

## **BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA)**

**Panelists**      Dr. Carol Linden, BARDA  
                      Dr. Robin Robinson, ASPR  
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### **Summary**

BARDA's role and responsibilities in support of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), and within PAHPA were discussed. A key function is to execute the medical countermeasure, advanced development and procurement programs for Project BioShield (Chemical, Biological, Radiological and Nuclear – CBRN – threats) and for pandemic influenza and other emerging infectious diseases. BARDA's accomplishments during its short history, and plans were outlined.

### **Session Highlights**

- In accomplishing its mission, BARDA cooperates with agencies throughout HHS, including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH), as well as with interagency partners such as the US Departments of Homeland Security, Defense, and Agriculture, and the Veterans' Administration, and with private-sector industry partners. The organization's philosophy was summed up as, "Don't tell us the obstacles and why you can't get there, tell us what you need to overcome them."
- BARDA recognizes that it needs to provide stakeholders with its advanced development and/or acquisition intents as early as possible; although both BARDA and its stakeholders recognize that the status of funding appropriations and availability are often not as clear as would be desired.

### **Key Questions and Comments**

- *What is the relationship between FDA Emergency-Use Authorization decisions and BARDA contracting decisions?* Under Project BioShield, medical countermeasures can be accepted into the Strategic National Stockpile (SNS) prior to licensure. BARDA uses regulatory milestones in their contracts to ensure that all products accepted into the SNS are sufficiently developed that they can be used in an emergency. The Emergency Use Authorization is not a regulatory milestone, it is a provision under the Project BioShield Act of 2004 that provides access to the best available medical countermeasures following a Declaration of Emergency by the Secretary of Health and Human Services. These concepts are related, but are not directly tied to one another, as there can be no Emergency Use Authorization (EUA) in the absence of a declared emergency. The FDA works closely with BARDA, providing guidance and consultation, on a product-by-product basis, about the evidence necessary (the size of human safety studies, the type of animal efficacy study, etc.) to provide support towards overall licensure and approval for assertions that a product will be effective against a particular threat or condition in an emergency. The FDA provides this guidance to individual manufacturers, and also recently published EUA guidance, which everyone was encouraged to read and discuss with the FDA. Ultimately, BARDA makes the decision when to accept product delivery.

- *A question was raised regarding the pandemic influenza “mix-and-match” program with adjuvants and H5N1 vaccine antigens, specifically on the progress of plans to use an adjuvant from one manufacturer with the H5N1 vaccine antigens from another manufacturer in the national pre-pandemic influenza vaccine stockpile. BARDA, working with FDA, CDC, the NIH, and various vaccine manufacturers under Antitrust exemptions provided by PAHPA, has developed a study plan that will look at five things: the properties of various adjuvants to determine if vaccine antigens can be mixed with them successfully (started in November 2007), immunogenicity studies to show effectiveness in mice, animal toxicity studies, ferret-challenge studies, and clinical safety and immunogenicity studies that would be handled by NIH.*
- *How can a company go from Technology Readiness Level (TRL) 5 to the more advanced stage at which BARDA advanced development support could be available? Options discussed by the panel included using internal company resources, venture capital, and/or government support from the US Department of Defense (DOD) or NIH.*
- *Given the fact that the FY 2008 budget has not yet been approved, will BARDA be issuing Requests for Proposals (RFPs) based on the availability of funds – to give potential responders time to respond? BARDA will be issuing RFPs contingent upon the availability of funds and has developed several different scenarios for FY 2008, depending on the funding received.*
- *What alternatives do companies have if their product is not sufficiently advanced to compete for a particular RFP for pandemic influenza vaccines at the time the RFP is issued? BARDA, with NIH, works closely to monitor technological development in these areas. As promising new technologies continue to be developed in either the vaccine or antiviral fields that may improve US Government (USG) capabilities, additional RFPs will be considered.*
- *How will HHS be maximizing utility of the SNS, in light of questions raised during recent Congressional hearings? While the initial HHS focus was on filling gaps in medical countermeasure preparedness, it is clear that life-cycle management issues also are critical in maintaining that preparedness over time. BARDA is currently working through these issues with its interagency partners. An example discussed was on-going work with the Department of Defense to jointly manage the USG stockpile of Emergent Biosolution’s anthrax vaccine product, so that ongoing DOD vaccination needs are met and less product expires unused. BARDA is also building infrastructure and surge capacity to respond at the time of an event, such as an influenza pandemic.*
- *When will additional RFPs be released for pandemic influenza? An RFP for a recombinant influenza vaccine is currently "on the street", and an RFP for cell-based influenza vaccine manufacturing facilities is anticipated in FY 2008. Additional solicitations may also be forthcoming, depending on the results of current contracts and pending clinical results.*