

# Alliance for Biosecurity

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January 31, 2007

## **By Hand**

Gerald Parker, DVM, PhD, MS  
Principal Deputy Assistant Secretary  
Office of the Assistant Secretary for Preparedness and Response  
US Department of Health & Human Services  
Washington, DC 20201

Re: Implementation Plan for DHHS PHEMCE Strategy for Chemical, Biological,  
Radiological and Nuclear Threats

Dear Dr. Parker,

Thank you again for addressing the Alliance for Biosecurity Board of Directors at our last meeting on 7 December in Baltimore. We were very appreciative of your efforts to attend the meeting, and our Board was particularly encouraged by your willingness to keep open lines of communication as both industry and government seek to make progress in the development of medical countermeasures needed to improve the state of our nation's biosecurity. We are delighted – as we know you are – that Congress passed the BARDA measure. The Alliance is now urging the House and Senate Committees on Appropriations to provide adequate funding in 2007 to permit DHHS to implement fully the BARDA activities and authorities specified in the legislation. We look forward to speaking with you soon about implementation of BARDA.

We write today on a matter of significant importance – the pending Strategy document and Implementation Plan for the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). We understand that there may be delays associated with the completion of the Implementation Plan, originally expected to be published in January. We strongly urge your office to undertake all measures necessary to promptly finalize and publish the Strategy document and a meaningful Implementation Plan with sufficient specificity to guide industry in its efforts to further invest in medical countermeasure development. The Alliance stands ready to assist in any way we can to help expedite publication of this crucial document.

The draft PHEMCE Strategy listed ten critical strategic policies that will be addressed by the Implementation Plan, including a much-needed prioritization of threats and anticipated countermeasure requirements. The successful discovery and development of a single medicine or vaccine is a complex, lengthy, and resource intensive endeavor with considerable risk. Therefore, it is necessary to prepare as early as possible for future biothreats and pandemics. The sooner industry can understand the government's priorities, the sooner companies can work in a focused way to produce those countermeasures with the characteristics deemed to be necessary for our national security. We understand that the DHHS is unlikely to issue new

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Emergent BioSolutions • GlaxoSmithKline • Human Genome Sciences, Inc. • Iomai Vaccines  
Novartis Vaccines and Diagnostics, Inc. • Pfizer Inc. • PharmAthene**

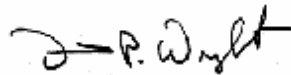
RFPs for medical countermeasures before publication of the Implementation Plan. A delay in publication of the Plan therefore essentially puts on hold vital efforts by industry to aggressively pursue development of needed countermeasures, discourages investment in biodefense thus adversely affecting the financial viability of smaller biodefense companies, and discourages future research and development in the CBRN countermeasure area.

We appreciate the complexity of the strategic issues to be addressed by the Implementation Plan and the enormity of such a task. We certainly do not want to rush publication of an incomplete document; however, all parties – DHHS, the biodefense industry, and the American people – will benefit from prompt publication of the Plan. Please let us know if we can provide any useful information or help in other ways to expedite completion of the document.

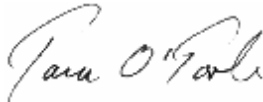
Respectfully submitted on behalf of the Alliance,



Susan Berger, Ph.D.  
Director of Science Policy  
Pfizer Inc.  
Co-Chair, Alliance for Biosecurity



David P. Wright  
President & CEO  
PharmAthene  
Co-Chair, Alliance for Biosecurity



Tara O'Toole, MD  
CEO & Director, Center for Biosecurity  
University of Pittsburgh Medical Center  
Strategic Director, Alliance for Biosecurity

**Copies to:**

The Honorable Joe Barton, Ranking Member, Committee on Energy and Commerce, U.S. House of Representatives

The Honorable John D. Dingell, Chairman, Committee on Energy and Commerce, U.S. House of Representatives

The Honorable Michael B. Enzi, Ranking Member, Committee on Health, Education, Labor, and Pensions, U.S. Senate

The Honorable Edward M. Kennedy, Chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate

Michael O. Leavitt, Secretary of Health & Human Services, DHHS

Benjamin Petro, Director of Biodefense, White House Homeland Security Council, Executive Office of the President

William Raub, Science Advisor to the Secretary, DHHS

Craig Vanderwagen, Deputy Assistant Secretary for Preparedness and Response and Chief Preparedness Officer, DHHS

Rajeev Venkayya, Special Assistant to the President for Biodefense, White House Homeland Security Council, Executive Office of the President