



History of the Alliance for Biosecurity

The Alliance for Biosecurity was formed in mid-2005 by a number of biotechnology companies, large pharmaceutical companies, and the Center for Biosecurity of the University of Pittsburgh Medical Center. The Alliance was initiated to improve the partnership between government and the biopharma industry, in which resides the vast majority of the expertise required to make the medicines and vaccines the country will need to cope with bioterrorist attacks and destabilizing pandemics. The Alliance seeks to promote a new era in the prevention and treatment of severe infectious diseases that present global security challenges through innovative and accelerated research, development, and production of medical countermeasures.

Legislative Initiatives

In 2006, the Alliance actively engaged in educating Members of Congress and key staff about the current state of preparedness for a bioterrorist attack or naturally occurring pandemic and the need for Congressional action to bolster biosecurity. Senator Richard Burr (R-NC), Senator Ted Kennedy (D-MA), Representative Mike Rogers (R-MI), and Representative Anna Eshoo (D-CA) sought information and feedback from the Alliance for Biosecurity on their respective biodefense bills. Both the Senate and House bills contained provisions to create the Biodefense Advanced Research and Development Authority ("BARDA") to facilitate funding and advanced development of biosecurity countermeasures.

The Alliance developed a consensus analysis of ways to improve drug and vaccine development and identified elements of a much stronger government/industry partnership. The Alliance sent a series of letters summarizing this analysis to members of the Senate and the House and to senior members of the Administration.

Members of the Alliance testified before the House Energy & Commerce Committee, sponsored an educational briefing on biosecurity hosted by Reps. Rogers and Eshoo, and spearheaded and participated in a congressional staff briefing on biosecurity. Throughout the course of the year, Alliance staff and leadership met with Members of Congress and senior staff from the committees of jurisdiction, including the primary sponsors of the House and Senate legislation. The Alliance Secretariat provided Alliance members with regular reports on such meetings, as well as updates and analysis of congressional activity.

These Alliance initiatives contributed to the successful passage and enactment of the BARDA legislation (S. 3678) in December, 2006.

2006 Alliance for Biosecurity Events

- § 30 January: *Alliance Strategic Planning Committee Meeting.*
- § 24 February: *Alliance Board of Directors Meeting (Guest Speaker: Bob Kadlec, former Staff Director of Senate Sub-Committee on Bioterrorism & Public Health Preparedness).*
- § March-September: *Alliance meetings with Members of Congress and key staff to educate on biosecurity issues and BARDA legislation.*
- § 6 April: *Alliance testifies before House Energy & Commerce Committee.*
- § 24 May: *Alliance leadership meeting with Rep. Rogers (R-MI).*
- § 6 June: *Alliance Educational Briefing on biosecurity in conjunction with Rep. Rogers (R-MI) and Rep. Eshoo (D-CA).*
- § 8 June: *First meeting of Alliance Animal Model Working Group.*
- § 25 July: *Alliance Board of Directors Meeting (Guest Speaker: Rajeev Venkayya, Special Assistant to President for Biodefense).*
- § 6 September: *Alliance spearheads participation in House Staff Briefing on biosecurity.*
- § 25-26 September: *Alliance participates in and presents at HHS BioShield Stakeholders Workshop.*
- § 6 December: *Alliance Animal Model Working Group Meeting (Guest Speaker: Judith Hewitt, Research Resources Program Officer, Office of Biodefense Research Affairs, Division of Microbiology & Infectious Diseases/NIAID).*
- § 7 December: *Alliance Board of Directors Meeting (Guest Speaker: Gerald Parker, Principal Deputy Assistant Secretary, Office of Public Health Emergency Preparedness, DHHS).*

Interactions with DHHS

During the second half of the year, the Alliance engaged with the Department of Health and Human Services to provide input on a variety of issues. For instance, the Alliance developed consensus positions and sent correspondence to the Office of Public Health Emergency Medical Countermeasures (OPHEMC) that outlined a number of suggestions for improving the public/private partnership on medical countermeasure development. OPHEMC sent a substantive response to this letter and suggested future dialogue with the Alliance on a variety of issues.

The Alliance attended DHHS's BioShield Stakeholders Workshop on September 25-26 in Arlington, Virginia, and presented Alliance consensus views during a panel discussion at the Workshop. The Alliance also submitted formal comments on the draft "Public Health Emergency Medical Countermeasures Enterprise Strategy for Chemical, Biological, Radiological and Nuclear Threats (PHEMCE Strategy) published in the Federal Register.

To continue the Alliance's substantive and constructive contributions in this area, Dr. Gerald Parker, Principal Deputy Assistant Secretary for Public Health Emergency Preparedness at DHHS, gave a presentation at the Alliance Board meeting in December and indicated his interest in maintaining a dialogue with the Alliance on BARDA implementation and other significant issues.

Animal Model Working Group

In mid-2006, the Alliance for Biosecurity formed an Animal Model Working Group to engage with the Food and Drug Administration (FDA) and other government agencies and stakeholders to accelerate animal model development and improve the process for the regulatory approval of medical products that use animal models to demonstrate efficacy. In addition to the Center for Biosecurity and other Alliance member companies, Battelle Medical Research and Evaluation Facility and Lovelace Respiratory Research Institute joined this Animal Model Working Group. Since its inception, the Working Group has focused on: (1) authoring a paper that presents possible solutions to current barriers to successful animal model development; (2) initiating a collaboration with the FDA under the FDA's Critical Path Initiative; and (3) securing key documents from the government on animal models for specific disease threats.

Publication

The Working Group prepared a paper titled "*The FDA Animal Efficacy Rule and Biodefense Countermeasures: A Way Forward*". In the paper, the Alliance proposes steps to enhance implementation of the FDA Animal Efficacy Rule, in order to facilitate the development of medical

countermeasures. It is the intention of the Working Group to submit the paper for possible publication as a commentary in the Journal of the American Medical Association (JAMA). The Alliance Board is currently reviewing the completed paper and will provide final approval before submission to JAMA.

Collaboration with FDA

The Animal Model Working Group sent a letter to the Directors of the FDA's Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER), requesting the opportunity to discuss the creation of a process to facilitate a constructive, sustained dialogue between the Alliance and FDA about animal model development issues. FDA agreed to this request and concluded that the identification of better predictive models to test countermeasures falls within the remit of FDA's Critical Path Initiative. FDA has organized a team of people from CDER, CBER, and the Office of the Commissioner to interact with the Alliance on this initiative. Members of the Animal Model Working Group will be meeting with this FDA team on March 5, 2007, in order to plan for future events, including a Roundtable Session in 2007 and a series of workshops. It is the intention of both FDA and the Alliance to include other relevant government agencies and departments in such future events.

NBACC Documents

Working Group members identified the existence of a series of seven documents on animal models for specific threats commissioned by the Department of Homeland Security's National Biodefense Analysis and Countermeasures Center (NBACC). These documents have not been made public. Through an agreement with NBACC initiated by the Working Group, Alliance members who signed the agreement were given copies of the seven NBACC documents.

Upcoming Meetings in 1Q 2007

- § *Strategic Planning Committee Meeting: Feb. 6th*
- § *Alliance/FDA Organizational Session: March 5th*
- § *Animal Model Working Group: March 20th*
- § *Alliance Board of Directors: March 21st*

Contact Anita Cicero, Executive Secretary, for Alliance documents and testimony.

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