



**HHS**  
**Public Health Emergency Medical**  
**Countermeasures Enterprise**  
**Stakeholders Workshop 2008**  
**& BARDA Industry Day**  
**Report**

**September 24–26, 2008**

**Crystal Gateway Marriott**

**Arlington, VA**



**U.S. Department of Health and Human Services**  
**Assistant Secretary for Preparedness and Response**  
**Biomedical Advanced Research and Development Authority**

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**REPORT**

**HHS Public Health Emergency Medical Countermeasures Enterprise  
(PHEMCE) Stakeholders Workshop 2008 and BARDA Industry Day**

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## EXECUTIVE SUMMARY

“Through anticipation and through collaboration, we can make the kinds of strides necessary to ensure preparedness against colossal health threats, whether they’re manmade or whether they are natural. ...Every aspect of society – whether it’s the Federal Government, the State government, the local government, the private sector, community groups, families, individuals – all of us have to share in the responsibility to prepare for a bioterrorism attack or an influenza pandemic. Public and private collaboration is critical... .”

Then-HHS Secretary Michael O. Leavitt  
*September 24, 2008*

### GOALS

The U.S. Department of Health and Human Services (HHS) Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Stakeholders Workshop 2008 (PHEMCE Stakeholders Workshop) and BARDA Industry Day was held on September 24–26, 2008, to bring together public and private stakeholders to discuss critical issues surrounding medical countermeasure development and

procurement, and to share visions for ensuring adequate public health emergency preparedness. The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response (ASPR) at HHS, hosted the meeting. BARDA supports the PHEMCE’s efforts to increase civilian medical countermeasure preparedness by coordinating the definition and prioritization of medical countermeasure needs and by coordinating and executing advanced research and development of critical medical countermeasures against weapons of mass destruction or other public health threats. The expertise, resources, and commitments of numerous stakeholders, both within and outside the Federal Government, are critical to this mission. The goals of the PHEMCE Stakeholders Workshop and BARDA Industry Day were

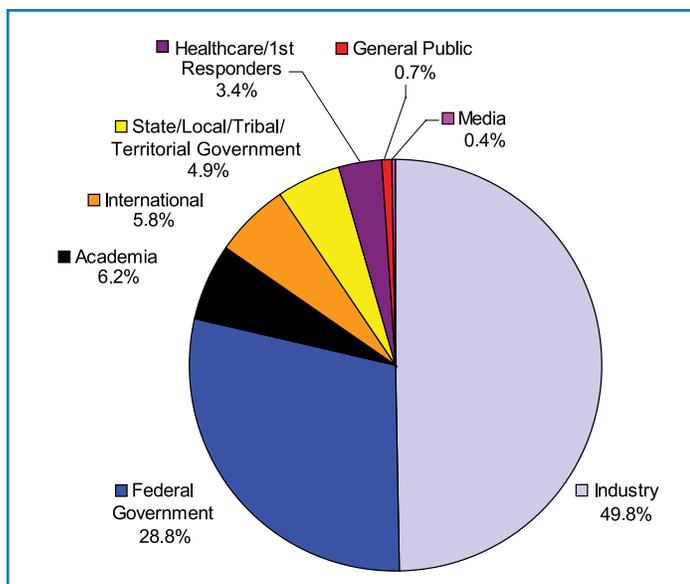
1. to bring together public and private sector stakeholders for a dynamic dialogue on the current state of medical countermeasure preparedness, PHEMCE initiatives in the past year, and plans for moving forward to enhance national capabilities to respond to a public health emergency;

2. to provide attendees with insight into, and a chance for individual stakeholder feedback on, the PHEMCE programs and procedures for medical countermeasure requirement-setting, research, development, acquisition, deployment, and utilization;
3. to provide attendees with insight into how their own efforts and resources are critical to the nation's preparedness for public health emergencies;
4. to provide unique opportunities, through BARDA Industry Day, for biotechnology and pharmaceutical industry representatives to showcase their latest breakthroughs in vaccines, therapeutics, diagnostics, and platform technologies targeting chemical, biological, radiological, nuclear and naturally emerging threats, including pandemic influenza.

## ATTENDEES

More than 550 participants attended the three-day event, while scores more viewed the Webcast (available through a link at [www.hhs.gov/aspr/barda/phemce/workshop/2008/2008workshop.html](http://www.hhs.gov/aspr/barda/phemce/workshop/2008/2008workshop.html)). Attendees included Federal, State, and local government representatives; academicians; first responders and emergency personnel; professional association and non-profit staff; and pharmaceutical and biotechnology industry representatives. Notably, 6% of the attendees this year were international stakeholders, and the live or recorded Webcast was viewed by people from the U.S. and seven other countries. Appendix 1 contains a list of the organizations and agencies represented at the event; a separate list of the attendees is available at the Workshop Web site referenced at the beginning of this paragraph.

The following chart shows the distribution among categories of registered attendees:



## PROGRAM OVERVIEW

### Opening Address

Then-HHS Secretary Michael O. Leavitt opened the PHEMCE Stakeholders Workshop 2008 and BARDA Industry Day with an address that highlighted collaboration and advanced preparation as key factors in providing public health emergency medical countermeasures. He emphasized the role of individual responsibility in emergency preparedness. He also described the progress that has been made in the past several years, including creation of the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and of the Biomedical Advanced Research and Development Authority (BARDA); creation and licensing of the first vaccine for humans against the H5N1 influenza virus; stockpiling of 26 million doses of the H5N1 vaccine; development of cell-based influenza vaccine manufacturing capability; advanced development of treatments for acute radiation syndrome; further development of a second-generation anthrax vaccine; and progress in state and local preparedness.

### Keynote Addresses

Following the opening address were keynote addresses by Dr. Robert P. Kadlec, the Special Assistant to the President for Homeland Security, and by RADM W. Craig Vanderwagen, the HHS Assistant Secretary for Preparedness and Response. A keynote address on the second day was presented by Dr. Tevi Troy, the HHS Deputy Secretary. Each of the speakers emphasized that, although the country has made substantial progress, much work remains to be done in enhancing public health emergency preparedness that will require substantial innovations. In pursuit of this mission, as noted by Dr. Kadlec, BARDA can serve as a national and global virtual pharmaceutical company that will harness and integrate a wide range of considerations and talents in ways that have the potential to transform how public health is approached in the 21st century – the century of the life sciences.

### Survey of Progress

Following the first day's opening session, Federal Government officials surveyed the progress in medical countermeasure preparedness made by the U.S. Department of Homeland Security, the U.S. Department of Defense, and by several HHS agencies and offices. The speakers echoed then-Secretary Leavitt's emphasis on the importance of broad-based collaborative efforts and the anticipation of future needs. An important element of medical countermeasure preparedness, which has been realized in some areas, is building the support and infrastructure to prepare for future threats, including products, production



platforms, and development approaches with broad-spectrum applicability. Several of the speakers emphasized the substantial funding that will be essential for effective future progress.

### **Plenary Sessions**

Presentation topics for plenary sessions included developing and sustaining a biodefense industry; the progress made by and the path forward for BARDA (including perspectives from industry partners on working with BARDA and an overview of the final BARDA Strategic Plan to be published after the conference); and the work of the National Biodefense Science Board. Four major sessions over the first two days of the Workshop addressed utilizing medical countermeasures at the point of care, including (1) obtaining medical countermeasures, using them, and regulations and liabilities associated with their use; (2) the role of point-of-care diagnostics in triage and treatment; (3) rapid medical countermeasure dispensing and associated communications; (4) event planning, preparedness, and coordination at all levels, including hospital, city, county, tribal, territorial, state, and Federal entities; and (5) specific issues associated with radiological and nuclear events. Presenters in these plenary sessions included Federal, State, and local government officials and non-governmental stakeholders with expertise in the topics addressed, exemplifying the theme of collaboration among the diverse participants in medical countermeasures-related endeavors. On the final day of the Workshop, simultaneous sessions addressed (1) international perspectives on medical countermeasure preparedness; (2) challenges and opportunities associated with at-risk populations (such as children or elderly, disabled, or immunocompromised people); and (3) medical countermeasure innovations to facilitate public health emergency response.

### **BARDA Industry Day**

Several BARDA Industry Day sessions were held. Oral presentations ran simultaneously during the first two afternoons of the Workshop, and posters, available throughout the Workshop, were presented in evening sessions. These sessions provided an opportunity for industry stakeholders to present information on their products and activities for public awareness and consideration. Topics included pandemic influenza medical countermeasures; pandemic influenza vaccines; anthrax therapeutics; vaccine innovations; therapeutics (various); platform technologies; diagnostics, biosimetry, and bioassay; and therapeutics for chemical, radiological, and nuclear threats.

### **Breakout Sessions**

On the last day of the Workshop, participants in focused interactive breakout sessions discussed several topics of interest to them and to the government. The discussions are summarized in a separate section of this report. The topics were (1) performance measures for medical countermeasure distribution and utilization in public health emergency response; (2) challenges for planning community preparedness for all-hazards response; (3) building and sustaining medical countermeasure industries for chemical, biological, radiological, and nuclear (CBRN) threats and pandemic influenza; and (4) opportunities and challenges associated with novel medical countermeasure forward deployment and dispensing models.

### **Networking**

In addition to the formal sessions, participants in the PHEMCE Stakeholders Workshop 2008 and BARDA Industry Day had various informal opportunities to network and exchange ideas during breaks, substantial lunch periods, and evening receptions in the Exhibit Hall.

## KEY THEMES

### The Mission

HHS leaders expressed that the mission of developing and acquiring emergency medical countermeasures and supporting their effective utilization transcends politics and must focus on those critical needs in the event of a public health emergency. The medical countermeasures endeavor must be considered as an element of an all-hazards approach to public health preparedness. The development of medical countermeasures may also provide a stimulus to the breakthrough of novel technologies and a test bed for evaluating them that can be applied profitably beyond the realm of biodefense. The aim is not only to provide medical countermeasures to respond to today's threats, but also to develop the capacity to respond to any and all threats in the future – the “unknown unknowns.”

### Progress

Both government and industry speakers recognized that the public health emergency medical countermeasures endeavor has made great strides in recent years. Under the PHEMCE, HHS seeks to organize civilian medical countermeasure activities and to broaden ownership of the mission to all stakeholders, including the end-user public health and responder community. Progress has been made at both the federal level and at the state and local levels in more effectively deploying and dispensing medical countermeasures and increasing public health capacity for intentional, accidental, and natural threats. The U.S. Government has made substantial advances in building and sustaining the medical countermeasures arena through establishing BARDA and selecting the first BARDA director; developing the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for Chemical, Biological, Radiological and Nuclear (CBRN) Threats and the HHS PHEMCE Implementation Plan for CBRN Threats;<sup>1</sup> providing outreach and engagement with industry and other stakeholders; releasing solicitations and announcements for participation in funded programs; and awarding contracts and grants. The BARDA authority (from the Pandemic and All-Hazards Preparedness Act, P.L. 109-417) to award advanced milestone payments in development contracts has greatly improved both the potential capability of industry to develop emergency medical countermeasures and the value of such contracts. The PHEMCE has developed infrastructure for production capabilities and innovations for using resources efficiently and effectively. The Division of the Strategic National Stockpile (DSNS) of the Centers for Disease Control and

<sup>1</sup>Both documents are available through links at [www.hhs.gov/aspr/barda/phemce/enterprise/strategy](http://www.hhs.gov/aspr/barda/phemce/enterprise/strategy).

Prevention (CDC) has grown substantially in its roughly 10 years, and is working to foster and assess capabilities of its state and local partners to effectively dispense emergency medical countermeasures. These DSNS efforts are in collaboration with organizations such as the National Association of County and City Health Officials (NACCHO) and the Association of State and Territorial Health Offices (ASTHO).



Although substantial progress has been made in these endeavors, presenters from both government and industry recognized that more remains to be done. Substantial challenges remain to industry's involvement in the medical countermeasure mission, including a lack of clarity regarding regulatory pathways, limited product development funding, coordination of funding and regulatory timelines with business considerations, and the size and sustainability of commercial markets. Gaps in the capabilities for local response to radiological or nuclear events were also highlighted, including the need for clinical bioassays, community radiation reception centers, and pre-event education and training.

### Collaboration and Cooperation

The public health emergency medical countermeasure mission is highly collaborative; its effectiveness relies upon sharing responsibility across boundaries: internationally; public-private; Federal-State-local; academic-industry-government; among Federal agencies; individual-collective. In this vein, the Federal Government is moving toward a one-portfolio approach to emergency medical countermeasures for the U.S. military and civilian sectors. PHEMCE members have also been fostering effective partnerships both within the United States and around the world, built on frequent interactions, open communication, and building trust. For example, CDC provides guidance, assistance, and support to state and local public health emergency organizations, including medical countermeasures from



the Strategic National Stockpile (SNS), training materials and communication resources (toolkits), planning guidance, and preparedness assessments.

### **The Biodefense Industry, Innovation, And Broad-Spectrum Approaches**

For businesses, developing emergency medical countermeasures is not business as usual – it requires innovation that is best fostered by collaborative efforts among diverse organizations – no single organization has all the answers. In a session dedicated to innovations, a number of products and processes were presented that aim to facilitate public health emergency response, including operationally simplified ways to diagnose health effects and to administer medical countermeasures. Innovation in developing and integrating response approaches will help to meet the challenges of public health preparedness on the local level. A useful and efficient emphasis for future medical countermeasure development and innovation could be on broad-spectrum medical countermeasures that could be widely applicable, especially as novel threats continue to evolve. Broad-spectrum approaches can be applied not only to products, but also in leveraging product enhancement technologies and in improved production platforms.

### **The U.S. Government's Role**

With respect to the Federal Government's role, participants noted that equity across social and economic boundaries is important. The U.S. Government must also be a proactive driving force, finding avenues to engage the active interest of the biotechnology and pharmaceutical industries,

and rewarding performance in meeting emergency medical countermeasure goals. Representatives from these industries indicated that the effective incentives could include exploration of international market opportunities where available, improving identification and predictability of U.S. government needs, and making U.S. government solicitation processes more efficient, transparent, and timely. The forthcoming BARDA Strategic Plan will address many of these areas and will describe BARDA's continued commitment to listening to stakeholders and working effectively with them, as well as fostering innovation in processes and products.

### **Public Perceptions, Communication, and Involvement**

Regarding the attention, perceptions, and attitudes of members of the general public and the public health and responder communities, speakers recognized that challenges include effective communication to the public and preparedness "fatigue." To be effective, the importance of social acceptance of preparedness technologies and policies cannot be underestimated. As such, frequent and transparent communication with all stakeholders, including individual end-user groups, is crucial. For example, survey results reported at the Workshop showed that members of the medical responder community are highly dedicated to their professional duties, but have concerns about the safety of loved ones and adequacy of space, resources, and staffing in responding hospitals. These issues will need to be addressed to ensure an effective medical response in a public health emergency.

### **FOR MORE INFORMATION**

To find out more about the PHEMCE Stakeholders Workshop 2008 and BARDA Industry Day, please visit [www.hhs.gov/aspr/barda/phemce/workshop/2008/2008workshop.html](http://www.hhs.gov/aspr/barda/phemce/workshop/2008/2008workshop.html). This Web site provides a wide range of information on the event, including the agenda, Webcasts of the plenary sessions, and access to presentation slides.

### **UPCOMING EVENTS**

The Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Stakeholders Workshop and BARDA Industry Day is an annual event. The next PHEMCE Stakeholders Workshop and BARDA Industry Day will be held in fall-winter 2009-2010. Updates and further information on this event will be posted on the BARDA Web site at [www.hhs.gov/aspr/barda](http://www.hhs.gov/aspr/barda). To be notified when this information is available, please email BARDA at [BARDA@hhs.gov](mailto:BARDA@hhs.gov).

# SIMULTANEOUS BREAKOUT SESSIONS

September 26, 2008

Stakeholders were divided into breakout groups, which were asked to discuss questions from a predetermined set of four topics. The full text of each question can be found in Appendix 3. A summary of individual stakeholder views expressed in response to each question is presented below. The opinions and views expressed do not necessarily reflect official positions or policies of the Department of Health and Human Services.

## BREAKOUT SESSION A:

### Performance Measures for Medical Countermeasure Distribution and Utilization in Public Health Emergency Response

#### Assessment Methods

Currently, the Cooperative Agreement on Public Health Preparedness and Response for Bioterrorism is driving state and local preparedness planning. This is an agreement that since 1999 has supported preparedness nationwide in state, local, tribal, and territorial public health departments. Jurisdictions are submitting preparedness plans as required to obtain funding. Preparedness assessment is often restricted to a checkbox of “Do I have a plan or not?” However, preparedness involves much more than simply having a plan. In this context the differences were not entirely clear between what the ASPR and the CDC/DSNS do to assist individual jurisdictions in planning and evaluating their preparedness.

#### Variation among States

Because different states do things differently, achieving a credible evaluation of capabilities outlined in the plan can be challenging. Most states and localities have been working on written preparedness plans and have not yet evaluated their ability to implement and adapt those plans. A federal evaluation has been done on the capabilities particular states need in order to receive and dispense medical countermeasures. The group agreed that assessment of key capabilities is difficult to standardize because laws, plans, requirements, and capabilities differ among states. Some participants felt that the responsibility lies with the individual state to distribute the materials to the local level. However, this “relay race” to distribute medical countermeasures from the federal, to the state, to the local levels, and finally to the patient level could be impeded at any point along its route.

In 2002 the focus was on state plans and the project areas. This included the 50 states, as well as separately funded cities and territories with capability at the local level. The focus has since shifted to a greater emphasis on the city level. Beginning in fiscal year 2004, the Cities Readiness Initiative (CRI), a Federally funded effort to pre-



pare major U.S. cities and metropolitan areas to effectively respond to a large-scale bioterrorist event, began developing the capability to dispense antibiotics to each city’s entire identified population within 48 hours of the decision to do so.

#### Preparedness Assessment: No Common Framework

The group discussed whether any requirement exists for evaluating and reporting the status of implementation of the various plans, and, if so, whether the requirement supports the development of performance measures. Some support exists for evaluating some aspects of implementation. Recently, the CDC’s Division of the Strategic National Stockpile (DSNS) stockpiled antibiotics for distribution in the event of a pandemic and a common framework was proposed for evaluation of state capabilities to distribute the antibiotics. A general framework for overall preparedness assessment, however, is lacking. There is no research known on potentially useful performance measures. Few measures exist, and many of those are not clearly

relevant because they are developed “on the fly” without a clear basis of understanding.

Preparedness assessments should be done using such questions as these:

- Do you implement, utilize, and exercise the plan?
- Do you have a communications plan?
- Did you submit a preparedness plan to HHS?
- Are you prepared to address feedback?

Having a plan is often driven by filling the requirement for funding, rather than by the goal of a quality plan to serve effective preparedness. The attitude often seems to be, “I’ve got a plan; I am okay.” However, preparedness is a journey, not a destination.

More specifically, a systematic approach for measuring the utility of a preparedness plan would include some or all of the following considerations:

- **Observation and fact collection.** The most basic element in evaluation is asking questions at the local level to determine what is being done, how, when, and in the context of what requirements.
- **Performance measures.** Stakeholders must develop and understand performance measures.
- **Replicable models of assessment.** HHS should look to other agencies that have seasoned preparedness assessment plans and consider adapting them. The research and best practices of agencies such as the U.S. Department of Homeland Security (DHS) and the U.S. Department of Defense (Army, Navy, and Air Force branches) should be adapted to field medical countermeasures. For example, Army employees prepare a monthly status report that discusses where they are in terms of people, equipment, and execution of core missions. Standard Army-wide requirements exist for the different specialties, entities, and organizations.
- **Objective assessments.** Evaluations should be based on performance measures rather than subjective impressions.
- **Evaluation of training and exercises.** Heretofore evaluation has been limited to an evaluation of the written plans.
- **Collaboration.** Using exercises to measure preparedness can be resource-intensive, and some aspects of preparedness may prove difficult to measure (e.g., communication to the public). However, jurisdictions may benefit by working together, supporting each other in conducting exercises. Moreover, responsibility for evaluation could be restructured so that the federal

level evaluates states, while states evaluate locals. Participants discussed what measures of preparedness jurisdictions should be held to that will help them improve capabilities.

- **Comprehensiveness.** Current assessments of preparedness plans include field audits of the documentation (e.g., if the plan calls for a specific item, auditors check to see if planning for that item exists) and some localities study delivery of seasonal influenza vaccine as a measure of potential performance during a pandemic influenza outbreak. However, no standardized evaluation of this performance is within the pandemic influenza plans. Some standards (or national frameworks) exist for distribution of some biodefense medical countermeasures (e.g., delivery of antibiotics as prophylaxis in the event of aerosolized anthrax). However, few nationwide standards exist for effective preparedness/distribution of most medical countermeasures.
- **Communications.** Recommendations from the group included a clearly outlined communications piece in preparedness plans; this could be one measurement of the plan. Participants expressed that jurisdictions should ensure that communications are clearly outlined and that communication mechanisms are effective (the CDC requires testing of communication systems, which must comply with a certain percentage of capability in order to receive funding). However, assessment using performance measures of communication preparedness is difficult.
- **Feasibility.** Standards need to be developed that are doable at the local level.
- **Planning, training, and exercise.** Evaluating progress toward preparedness and response requires planning, training, and exercise, and each of these components requires an evaluation as well. Emergency Preparedness Plans should closely follow ordinary procedures. Personnel, especially local doctors, should train on the emergency plan daily; emergency procedures should be routine knowledge.

### ***Point-of-Dispensing Exercises***

A critical feature of state and local preparedness is the ability to rapidly dispense medical countermeasures to their entire population, often using Points of Distribution (POD) models. Comparing the number of PODs to the population served may allow an initial assessment of the readiness to carry out mass prophylactic campaigns, for example. Exercises can provide measures of what is expected. However, exercises do not inherently measure performance and can be resource-intensive.



The CDC supports states and localities with POD planning and helps coordinate the exercises. However, because the CDC lacks the resources to carry out and fully evaluate all POD exercises across the nation, jurisdictions may benefit from working together on exercises to support each other. The CDC's DSNS conducts throughput modeling based upon a number of elements in PODs. **Throughput** on an individual POD can thus be obtained, and then **evaluation** is conducted to see if the jurisdiction is on track to achieve prophylaxis for that area.

### Advantages, Disadvantages, and Evidence in Preparedness Measuring

Participants identified the following practices as beneficial to implementing and evaluating preparedness plans:

- Spread out the responsibility for evaluating plans. By charging the states with the evaluation of local plans, the Federal Government could concentrate on the evaluation of state plans.
- Ensure proper organization and sufficient assets. Written plans are just one step towards preparedness.
- Conduct proper training followed by drills and exercises.
- Determine consistent nationwide standards of performance. However, it will be difficult to set these standards because each state and each locality is different.
- Evaluate the various aspects of preparedness plans separately.

Use of an emergency response organizational plan should not be extraordinary but a daily practice that familiarizes people with what to expect and do in an emergency.

- **Written plan:** Its main advantage is that it describes

how to play this out and identifies who is responsible for different parts of the plan.

- **Performance measures:** The performance measures are better than a written plan at identifying whether the plan will be executed. You need the ability to get people to perform according to the plan and to take corrective actions if a problem arises. Are you organized correctly? Have you trained people as to the rules and what is to happen?
- **Drills and exercises:** They allow corrective actions to be taken to improve your plan and cover the gaps you want covered. The more you can exercise the plan, the better you can see how it will function.

When asked whether effective preparedness is shaped at least in part by nationwide, uniform measures and standards, participants noted HHS and DHS standards delineating the time frame for delivery and dispensing of anthrax countermeasures. In discussing the types of evidence and data on which to base preparedness standards, participants noted that prior to 2003 no standard was in place governing the time frame for delivery of antibiotics in response to a terrorism event. The anthrax scare prompted development of a standard for the administration of antibiotics to infected individuals. The post-2003 standard for anthrax is a prophylactic agent dispensed within 48 hours to an entire population. The countermeasure must be received by the locality within 12 hours of notification of the event to ensure the locality has at least 36 hours to distribute and dispense it.

In the group's view, HHS and DHS must formulate standards with an understanding of the environmental constraints (i.e., what is achievable at the local level) and of the fact that these constraints vary by state and locality. Standards and best practices should not be arbitrary nor indiscriminately applied from one instance (e.g., countermeasure, locality, population) to another. Participants called for the development of standards specific to a range of threat agents. Standards as to the speed with which messages are communicated and disseminated are also needed.

### Distribution Accountability And The National Public Health Performance Standards

Despite acknowledging the formidable challenges, participants agreed that the National Public Health Performance Standards should be modeled after the exemplary effort of the Joint Accreditation for Hospitals to develop standards for hospitals across the United States. Current credentialing standards of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) now cover hospitals of all sizes, in all geographic areas, and with varied responsi-

bilities. A JCAHO-like standard for public health emergency preparedness could be developed for countermeasure distribution.

Participants distinguished between two types of standards: standards representing ideal levels of performance (i.e. “goals”) and standards representing minimum acceptable levels of performance. Standards development should be led by the Federal Government, in conjunction with entities at the state and local levels and with contributions from the private sector varying by location.

Accountability for distribution of medical countermeasures is the principal determinant in – and in some ways can be considered synonymous with – accountability for emergency medical response. Assuring the distribution capability and readiness-to-respond of all jurisdictions down to the local levels is of cardinal importance.

An important early step in determining appropriate emergency performance standards is to build an infrastructure for daily public health preparedness and response. The essential elements of this infrastructure are already in place. Key personnel understand their roles and accompanying expectations. Laboratory capabilities, computer capabilities, and distribution mechanisms have also been established in many cases. Before standards for emergency preparedness can be developed, everyone needs to be ready for performing during non-emergency periods at a consistent level across all states. Once the basic response infrastructure has been built, stakeholders should leverage all their intellectual resources / capital to formulate a strategic vision for how the infrastructure behaves in an emergency. Tactically, minimum standards for countermeasure distribution could be developed to enforce the strategies and objectives.

### Tracking Distribution in Real Time

While an existing mechanism tracks distribution and delivery down to general areas, no efficient method is currently available for tracking medical countermeasure distribution and dispensing all the way from storage to the end-user in real or close-to-real time. A system to do so would be helpful in determining where a medical countermeasure is needed during a public health emergency. However, the cost of such a system would need to be weighed against the benefit. Also, a standard that does not result in unacceptable delay or complication of the ultimate goal of response should be developed for tracking patient information.

States are increasingly using third-party logistics systems to track distribution and delivery. Pharmaceutical and medical supplies are potentially available throughout the supply chain. The aim is to direct states to an appropriate

point of supply, exemplified by a tracking system utilized by the city of Denver.

**Comprehensiveness.** The current logistics system allows the CDC to track product only to a certain level in the delivery process, at which point the state assumes responsibility. Depending on how a state’s distribution modes are set up, final provision to the end-user (patient) could be three or four levels beyond that of the CDC’s routine tracking.

**Standards.** Some participants suggested that identification of any existing standards for tracking medical countermeasure distribution might be helpful, as well as determining whether these standards already discriminate between types of medical countermeasures.



In the development of standards for tracking distribution of medical countermeasures, participants considered how far down the chain the tracking should be required to go. A tracking system like the ones used by drug companies to counteract drug counterfeiting could foster companies’ corporate responsibility for their products. A comment was made that such a system is currently in the works at FDA, and that FDA could make an effective partner in the effort to implement or adapt standards for tracking distribution. Additionally, FDA has different requirements for tracking use, and the results of use, of different types of products (e.g., products used under an Investigational New Drug Application [IND] versus products used under a New Drug Application [NDA]). Widely used products approved for the given indication (e.g., Ciprofloxacin) might require simpler tracking at the state level than products not yet fully approved for the indication.

Participants asked if BARDA was intending to implement such a tracking system for the products it acquires, or was working on standards for pharmaceutical manufacturers to follow independently.

**Efficiency and Effectiveness.** An electronic tracking system would be far more efficient than a paper tracking system, and could facilitate states’ abilities to collect and

provide information. A real-time electronic data tracking system would circumvent the time-consuming aspects of recording data on paper (i.e., entering it into a spreadsheet, collating, shipping, and faxing it). Retailers use electronic tracking systems to track products anywhere in the supply chain, which allows rapid identification and solution of problems. Such practices applied in an emergency situation could enhance timeliness and effectiveness of responses.

**Obstacles and Liabilities.** Electronic tracking capability is very costly, potentially prohibitively so for government agencies. Moreover, tracking down to the patient level may not be feasible during an emergency without unacceptably compromising efficiency of the response. Stakeholders must take care not to bog down the system in information collection requirements. During a public health emergency, the priority must be effective dispensing of the needed medical countermeasures. Once the emergency ends data collection and other issues regain importance. Information collection requirements that compete with public emergency response needs are not likely to be met. If states are required to fill out a 12-page questionnaire for everyone, the questionnaire will sit in a drawer and no one will fill it out. A system, to be viable, would need to enhance rather than impede response.

## SUCCESSSES AND CHALLENGES

### *CDC Division of the Strategic National Stockpile (DSNS)*

The DSNS is working well in that it conducts exercises and rapidly adapts to the results of the exercises. The DSNS is a dynamic model of good leadership. The DSNS is very well organized in the way that it works with the states. Through the efforts and leadership of the DSNS, the states are better prepared and know better what is expected of them. DSNS has done a good job of adapting to changing circumstances effectively and has shown a great deal of improvement in responding to local, regional, and state concerns.

### *Delivery & Distribution*

In an effort to improve the efficiency of the delivery and distribution system, participants recommended the following:

- Minimum standards for the delivery, distribution, and dispensing of medical countermeasures, including specific standards that require performance measures
  - Nationally standardized systems, to reduce the burden on states and localities
  - Raising state and local jurisdictions' capabilities for

dealing with the assets from the Strategic National Stockpile, to a minimum standard level

- A Best Practices document through which DSNS could share lessons learned and provide illustrative examples of both effective and failed approaches to preparedness among the states – a Best Practices document would facilitate standardization by helping raise all states to an acceptable level of preparedness.
- Improvements in communication and collaboration between the public and the private sectors, to include dissemination of standards – to foster greater stakeholder familiarity with diverse roles and expectations
- Federal collection of more information at the local and individual level, with greater evaluation of local capabilities for distribution and delivery
- Increase in private sector involvement to reduce the government's burden of distributing and delivering countermeasures – the private sector is already contributing a great deal towards efforts relating to performance evaluation and countermeasure distribution.
  - An example organization is the Business Executives for National Security program (BENS), which strives to help close gaps in Homeland Security by designing and facilitating public/private partnerships to fill those security gaps that cannot be addressed by either government or business working independently.
- Federal Government participation:
  - U.S. Government should demonstrate awareness of private industry work in the area of preparedness.
  - The U.S. Government should coordinate efforts among Federal agencies so efforts are not duplicated.
- Collaboration, which is vital to resolving issues in distribution and utilization, and a holistic view of the entire supply chain for medical countermeasures must be fostered.



## BREAKOUT SESSION B:

### Community Preparedness for All-Hazards Response: Challenges for Planning

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#### Successes And Challenges in Coordination of Distribution and Dispensing

Participants extolled the general excellence of the Strategic National Stockpile distribution plans, which they deemed well thought out at the federal, state, and local levels, specifically Plan 9 through the National Association of County and City Health Officials. While relationships across local, state, and federal levels have improved, relationships with territories and tribal nations have more room for growth. Local and tribal authorities are vital because they understand the needs of their people and will be directly involved in emergency response.

Participants agreed that incentives are needed to improve communication between hospitals and local organizations and to encourage timely and substantive feedback from local organization members. Participants also noted the disconnect between the primarily prevention-focused public health organizations and some healthcare organizations, which are focused on treatment.

Critical resources of the private sector, including individuals, families, and apartment building communities with coordinated nongovernmental disaster response units should be included in planning.

#### Personal Preparedness

Participants discussed the need for businesses, individuals, and families to be involved in community and personal preparedness planning from the beginning. The multi-family housing (e.g., high-rise apartment buildings) sector should take advantage of shelter-in-place opportunities, for example by having a designated point of dispensing (POD) located in the building. Promoting personal preparedness relieves the burden on public health organizations and capabilities during an event and enables immediate implementation of proper response. Community and personal preparedness efforts are challenged however by the need to account for individualities; to deal with special-needs or at-risk populations; to ensure appropriate use of medications; to monitor expiration dates; to distribute equitably and ethically to populations of greater need. Participants suggested that a program of research should be implemented addressing home stockpiling with more vulnerable populations.

#### Balancing Considerations of Probability and Consequences

A medical countermeasure preparation model balancing likely lower-consequence events with unlikely catastrophic events should be locally tailored to the imaginable and predictable liabilities of each locale. Participants recommended addressing both types of events at the same time whenever possible. State, local, and tribal authorities should try to build in dual-use capacity so they can ramp up when they need to without delays or complications. However, only authorities at the federal level have easy access to the information they need to assess the risk of catastrophic events (i.e., biological, chemical, and radiological/nuclear terrorist events). At present, the provision of access to this information for state health directors is being considered.

#### Including Vulnerable Populations – Best Practices

Both New York City and Los Angeles County have planned for possible radiological attack, including the identification of vulnerable populations to receive medications preferentially over others (e.g., children and pregnant women) in the event of a shortage. In addition, Montgomery County, Maryland; Seattle King County, Washington; Cambridge, Massachusetts; and DeKalb County, Georgia, have all focused on vulnerable populations and on developing best practices for these communities in their planning efforts. In some states' influenza plans preference is given to first responders, healthcare providers, and those populations most vulnerable to the flu.

#### Challenges in Community Preparedness

Participants did not identify specific aspects of community preparedness that they determined were being well-conducted, but rather focused on these areas needing improvement or establishment:

- Improve communication, including Web-based modalities
- Establish a central portal for information on preparedness
- Disseminate and share preparedness knowledge and resources with communities that are too small to send representatives to preparedness conferences
- Increase funding for all community preparedness programs
- Increase the number of ASPR grants for healthcare organizations

## BREAKOUT SESSION C:

### Building and Sustaining Medical Countermeasure Industries for CBRN Threats and Pandemic Influenza

The three overarching questions of the breakout session were these:

- How do we develop the markets for CBRN and influenza (the manmade and the natural threats)?
- How do we bring to market the products that will protect the population (private-public partnership)?
- How do we continue transparency in the process so that everyone across the industry is “on the same page”?

#### Market Opportunity and Effects of Prioritizations

Facilitating emergency medical countermeasure product development requires that the PHEMCE enhance transparency to provide potential business partners the information they need to do business effectively. Such information would include an early public issuance of requirements and of the size and time frame of potential procurements, clear and coordinated priorities, product definitions and technology profiles desired, and quantification of market opportunities. All this information would help industry forecast (e.g., project annual sales) and strategize. This information, supported by a demonstration of the market viability for a medical countermeasure the government is seeking, is critical to securing the involvement of companies that rely on private investment. An updated strategic plan should seek to provide this information to industry.

Participants sought clarification and transparency on a range of associated issues:

- **Threat priorities:** A coordinated and comprehensive list of threat priorities would be helpful within HHS and across Federal interagency partners including the Department of Homeland Security (DHS) and the Department of Defense (DoD).
- Some participants suggested a broader distribution of emphasis across threats, which was seen as focused on a small subset of threats (i.e., anthrax, smallpox, flu) at the expense of others (i.e., other bioterrorism agents, recombinant organisms).
  - Participants would like articulation of priorities among pathogens in developing a plan for broad-spectrum therapeutics.
  - Participants were not aware of processes to keep current the categorized list of organisms and disease agents – categories A, B, C, as classified by the CDC. Keeping the categorization current might afford insight into potential risks and benefits associated with projects addressing the agents. The idea was raised of ranking all organisms sequentially by threat instead of by categories.
- **Countermeasure development opportunities, priorities, and requirements:** Participants would like more information about financing opportunities, PHEMCE priorities (and changes in them), and details of desired product characteristics (which impact drug development). To some participants, information from PHEMCE has come to lack credibility.
  - Participants noted a difference in priorities for orphan products with limited applications and those with wider, more general applicability.
  - Clearer and more specific statements from PHEMCE of its priorities among threats and countermeasures would support product-development strategy, affording companies and their potential investors greater assurance that a product will meet these requirements in a potentially volatile mission space. A certification by PHEMCE that a product development effort represents progress toward meeting the requirements (increasing the likelihood of a procurement contract) would encourage private investment in companies, which need operating funds as well as development grants. Clarity on requirements for important “second-tier” countermeasures would also be helpful.
  - Clear, early funding projections and purchase quantity forecasts, with time frames provided, would allow a clear understanding of the market opportunity for industry and venture investors (as opposed to the risky “If you build it, they will come” model of development).
  - Small companies often do not have the expertise to effectively and efficiently identify contract and funding opportunities scattered across multiple Federal agencies. During product development this lack of expertise also translates into difficulties navigating the maze of contract/procurement and regulatory requirements. Participants suggested that streamlining processes would liberate company resources for the benefit of product development, especially that of small companies

disproportionately affected by the resource burden. Potential remedies cited include

- ◆ a consolidated listing and/or a search engine capable of targeted searches across all agencies that support work in the field;
  - ◆ a clearer, operationally defined scope of the work to be conducted under a contract;
  - ◆ a flexible statement of work (SOW) to allow product development to adjust to the science and address the difficulty in coordinating between the research and contracting functions of government;
  - ◆ transparent capacity within the contract to deal with contingencies that might arise during product development, as contrasted with established products for which fixed-price contracts are acceptable;
  - ◆ enhance the standardization and consistency across agencies of nomenclature, standards, assays, and evaluation criteria;
  - ◆ enhance coordination and integration of the end-to-end process (from basic research through final product development), often funded by different agencies at various phases, to provide more continuity in the pipeline and a better sense of where a company's candidate stands in it (participants noted that the draft BARDA Strategic Plan is a step in the right direction);
  - ◆ indicate an acceptable unit cost for an end product and an estimate of an agency's investment toward that end so that companies are less likely to waste resources on approaches they cannot afford;
  - ◆ increase responsiveness to questions posed for clarification, although participants noted that increasing responsiveness to some questions is complicated in the CBRN environment by variability in the nature and sizes of the threats.
- Government research grants—e.g., from the NIH's National Institute of Allergy and Infectious Diseases (NIAID)—may advance science, but they don't always match what the investors are looking for; hence, they do not build momentum for the next stage of development. If a company has an advanced development contract with a PHEMCE agency, it will have established milestones as part of that contract, and the Government will agree to



and enforce those milestones. Meeting the milestones provides proof of progress. Similar mechanisms would be desirable for an earlier stage of development or for those products on a different development path—for example, a drug that already has U.S. Food and Drug Administration (FDA) approval for a different indication.

- Unsolicited grant proposals can elicit government support of product development. Companies working on promising countermeasures that do not match the agency's currently advertised priorities can submit proposals for grants outside a particular RFP or program announcement. Such grants can also be used to generate the efficacy data that are required for a pre-EUA application. Participants felt a BARDA-sponsored workshop on how to write and submit unsolicited grant proposals would be useful.
- **Contracting:** Participants suggested BARDA use processes other than the Federal Acquisition Regulation (FAR) for contracting for medical countermeasure development. The DoD, for example, uses a white paper submission process. The short pre-proposal makes it easier to know if a full proposal is warranted and facilitates federal comparisons of what is in development, to help reduce uncertainty and minimize an offeror's sunk costs early in the process before a contract is assured. Participants suggested that BARDA use the flexible DARPA model for research and development that involves flexible Statements of Work (SOWs), to accommodate effectively the evolving nature of the underlying scientific knowledge and processes. Participants raised the question of whether products with markets in addition to those for emergency medical use (e.g., influenza and respiratory care products) should be handled differently.

- **Stockpiling and distribution:** Participants discussed potential alternatives to centralized stockpiling as part of the Strategic National Stockpile, specifically the feasibility of facilitating market distribution directly to consumers through local pharmacies.
  - Participants expressed interest in alternative methods of distributing products, such as via a facilitative process or a cost-match process (see [www.sbir.dhs.gov/CostMatchInfo.aspx#22](http://www.sbir.dhs.gov/CostMatchInfo.aspx#22) for information about cost match). However, some participants expressed concern about the cost-match process.
- The perception that BARDA has moved too slowly on procurement was attributed to a lack of clarity on regulatory issues.
- Participants saw a need for an increased number of testing facilities, high-level biosafety labs, or Contract Research Organization (CRO) facilities for the required testing to support product development.
- Countries around the world should consolidate their product requirements and create a development plan and animal models for the effects of the various pathogens. Initial model development should be driven by market priorities.
- The efforts of the ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) should be supported toward equivalence of regulatory requirements, with particular consideration of Phase 1 safety issues. Small companies that have trouble learning and complying with FDA requirements and procedures cannot benefit from the potential of international sales if each new market involves a whole new set of requirements and procedures.

## REGULATORY RISK REDUCTION

Participants identified the following as areas in need of development or improvement:

- The U.S. Government should develop an effective partnership with industry. The Food and Drug Administration (FDA) should clarify its role and the issues surrounding animal model use and its expectations for the “animal rule.” Greater consistency and constructive interactions with the FDA regarding animal model issues are desirable. Participants inquired whether BARDA could facilitate a unified, consistent view of the FDA rule structure regarding animal models and demonstration of safety and efficacy. A central or coordinated resource listing viable animal models and their use for addressing the priority threats would be helpful, with an indication of therapeutic standards to be achieved. A unified understanding of regulatory risk would be desirable.
- Participants expressed a need for clear guidance from the FDA on the information needed for a pre-Emergency Use Authorization (EUA) package, as well as guidance on how to build an adequate data set for moving forward towards licensure or approval, including consistent guidance from CBER (Center for Biologics Evaluation and Research) and CDER (Center for Drug Evaluation and Research).
  - The FDA issued guidance in 2007 on EUAs, which permit “the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency involving a heightened risk of attack on the public or U.S. military forces, or a significant potential to affect national security.” Interested companies should contact the FDA to learn more about eligibility and supporting data for consideration of an EUA.

Participants acknowledged that obtaining clear and consistent guidance from the FDA on the use of animal models, while of crucial importance, is complicated by an increased emphasis on safety in response to public and Congressional concerns and by the fact that assessment of the predictive validity of the animal models is difficult in the absence of human trials – which are not ethically possible in the CBRN arena.

Participants advised candidates for an unsolicited grant proposal or for pre-EUA packages to maintain regular contact with the FDA, as is the advisable practice for investigational new drugs (INDs). Communication between the FDA and the company must be clear and ongoing, and assumptions should be set aside in favor of active efforts to clarify expectations and answer questions. Participants noted that FDA often prefers to respond to such questions rather than define standards a priori.

Participants identified conditions necessary to facilitate comparisons between competing products during development:

- Harmonization of animal models to determine which model is most appropriate for answering specific questions
- Appropriate experimental challenges in animal models and markers for correlates of protection

## Bottlenecks for Medical Countermeasure Testing, Production, and Delivery

Participants identified a range of conditions that pose obstacles to effective product development as well as bottlenecks detrimental to growing capacity:

- **Funding and funding processes**
  - Government funding has not been reliable and consistent. The separation into isolated single opportunities without associated follow-on funding leading smoothly from advanced development through procurement has tended to result in companies focusing on one particular product and having to cover gaps in government support with private funds or else lose continuity in development.
  - Continuity in funding could be enhanced through R01 grants and by lengthening advance funding.
  - A more open process for accepting proposals would facilitate participation. Participants recommended smaller scale grants (“mini-grants”) for pilot work in cases where the research yields proof of concepts.
  - Inconsistencies between pre-solicitation announcements and the subsequent associated Requests for Proposals (RFPs) result in costs to applicants that could be avoided.
  - Some participants felt that the RFP processes managed by NIH and by CDC are often too slow; BARDA’s has been better. Participants recommended an electronic submission process in all cases.
  - Review panels for funding proposals lack reviewers with industry expertise; the reviews tend to be too academic.
  - A focus on return on investment (ROI) can be problematic early in development.
  - Deliverability should be an important aspect of product selection and procurement considerations. The most efficacious intervention may not be preferable due to logistical difficulties in delivering it in a timely manner to a large number of persons.
- **Regulatory requirements and animal models**
  - Definition of animal models appropriate for testing under the FDA “Animal Rule” is important.
  - Animal models should be shared and, where possible, standardized; they should not be proprietary.
- The requirement for multiple animal models (species) can be burdensome, especially where funding is limited.
- Standardization of regulatory requirements in the international arena is important.
- Quickly identifying the appropriate Government office to contact for guidance or information regarding development of specific types of products (e.g., orally available small molecules or fragile proteins) at various points in the development process—from basic research to advanced development—is particularly important for startup companies; a solution may be as simple as a specialized search engine geared to those opportunities.
- **Testing and manufacturing capabilities**
  - Current biosafety level (BSL) 3 and 4 capacity for testing may become limiting; additional capacity and/or better management of the existing capacity could be required to avoid this limitation. A centralized service could help offset the substantial expense of this aspect of product development.
  - Greater availability of facilities for testing under Good Laboratory Practices (GLP) would be helpful, as would increased GLP training. Building additional BSL test facilities is not helpful in the absence of provisions for GLP training.
  - Nonhuman primates likely will be an integral part of most product testing; the long lead time and expense in developing sufficient quantities of animals is a potential bottleneck that may require a “triage” process to determine which candidates have priority in the available testing capacity; more capacity might be warranted.
  - Startup companies that have no approved products generating cash flow face a greater burden in establishing safety, efficacy, and manufacturing capacity for the new medical countermeasures they develop. The National Institutes of Health’s National Institute of Allergy and Infectious Diseases (NIH/NIAID) provides many of these services through contractors at the website labeled “Resources for Scientists.”
- **Market considerations**
  - Conflicts in requirements and procedures in overlapping jurisdictions (e.g., pandemic influenza) can result in delivery bottlenecks. At a minimum, investigators need to know whom to talk to in each agency; a better solution would be for the agen-

cies to convene, in advance of an emergency, to identify and minimize any conflicts.

- Uncertainty in market demand (anticipated funding and purchases) impedes efforts to secure manufacturing for small companies. Participants acknowledged that the medical countermeasure industry overall, however, appears to have ample manufacturing capacity.
- Products often are developed in isolation, without a clear sense as to alternative approaches also under development and with little consideration of the likely unit cost of competing products. A more complete and transparent awareness of all related products and their projected cost-benefit within the context of a strategic plan will help companies direct their individual efforts within the broader context.
- **Intellectual property**
  - The use rights and march-in rights retained by the Government for products discovered and developed with Federal funds act as a disincentive to industry – despite the fact the Government has never acted on these rights in the past and the Government does not anticipate that it will do so in the future.
  - The Government should issue a policy statement clarifying that the company that developed a countermeasure has the right of first refusal to manufacture and market it.
- **Representation at the 2008 PHEMCE Stakeholders Workshop and BARDA Industry Day**
  - Participants discussed the lack of representation at the Workshop of agencies with relevant expertise.
    - The absence of the U.S. Department of Agriculture (USDA) was noted, given the terrorist potential for chemical and biological contamination of the food supply and the USDA's regulatory role with regard to transgenic plants and animals that may be developed as “factories” for interventions.
    - The U.S. Department of Energy was also absent, although it has extensive expertise on radiation issues.
    - The transportation sector was also not represented, which has roles in the prevention of terrorist attacks and in emergency response.

## **PHEMCE Roles in Partnership Building**

Participants expressed the view that BARDA should expand its leadership role and facilitate product development through matchmaking, mentoring, and motivation (incentives). Through an approved vendor list, an interested partner list, and an international partnership conference, BARDA could help companies identify strategic partners with whom to share product knowledge or technology, make introductions to other small organizations/companies and ultimately minimize unnecessary competition, especially for nonprofit institutions. BARDA could provide companies with a road map for navigating the U.S. Government and contracting procedures, including a mentorship program in which a large corporation or university would serve as a role model for smaller companies for which regulatory challenges present a more daunting challenge.

As part of an effort to incentivize the for-profit industry, the PHEMCE could take the following measures:

- Expedite funding so Congress sees that the funds are needed / used.
- Expand funding for university Centers of Excellence in related fields.
- Establish a Center of Excellence in countermeasure development that would address advanced development needs (i.e., animal testing, validation of reagents, pilot-lot manufacturing).
- Identify and promote potential non-CBRN commercial markets and spin-offs for technologies and interventions developed with bioterrorism funding as a cross-subsidy and incentive.
- Leverage discretionary account funds to facilitate private-public partnerships.
- Afford academic and corporate investigators the opportunity to make their voices heard and understand the conditions that drive the formulation of Government requirements and prioritization.
- Arrange for legal guidance regarding collaboration to mitigate antitrust considerations that provide a disincentive for companies to share data and establish common standards of evaluation for candidate interventions. The guidance would include outlining the role that Government, professional, and/or trade associations might play in finessing legal impediments to greater collaboration.
- Provide information on or access to GLP, training, and testing capabilities, to facilitate participation of industry partners that need such assistance.

Partnerships within industry and between industry and Government were not the only type of partnerships promoted by participants. Citing the large scope of Government agencies that should be involved with these issues, participants underscored the importance of PHEMCE initiatives in building broader partnerships within Government agencies. Participants also identified the Biotechnology Industry Organization (BIO) as having a leading role on behalf of the industry sector.

## Successes and Challenges

Participants identified several general areas that were working well, including

- strong communication within the community;
- greater enthusiasm and resistance to bureaucracy;
- PHEMCE's openness to stakeholder input;
- a Stakeholders Workshop more productive than its 2007 predecessor;
- improved coordination between BARDA and NIH;
- a clearer vision of advanced development versus procurement;
- the willingness of BARDA to engage industry;
- recent policy changes, notably
  - the establishment of BARDA and Project Bio-Shield;
  - efforts to promote foreign sales of medical countermeasures;
  - movement of the countermeasure development and procurement process closer to the commercial model.

Additional challenges and successes were identified in the following areas:

- **PHEMCE Stakeholders Workshop and BARDA Industry Day**
  - Participants were pleased with the conference, particularly the practical training sessions. They consequently recommend the conference be extended by a day and scheduled more frequently than once a year, with special emphasis on discussion-facilitated workshops and breakout sessions.
  - Participants want to minimize "double-booking" at the Stakeholders Workshop, reduce the number of instances in which attendees were forced to choose between potentially helpful sessions running concurrently, and hold the breakout discussions earlier in the agenda, when more attendees and stakeholders are still present at the conference.

## ● Regulatory and Contracting

- Citing its role in anthrax issues and the advantages of its proposal model, specifically the 25-page, quad chart pre-proposal, participants expressed an interest in including DoD more prominently in the PHEMCE process.
- Participants want other biodefense agencies to model their procedures after the DoD to accelerate feedback and minimize wasteful expenditures of time and effort.
- Participants favor milestones and cost-plus over fixed-price contracts and favor the NIH practice of issuing RFPs for advanced development on a cycle to minimize political and budgetary influence on the equation.
- While grants were recognized as appropriate for early stage work (NIH), participants favored a more product-oriented, profit-related mechanism for transformational work to licensure and production.

## ● Outreach and Marketing Considerations

- Participants reported that PHEMCE needs to do a better job of outreach and envisioned a new Web portal presenting clear information on programs, procedures, priorities, and potential partners. The Division of Microbiology and Infectious Diseases at NIAID was cited as a model for this kind of systematic information.
- Participants recommend an effort to work toward a more comprehensive definition of global markets. Bringing international players into the discussion (e.g., collaboration between foreign governments and U.S. companies) can open potential markets and spread development costs.
- Participants expressed a need for a mentorship program to help small companies move through the discovery process.

## ● Funding

- Participants acknowledged that present budgetary constraints, specifically a significant shortfall in funding of BARDA, may be limiting efforts to "bring science to BioShield." The impact of this shortfall was outlined in a mid-September article in *Nature Biotechnology*.
- Participants would urge investigators who need help in getting the attention of Government agencies, or who want to express their support for the budgets of those agencies, to contact their congressional delegations.

## BREAKOUT SESSION D:

### Novel Medical Countermeasure Forward Deployment and Dispensing Models: Opportunities and Challenges



#### Challenges of Current Dispensing Programs

Participants identified the basic challenges to the planning and implementation of an emergency response and emphasized the multiplicity of potential solutions. Once the attack location and threat (e.g., anthrax) have been identified, buy-in from various municipal authorities (e.g., police) is obtained, the supply chain is activated, and logistical concerns including the following need to be addressed:

- traffic patterns & traffic control
- mass confusion & crowd control
- readiness and positioning of antibiotics
- safeguarding the postal service employees delivering medications
- a follow-up treatment regimen

The time/distance/physics challenge of quick dispensing has been historically underestimated; therefore, integrating community search capacity with the dispensing of the medications is critical. The quicker responders can detect, decide, distribute, and dispense, the better.

Creating political will (i.e., “this is a real threat and there’s a need to do this”) was also identified as a challenge.

#### Incentives to Stimulate Innovative Partnerships

Participants identified types of incentives to entice private-sector companies to enter into innovative partnerships with Government agencies to develop novel dispensing models:

- funding
- expedited review processes
- international cooperation (providing companies with a guarantee of a worldwide/global market)
- liability protection
- offering grants to non-traditional players
- assuring vaccinations for employees and families of manufacturers
- facilitating partnerships with potential organizations that have experience in moving large numbers of people (e.g., Disney)

Having funding in place at initiation and milestone payments for reimbursement were deemed vital to motivate companies to meet the challenge of redirecting or adapting items with daily utility for use in a disaster situation (i.e., dual-use assets).

#### Benefits and Challenges in “Push” and “Pull” Delivery Approaches

While participants cited no challenges associated with pull mechanisms, push mechanisms were deemed more advantageous with respect to targeting distribution and reaching poor and immigrant communities. Leveraging the trust of communities for charities and social entities is useful in situations where undocumented immigrants might not want to approach government buildings, police stations, fire stations, or post offices. Pull mechanisms were deemed more beneficial with respect to central location, security and accountability, and the potential for clinical screening. Furthermore, push mechanisms are challenged by the lack of precision in short time frames, perceived social inequity, and the need to assemble a labor pool.

Participants cautioned against viewing these high-level classifications for countermeasure delivery as an exclusive



either/or choice. Guided by an understanding of the benefits and challenges, communities are advised to develop a toolbox of robust push and pull mechanisms and a plan for best practices implementation.

### **Social Equity Issues in Pre-Positioning or Dispensing**

Participants recommended a Medkit tax voucher as a possible solution to medical access concerns, and a single consistent message in accessible languages to avoid misinformation.

The wealthier or employed are better served when receiving medical countermeasures through an employer rather than the civil health authorities (i.e., prepositioning), but participants noted the challenge of reaching the unemployed under this scenario. Participants noted that the population(s) designated to receive preferential delivery varies by threat and that under any scenario public perception and discontentment may present a challenge. For example, limiting medication in a survival scenario could be perceived as unfair and cause confusion or civil unrest.

Delivering treatment to the homebound and homeless was also identified as a challenge.

### **Far-Forward Deployment and Personal Stockpiles**

Home stockpiling or exposure testing, recommended by participants, would require training and education.

Participants raised concerns about the disease-agent specificity of the deployed countermeasure, the use of products in ways not intended, expiration dates, disposal and replacement of expired material, compliance with

state laws, and the loss of protective equipment. Given that individuals traditionally expect the Federal or local governments to take care of them, participants expressed the need for an incentive to assume personal initiative for preparedness. Opportunity to target prepositioned assets should be considered (e.g., Orange County, which is within a 10-mile radius of a nuclear reactor, has potassium iodide [KI] available to residents living in that zone).

### **Successes and Challenges**

As examples of forward deployment or dispensing models that are currently working well, participants identified the deployment of KI tablets to people near nuclear power plants, locally purchased antibiotics for first responders pre-positioned at their local agencies, and a German law requiring pharmacies and hospitals to keep supplies of all medications in quantities sufficient for a certain period of time.

Participants identified the following needs:

- Tools to determine who should receive therapeutics in mass-casualty scenarios
- Auto-injectors
- Improved CHEMPACKs for children including child-friendly anti-seizure medications
- The “virtual SNS” (substantial supplies at hospitals or other local institutions); could include cytokines for nuclear events
- Expanded list of critical medications for pre-positioning
- Expanded list of critical meds (e.g., radiological medications) that need to be prepositioned and forward placed in CHEMPACKS or similar packages



Participants disagreed over the need to improve the availability of antibiotic caches for family members of first responders. They acknowledged that putting critical medications in the homes of the first responders’ family members will help keep first responders on the job.

# APPENDIX 1

## ATTENDANCE

A list of participants is available at the Stakeholders Workshop Web site ([www.hhs.gov/aspr/barda/phemce/workshop/2008/2008workshop](http://www.hhs.gov/aspr/barda/phemce/workshop/2008/2008workshop)).

### Summary

Stakeholder Group	Number of attendees
Industry.....	282
Federal Government.....	163
Academia.....	35
International Government.....	33
State/Local/Tribal/Territorial Government.....	28
Healthcare Provider/First Responder.....	19
General Public.....	4
Media.....	2
<b>Total .....</b>	<b>566</b>

## ORGANIZATIONS AND AGENCIES 2008

3-V Biosciences  
 Accuthera, Inc.  
 Achaogen, Inc.  
 ACS Federal Solutions  
 Adamas Pharmaceuticals, Inc.  
 Advanced Life Sciences  
 Akorn  
 Alliance for Biosecurity  
 AlphaVax, Inc.  
 America Association for the Advancement of Science  
 American Association on Health and Disability  
 American College of Radiology  
 American Medical Association  
 American Red Cross  
 American Samoa Department of Health  
 American Trucking Associations  
 American Type Culture Collection (ATCC)  
 ANSER, Inc.  
 Arizona State University Biodesign Institute  
 Association of Public Health Laboratories  
 Association of State and Territorial Health Offices (ASTHO)  
 Assurance Oncology Services, LLC  
 Aton Pharma, Inc.  
 Auburn Health Strategies, LLC  
 Avila Therapeutics, Inc.  
 Battelle  
 Bavarian Nordic, Inc.  
 Baxter Healthcare Corporation

Bayside Materials Technology  
 Beckman Coulter, Inc.  
 Biocad, Ltd.  
 Biokinetics, Inc.  
 BioProtection Systems Corporation  
 Biotechnology Industry Organization (BIO)  
 BioWorld Today/AHC Media, LLC  
 Blue Highway  
 Booz Allen Hamilton, Inc.  
 Boston (Massachusetts) Emergency Medical Services  
 Buchanan, Ingersoll, and Rooney  
 Cangene Corporation  
 Cenomed BioSciences, LLC  
 Center for Biosecurity of the University of Pittsburgh  
 Medical Center  
 Centreville (Virginia) Police Department  
 Cepheid  
 Chemo-Sero-Therapeutic Research Institute  
 Chester County Health Department  
 Children's National Medical Center  
 Cleveland BioLabs, Inc.  
 College of American Pathologists  
 Columbia University  
 Computer Sciences Corporation  
 Countervail Corporation  
 Cyto Pulse Sciences, Inc.  
 Dalrymple & Associates, LLC  
 Diane Schulte & Associates  
 District of Columbia, Department of Health  
 DynPort Vaccine Company LLC, a CSC Company  
 Elusys Therapeutics, Inc.  
 Emergent BioSolutions, Inc.  
 Emory University  
 Endacea, Inc.  
 European Commission  
 Evolva - Genetic Chemistry, Inc.  
 Exiqon, Inc.  
 Exponential Biotherapies, Inc.  
 E-Z-EM, Inc.  
 Fabiani and Company  
 Fairfax County (Virginia) Health Department  
 Fairfax County (Virginia) Police Department  
 Fastrack Consulting  
 First Light Biosciences  
 Foley Hoag, LLP  
 Four Seasons Ventures  
 Framework Therapeutics, LLC  
 Fraunhofer USA Center for Molecular Biotechnology  
 Fulcrum Corporation  
 Functional Genetics, Inc.  
 Gencarelli Group  
 Genetic Chemistry, Inc.  
 GenPhar, Inc.  
 George Mason University  
 George Washington University  
 Georgetown University  
 Georgia Institute of Technology

Government of Canada  
*Department of National Defence*  
*International Affairs Directorate, Health*  
*Centre for Security Science*

Government of Japan  
*Ministry of Health, Labour and Welfare, Office of Health*  
*Emergency Preparedness and Response*

Hackensack University Medical Center  
HCR Manor Care  
Hematech, Inc.  
Heyltech Corporation  
Hospira  
Human Genome Sciences, Inc.  
HX Diagnostics  
Hyman, Phelps & McNamara, P.C.  
Ichor Medical Systems  
iJET International  
Imigene, Inc.  
ImmuneRegen BioSciences, Inc.  
Implicit Bioscience  
Indiana University School of Medicine  
Infectious Diseases Society of America  
INOVA Health System  
Institute of Chemical Biology and Fundamental Medicine,  
Novosibirsk, Russia  
Institute of Medicine  
Integrated BioTherapeutics Inc. (IBT)  
Intercell USA, Inc.  
Interdisciplinary Solutions, LLC  
International Science and Technology Center (Moscow, Russia)  
Invitrogen Federal Systems  
Iomai Corporation  
Iowa Department of Public Health  
Johns Hopkins University  
*Applied Physics Laboratory*  
*Office of Critical Event Preparedness and Response*  
*School of Medicine*

K&L Gates, LLP  
Keio (Japan) University, Bio-Preparedness Research Laboratory  
Kimbell & Associates  
King & Spalding  
Kirov (Russian Federation) State Medical Academy  
L & Q International, Inc.  
Lentigen Corporation  
Linda Jenckes and Associates  
Los Angeles County (California) Department of Public  
Health  
Lovelace Respiratory Research Institute  
Luminex Corporation  
MacroGenics, Inc.  
Martin, Blanck & Associates  
MaxCyte, Inc.  
Maxygen, Inc.  
McKenna, Long & Aldridge, LLP  
Medical Conservation Devices, LLC  
MedImmune, Inc.  
Meso Scale Diagnostics, LLC

Midwest Research Institute  
Missouri Department of Health and Senior Services  
Moldex-Metric, Inc.  
Montgomery County (Maryland) Department of Health and  
Human Services  
Mystic Pharmaceuticals, Inc.  
Nanogen, Inc.  
Nanotherapeutics, Inc.  
Nashville and Davidson County (Tennessee) Metro Public Health  
Department  
National Academy of Sciences  
National Association of County and City Health Officials  
(NACCHO)  
National Heart & Lung Institute, Imperial College, London  
National Sheriffs Association  
Neumedicines, Inc.  
New Parkway Hospital  
New York City Department of Health and Mental Hygiene  
New York Medical College School of Public Health  
New York State Department of Health  
NexBio, Inc.  
NexGenisys  
Noblis  
North Carolina Department of Health  
Northrop Grumman Corporation  
Novartis Vaccines and Diagnostics  
Novavax, Inc.  
Oak Ridge National Laboratory  
Oncovir  
ORC Worldwide  
Ortho-McNeil Janssen Scientific Affairs, LLC  
Ortho-McNeil-Janssen Pharmaceuticals, Inc.  
P3S Corporation  
PanThera Biopharma, LLC  
Paul-Ehrlich-Institut  
Peregrine Pharmaceuticals, Inc.  
Pharmaceutical Product Development, Inc.  
PharmAthene, Inc.  
Planet Biotechnology, Inc.  
Promosome, LLC  
ProThera Biologics  
PRTM Management Consultants  
QuantaLife, Inc.  
Quintiles Public Health and Government Services  
Radeco, Inc.  
Radiation Detection Company, Inc.  
ReadyMoms Alliance  
République Française  
*Agence Française de Sécurité Sanitaire des Produits de Santé*  
*Commissariat à l'Energie Atomique (CEA)*  
*French Health Ministry, Health General Directorate, Public*  
*Health Emergencies Preparedness and Response*  
*French Institute for Radiological Protection and Nuclear*  
*Safety*

Robert Koch Institute, Federal Information Centre for Biological  
Safety, Germany  
Roswell Park Cancer Institute  
Russian Federation

*Research Institute of Influenza, St. Petersburg*  
*Saratov Scientific and Research Veterinary Station of the*  
*Russian Academy of Agricultural Sciences*  
*State Research Center for Applied Microbiology &*  
*Biotechnology, Obolensk*  
*State Research Center of Virology and Biotechnology*  
*State Research Institute of Highly Pure Biopreparations, St.*  
*Petersburg*

RxBio, Inc.  
SAFC (Division of Sigma-Aldrich, Inc.)  
SAJE Consulting, LLC  
Salix Pharmaceuticals  
Sanofi Pasteur  
Scientific Applications International Corporation (SAIC)  
Scripps Research Institute  
Secant Pharma, LLC  
SIGA Technologies, Inc.  
Sigma-Aldrich, Inc.  
Silva Consulting Services  
Sirnaomics, Inc.  
Skyline Integrated Technologies Enterprises  
Smart Transitions  
Southern Illinois University  
Southern Research Institute  
Spacelabs Healthcare, Inc.  
Spaltudaq Corporation  
St. Jude Children's Research Hospital  
Stabilitech, Ltd.  
StormBio, Inc.  
Summit Drug Development Services  
Sydion  
Syntiron LLC  
Tennessee Department of Health  
Thomson Reuters  
Trius Therapeutics, Inc.  
Troutman Sanders, LLP  
Tunnell Consulting  
United Kingdom Government  
*Defense Science and Technology Laboratory*  
*Department of Health*  
*Health Protection Agency*

United States Government  
Executive Office of the President  
*Homeland Security Council*  
*Office of Management and Budget*  
*Office of Science and Technology Policy*

Federal Trade Commission  
Library of Congress  
*Congressional Research Service*

National Oceanic and Atmospheric Administration  
U.S. Department of Defense  
*32 CST-WMD Response Team*  
*Armed Forces Radiobiology Research Institute (AFRRI)*  
*Center for Health Promotion and Preventive Medicine*  
*Chemical and Biological Defense and Chemical*  
*Demilitarization Programs*  
*Chemical Biological Medical Systems (CBMS)*  
*Computer-Based Medical Systems*

*Defense Threat Reduction Agency (DTRA)*  
*Joint Requirements Office, Joint Chiefs of Staff*  
*Joint Vaccine Acquisition Program (JVAP)*  
*Office of the Army Surgeon General*  
*Office of the Assistant Secretary of Defense*  
*Office of the Assistant Secretary of Defense for Health Affairs*  
*U.S. Air Force*  
*U.S. Army*

U.S. Department of Health and Human Services  
*Health Resources and Services Administration*  
*Centers for Disease Control and Prevention*  
*Centers for Medicare & Medicaid Services*  
*Food and Drug Administration*  
*National Institutes of Health*  
*Office of the Assistant Secretary for Preparedness and*  
*Response*  
*Office of the Inspector General*

U.S. Department of Homeland Security  
*Federal Protective Service*  
*Office of Health Affairs*  
*Science & Technology*  
*U.S. Coast Guard*

U.S. Department of Justice  
U.S. Department of Veterans Affairs  
U.S. Government Accountability Office  
U.S. House of Representatives  
*Office of Representative Anna Eshoo*

U.S. Senate  
*Office of Senator Richard Burr*

Unither Virology  
University of Alabama at Birmingham  
University of Colorado Denver  
University of Maryland  
*Baltimore County Medical School*  
*Center for International and Security Studies at Maryland*  
*School of Medicine*

University of Medicine and Dentistry of New Jersey; Robert Wood  
Johnson Medical School  
University of Newcastle Upon Tyne  
University of Texas at Austin  
University of Texas Health Science Center at San Antonio  
University of Texas Medical Branch, Galveston  
Valeant Pharmaceuticals International  
Vascular BioSciences  
VaxDesign Corporation  
VaxInnate Corporation  
VECTOR  
Veritas, Inc.  
Viral Defense Foundation  
Virginia Department of Health  
Vironova AB  
Washington Hospital Center  
WBB Securities, LLC  
Westat  
Women and Children's Hospital of Buffalo  
XOMA (US), LLC

# APPENDIX 2



HHS PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE

STAKEHOLDERS WORKSHOP 2008

BARDA  
INDUSTRY  
DAY



September 24–26, 2008 | Crystal Gateway Marriott, Arlington, VA

Wednesday, September 24, 2008

## Opening and Keynote Addresses

8:00 – 9:30 am

Robin A. Robinson, PhD  
Deputy Assistant Secretary for Preparedness and Response  
Director, Office of Biomedical Advanced Research and Development Authority  
U.S. Department of Health and Human Services

*Introduction of Secretary Michael O. Leavitt by*  
RADM W. Craig Vanderwagen, MD  
Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

Secretary Michael O. Leavitt  
U.S. Department of Health and Human Services

Robert P. Kadlec, MD  
Special Assistant to the President for Homeland Security  
Senior Director, Biodefense Policy  
Homeland Security Council, The Executive Office of the President

RADM W. Craig Vanderwagen, MD  
Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services



## BREAK

9:30 – 9:50 am

## EXHIBITS

8:00 am – 7:00 pm

### PHEMCE PARTNER EXHIBITS

U.S. DEPARTMENT OF DEFENSE  
• Armed Forces Radiobiology Research Institute (AFRRI) •

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
• Centers for Disease Control and Prevention (CDC) Radiation Studies Branch •

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; NATIONAL INSTITUTES OF HEALTH  
• Biodefense and Emerging Infections Resource Program, NIAID •  
• National Library of Medicine •

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE  
• Biomedical Advanced Research and Development Authority (BARDA) •  
• MedicalCountermeasures.gov •

• U.S. DEPARTMENT OF HOMELAND SECURITY •

### BARDA INDUSTRY DAY EXHIBITS

CLEVELAND BIOLABS, INC.  
• Single Injection of Novel Radioprotector CBLB502 Rescues Lethally Irradiated Non-Human Primates •

NATIONAL WEATHER SERVICE, NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION  
• But I'm Not a Meteorologist: U.S. Public and Private Weather Enterprise Support to the Medical Community •

STATE UNIVERSITY OF NEW YORK AT BUFFALO AND MEDICAL CONSERVATION DEVICES, LLC  
• Aseptic Shared Ventilation: An Alternative to Pandemic Ventilator Rationing •



**Wednesday, September 24, 2008**

**Federal Progress in**

**9:50 am – 12:30 pm**

**Medical Countermeasure Preparedness**

*Moderator:* Carol D. Linden, PhD

Principal Deputy Director, Office of Biomedical Advanced Research and Development Authority  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

Jon R. Krohmer, MD, FACEP

Acting Assistant Secretary and Chief Medical Officer  
Office of Health Affairs  
U.S. Department of Homeland Security

Michael Kurilla, MD, PhD

Director, Office of Biodefense Research Affairs, Division of Microbiology and Infectious Diseases  
Associate Director for Biodefense Product Development, National Institute of Allergy and Infectious Diseases  
National Institutes of Health  
U.S. Department of Health and Human Services

Robin A. Robinson, PhD

Deputy Assistant Secretary for Preparedness and Response  
Director, Office of Biomedical Advanced Research and Development Authority  
U.S. Department of Health and Human Services

Jean D. Reed, SES

Special Assistant to the Secretary of Defense for Chemical and Biological Defense and Chemical Demilitarization Programs  
Office of the Assistant to the Secretary of Defense (Nuclear, Chemical, and Biological Programs)  
U.S. Department of Defense

Greg Burel

Director, Division of Strategic National Stockpile  
Coordinating Office for Terrorism Preparedness and Emergency Response  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services

Kevin Yeskey, MD

Deputy Assistant Secretary for Preparedness and Response  
Director, Office of Preparedness and Emergency Operations  
U.S. Department of Health and Human Services



**LUNCH ON YOUR OWN**

**12:30 – 2:00 pm**



This icon indicates sessions that will be webcast live  
and that will be available for viewing  
on the BARDA website beginning October 2008.

[WWW.HHS.GOV/ASPR/BARDA](http://WWW.HHS.GOV/ASPR/BARDA)



Wednesday, September 24, 2008

BARDA INDUSTRY DAY: Session I

2:00 - 4:00 pm

ANTHRAX THERAPEUTICS

Moderator: Michael A. Balady, PhD, MPH
Director for Acquisition Management Systems;
Office of Biomedical Advanced Research and
Development Authority;
U.S. Department of Health and Human Services

2:00 - 2:30 pm

Valortim™, an Anti-toxin
Monoclonal Antibody,
for the Treatment and
Post-exposure Prophylaxis
of Inhalational Anthrax

Matthew Meldorf
PharmAthene, Inc.

2:30 - 3:00 pm

Development of a Human
Anthrax Immune Globulin
Intravenous (AIGIV)
Therapeutic Agent for
Treatment of Anthrax Disease

Ajoy Chakrabarti
Emergent Biosolutions

3:00 - 3:30 pm

An Immunoadhesin
Therapy for
Inhalation Anthrax

Archana Belle
Planet Biotechnology, Inc.

3:30 - 4:00 pm

Characterization of B. anthracis
Inhalation Model in Cynomolgus
Monkeys and Rabbits for
Evaluation of Therapeutic
Treatment

Thi-Sau Migone
Human Genome Sciences, Inc.

VACCINE INNOVATIONS

Moderator: Gerald R. Kovacs, PhD
Acting Associate Director for CBRN Programs;
Office of Biomedical Advanced Research and
Development Authority;
U.S. Department of Health and Human Services

2:00 - 2:30 pm

Alternative Vaccine Delivery:
Advanced Intranasal Delivery
Platform for Packaging,
Stockpiling and Dispensing
Liquid and Reconstituted
Emergency Vaccines and
Bioreactor Countermeasures in
Chaotic and Austere Conditions

Timothy Sullivan
Mystic Pharmaceuticals

2:30 - 3:00 pm

The LT Adjuvant Patch
as a Platform Technology to
Enhance Biodefense Vaccines

Nigel Thomas
Intercell USA, Inc.

3:00 - 3:30 pm

The Broadly Applicable
alphaGal Technology
for Antiviral Vaccines

Ramon Flick
BioProtection Systems Corporation

3:30 - 4:00 pm

Thermo-stabilization to Enable
Extended Ambient Storage
of Viral Vaccines

Andre Habel
Stabilitech Ltd

CHEMICAL, RADIOLOGICAL, AND NUCLEAR THERAPEUTICS

Moderator: Ronald Manning, PhD
Branch Chief, Chemical, Radiological, and Nuclear
Medical Countermeasures; Office of Biomedical
Advanced Research and Development Authority;
U.S. Department of Health and Human Services

2:00 - 2:30 pm

Rectal Diazepam in
Nerve Agent Attacks:
Efficacy in Seizure Control
and Cognitive/Behavioral
Recovery

Romy Nocera
Valeant Pharmaceuticals

2:30 - 3:00 pm

Effectiveness of Donepezil,
Rivastigmine and (±)Hupezine-A
in Preventing Soman Acute
Toxicity and Lethality:
Comparison with Galantamine

Edson Albuquerque
University of Maryland School of Medicine

3:00 - 3:30 pm

Developing Treatments for
Chemical Weapon Attacks:
The UMDNJ-Rutgers University
CounterACT Research Center
of Excellence

Jeffrey Laskin
UMDNJ-Robert Wood Johnson
Medical School

3:30 - 4:00 pm

Therapeutic Solution for the
Mitigation of the Hematopoietic
Syndrome Resulting from Acute
Exposure to Ionizing Radiation

Lena A. Basile
Neumedicines, Inc.



**Wednesday, September 24, 2008**

**Medical Countermeasures at the Point of Care**

**2:00 – 3:00 pm**

**Session I**

*Moderator:* Maribeth Love

Deputy Director for Logistics  
Office of Preparedness and Emergency Operations  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

**THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS (PREP) ACT**

Brian Kamoie, JD, MPH  
Deputy Assistant Secretary for Preparedness and Response  
Director, Office of Policy, Strategic Planning, and Communications  
U.S. Department of Health and Human Services

**ADDRESSING END USER QUESTIONS ABOUT THE EMERGENCY USE AUTHORIZATION**

CDR Carmen Maher, BSN, MA, RN, RAC  
Policy Analyst  
Office of Counterterrorism and Emerging Threats  
Office of the Commissioner  
Food and Drug Administration  
U.S. Department of Health and Human Services

Stephen Papagiotas, MPH  
Public Health Advisor / Emergency Coordinator  
Division of Bioterrorism Preparedness and Response  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services

Susan E. Gorman, PharmD, MS  
Associate Director for Science, Division of Strategic National Stockpile  
Coordinating Office for Terrorism Preparedness and Emergency Response  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services

**REQUESTING FEDERAL MEDICAL COUNTERMEASURE ASSETS**

Kevin Yeskey, MD  
Deputy Assistant Secretary for Preparedness and Response  
Director, Office of Preparedness and Emergency Operations  
U.S. Department of Health and Human Services

Greg Burel  
Director, Division of Strategic National Stockpile  
Coordinating Office for Terrorism Preparedness and Emergency Response  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services





**Wednesday, September 24, 2008**

**Medical Countermeasures at the Point of Care, Session I** *continued*

**3:00 – 4:00 pm**

**The Role of Point-of-Care Diagnostics in Triage and Treatment Decisions**

**Moderator:** Jerome A. Donlon, MD, PhD

**POINT-OF-CARE DIAGNOSTIC NEEDS  
FOR CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR THREATS**

Jerome A. Donlon, MD, PhD  
Chief Science Advisor

Office of Biomedical Advanced Research and Development Authority  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

**THE INFLUENZA POINT-OF-CARE DIAGNOSTICS EXPERIENCE**

Roxanne Shively, MS, MT (SM)  
Project Officer

Office of Biomedical Advanced Research and Development Authority  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

**END USER CONSIDERATIONS**

Luciana Borio, MD  
Senior Associate

The Center for Biosecurity of the University of Pittsburgh Medical Center  
Baltimore, Maryland

**REGULATORY PATHS FOR POINT-OF-CARE DIAGNOSTICS**

Sally A. Hojvat, PhD

Director, Division of Microbiology Devices  
Office of In-vitro Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health  
Food and Drug Administration  
U.S. Department of Health and Human Services

**QUESTIONS FOR THE PANEL**



**B R E A K**

**4:00 – 4:20 pm**



Wednesday, September 24, 2008

BARDA INDUSTRY DAY: Session II

4:20 – 6:00 pm

ANTHRAX THERAPEUTICS  
*continued*

Moderator: Matthew Lawlor, PhD  
Program Analyst  
Office of Biomedical Advanced Research  
and Development Authority  
U.S. Department of Health and Human Services

4:20 - 4:45 pm

TR-701: A New OXAZOLIDINONE Therapeutic with Activity Against *Bacillus anthracis* and a Broad Spectrum of Clinically Relevant Drug-Resistant Pathogens

Jeffrey Stein  
Trius Therapeutics

4:45 - 5:10 pm

Antisense Screening in *Bacillus anthracis* for Drug Discovery

Karen Shaw  
Trius Therapeutics

PLATFORM TECHNOLOGIES AND DIAGNOSTICS

Moderator: Dawn Myscofski, PhD, MBA  
Deputy Director, Policy, Planning, and Requirements Division  
Office of Biomedical Advanced Research and Development Authority  
U.S. Department of Health and Human Services

4:20 - 4:45 pm

Development of a Clinical Stage Electroporation Delivery Platform to Enhance DNA Vaccines

Brian Livingston  
Ichor Medical Systems

4:45 - 5:10 pm

Technology Platform for Rapid Identification of Highly Pathogenic Viruses

Ida-Maria Sintorn  
Vironova AB

5:10 - 5:35 pm

Point-of-Care and Laboratory Diagnostics for Detection of Potentially Pandemic Influenza Strains

George Sigal  
Meso Scale Diagnostics, LLC

5:35 - 6:00 pm

Rapid Clinical Surge-Testing for Biodefense and Emerging Infectious Disease

Don Straus  
First Light Biosciences

RADIOLOGICAL AND NUCLEAR THERAPEUTICS

Moderator: Joanna M. Prasher, PhD  
Senior Policy Analyst  
Office of Biomedical Advanced Research and Development Authority  
U.S. Department of Health and Human Services

4:20 - 4:45 pm

Protectan CBLB502 Prevents and Mitigates Hematopoietic and Gastrointestinal Acute Radiation Syndromes by Mobilizing Multiple Natural Defense Mechanisms

Andrei Gudkov  
Cleveland BioLabs, Inc. and Roswell Park Cancer Institute

4:45 - 5:10 pm

SPARED: The Salix Program of Radioprotector Evaluation and Development

Christopher Jahraus  
Assurance Oncology Services, LLC

5:10 - 5:35 pm

Nanotherapeutics Inhaled Gentamicin and Oral DTPA Programs

James Talton  
Nanotherapeutics, Inc.



**Wednesday, September 24, 2008**

**Medical Countermeasures at the Point of Care  
Session II: Rapid Medical Countermeasure Dispensing**

**4:20 – 6:00 pm**

*Moderator:* Greg Burel

Director, Division of Strategic National Stockpile  
Coordinating Office for Terrorism Preparedness and Emergency Response  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services

**FEDERAL PREPARATION AND SUPPORT FOR EMERGENCY COMMUNICATIONS**

Gretchen Michael  
Communications Director

Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

**STRATEGIES AND SUGGESTIONS**

Matthew Minson, MD

Senior Medical Officer for Strategic Initiatives  
Office of Policy, Strategic Planning, and Communications  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

**DISPENSING AT THE STATE LEVEL: COMMONWEALTH OF VIRGINIA**

Robert Mauskopf

State Strategic National Stockpile Planner  
Virginia State Department of Health  
Richmond, Virginia

**THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**CHEMPACK PROGRAM**

Steven Adams, MPH

Deputy Director, Division of Strategic National Stockpile  
Coordinating Office for Terrorism Preparedness and Emergency Response  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services

**THE MEDKITS MODEL**

Richard Besser, MD

Director  
Coordinating Office for Terrorism Preparedness and Emergency Response  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services

**PERSONAL PREPAREDNESS AND ANTHRAX ANTIMICROBIAL MEDKITS**

Alan Liss, PhD

Deputy Director, Regulatory and Quality Affairs  
Office of the Biomedical Advanced Research and Development Authority  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services





Wednesday, September 24, 2008

**BARDA Industry Day Poster Session  
and Networking Reception**

**6:00 – 7:00 pm**

**VACCINES**

- Agostini H** EMERGENT BIOSOLUTIONS  
Development of a Trivalent LHN ABE Recombinant Botulinum Vaccine
- Aman MJ** INTEGRATED BIOTHERAPEUTICS INC.  
Advanced Development of a Recombinant Staphylococcal Enterotoxin B (SEB) Vaccine (STEBVax)
- Gaal M** SAFIC PHARMA  
Challenges and Strategies for Rapid Construction and Manufacture of Viral Vaccines and Therapeutics
- Yokote H** THE CHEMO-CERO-THERAPEUTIC RESEARCH INSTITUTE (KAKETSUKEN)  
Update of an Attenuated Smallpox Vaccine LC16m8 Research

**PLATFORM TECHNOLOGIES**

- Kincaid R** VERITAS, INC.  
A Novel, Rapidly Deployable Bacteriophage Vector System for Emergency Preparedness Vaccination
- Mann D** VASCULAR BIOSCIENCES, INC.  
Vascular Pharmacogenomics via Endoarterial Biopsy: A Model for Medical Countermeasures against CBRN Pulmonary Vascular Injuries
- Stephen E** DEFENCE R&D CANADA  
Defence R&D Canada's Nucleic Acid-Based Anti-Viral Program
- Wajid A** XOMA (US) LLC  
Use of Platform Technologies to Accelerate Development and Production of Antibodies against Botulinum Toxin Type A

**DIAGNOSTICS / BIODOSIMETRY / BIOASSAY**

- Aristarkhov A** EXIQON  
Systematic Approach for Detection of Radiation Exposure
- Colston B** QUANTALIFE INC.  
Quantitative PCR using Picoliter Droplets
- D'Costa S** BECKMAN COULTER, INC.  
The CD4 Initiative: Enabling the Development of a Simple Point of Care Assay for CD4 Testing in HIV Infected Individuals in Resource Limited Settings
- Gillet D** CEA  
Application of Different PCR-Based Technologies for Rapid Screening of Botulinum Neurotoxins A, B, E, F Producing *Clostridium Botulinum*, *Clostridium Baratii*, and *Clostridium Butyricum*

**OTHER**

- Benninger G** UNIVERSITY OF TEXAS MEDICAL BRANCH, GALVESTON



**Wednesday, September 24, 2008**

**BARDA Industry Day Poster Session, *continued***

**THERAPEUTICS**

**Armstrong S** DSTL

Recombinant Butyrylcholinesterase (rBuChE) Therapy Following VX Poisoning by the Percutaneous Route: Preliminary Results from Guinea Pig Studies

**Benson C** ORTHO-MCNEIL-JANSSEN SCIENTIFIC AFFAIRS, LLC

Length of Stay in Hospitalized Community-Acquired Pneumonia (CAP) Patients Treated with Levofloxacin 750 mg IV or Moxifloxacin 400 mg IV

**Kirman I** ELUSYS THERAPEUTICS

Pharmacokinetic and Safety Parameters of ETI-204, a Therapeutic Monoclonal Antibody Targeting Anthrax Protective Antigen (PA)

**McCool WS** RXBIO, INC.

Rx100 – A Novel Radioprotectant & Radiomitigator

**Meldorf M** PHARMATHENE, INC.

Efficacy of Intravenous Valortim™, an Anti-toxin Monoclonal Antibody, in the Treatment of Inhalational Anthrax in the African Green Monkey Model

**Mody S** ORTHO-MCNEIL-JANSSEN SCIENTIFIC AFFAIRS

Reduced Length of Mechanical Ventilation in Patients with Ventilator Associated Pneumonia Treated with Doripenem versus Imipenem

**Orschell C** INDIANA UNIVERSITY SCHOOL OF MEDICINE

Effect of a Long-lasting G-CSF in Mitigating Lethality in Mice after Exposure of LD20/30 or LD45/30 Dose of Radiation

**Pinyerd H** IMMUNEREGEN BIOSCIENCES INC.

Viprovex® Enhances Tamiflu® Safety/Efficacy in Influenza A/H3N2 Exposed Cotton Rat

**Ramstedt U** UNITHER VIROLOGY

Broad Spectrum Antiviral Therapeutic Based on Iminosugar Derivatives

**Repine J** UNIVERSITY OF COLORADO DENVER HEALTH SCIENCES CENTER

Ergothioneine Treatment for the Acute Respiratory Distress Syndrome

**Ruiz A** THE UNIVERSITY OF TEXAS AT AUSTIN

Comparison of Levofloxacin 750mg Daily vs. Ceftriaxone 1g plus Azithromycin 500mg Daily for the Empiric Treatment of Hospitalized Community-Acquired Pneumonia (CAP) Patients

**Saward L** CANGENE CORPORATION

Correlation of the Immunological Epitopes in the HC50 Region of the Botulinum Toxins with Neutralizing Potency of the Equine Anti-toxin Antibodies

**Toth D** CANGENE CORPORATION

Characterization of the Immune Response Profile of an Intravenous Immunoglobulin (Cangene AIG-IV) to Anthrax Lethal Toxin with Correlation to In-Vitro Potency

**Wilson C** ENDACEA, INC.

Efficacy for L-97-1 as a Medical Countermeasure in a Bioterrorism Animal Model of Pneumonic Plague

## DAY 2



HHS PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE

**STAKEHOLDERS WORKSHOP 2008**

**& BARDA  
INDUSTRY  
DAY**



September 24–26, 2008 | Crystal Gateway Marriott, Arlington, VA

**Thursday, September 25, 2008**

### **Keynote Address**

**8:00 – 8:15 am**

*Introduction of Deputy Secretary Tevi D. Troy by*  
Gerald W. Parker, DVM, PhD, MS  
Principal Deputy Assistant Secretary  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

#### **PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURE RESPONSE**

Tevi D. Troy, PhD  
Deputy Secretary  
U.S. Department of Health and Human Services



### **A NATION PREPARED**

**8:15 – 9:00 am**

#### **Public Health Emergency Medical Countermeasure Response at the Federal, State, and Local Levels**

*Moderator:* Gerald W. Parker, DVM, PhD, MS  
Principal Deputy Assistant Secretary  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

#### **HHS SUPPORT FOR STATE MEDICAL COUNTERMEASURE PREPAREDNESS**

Stephanie M. Dulin, MBA  
Chief, Program Preparedness Branch; Division of Strategic National Stockpile  
Coordinating Office for Terrorism Preparedness and Emergency Response  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services

#### **LOCAL PUBLIC HEALTH PREPAREDNESS**

Jack Herrmann, MEd, NCC, LMHC  
Senior Advisor, Public Health Preparedness  
National Association of County and City Health Officials (NACCHO)  
Washington, DC

#### **CONCERNS AND INFORMATION NEEDS OF THE GENERAL PUBLIC**

Steven M. Becker, PhD  
Associate Professor of Public Health  
Vice Chair, Department of Environmental Health Sciences  
The University of Alabama at Birmingham



### **EXHIBITS**

**8:00 am – 7:00 pm**

*See previous List of PHEMCE Partner and BARDA Industry Day Exhibits*



**Thursday, September 25, 2008**

**Strategies and Suggestions for  
Developing and Sustaining a Biodefense Industry**

**9:00 – 10:00 am**

*Moderator:* Robin A. Robinson, PhD  
Deputy Assistant Secretary for Preparedness and Response  
Director, Office of Biomedical Advanced Research and Development Authority  
U.S. Department of Health and Human Services

Thomas V. Inglesby, MD  
Deputy Director and Chief Operating Officer  
The Center for Biosecurity of the University of Pittsburgh Medical Center; Baltimore, Maryland

Patrick J. Scannon, MD, PhD  
Executive Vice President, Chief Biotechnology Officer  
XOMA (US) LLC; Berkeley, California

Sara Radcliffe, MPH, MP  
Vice President, Science and Regulatory Affairs  
Biotechnology Industry Organization (BIO); Washington, DC

**QUESTIONS FOR THE PANEL**



**B R E A K**

**10:00 – 10:20 am**

**Progress and Path Forward for BARDA**

**10:20 am – 12:00 pm**

*Moderator:* Monique K. Mansoura, PhD  
Director of Policy, Planning, and Requirements Division  
Acting Deputy Director, Office of Biomedical Advanced Research and Development Authority  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

**WORKING AS AN INDUSTRY PARTNER WITH BARDA**

Paul Chaplin, PhD  
Executive Vice President, Research and Development and Chief Science Officer  
Managing Director, Bavarian Nordic GmbH; Martinsried, Germany

James T. Matthews, PhD  
Senior Director, Public Policy, Science and Health Policy; sanofi pasteur; Washington, DC

James H. Davis, PhD, JD  
Executive Vice President and General Counsel; Human Genome Sciences; Rockville, Maryland

**THE BARDA STRATEGIC PLAN**

Robin A. Robinson, PhD  
Deputy Assistant Secretary for Preparedness and Response  
Director, Office of Biomedical Advanced Research and Development Authority  
U.S. Department of Health and Human Services





Thursday, September 25, 2008

**National Biodefense Science Board**

**12:00 – 12:30pm**

*Moderator:* Patricia Quinlisk, MD, MPH  
Chairperson, National Biodefense Science Board (NBSB)

**MARKETS AND SUSTAINABILITY**

MG John S. Parker, MD, FACS, FCCP (U.S. Army, Retired)  
Member, National Biodefense Science Board  
Chairperson, NBSB Markets and Sustainability Working Group

**MEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT PROCESSES**

Patrick J. Scannon, MD, PhD  
Member, National Biodefense Science Board  
Chairperson, NBSB Medical Countermeasure Research and Development Processes Working Group

**PANDEMIC INFLUENZA**

Andrew T. Pavia, MD  
Member, National Biodefense Science Board  
Chairperson, NBSB Pandemic Influenza Working Group; Co-Chairperson, NBSB Personal Preparedness Working Group

**DISASTER MENTAL HEALTH**

Patricia Quinlisk, MD, MPH  
Chairperson, National Biodefense Science Board  
Chairperson, NBSB Disaster Mental Health Subcommittee



**Summary Remarks**

**12:30 – 12:40 pm**

Carol D. Linden, PhD  
Principal Deputy Director  
Office of Biomedical Advanced Research and Development Authority  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services



**LUNCH ON YOUR OWN**

**12:40 – 2:00 pm**



**Thursday, September 25, 2008**

**BARDA INDUSTRY DAY: Session III**

**2:00 – 4:00 pm**

**PANDEMIC INFLUENZA  
 MEDICAL COUNTERMEASURES**

*Moderator: Michael L. Perdue, PhD*

*Acting Director, Division of Influenza and Emerging Diseases  
 Office of Biomedical Advanced Research and Development Authority  
 U.S. Department of Health and Human Services*

2:00 - 2:30 pm

Host-Targeted Protection from Pandemic Influenza, SARS and other Respiratory Threats with Hiltonol® (Poly-ICLC) Nasal Spray: Broad Spectrum Activation of Mucosal Innate and Adaptive Immunity in Mice and Humans

*Andres Salazar  
 Oncovir, Inc.*

2:30 - 3:00 pm

Update on Development of Fludase® as a Broad-Spectrum Therapeutic and Prophylactic Agent for Pandemic Influenza

*David Wurtman  
 NexBio, Inc*

3:00 - 3:30 pm

Novel Methods for Mediating Hypercytokinemia in Influenza A (H5N1) Infections

*Jose I. Saldana  
 National Heart and Lung Institute, Imperial College London*

3:30 - 4:00 pm

A System for Rapid Production of Medical Countermeasures

*Vidadi Yusibov  
 Fraunhofer USA CMB*

**VACCINES**

*Moderator: Gary L. Disbrow, PhD*

*Chief, Smallpox Vaccines and Therapeutics  
 Office of Biomedical Advanced Research and Development Authority  
 U.S. Department of Health and Human Services*

2:00 - 2:30 pm

The Development of a Safer Smallpox Vaccine Suitable for Use in Healthy and Immune Suppressed People

*Paul Chaplin  
 Bavarian Nordic*

2:30 - 3:00 pm

Current Status of BioThrax® (Anthrax Vaccine Adsorbed) Enhancement Programs

*Gary Nabors  
 Emergent BioSolutions, Inc.*

3:00 - 3:30 pm

Efficient and Versatile Pan-Filo Vaccine is 100% Effective as a Biodefense Vaccine Against Ebola and Marburg Viruses

*John Y. Dong  
 GenPhar, Inc.*

3:30 - 4:00 pm

A Pan-Filovirus Vaccine Based on Virus-like Particles (VLPs) against Ebola and Marburg Virus Infection

*Kelly Warfield  
 Integrated Biotherapeutics, Inc.*



Thursday, September 25, 2008

**Medical Countermeasures at the Point of Care**

**2:00 – 4:00 pm**

**Session III: Responding to a Radiological or Nuclear Event**

*Moderator:* C. Norman Coleman, MD

Associate Director, Radiation Research Program, National Cancer Institute  
Senior Medical Advisor and Chief of the CBRN Team, Office of Preparedness and Emergency Operations  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

**NATIONAL RESPONSE PLANNING FOR A RADIOLOGICAL OR NUCLEAR EVENT**

B. Tilman Jolly, MD

Associate Chief Medical Officer for Medical Readiness  
Office of Health Affairs  
U.S. Department of Homeland Security

**FEDERAL AND STATE COORDINATION FOLLOWING AN EVENT**

Robert C. Whitcomb, Jr., PhD, CHP

Senior Scientific Advisor, Radiation Studies Branch  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services

C. Norman Coleman, MD

Associate Director, Radiation Research Program, National Cancer Institute  
Senior Medical Advisor and Chief of the CBRN Team, Office of Preparedness and Emergency Operations  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

**CITY PREPAREDNESS EFFORTS**

Katherine Uraneck, MD

Senior Medical Coordinator  
Healthcare Emergency Preparedness Program  
New York City (New York) Department of Health and Mental Hygiene

**COUNTY PREPAREDNESS EFFORTS**

Glen K. Tao, PharmD

Pharmacy Services Chief, Strategic National Stockpile Coordinator  
Emergency Preparedness and Response Program  
County of Los Angeles (California) Department of Public Health

**HOSPITAL PREPAREDNESS EFFORTS**

Mark S. Smith, MD, FACEP

Chairman, Division of Emergency Medicine  
Director, ER One  
Washington Hospital Center, Washington, DC



**B R E A K**

**4:00 – 4:20 pm**



**Thursday, September 25, 2008**

**BARDA INDUSTRY DAY: Session IV**

**4:20 – 6:00 pm**

**PANDEMIC INFLUENZA VACCINES**

*Moderator: Sheng Q. Li, DVM  
Project Officer, Pandemic Influenza Program  
Office of Biomedical Advanced Research and Development Authority  
U.S. Department of Health and Human Services*

4:20 - 4:45 pm

Depot Formulations for a  
Single Dose Pandemic Influenza Vaccine

*Marc Mansour  
ImmunoVaccine Technologies, Inc.*

4:45 - 5:10 pm

Rapid and Efficient Production  
of Potent Influenza Vaccines

*Alan Shaw  
VaxInnate Corporation*

5:10 - 5:35 pm

Live Attenuated Influenza Vaccine –  
A Viable Solution to Meet US Pandemic  
Preparedness Goals!

*Alan Taggart  
MedImmune*

5:35 - 6:00 pm

Development of Alphavirus Replicon  
Vaccines Against Biological Threat Agents

*Jonathan Smith  
AlphaVax, Inc.*

**THERAPEUTICS**

*Moderator: Kevin Gilligan, PhD  
Branch Chief, Antiviral Drugs Pandemic Influenza  
Office of Biomedical Advanced Research and Development Authority  
U.S. Department of Health and Human Services*

4:20 - 4:45 pm

Discovery and Development of  
Antiviral Drugs for Biodefense

*Dennis Hruby  
SIGA Technologies*

4:45 - 5:10 pm

IC14 is a Potential Countermeasure  
for Serious CBRN and Public Health  
Threats Including Pandemic Flu,  
Blast Injury and Bioterrorism

*Timothy Axtelle  
Implicit Bioscience, Inc.*

5:10 - 5:35 pm

A Rapidly Responsive Platform  
for Antiviral Therapeutics Using  
Multi-targeted siRNA Cocktail Against  
High-Pathogen Viral Infection

*Patrick Lu  
Sirmaomics, Inc.*



**Thursday, September 25, 2008**

**Medical Countermeasures at the Point of Care**

**4:20 – 6:00 pm**

**Session IV: Issues in a Radiological or Nuclear Event**

*Moderator:* Richard J. Hatchett, MD

Associate Director for Radiation Countermeasures Research and Emergency Preparedness  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health  
U.S. Department of Health and Human Services

**STRATEGIC NATIONAL STOCKPILE RESOURCES**

Steven Adams, MPH  
Deputy Director, Division of Strategic National Stockpile  
Coordinating Office for Terrorism Preparedness and Emergency Response  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services

**TREATMENT DECISIONS FOLLOWING A RADIATION EVENT**

CAPT Judith L. Bader, MD  
Senior Medical Advisor  
Office of Preparedness and Emergency Operations  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

**MEDICAL COMMUNITY PERCEPTIONS, CONCERNS, AND REACTIONS  
TO A RADIATION EVENT**

Steven M. Becker, PhD  
Associate Professor of Public Health  
Vice Chair, Department of Environmental Health Sciences  
The University of Alabama at Birmingham

**BIOASSAYS FOR TREATMENT DECISIONS**

Robert L. Jones, PhD  
Chief, Inorganic and Radiation Analytical Toxicology Branch  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services

**BIODOSIMETRY NEEDS FOR TRIAGE AND POPULATION MONITORING**

Ronald Manning, PhD  
Project Officer and Branch Chief, Chemical, Radiological, and Nuclear Medical Countermeasures  
Office of the Biomedical Advanced Research and Development Authority  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

**LONG-TERM HEALTH NEEDS FOLLOWING A RADIATION EVENT**

Robert C. Whitcomb, Jr., PhD, CHP  
Senior Scientific Advisor, Radiation Studies Branch  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services



**BARDA Industry Day Poster Session  
and Networking Reception**

**6:00 – 7:00 pm**

*See previous List of Poster Presentations*

## DAY 3



HHS PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE  
**STAKEHOLDERS WORKSHOP 2008**

**BARDA  
INDUSTRY  
DAY**



September 24–26, 2008 | Crystal Gateway Marriott, Arlington, VA

**Friday, September 26, 2008**

### **Medical Countermeasure Preparedness: An International Perspective**

**8:00 – 10:00 am**

*Moderator:* Gerald W. Parker, DVM, PhD, MS  
Principal Deputy Assistant Secretary  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

#### **THE FRENCH RNBC PROGRAM**

Daniel Gillet, PhD  
Coordinator for Biology for the French RNBC Program  
Adjoint au Chef du Service d'Ingénierie Moléculaire des Protéines  
Institut de Biologie et des Technologies de Saclay, Commissariat à l'Energie Atomique  
Gif sur Yvette, France

#### **THE UNITED KINGDOM'S HEALTH PROTECTION AGENCY (HPA) RESEARCH AND DEVELOPMENT INITIATIVES**

Miles Carroll, PhD  
Deputy Director, Head of Research and Development  
Centre for Emergency Preparedness and Response, Health Protection Agency  
United Kingdom

#### **GERMANY'S PRIORITY RESEARCH ISSUES**

Gerd Sutter, DVM  
Head, Department of Virology  
Paul Ehrlich Institute  
Langen, Germany

Walter Biederbick, PhD  
Head, Federal Information Centre for Biological Safety  
Robert Koch Institute  
Berlin, Germany

#### **THE CANADIAN CHEMICAL, BIOLOGICAL, RADIOLOGICAL-NUCLEAR, AND EXPLOSIVES (CBRNE) RESEARCH AND TECHNOLOGY INITIATIVE (CRTI)**

Mark A. Williamson, PhD  
Deputy Director General, Defense Research and Development Canada (DRDC)  
Centre for Security Science  
Ottawa, Ontario, Canada

#### **MEDICAL COUNTERMEASURE ENTERPRISE: INNOVATION FROM JAPAN**

Tomohiko Makino, PhD  
International Risk Management Coordinator  
Office of Health Emergency Preparedness and Response, Health Science Division, Minister's Secretariat  
Japanese Ministry of Health, Labour and Welfare  
Tokyo, Japan

**QUESTIONS FOR THE PANEL**





**Friday, September 26, 2008**

**At-Risk Populations and Medical Countermeasures: 8:00 – 10:00 am**  
**Current Challenges and Opportunities**

*Moderator and Speaker:* Mary Kruger, MPP  
Policy Director, Office of Policy, Strategic Planning and Communications  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

Daniel Dodgen, PhD  
Director, Office of At-Risk Individuals, Behavioral Health, and Human Services Coordination  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

CDR Scott Santibañez, MD, MPHTM  
Medical Officer and Senior Advisor for Vulnerable Populations, Influenza Coordination Unit  
Coordinating Center for Infectious Diseases; Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services

Susan R. Cooper, MSN, RN  
Commissioner  
Tennessee Department of Health  
Nashville, Tennessee

Kay Aaby, RN, MPH  
Program Coordinator, Public Health Emergency Preparedness and Response  
Montgomery County (Maryland) Department of Health and Human Services; Rockville, Maryland



**Innovations to Facilitate 8:00 – 10:00 am**  
**Public Health Emergency Response**

*Moderator:* Jerome A. Donlon, MD, PhD  
Chief Science Advisor  
Office of Biomedical Advanced Research and Development Authority  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services

**BIOMIMETIC IMMUNE MODELS FOR RAPID VACCINE ASSESSMENT**

William Warren, PhD  
Chief Executive Officer, VaxDesign Corporation  
Orlando, Florida

**DISSOLVABLE MICRONEEDLE DELIVERY SYSTEM**

Sean Sullivan  
Senior Graduate Researcher, School of Chemical and Biomolecular Engineering  
Georgia Institute of Technology; Atlanta, Georgia

**BREATH ANALYSIS TO DETECT RESPIRATORY DISEASE**

Joany Jackman, PhD  
Senior Scientist, Johns Hopkins Applied Physics Laboratory  
Laurel, Maryland

**TRANSLATION ENHANCING ELEMENTS IN  
BIOPHARMACEUTICAL PRODUCTION CELL LINES**

Vincent P. Mauro, PhD  
Lead Scientist, Promosome LLC  
Associate Professor, Department of Neurobiology, The Scripps Research Institute  
La Jolla, California





HHS PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE

**STAKEHOLDERS WORKSHOP 2008**

**& BARDA  
INDUSTRY  
DAY**



September 24–26, 2008 | Crystal Gateway Marriott, Arlington, VA

**Friday, September 26, 2008**

**B R E A K**

**10:00 – 10:20 am**

**Breakout Sessions**

**10:20 am – 12:00 pm**

**SESSION A**

Performance Measures for Medical Countermeasure  
Distribution and Utilization in Public Health Emergency Response

**SESSION B**

Community Preparedness for All-Hazards Response:  
Challenges for Planning

**SESSION C**

Building and Sustaining Medical Countermeasure Industries  
for CBRN Threats and Pandemic Influenza

**SESSION D**

Novel Medical Countermeasure Forward Deployment and Dispensing Models:  
Opportunities and Challenges

**SEE YOU NEXT YEAR!**

HHS PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE  
2009 STAKEHOLDERS WORKSHOP & BARDA INDUSTRY DAY

To be held in the Washington, DC area

**SEPTEMBER 22 – 24, 2009**

*Subject to confirmation*

Watch the BARDA Website  
for Location, Registration, and Abstract Submission Deadlines

**WWW.HHS.GOV/ASPR/BARDA**

## APPENDIX 3

### BREAKOUT SESSION QUESTIONS

#### Session A:

#### Performance Measures for Medical Countermeasure Distribution and Utilization in Public Health Emergency Response

1. How do Federal, State, Territorial, Local, and Tribal authorities currently measure a jurisdiction's ability to implement and adapt preparedness plans? How should key capabilities be assessed?
2. What are the advantages and disadvantages to some of the approaches used to measure preparedness (i.e. written assessments, exercises and drills)? What types of evidence and data should preparedness standards and metrics rely on?
3. How should accountability for distribution of medical countermeasures be divided among the various public and private entities (e.g. corporations, hospitals, HMOs)? Do the National Public Health Performance Standards provide any beneficial guidance?

The CDC's National Public Health Performance Standards is composed of three instruments that help identify areas for system improvement, strengthen state and local partnerships, and provide a benchmark for improvement standards. The three instruments are: 1 – The State Public Health System Assessment Instrument; 2 – The Local Public Health System Assessment Instrument; and 3 – The Local Public Health Governance Assessment Instrument.

[www.cdc.gov/od/ocphp/nphpsp](http://www.cdc.gov/od/ocphp/nphpsp)

4. Is there an efficient way to track medical countermeasure distribution and delivery in close-to-real time? Would just-in-time tracking help determine where a medical countermeasure is needed or wanted during a public health emergency?
5. What are areas that are currently being done well? In what areas is improvement needed?

#### Session B:

#### Community Preparedness for All-Hazards Response – Challenges for Planning

1. What do you see as the greatest strength in the current coordination of Federal, State, Territorial, Local, and Tribal authorities to distribute and dispense medical countermeasures in natural or manmade public health emergencies? What is the greatest opportunity for improvement in coordination?
2. Should local communities promote personal preparedness (i.e., home stockpiling of medical countermeasures for CBRN threats and pandemic influenza)? If so, how? What types of reactions may be encountered if personal preparedness were emphasized in your community's preparedness planning?
3. How should State, Local, and Tribal authorities balance medical countermeasure preparation for likely but lower consequence events versus unlikely but catastrophic events?
4. Can you describe a best practice where a community has included uniquely vulnerable populations in its all-hazards planning?
5. Which aspects of community preparedness are currently being done well? Where is improvement needed?

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## Session C:

### Building and Sustaining Medical Countermeasure Industries for CBRN Threats and Pandemic Influenza

1. How should the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) define, specify, and communicate the market opportunity for a medical countermeasure? How do threat and/or medical countermeasure prioritizations affect industry participation?
2. Suggest ways to reduce regulatory risk in the development of medical countermeasure products (i.e. risk that the product will not ultimately be licensed/approved/cleared for use by the FDA).
3. What are the current bottlenecks that the PHEMCE should work to remove to expand the nation's capacity for testing, producing, and delivering medical countermeasures?
4. What roles should the PHEMCE play in building partnerships with and among industry?
5. What is currently being done well in this area? Where are improvements needed?

## Session D:

### Novel Medical Countermeasure Forward Deployment and Dispensing Models: Opportunities and Challenges

1. What are some of the challenges that are faced by current medical countermeasure dispensing programs? (e.g. programs to ensure administration of antibiotics within 48 hours)
2. What types of incentives would entice private sector companies to enter into innovative partnerships with government agencies to develop novel medical countermeasure dispensing models?
3. 'Push' mechanisms deliver countermeasures through social services such as the Postal Service or charities. 'Pull' mechanisms require the public to come and pick up the countermeasure at a location such as a POD (Point of Distribution) or school. What are some of the benefits provided by each mechanism? Challenges?
4. Which social equity issues must be considered in planning for pre-positioning and/or dispensing of medical countermeasures? For example, what provisions are needed to support communities with diverse levels of available medical support and health screening capabilities?
5. In what circumstances would Federal far forward deployment of medical countermeasures (e.g. the CHEMPACK model) be appropriate? How far is far enough for such pre-positioning? In which cases could personal stockpiles (i.e. home medkits) be appropriate?
6. Provide examples of forward deployment or dispensing models that are currently working well. Provide examples where additional work is required.

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**U.S. Department of Health and Human Services**  
**Office of the Assistant Secretary for Preparedness and Response**  
**Biomedical Advanced Research and Development Authority**

