

## Implementation of Project BioShield and BARDA: A Dialogue with HHS: A Summary

On Friday, May 18, 2007, McKenna Long & Aldridge LLP (MLA) hosted a public meeting on the "Implementation of Project BioShield and BARDA: A Dialogue with HHS." Participants from HHS included:

*Gerald W. Parker, DVM, Ph.D., MS*  
Principal Deputy Assistant Secretary, Office of the Assistant Secretary for Preparedness and Response

*Monique Mansoura, Ph.D.*  
Acting Deputy Director for Policy, Planning and Requirements, Office of the Biomedical Advanced Research & Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response

*Brian Kamoie, JD, MPH*  
Deputy Assistant Secretary, Office of the Assistant Secretary for Preparedness and Response

*Carol D. Linden, Ph.D.*  
Principal Deputy Director and Acting Director Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response

*Michael Kurilla, MD, Ph.D.*  
Director, Office of Bio-Defense Research Affairs, Associate Director for Bio-Defense Product Development, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health

### Departmental Overview

The Office of the Assistant Secretary of Preparedness and Response (ASPR) works with the HHS Secretary's principal advisory staff on matters related to bioterrorism and other public health emergencies. ASPR coordinates interagency activities between HHS, other Federal departments, agencies, offices and state and local officials responsible for emergency preparedness and the protection of the civilian population from acts of bioterrorism and other public health emergencies. ASPR has a broad mission and it is necessary for the organization to rely on their strategic partners both inside and outside of the government to aid in accomplishing their mission and goals.

The Biomedical Advanced Research and Development Authority Office (BARDA) is tasked with implementing Project BioShield medical countermeasure acquisition programs, utilizing the \$5.6 billion Special Reserve Fund; with supporting advanced development of vaccines, antiviral drugs, and diagnostics to protect against pandemic influenza; and with leading the U.S. Government's efforts to identify requirements for medical countermeasures against Chemical, Biological, Radiological, Nuclear and Explosive (CBRNE) threats.

### Project BioShield

The aim of Project BioShield is to accelerate research and development of medical countermeasures by instituting a secure funding source (\$5.6 Billion over 10 years) for the purchase of critical medical countermeasures, such as vaccines, therapeutics, and diagnostics. Project BioShield also grants the National Institutes of Health/National Institute of Allergy and Infectious Diseases authorities to expedite

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### CONTACTS

If you would like more information, please contact any of the McKenna Long & Aldridge attorneys or public policy advisors with whom you regularly work. You may also contact:

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and simplify the solicitation, review, and award of grants and contracts for the development of critical medical countermeasures. Finally, Project BioShield establishes the Emergency Use Authorization (EUA) to provide access to the best available medical countermeasures following a Declaration of Emergency by the Secretary of Health and Human Services.

To date, Project BioShield observations and lessons learned include:

- overall development is risky, emphasizing that the legislation does not remove the risk
- more work has been done with small biotechnology companies
- terms of contracts are challenging
- those interested in developing countermeasures must be fully engaged with the FDA

### **Pandemic Influenza**

Pandemic influenza preparedness planning, a cooperative effort between CDC, FDA, NIH and industry, includes a focus is on vaccines, antivirals and diagnostics:

- Vaccines
  - o H5N1 stockpiles~available for 20 million persons (2 doses/person)
  - o pandemic vaccine~600 million doses
- Antivirals
  - o influenza antiviral drug stockpile~75 million treatment courses
  - o influenza antiviral drug stockpile for strategic limited containment~6 million treatment course
- Diagnostics
  - o new high-throughput laboratory & point-of-care diagnostics

### **BARDA**

The purpose of BARDA is to promote innovation through an advanced development fund, separate from the Project BioShield reserve fund. Overall, BARDA supports innovation. Similar to the Defense Advanced Research Projects Agency (DARPA), BARDA promotes high-risk, cutting edge processes and seeks to help “pull” products through the pipeline by awarding milestone advance payments.

### **Discussion**

Other key issues of interest include:

- The next generation anthrax vaccine contract was terminated by HHS due to contract issues, and the company's failure to meet a significant milestone. HHS is still interested in an anthrax vaccine and mentioned the sources sought synopsis issued May 14, 2007 for a rPA vaccine.
- Innovation in the biodefense area can be described in a number of ways including:
  - o Innovation is positive and means new technologies and processes, one of the unique things about BARDA is the ability for a company to explore a biodefense application for a technology.
  - o Innovation is needed, but it is ultimately dependent on new technological developments. For example, with new delivery platforms, with adjuvants, and with delivery systems. Innovation should focus on these areas.
  - o Innovation is expediting drug development.
  - o More innovation is required within the government, there is not enough coordination within the government and the focus should be here.
- In addressing the interaction of prevention and response, it is extremely difficult to predict a bioterrorism attack and determine the actual threat, but the government is planning and has developed their strategy using a risk-benefit ratio. If an event or multiple events were to occur, the risk-benefit ratio would be recalculated. The *Public Health Emergency Medical Countermeasures Enterprise Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats* does list the threats on which the government is currently concentrating their focus.
- The BARDA legislation has a built-in mechanism to ensure the FDA has the resources needed to handle advanced development through BARDA and the FDA has really “stepped up” and provided support. The need for interested medical countermeasure developers to get involved with FDA early in the development process.

## HHS' Final Thoughts

Regarding the involvement of industry, transparency and communication with the industry stakeholders is crucial. Industry should also consider entering into partnerships with one another in order to leverage capabilities, and reduce risk. It would also be beneficial for industry to calibrate their expectations understanding that overall, it is still early in the process of creating a large biodefense research and development base. Industry stakeholders should view BioShield and BARDA in “long term mode” focusing on “short successes.”

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