

BioShield Stakeholders Workshop Overview

Conference Overview

From July 31 through August 2, 2007, the Office of Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response (ASPR), of the Department of Health and Human Services (HHS) hosted a workshop with Stakeholders to discuss the Public Health Emergency Medical Countermeasures (PHEMC) Enterprise. The Workshop provided an opportunity to discuss and receive individual stakeholder feedback on HHS implementation of the *HHS Pandemic Influenza Plan*, the *HHS PHEMCE Implementation Plan for Chemical, Biological, Radiological, and Nuclear Threats*, the Project BioShield Act of 2004, and the new HHS authority provided in the Pandemic and All-Hazards Preparedness Act. Given the nature of the meeting and the number of presentations, McKenna Long & Aldridge LLP has provided this tailored briefing as an overview of the conference, highlighting broad topic areas. Additional information is available on any topic presented in this briefing and can be made available upon request. Please contact MLA for additional information and further discussion.

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 requiring 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 the research and development of medical countermeasures by instituting a secure funding source (\$5.6 Billion over 10 years) for the purchase of critical

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UPCOMING EVENTS

A Roundtable Discussion: Preparing Business for Pandemic Influenza

Monday, September 17 2007
8:30am-4:30pm
Metro Atlanta Chamber of
Commerce
235 Andrew Young
International Blvd. NW
Atlanta, GA

medical countermeasures, such as vaccines, therapeutics, and diagnostics. Project BioShield also grants the National Institutes of Health/National Institute of Allergy and Infectious Diseases (NIH/NIAID) authorities to expedite 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.

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Pandemic Influenza

The National Strategy for Pandemic Influenza (released November 2005) designates HHS as the lead agency for public health and medical response for pandemic preparedness and response. Effective implementation of the HHS Pandemic Influenza Plan relies on support from partners throughout HHS, other federal, state, and local governmental agencies, and industrial partners.

BARDA

BARDA, in the Pandemic and All-Hazards Preparedness Act, gives HHS the authority to invest in the advanced development of medical countermeasures and will carry products through the so-called "Valley of Death" to meet medical countermeasure requirements, reduce risk to both medical countermeasure developers and the Government, and promote innovation. 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.

Conference Overview

The need for coalition building, greater transparency, and coordination among public and private partners emerged as the major themes of the conference. Interestingly, it was acknowledged by government representatives that the need for greater coordination was not limited to public-private partnerships but also included the need for greater coordination among and within the relevant government agencies. HHS identified the Department of Defense (DoD), Veteran's Affairs (VA), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA) as critical partners for the success of public health preparedness efforts. Dr. Andrew von Eschenbach, Commissioner of the FDA, discussed the needs and efforts underway at the FDA to integrate the various partners within the agency who are working on public health preparedness. For example, an agency-wide task force has been established to help coordinate issues associated with drugs, biologics, and devices in development for pandemic influenza. Furthermore, Dr. von Eschenbach described the integration of federal agencies as a "network of safety" for the public. Government representatives recognized the difficulties in rebuilding America's public health infrastructure, and readily acknowledged the inherent risks associated with pharmaceutical research and development (R&D), funding constraints through the valley of death, and regulatory issues surrounding the registration of non-traditional medical countermeasures (MCMs).

The planning for a public health event is at the forefront of efforts by the BARDA office. This planning includes efforts to describe critical benchmarks and milestones that will be used to gauge progress and ultimately success. As described by ADM John Agwunobi, the Assistant Secretary of Health at HHS, success will be determined both by whether or not plans make a difference in the event of a public health event, and also by the sustainability of the preparedness plans over time. Jack Herman, Project Director for Public Health Preparedness at the National Association of County and City Health Officials (NACCHO), asked that consideration be given to community-wide actionable best practices and processes during the development of the planning guidelines.

As the government is becoming increasingly knowledgeable about the need for effective coordination among the agencies and streamlining of processes, they are also allocating internal resources to optimize agency specific action items. For example, Mr. Greg Burel, Acting Director, Division of Strategic National Stockpile (SNS) at the CDC, described the gap analysis underway to identify which

products currently in the SNS could be used more effectively and which product classes are missing entirely from the SNS. Mr. Burel specifically identified the need to purchase additional supplies of personal protective equipment (PPE). In order to ensure the effective management of public health efforts, including the resources of the SNS, RADM Craig Vanderwagen, Assistant Secretary for Preparedness and Response at HHS, outlined the requirement his office has for a quadrennial defense review to determine outstanding public health needs and to develop a strategy to move forward.

A theme which surfaced throughout the course of the conference was the need to understand distribution mechanisms for MCMs, regardless of the public health emergency, and provide coordination for first responders. As mentioned by RADM Vanderwagen, concepts of operations (CONOPS) are critical for each MCM, and a purchase into the SNS must be considered in conjunction with an understanding of how the MCM will be delivered to the community. Mr. Burel from the SNS also specifically mentioned the need to build flexibility into the SNS system to meet the variation in state and local needs. James Blumenstock from the Association of State and Territorial Health Officials (ASTHO) discussed the need for a robust and integrated tracking system to allow for better MCM management and administration by state and local officials. Dr. Bruce Gellin, Director of the National Vaccine Program Office, highlighted some of the outstanding questions that HHS is still grappling with, including how to deliver antivirals and vaccines to households if traditional delivery mechanisms are not available, and how to identify individuals who should receive medications.

In conjunction with significant discussion about the recently released “Public Health Emergency Medical Countermeasures Implementation Plan” (document can be accessed at: http://www.hhs.gov/aspr/barda/documents/phemce_implplan_041607final.pdf), there was further clarification of specific MCMs needed and technologies under development through government funding. Dr. Jeffrey Runge, Assistant Secretary for Health Affairs and Chief Medical Officer at the Department of Homeland Security (DHS), highlighted the top DHS planning scenarios, namely, the detonation of a 10,000 pound nuclear device, an aerosolized anthrax attack, pandemic influenza, and plague. Per the implementation plan, significant investment will be given to the development of novel platforms for manufacturing, broad-spectrum antibiotics and antivirals, and vaccines for explosive threats such as Smallpox, Ebola, and Marburg.

In addition to the MCMs for biodefense applications, significant time was spent reviewing development and acquisitions for pandemic preparedness. Dr. Gellin discussed the rationale behind the stockpiling a pre-pandemic (unmatched) influenza vaccine and the assembly of the pandemic influenza portfolio. This research portfolio includes expansion of egg-based vaccine production, R&D into cell-based production and manufacturing technologies, antigen-sparing technologies, next generation antivirals, and enhancement of international vaccine production capacity. Part of the pandemic preparedness portfolio includes ongoing research into the long-term stability of influenza vaccines, and the ability to mix and match antigen and adjuvants. Furthermore, the solicitations for recombinant flu vaccines, the enhancement of domestic cell-based production capacity, and the development new and/or combination antiviral drugs will be announced in the near term. Dr. Roland Levandowski from the NIAID described five influenza vaccine programs under development through NIAID: live-attenuated, recombinant sub-unit, DNA, vector-based, and universal.

Diagnostic technologies for pandemic influenza are clearly an integral part of an effective response, as highlighted by Dr. Stephen Redd, Influenza Team Lead at CDC. Diagnostic tools are needed to ensure speed of response, delivery of appropriate treatment, containment of an outbreak, characterization of virus, and to monitor the impact of interventions. A number of Requests for Information (RFIs) and Requests for Proposals (RFPs) have been released for influenza diagnostics, including a point-of-care, CLIA-waved test; a fully automated test for use in reference labs; and a test which can detect influenza-like-illnesses in a lab setting.

As science and technology advances, the government is becoming increasingly concerned about unknown, emerging, and bioengineered threats. Dr. Anthony Fauci of the National Institute of Allergy and Infectious Diseases (NIAID) highlighted this point by suggesting that, at least in the eyes of NIAID and their goal of balancing public health opportunities with research needs, emerging microbes are concomitant with biodefense pathogens. Concerns regarding these technologies and the regulations

that govern them were covered extensively during a conference session outlining the CDC Select Agent Regulations.

A vital detail that must be included in discussions of all public health preparedness MCMs is the requirement for FDA regulation and oversight. Dr. Mark Goldberger from the FDA highlighted the role of the FDA in this process, accentuating the need for cooperation among the agencies to understand the technologies coming through the pipeline and to determine the type of guidance that FDA may need to develop. FDA is also interested in establishing mechanisms to monitor the supply of critical pharmaceutical products and devices in the event of a pandemic. In addition they are considering processes for Serious Adverse Event reporting during an influenza pandemic, and is actively harmonizing regulatory issues globally to prevent a delay if and when a pandemic emerges.

Throughout the conference, recurring concerns vocalized by industry representatives included uncertainty surrounding sources of funding, the sustainability of funding, the relatively few solicitations made throughout the year, and the lack of transparency in the process. Representatives from the government acknowledged previous missteps and agreed that greater openness, visibility, and focus would remove a number of barriers and support research and development efforts by industry. In addition to merely supporting a market for biodefense and emerging pathogens MCMs, BARDA hopes to promote innovation. The BARDA office is developing R&D plans through the year 2020, so they, too, are committed to the appropriation of needed funds to advance programs beyond the scope of BioShield.

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