparedness will weaken biosecurity overall, and is not a sound policy option. We hope you share this view, and we urge you to oppose any proposals to use SRF funds for any purpose other than CBRN medical countermeasures.

Respectfully submitted on behalf of the Alliance,



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cc: RADM W. Craig Vanderwagen, MD, Assistant Secretary of Preparedness and Response
Dr. Robin Robinson, PhD, Principal Deputy Director, Office of The Biomedical Advanced
Research and Development Authority