

Alliance for Biosecurity

Office of the Secretary and Legal Counsel

1500 Street, NW, Suite 1100

Washington, DC 20005

Telephone: 1.202.230.5163 • Facsimile: 1.202.842.8465

The Honorable Daniel K. Inouye
Chairman, Senate Committee on
Appropriations
722 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Thad Cochran
Ranking Member, Senate Committee on
Appropriations
113 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Tom Harkin
Chairman, Senate Labor, Health and Human
Services, and Education Subcommittee
731 Hart Senate Office Building
Washington, D.C. 20510

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

The Honorable Jerry Lewis
Ranking Member, House Committee on
Appropriations
2112 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Todd Tiahrt
Ranking Member, House Labor, Health and
Human Services, and Education Subcommittee
2441 Rayburn House Office Building
Washington, D.C. 20515

June 1, 2009

Dear Senators Inouye, Cochran, and Harkin and Representatives Obey, Lewis, and Tiahrt:

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.

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

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.

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 perspective. 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,



Susan Berger, Ph.D.
Senior Director of Operations and Communications
Pfizer Inc.
Co-Chair, Alliance for Biosecurity



Eric A. Rose, MD
Chairman & CEO
SIGA Technologies, Inc.
Co-Chair, Alliance for Biosecurity

cc: Members of the Senate and House of Representatives Appropriations Committees