

# Alliance for Biosecurity

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September 8, 2006

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

Dr. Noreen Hynes, Director  
Office of Public Health Emergency Medical Countermeasures  
Department of Health & Human Services  
330 C Street, SW, Room G640, Washington, DC 20201

Re: BioShield Stakeholders Workshop, September 25-26, 2006

Dear Dr. Hynes,

On behalf of the Alliance for Biosecurity, we write to provide input to OPHEMC on the upcoming BioShield Stakeholders Workshop planned for September 25-26, 2006 in Arlington, Virginia, and to request the opportunity to present consensus Alliance views at the Workshop. The Alliance for Biosecurity is a collaboration between 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 to help realize the potential of BioShield to accelerate the research, development, and procurement of effective medical countermeasures. The Alliance mission and membership list are attached.

Alliance members are very encouraged by Secretary Leavitt's pledge earlier this year to streamline and make more transparent the current interagency BioShield process. We see great value and potential in DHHS's current efforts to prepare the *Public Health Emergency Medical Countermeasures Strategy for Chemical, Biological, Radiological, and Nuclear Threats*, and the Alliance is eager to review and provide input on the draft strategy. Alliance members look forward to actively participating in DHHS's upcoming BioShield Stakeholders workshop.

The goals of the Stakeholders Workshop, as stated in the Federal Register are to (1) provide attendees with insight into the current BioShield interagency governance process; and (2) provide stakeholders with "an opportunity to help guide the future implementation of project BioShield by providing input into the draft [strategy document]" (71 Fed. Reg. 161, p. 48547). This second stated purpose of the workshop – seeking stakeholder input – is indeed crucial. We appreciate that DHHS is undertaking this strategic planning process, in part, to respond to requests from across the biodefense and policy communities for additional transparency and clarity in the BioShield process. Obtaining thoughtful views and "lessons learned" from stakeholders and identifying potential consensus stakeholder positions could prove to be a very efficient and productive way for DHHS to take into consideration input from stakeholders who actively engage or seek to engage with the BioShield process.

There are significant initiatives that industry and government could consider implementing to improve the BioShield program. A selection of such initiatives is described below. The Alliance

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Acambis, Inc. ▪ Cangene Corporation ▪ Center for Biosecurity of UPMC ▪ DOR BioPharma, Inc.  
Elusys Therapeutics, Inc. ▪ Emergent BioSolutions ▪ GlaxoSmithKline ▪ Human Genome Sciences, Inc. ▪  
Novartis Vaccines and Diagnostics, Inc. ▪ Pfizer Inc. ▪ PharmAthene ▪ VaxGen, Inc.

would be happy to discuss these further with you and other officials in DHHS or other government agencies. Each of the below initiatives is aimed at strengthening the public-private partnership for medical countermeasure development by increasing the communication and 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 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 discussion related to products that are not under review could be allowed. Company input during the pre-requirements and requirements phase should be encouraged to inform the requirements development process.
- 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, HHS, 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 and potentially useful biomarkers. Developing acceptable animal models and biomarkers 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. Promoting open communications on animal models and biomarkers 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 and biomarkers (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 or biomarkers to speed product development.

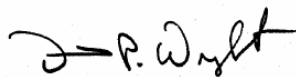
In addition to these possible topics for discussion at the BioShield Stakeholders Workshop, the Alliance would like to make some suggestions aimed at increasing the value of stakeholder input to the Workshop itself. To encourage the most organized, useful, and pertinent comments from stakeholders at the workshop, it would be very helpful to reserve a number of speaking or panel slots at the workshop for non-governmental stakeholders, including industry representatives. It would also be beneficial to hear the consensus views of groups of companies and other stakeholders, rather than limiting formal stakeholder feedback at the Workshop to spontaneous and potentially disjointed reactions of specific individuals or individual companies. We encourage DHHS to draw out more considered, collective stakeholder suggestions, and the Alliance would be pleased to contribute the consensus views of its members in this fashion.

A productive partnership between government and relevant stakeholders requires dialogue and collective thinking in order to best prepare our nation for biosecurity threats in the 21<sup>st</sup> century. We seek to be active and constructive partners in this dialogue, and we stand ready to work with DHHS to maximize the potential of the upcoming Stakeholders Workshop. Please contact us if you have any questions or if there may be opportunities for us provide speakers or to submit written materials in advance of the workshop.

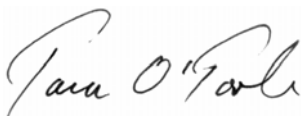
Respectfully submitted on behalf of the Alliance,



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:**

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

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

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