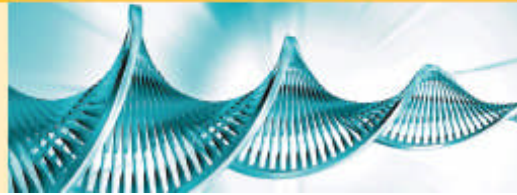


LIFE SCIENCES AND PUBLIC HEALTH PREPAREDNESS



HHS PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE STAKEHOLDERS WORKSHOP AND BARDA INDUSTRY DAY September 24-26, 2008

About the Workshop

The U.S. Department of Health and Human Services (HHS) Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) sponsored the third annual Stakeholders Workshop and BARDA Industry Day last week in order to bring together key stakeholders from the public and private sectors to discuss issues in biodefense and public health preparedness. In the past, industry has communicated the need for transparency and clear lines of communication between the government and private industry partners and this workshop acted as a venue to fulfill these requests.

The dialogue and common themes throughout this third annual meeting included the current state of medical countermeasure preparedness, PHEMCE initiatives in the past year, and plans for moving forward to enhance national capabilities to respond to a public health emergency. In addition to Stakeholder Workshop sessions, the BARDA Industry presentations offered workshop attendees and government decision makers the opportunity to learn about the latest technological advances in medical countermeasure research and development.

Many high level federal government officials were present and addressed the attendees of the workshop. This high level participation exemplifies the government's commitment to biodefense and public health preparedness, and demonstrates the priority of these issues across Federal agencies. Speakers included Michael O. Leavitt, Secretary of the Department of Health and Human Services; Dr. Robert P. Kadlec, Special Assistant to the President for Homeland Security, Senior Director, Biodefense Policy, Homeland Security Council, The Executive Office of the President; RADM W. Craig Vanderwagon, MD, Assistant Secretary for Preparedness and Response, HHS; and Tevi D. Troy, Ph.D., Deputy Secretary, HHS.

The BARDA Strategic Plan

Robin Robinson, Ph.D., Deputy Assistant Secretary for Preparedness and Response, Director, Office of Biomedical Advanced Research and Development Authority presented the BARDA Strategic Plan and a vision of the future for BARDA. The BARDA Strategic Plan 2008 Draft is slated to be released in October and will be available for public review (McKenna Long & Aldridge LLP (MLA) will circulate an announcement once that document is made public). Dr. Robinson emphasized the importance of submitting Strategic Plan comments.

The BARDA staff is focused on development and maintenance of a program based on advanced development combined with stockpile establishment and procurement, while strengthening U.S. manufacturing capacity and supporting innovation. Dr. Robinson stated that in order for BARDA to be successful, the private industry must communicate their needs, capabilities, and ideas to form a lasting

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partnership between the public and private sectors. Dr. Robinson described how BARDA will be taking a different approach to outreach and steps forward as the Strategic Plan is initiated to include:

- Visits to industry by BARDA officials and technology watch activities;
- Specialized workshops to include proposal writing, contract management, and countermeasure-focused events;
- Nurturing medical countermeasure platform technologies for cross-indication usage;
- Continuing to foster advanced development for multiple product types;
- Implementing incremental milestone acquisitions; and
- Establishing a network of formulation and fill-finish manufacturers for emergency production and distribution.

Additional Areas of Interest

In addition to BARDA discussions, the Stakeholder Workshop and BARDA Industry Day consisted of presentations on a variety of issue-specific topics including:

- The Public Health and Emergency Preparedness (PREP) Act;
- Addressing end user questions about Emergency Use Authorization (EUA);
- Rapid Medical Countermeasure Dispensing, Personal Preparedness and Anthrax Antimicrobial Medkits;
- Strategies and Suggestions for Developing and Sustaining a Biodefense Industry;
- The National Biodefense Science Board; and
- An International Perspective on Medical Countermeasure Preparedness

Please contact a member of the Life Sciences and Public Health Preparedness Team at MLA if you would like more information on the BARDA Strategic Plan 2008 or any other topics discussed at the PHEMCE Stakeholders Workshop 2008. The MLA Team is committed to following federal government action in the realm of public health preparedness and will continue to report on advancements at BARDA.

About Us

McKenna Long & Aldridge LLP is an international law firm of attorneys and public policy advisors. The firm provides business solutions in the areas of environmental regulation, international law, public policy and regulatory affairs, corporate law, government contracts, intellectual property and technology, complex litigation, real estate, energy and finance. To learn more about the firm and its services, log on to www.mckennalong.com.

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