

# Alliance for Biosecurity

Office of the Secretary and Legal Counsel  
1301 K Street, NW, Suite 900 East Tower  
Washington, DC 20005  
Telephone: 1.202.230.5619 • Facsimile: 1.202.230.5300

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October 10, 2006

## ***Via E-mail***

Susan Coller, PhD  
Policy Analyst  
Office of Public Health Emergency Preparedness  
Department of Health & Human Services  
330 Independence Avenue, SW, Room G640  
Washington, DC 20201

Re: Alliance for Biosecurity Comments on Draft HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for Chemical, Biological, Radiological and Nuclear (CBRN) Threats

Dear Dr. Coller:

On behalf of the Alliance for Biosecurity, we write to provide comments on the DHHS draft *Public Health Emergency Medical Countermeasures Enterprise Strategy for Chemical, Biological, Radiological and Nuclear Threats* (PHEMCE Strategy). The Alliance for Biosecurity is a collaboration among the Center for Biosecurity of the University of Pittsburgh Medical Center, pharmaceutical companies, and biotechnology companies working to develop vaccines and medicines for our nation's Strategic National Stockpile. We seek to partner responsibly with government and other stakeholders to help realize the potential of Project BioShield to accelerate the research, development, and procurement of effective medical countermeasures.

The Alliance is encouraged by Secretary Leavitt's pledge to streamline and make more transparent the current interagency BioShield process. Many of our members actively participated in the DHHS BioShield Stakeholders Workshop on 25-26 September, 2006, and we applaud DHHS's efforts to obtain and respond to stakeholder input during this critical strategic planning process. We are pleased to provide consensus Alliance comments on the PHEMCE Strategy, and we will look forward to future opportunities to interact with DHHS on these critical issues.

From our perspective, government, industry, and other stakeholders are at a defining moment in our shared national endeavor to identify, create, and obtain medical countermeasures that will protect our citizens against bioterrorist attacks and potentially destabilizing emerging infectious diseases. Development of a medical countermeasures arsenal is a challenging and

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relatively new responsibility for us all, but we now collectively share 5 years of experience since the anthrax attacks in 2001, and we hope that government and industry can work together to leverage lessons learned and accelerate our efforts to achieve a better state of biosecurity over the years to come. Adopting a sound PHEMCE Strategy will certainly support these efforts.

### **General Comments:**

The PHEMCE Strategy provides an excellent overview and description of the limitations and tough choices that need to be made in medical countermeasure procurement. We concur with the Strategy's statements about the nature and variety of the threats. The Alliance agrees that naturally occurring infectious diseases pose potentially serious threats to national security; we share DHHS's view that advances in biotechnology and science will result in novel bio-engineered threats; and we concur with the Strategy's conclusion that the greatest potential for medical mitigation exists for biological threat agents.

The Alliance strongly supports the Strategy's goals of increasing transparency and predictability, as well as DHHS's stated commitment to expand its advanced development program, increase staff levels, and strengthen and streamline the execution of Project BioShield procurements. By providing greater transparency to the decision-making process, DHHS will help the private sector to direct its research and development efforts in a manner that will allow it to be a more effective partner with PHEMCE.

We think that it is appropriate as part of DHHS's Strategy to develop near-term, mid-term, and long-term development and acquisition goals. While the government has no choice but to focus in the near-term and mid-term on addressing specific high priority threats, it should understand that to be effective in the long-term, development programs would need to start now to address advanced threat agents. However, the reality is that the development of countermeasures and technologies for next generation threats has not yet begun, since companies are focused on more pressing barriers associated with the development of countermeasures for near-term threats. Our nation's overall success in addressing near-term to long-term biosecurity threats will depend largely on whether Congress and the Administration prioritize biosecurity and ultimately provide the necessary funding, resources, and staffing to ensure progress in this area.

The need to rapidly accelerate countermeasure research, development, and production is more than just an "acquisition problem." Rather, it is an issue that affects the ongoing national security effort to counteract chemical, biological, radiological, and nuclear agents. While efforts to stockpile specific medical countermeasures for specific threats is appropriate in the short-term, evolving threats, and the need to respond to novel, unanticipated bioweapons, requires a defense strategy different from the stockpile-based approach now being pursued. Such a strategy may include a national effort to:

- Radically accelerate research, development, and production of medical countermeasures;

- Develop broad spectrum therapeutics; and
- Support the development of compound banks and screening facilities to serve as a resource for new anti-bacterial and anti-viral agents in the future, or to rapidly screen licensed drugs against new threats.

The PHEMCE Strategy is an important step in the right direction, but it should provide for the ability to respond dynamically to long-term threats.

### **Communication and Collaboration:**

A refocused, productive partnership between government and relevant stakeholders in the biosecurity enterprise will require a significantly increased level of dialogue and collective thinking. The Alliance outlines below some specific ways to immediately increase communication in the BioShield process. Each of the below initiatives is aimed at strengthening the public-private partnership for medical countermeasure development by increasing collaboration between government and industry.

- Institute a consistent mechanism at DHHS to alert industry to key activities and developments, such as the issuance of an upcoming Request for Information (RFI), Request for Proposal (RFP), or other notice. Other agencies do this effectively. For example, NIH often contacts interested parties by e-mail or phone if a relevant notice is released or upcoming. DOD staff also will alert interested parties prior to the issuance of a relevant notice.
- Hold annual or biannual “advance planning briefings” at DHHS. Each year DOD holds planning briefings for industry and other interested partners where the department provides information on the current systems and programs, identifies new areas of interest, and seeks industry partners. Program managers give presentations about department needs and then meet with interested companies one-on-one.
- Provide clarification of the role of each of the participants in the countermeasure development process (e.g., NIH, FDA, industry, etc.). This would be helpful in accelerating the overall countermeasure development timeline. Each participant has a unique and critical role to play in the process; however, the role of each is not always clear. Better coordination of the expertise and efforts of all key partners in the countermeasure development enterprise will ensure that activities are efficient and complementary and will facilitate bringing new meaningful preventive measures and therapies to the nation’s stockpile and to the public.
- Allow industry to present data on their technologies to inter-agency working groups. The decision-making process for biodefense products is fragmented and involves many different agencies and departments. It is difficult for companies to identify all of the parties involved and present information or seek guidance. DHHS could provide an opportunity for companies with promising technologies to regularly engage in discussions with interagency working group members. These types of interactions

would help industry to develop medicines and vaccines that better meet the government's needs.

- Increase appropriate communication between industry and government. Industry communication should not be limited to written responses to RFIs or RFPs. Appropriate prohibitions on the discussion of products under review should be maintained, but it would be appropriate and productive to have discussions related to products that are not under review. Company input during the pre-requirements and requirements phase should be encouraged to inform the requirements development process. The length and formality of the current RFI process virtually assures that government will not be in a position to issue an RFP until one year after the RFI issuance. This long lag time often dates and sometimes renders irrelevant the information collected through the RFI. We urge the government to establish other mechanisms through which companies can update DHHS of significant developments in real time in order to obtain helpful input, and to inform guidance and funding decisions in a timely manner.
- Encourage involvement of industry scientists and others with explicit expertise in the development and production of vaccines and medicines in the review of NIH contracts and grants related to development projects. It is critical to have a robust connection between the basic science undertaken by NIH (and funded through NIH grants) and the identification of viable approaches that the pharmaceutical and biotechnology industries can bring forward to develop new countermeasures. In this regard, it would be constructive to develop a more formalized mechanism by which NIH, DHHS, and industry could exchange information on the types of basic research most likely to aid in the development of countermeasures appropriate for stockpiling and administration. This would result in the funding of better designed projects, leading to higher degrees of success.
- Allow industry access to data on relevant animal models, potentially useful biomarkers, genomic data, and other assays that allow for efficient study design. Developing acceptable animal models, biomarkers, etc. is a key factor in the success of medical countermeasure development and is critical to the acceptance of company data by the FDA. Currently, each company is proceeding with its own interpretation of the published literature; this could lead to inconsistencies in study design and, ultimately, more difficulty in evaluating the potential of one medicine versus another. DHHS should develop standard protocols so that studies can be evaluated against the same measures. Furthermore, promoting open communications on animal models, biomarkers, etc. would provide opportunities for industry to more consistently and effectively design successful animal studies to determine the efficacy of medicines/vaccines. A number of agencies and departments are involved in the development of animal models, biomarkers, etc. (including, to varying degrees, FDA, NIH, CDC, and DOD). DHHS could take the lead in establishing a mechanism to work more closely with industry, particularly for countermeasures identified in RFPs for which there are no current animal models, biomarkers, etc. to speed product development. This mechanism could take the form of regular public workshops in which relevant government agencies and

stakeholders could participate. Output could include information for guidance or points to consider documents and publications in peer-reviewed journals.

In addition to the above initiatives aimed at increasing communication between government and stakeholders engaged in countermeasure development, the Alliance offers the following comments on other specific issues relevant to the PHEMCE Strategy:

#### **Production Issues:**

- The Alliance supports the PHEMCE Strategy's emphasis on encouraging faster production methods.
- We have some concerns about the Strategy's intention of obtaining product largely through surge capacity rather than stockpiling. While it makes sense for a number of reasons to rely on surge capacity, this could have the indirect effect of decreasing industry interest in countermeasure development unless there is sufficient financial support for companies to develop and maintain surge capacity.
- The Alliance agrees with DHHS that success in this biodefense endeavor will require "unprecedented cooperation" and the efforts of "multiple key stakeholders, including both domestic and international industrial, academic and governmental biomedical research and development communities...." (71 Fed. Reg., No. 174, p. 53098) Central to this cooperation is the recognition that in the near-term, the United States is dependent in some cases on its international partners for some of the most critical medical countermeasures needed for high priority threats. Manufacturing for certain countermeasures now occurs outside of the US, and such operations require the same degree of support as domestic manufacturing sites in order to ensure manufacturing capabilities in times of urgent need. We ask that DHHS address this issue in its Strategy or implementation plan.

#### **Prevention/Mitigation vs. Treatment:**

- The Alliance supports a post-event medical intervention strategy for large civilian populations, but we caution that there may be threats that can only be addressed with a vaccine, such as smallpox. Additionally, there may be situations in which a vaccine could be of critical importance for protecting U.S. citizens geographically distant from an outbreak or attack in a post-event but pre-exposure context. We ask that DHHS include explicit language in the Strategy about the use of a vaccine when there is a scientific and strategic rationale for doing so.

#### **Liability Protection and Compensation:**

- The PHEMCE Strategy mentions the "application of liability protections where appropriate," but no details are provided. In some of the breakout sessions during the DHHS BioShield Stakeholders Workshop, it was evident that government and industry stakeholders had varying impressions about the circumstances and details surrounding the available avenues for obtaining liability protection. For example,

under what circumstances and when will the Secretary issue a declaration triggering liability protections under the Public Readiness and Emergency Preparedness (PREP) Act (P.L. 109-148)? It would be useful for industry stakeholders if DHHS were to set a presumption in the Strategy that all products procured under Project BioShield will be the subject of a PREP Act declaration at the time of acquisition (at least if not already commercially available).

- The Alliance also urges the Office of Public Health Emergency Preparedness to utilize existing statutory authority to develop a system for compensating individuals who may be harmed by medical countermeasures that are deployed during a public health emergency. An effective compensation program is an appropriate counterpart to liability protection for countermeasure developers and it is likely to encourage compliance among individuals to use medical countermeasures as directed – thereby enabling a more effective public health response.

### **Emergency Use Authorization**

Currently, there is no guidance on the specific application of Emergency Use Authorization (EUA) to medical countermeasures. Consequently, there is a lack of clarity as to how and when EUA will be used and the implications of such a designation for product development and procurement contracts. While EUA will determine the licensure and use of medical countermeasures, the FDA will issue the EUA only upon an immediate threat. The government is essentially asking companies to commit to the development of countermeasures without spelling out in advance how and under what circumstances EUA will be issued. Guidance on EUA for medical countermeasures should be provided now, rather than asking companies to wait until an event occurs to understand government expectations. The PHEMCE Strategy and/or its Implementation Plan should provide additional detail as to how the EUA process will be applied to medical countermeasures.

### **Incorporation of Public Health Response:**

The Alliance encourages OPHEMC to pay particular attention to the interplay between its Strategy and the broader mandate of the Office of Public Health Emergency Preparedness, particularly as it relates to overall public health preparedness and response. The Strategy should contain components that facilitate the work within OPHEP and other Federal agencies to identify outbreaks of infectious disease and promote rapid diagnosis, infection control, and isolation plans for controlling naturally occurring infections that can be adapted for bioterror attacks. Each of these areas will enhance the Strategy and lead to greater integration with the Federal government's various response strategies.

The preceding Alliance comments provide a number of specific proposals. On a broader level, the Alliance believes that the strongest defense against bioterror in the long run will be a combination of a strong public health infrastructure in conjunction with robust research and development programs within academia and industry focused on all infectious disease threats, including bioterrorist and naturally occurring infectious diseases, drug resistant pathogens, and emerging pathogens. Funding of research and development of

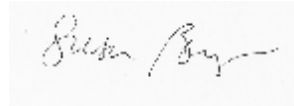
medical countermeasures that are “dual use” (i.e., effective against natural and bioterrorist biotreats) will be key to invigorating research and attracting additional companies that can appreciably contribute to countermeasure development efforts. The U.S. Government should take full advantage of medical countermeasures that may have a commercial market (e.g. broad spectrum therapeutics). This approach could provide some cost efficiencies for the USG and could ultimately encourage more companies – including large pharmaceutical companies – to enter the market to develop medical countermeasures. The Alliance proposes that the PHEMCE Strategy and its implementation plan place appropriate emphasis on these issues.

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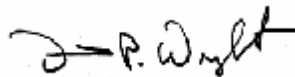
On behalf of the Alliance, we thank DHHS for this opportunity to comment on the draft PHEMCE Strategy. The final Strategy will serve as the key foundational document that will guide government, academia, and industry efforts in countermeasure research, development, and procurement. It should be noted, however, that the Implementation Plan to be developed by DHHS/OPHEP/OPHEMC will be as important, and possibly more important, than the Strategy in years to come. The Implementation Plan is expected to include more detail, direction, and clarification of issues based on the guiding principles laid out in the Strategy. Due to the significance of the Implementation Plan, we urge DHHS/OPHEP/OPHEMC to seek stakeholder input on the draft plan prior to its final adoption.

We are pleased with the forward progress that DHHS has demonstrated with the Strategy and the BioShield Stakeholders Workshop, and we look forward to future dialogue and partnership with you. Please contact us if you have any questions regarding this submission.

Respectfully submitted on behalf of the Alliance,



Susan Berger,  
Director, Science, Knowledge & Policy  
Pfizer, Inc.  
*Co-Chair, Alliance for Biosecurity*



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



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

***Copies to:***

Richard B. Cheney, Vice President of the United States

Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases, NIH

Thomas Fuerst, Office of Public Health Emergency Medical Countermeasures,  
DHHS

Steven Galson, Director, Center for Drug Evaluation and Research, FDA

Jesse Goodman, Director, Center for Biologics Evaluation and Research, FDA

Boris Lushniak, Assistant Commissioner for Counterterrorism Policy, FDA

Noreen Hynes, Deputy Assistant Secretary for Public Health Emergency Medical  
Countermeasures, DHHS

Maureen McCarthy, Director of the Office of Research and Development, Science  
and Technology Directorate, DHS

Monique Mansoura, Senior Planning Officer, Office of Public Health Emergency  
Medical Countermeasures, DHHS

Gerald Parker, Principal Deputy Assistant Secretary for Public Health Emergency  
Preparedness, DHHS

William Raub, Science Advisor to the Secretary, DHHS

Jay Cohen, Undersecretary for Science and Technology, DHS

Stan Sokul, Acting Chief of Staff, Office of Science and Technology Policy,  
Executive Office of the President

Craig Vanderwagen, Assistant Secretary for Public Health Emergency  
Preparedness, DHHS

Rajeev Venkayya, Director for Health and Biodefense, Homeland Security Council,  
Executive Office of the President

John Vitko, Director, Chemical and Biological Countermeasures Portfolio, Science  
and Technology Directorate, DHS