

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

HHS Public Health Emergency Medical Countermeasures Enterprise Stakeholders Workshop

July 31–August 2, 2007
The Fairmont Hotel Washington
Washington, DC

Workshop Report

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HHS Public Health Emergency Medical
Countermeasures (PHEMC) Enterprise
Stakeholders Workshop



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HHS PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES (PHEMC) ENTERPRISE STAKEHOLDERS WORKSHOP

July 31–August 2, 2007

EXECUTIVE SUMMARY

"We have got to maintain good lines of communication among all parts of this coalition, the federal government, the state government, local and tribal governments, and between government and the private sector so we can maximize the work that we do together...to continue to aggressively pursue the strategies that we have in this vast and important enterprise...."

HHS Secretary Michael O. Leavitt
2007 PHEMC Enterprise Stakeholders Workshop
July 31, 2007

GOALS

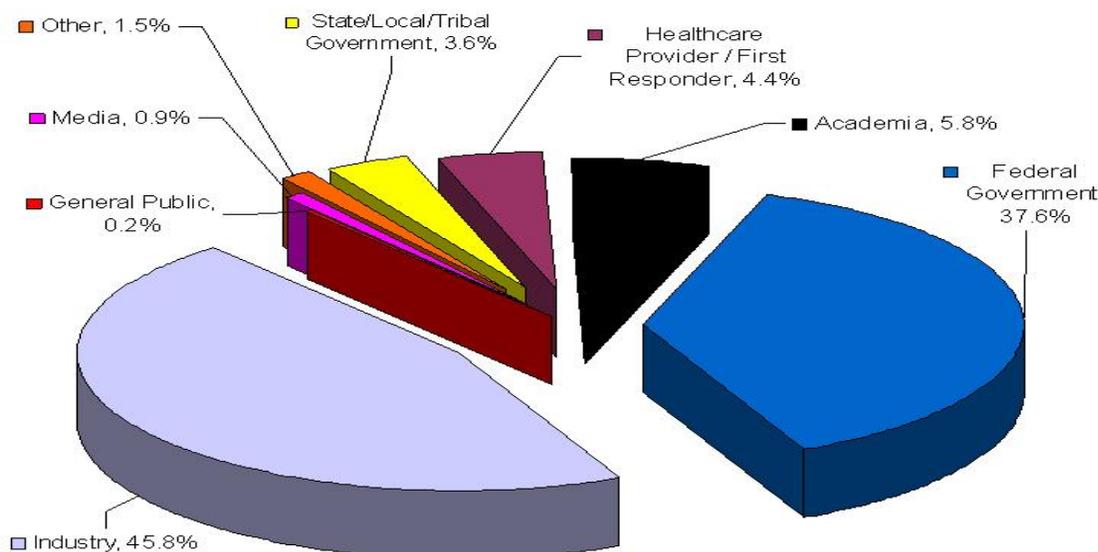
The HHS Public Health Emergency Medical Countermeasures (PHEMC) Enterprise Stakeholders Workshop (Enterprise Stakeholders Workshop) was held on July 31–August 2, 2007. Its purpose was to bring together public and private stakeholders to discuss critical issues surrounding medical countermeasure development and procurement, and to share visions for ensuring adequate public health emergency preparedness. The Biomedical Advanced Research and Development Authority (BARDA) within the Department of Health and Human Services (HHS) seeks to increase civilian preparedness by providing leadership in research, development, acquisition, deployment, and guidance for the effective use of medical countermeasures for public health emergencies. BARDA recognizes that the expertise, resources, and commitments of numerous stakeholders, both within and without the federal government, are critical to this mission. The goals of the Enterprise Stakeholders Workshop were:

1. To provide its attendees with insight into the current interagency governance process; and
2. To provide individual stakeholders with an opportunity to discuss and for HHS to receive individual stakeholder feedback on HHS implementation of the *HHS PHEMCE Implementation Plan for Chemical, Biological, Radiological, and Nuclear Threats*, the *HHS Pandemic Influenza Implementation Plan*, the Project BioShield Act of 2004, and the new HHS Biomedical Advanced Research and Development Authority (BARDA) established by the Pandemic and All-Hazards Preparedness Act.

ATTENDEES

More than 400 participants from around the country – including federal, state, local and tribal government representatives; academicians; first responders and emergency personnel; professional association and non-profit staff; and pharmaceutical and biotech industry insiders – engaged in roundtable discussions and received presentations from speakers and panels on issues related to chemical, biological, radiological and nuclear (CBRN) threats and pandemic flu response planning. Appendix 1 contains a listing of the organizations and agencies represented at the Enterprise Stakeholders Workshop. Over 1,000 additional stakeholders tuned in via Webcast during and in the week after the conference.

Enterprise Stakeholders Workshop Registered Attendees



PROGRAM OVERVIEW

HHS Secretary Michael O. Leavitt opened this year's Enterprise Stakeholders Workshop with a keynote address that emphasized the importance of both building a coalition of federal, state, and private stakeholders with expertise in emergency medical preparedness and seeking constructive feedback from the stakeholders. He also described some of the federal government's efforts to increase preparedness since the last Stakeholders Workshop including: establishment of the Office of the Assistant Secretary of Preparedness and Response and BARDA; use of new authorities under the Pandemic and All-Hazards Preparedness Act to provide advance and milestone payments for the next generation smallpox vaccine currently under development; continued efforts to build the Strategic National Stockpile; and the testing of different approaches to deliver these stockpiled medicines to the people who may need them.

Following the keynote address were presentations by a number of federal government officials, panel discussions involving external stakeholders, and seminar sessions on topics related to public health emergency preparedness for pandemic influenza and for chemical, biological, radiological, and nuclear (CBRN) threats. Most important, however, was the opportunity for stakeholders to talk to each other, voice questions and concerns, and discuss ideas for program improvements during the question and answer periods, simultaneous work sessions, and during Workshop breaks.

The five plenary sessions involved presentations by key representatives from several federal agencies, including the HHS National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and Food and Drug Administration (FDA), as well as the Department of Homeland Security (DHS), and Department of Defense (DoD). These sessions elucidated the medical and public health consequences of both CBRN and pandemic influenza threats, and medical countermeasure preparedness efforts to meet these threats including research, development, acquisition, and effective deployment and utilization.

The external stakeholder panels held on the first two days of the Workshop included representatives from industry, academia and science, medicine and public health, and state, local, and tribal government bodies. During these sessions, stakeholders presented their views

on medical countermeasure preparedness efforts involving both CBRN and pandemic influenza, and suggested ways that federal preparedness efforts could be improved.

The topics for the four seminar sessions were chosen to provide additional, in-depth information on subjects stakeholders had expressed interest in during the first Stakeholders Workshop. These included contracting practices and policies at HHS regarding medical countermeasure development and acquisition; select agent regulations; FDA regulations, roles, and responsibilities in medical countermeasure development; and liability immunity protections, intellectual property issues, and the new Biomedical Advanced Research and Development Authority provisions of the Pandemic and All-Hazards Preparedness Act.

Five work sessions broke down participants into small discussion groups on targeted topics to obtain stakeholder feedback on medical countermeasure planning and implementation. In these sessions, Enterprise Stakeholders Workshop attendees participated in facilitated discussions involving BARDA implementation, federal partnerships, incentivizing private industry, medical countermeasure development and end-user utility, and technological innovations. A detailed summary of these sessions follows this section of the report.

KEY THEMES

Regarding the threat from pandemic influenza, the stakeholders learned that scientific knowledge of influenza, vaccines, and antivirals has expanded. Guidance and strategies are being developed and revised, new medical countermeasures are being evaluated, and production capacity is increasing. However, new treatments, new preventions, and new diagnostic test options are needed. Medical countermeasure production and stockpiling must be increased to meet the projected need. HHS is committed to overcoming barriers in all phases of national public health preparedness efforts, thus improving the nation's ability to respond to a pandemic.

Regarding the threat posed by CBRN agents, the stakeholders learned that as new information from DHS risk assessments becomes available it will be factored into the periodic review and revision of both the *HHS PHEMCE Implementation Plan for CBRN Threats* and the Strategic National Stockpile annual review. Other factors that are being considered as HHS moves forward are improvements in the state of the science, the multiplier effects of multiple events or need for forward deployment of medical countermeasure; the issue of enhanced, emerging, or advanced threat agents; and federal delivery and response planning that is integrated with local capabilities. The draft *BARDA Strategic Plan* comprises BARDA's efforts to address both pandemic influenza and CBRN threats and will be finalized following appointment of the new BARDA Director.

Other themes that emerged from the Workshop involve the importance of coordinating the medical countermeasure pipeline from development to utility for end users, that is, "putting pills in the palms of people who need them." The center of gravity for preparedness was recognized to be at the state and local levels. Given the number of competing interests to be managed, the greatest challenge to effective public health preparedness and response capacity at all levels may be complacency and a lack of will to sustain preparedness levels once they are achieved. The public-private partnership is critical, and inclusiveness and effective communication are the keys to success of the coalition.

FOR MORE INFORMATION

To find out more about the Enterprise Stakeholders Workshop, please visit www.hhs.gov/aspr/barda/phemce/workshop/2007/2007workshop.html. This Web site provides a wide range of information on the Enterprise Stakeholders Workshop, including the agenda, a Webcast of the plenary sessions, presentation slides, the *HHS Pandemic Influenza Plan*, and the *HHS PHEMCE Strategy* and *HHS PHEMCE Implementation Plan for CBRN Threats*. The Web site also includes information on the Project BioShield Act of 2004 and the Pandemic and All-Hazards Preparedness Act of 2006.

The Office of the Biomedical Advanced Research and Development Authority in the Office of the Assistant Secretary for Preparedness and Response can be reached by telephone at 202-260-1200; by fax at 202-205-4520; and by e-mail at BARDA@hhs.gov.

UPCOMING EVENTS

The Public Health Emergency Medical Countermeasure (PHEMC) Enterprise Stakeholders Workshop occurs annually. The date of the next PHEMC Enterprise Stakeholders Workshop is currently being determined. As it becomes available, information on this event will be posted on the BARDA Website at <http://www.hhs.gov/aspr/barda>.

**SIMULTANEOUS WORK SESSIONS ON MEDICAL COUNTERMEASURE
PLANNING AND IMPLEMENTATION
July 31, 2007**

Stakeholders were divided into breakout groups, which were asked to discuss questions from a predetermined set of five topics. The full text of each question can be found in Appendix 3. A comprehensive selection of individual stakeholder views expressed in response to each question is presented below.

**WORK SESSION 1
Biomedical Advanced Research and Development Authority (BARDA) Implementation**

Do you have any comments or concerns about the BARDA Strategic Plan?

BARDA Funding: Funding for BARDA is insufficient. The current funding amount should be viewed as a starting point, not as the total budget. A stable funding source, that is not subject to changes in the political landscape, is needed to stimulate sustained private interest in this field. Stakeholders want sustained support from BARDA. In general, HHS should acknowledge drug development timelines of between 7 and 12 years and plan a sustainable cash flow accordingly. Companies cannot change midstream easily. The Pandemic and All-Hazards Preparedness Act should guarantee seamless funding of programs as they move through various government agencies.

Lack of Clearly-Defined Needs and Drug Eligibilities: BARDA provides no defined dates or real funding numbers that companies can use for planning purposes. Neither the frequency of Requests for Proposals (RFPs) nor the number of awards is defined. Companies are left wondering what products will be desired (even though high priority categories have been selected). Eligible stages of drug development for BARDA funding must also be more clearly defined. Each RFP's funding level should be commensurate with the appropriate stage of development.

Clearly Defined Roles of Government Agencies: Interagency operability among HHS, CDC, and the National Institute of Allergy and Infectious Diseases (NIAID) has not been well defined. The current infrastructure might be lacking to the point that concern arises about whether the strategic plan can be implemented. The public may not have confidence in the current BARDA team. For example, currently there is uncertainty about where Project BioShield's processes leave off and BARDA's advanced development processes begin. Products also often begin development in one department or agency and then are moved to another. For example, research begun at NIH has been moved to BARDA because of lack of funding. Additionally, to date products acquired by HHS have largely come from the NIH research and development pipeline. Will that precedent continue into the future or will companies be able to move ahead without NIH pre-funding?

Indemnification: Some form of provider indemnification is needed. The SAFETY Act will protect providers in cases of emergency, but it has not yet been tested in the courts.

*Does the HHS PHEMCE Implementation Plan for CBRN Threats
or the targets identified within it effectively allow
for private industry business planning?*

Top-Priority Medical Countermeasure Programs: The priority list in the *PHEMCE Implementation Plan* is very helpful – it is clear that HHS policy has shifted priorities from prophylaxis to therapeutics. The identified priorities need even more definition so that funding can be properly allocated however. It is unclear what is the development pipeline for medical countermeasures against CBRN threat agents *not* listed in Table 2 (“CBRN Threats and Projected Future Top Priority Medical Countermeasure Programs”) of the HHS *PHEMCE Implementation Plan*. The changing material threat determinations (MTDs) list makes it difficult for industry to plan. There may be too few high priority medical countermeasure targets to attract corporate America.

A topic list could be created for companies to use to identify themselves as potential providers. This topic list would foster innovative ideas on how to best allow companies to target priorities and would facilitate partnerships with other interested companies.

Planning and Post-Licensure Costs: FDA should be more involved with the planning and pilot-testing of prospective drugs to ensure the programs are on the right track. Problems also arise when the costs for planning drug development initiatives (including pilot-testing and protocol development), personnel training, infrastructure, and FDA submission are not covered by the Government. During the post-licensure period, more consideration of warm-base manufacturing issues is required.

Advanced Development Risks: A willingness to fail, that is, to fund seed projects with uncertain prospects for success, is desirable. Government strategy regarding advanced development is not clear. For example, does HHS support multiple contracts for a particular drug? Multiple contracts would support the industry and provide alternative options if some drugs fail. Often advances in government contracts represent money that must be paid back by the company if the project fails. A fairer approach would be to share the risk with private industry by implementing more milestone payments rather than refundable advances. HHS also needs to recognize and transparently incorporate into their planning, drug development timelines.

Replication of RFP Processes From Other Government Agencies: HHS should put RFP and decision processes in place that are similar to the models found in DoD or other Government agencies and departments. This involves communication among all the agency components involved in research and development, advanced development, and procurement.

Material Threat Determinations (MTDs): Participants criticized the process by which the MTD list is determined, noting that the process is not open to public comment. Two elements are needed: (1) more transparency so that stakeholders can understand how decisions are made and (2) more opportunity for earlier stakeholder input.

What barriers might prevent bridging the valley-of-death funding gap?

Pipeline Milestones: Defining and funding the distinct milestones in the development pipeline is critical to bridging the valley of death. The milestones should be adjustable and open for review, and BARDA should be flexible.

Streamlining the Contracting Process: The current contracting process slows or stops parallel drug development. The process must be streamlined.

Acceptable Animal Models: FDA should be more involved in the process of preclinical development. Confusion regarding the definition of the appropriate animal model to use in development should be alleviated by guidance from FDA. A process is needed to bring products to the acquisition stage earlier than the current model allows. Currently a company must show existing results to obtain funding. The amount of work needed to fulfill this requirement and the time spent in the RFP process make it very difficult for companies to function and pursue their other activities. Workshops should be established so that investigators can meet with FDA to report on their activities and seek guidance.

Definition of Emergency Use Authorization (EUA): The criteria a product not approved or licensed by FDA must meet to be considered for use under an EUA should be more clearly defined. Stakeholders need a usable definition.

Opportunity Costs: BARDA should consider not only financial costs but also opportunity costs to industry. Opportunity costs are too high currently. To alleviate this, BARDA advanced development contracts should be tied to acquisition contracts. Contracts involving development alone are not attractive to many companies.

Additional Valleys of Death: There is more than one valley of death. A new valley of death exists between the proof of concept stage and early clinical trials. Another valley of death might occur after licensure.

***What additional avenues should HHS pursue
in outreach to and transparency with stakeholders?***

Timelines: From the corporate perspective, timelines are artificial. The RFP process should be ongoing and continuous to allow dynamic and responsive reactions from applicants. Companies currently write cookie-cutter proposals rather than proposals with innovative approaches. More emphasis should be given to the *product* that is needed rather than the *avenue* (for outreach). Stakeholders need to better understand how to develop a product through the proof-of-concept stage.

Outreach: The 2007 BARDA Industry Day is a good first step. At future Industry Days, BARDA should provide opportunities for individual companies to meet one-on-one with contracting officers. During DoD's Industry Day, product managers were on the floor talking with industry representatives about their expectations. Companies need specifics; they need help targeting product profiles earlier. As the product progresses, a company needs a defined point of contact for the product it is developing. Future Industry Days should include working meetings with all government agencies (HHS, DoD, DHS, FDA, CDC) in the same room, instead of several meetings with individual government agencies. Decision-makers should also be available at technical meetings and roundtables. For example, more HHS personnel should attend breakout sessions during the Enterprise Stakeholders Workshop and participate in discussions as workshop members. More such opportunities are needed for two-way dialogue. There should also be more two-way communication, training, and education at the level of local healthcare providers.

Fostering Partnerships; Matchmaking Database: HHS is in a unique position to interact with a cross section of stakeholders and to determine how technologies can be leveraged against one another. Therefore, HHS should develop a "matchmaker database" to help companies find partners and facilitate innovation. A company could research the database and find partners it did not know existed, while still protecting intellectual property. In general, to increase partnerships between companies, HHS should provide more outreach and solutions to problems of trust.

MedicalCountermeasures.gov: The Web portal is a good idea. However, it is years too late and too impersonal. Instructions for its use should be better disseminated to the public. The portal should not be made available online until it is ready, and then it should be evaluated at 6-month intervals.

Mechanisms To Help New Companies: HHS should develop a “New to Government” toolkit for small biotech companies that have not previously worked with the government. The toolkit should include tangible examples of success, such as a case study to demonstrate how a company successfully navigated the system.

Are there any additional issues to be considered?

Which Plan Should Be Used? Stakeholders need more coaching on which plan to use, when each plan was developed, and what each one means (e.g., *HHS PHEMCE Implementation Plan for CBRN Threats*, *Pandemic Implementation Plan*, and *Draft BARDA Strategic Plan*). In addition, they would like a central point of contact they can go to for help in navigating the system.

Incubator Opportunities: Incubator opportunities help foster a sense of interaction among innovative organizations. These opportunities would help usher products through the early stages of development.

Focused Conferences: HHS should hold more narrowly focused, topical conferences that discuss only one or two threat scenarios.

WORK SESSION 2
Federal Partnership with State, Local, and Tribal Authorities
in Preparedness and Response

What should be the role of the federal government, as well as state, local, and tribal authorities, regarding CBRN attacks or pandemic influenza?

General Themes: There is a need for (1) education at all levels, (2) increased federal funding, and (3) better coordination between the federal government and state governments. Different responsibilities exist at different levels (e.g., federal, state, local), and both pre-event and post-event planning must be considered. Small cities and tribal organizations, in particular, should not be left out of these discussions.

Federal Role:

Funding: It was felt that the federal government’s primary role is to provide funds to support the planning and partnership of countermeasure activities at the state, local, and tribal levels. In many cases, federal funding is too specific; in other words, states need greater flexibility in how they apply for and spend federal funds. The federal focus seems to be on procuring, but storing and sustaining must be addressed as well.

Standardization: The federal role also should be that of providing leadership and standardization. Standardization is needed at all levels. For example, there should be a universal priority scheme to decide who gets vaccines, antivirals, and antibiotics. Similarly, training for first responders should be more standardized as well as more extensive. The federal government also should provide more support for public health educators at all levels (from federal to local), thereby allowing jurisdictions to become more independent. The federal

government should listen to and foster leadership at the state and local levels. What is the federal responsibility to assess local awareness and preparation response plans?

Cohesiveness: The federal government should provide greater cohesiveness among all levels of government (federal, state, local, and tribal) so that stakeholders know which messages and priorities to follow. Substantial inconsistency currently exists among federal agency programs and messages. Better communication is also needed between the federal and state and local governments. The federal government must play a greater role in disseminating information about what resources are currently available and what countermeasure supplies would be covered by current grant programs.

Preparedness Grants: The federal government should include first responders, community groups, and private businesses (e.g., insurance companies), as well as state, local, and tribal government representatives, in the making of preparedness grant policy and setting of standards for emergency preparedness and response. At present, there is no agreement on critical performance measures for judging public health emergency response capability.

State or Tribal Roles:

Distribution of Products: States or tribal governments should be responsible for the distribution of countermeasure products. Regardless of who is responsible for what tasks (e.g., threat analysis and stockpiling of products), each level of government must coordinate with the other levels. Products should not necessarily be distributed ahead of time to the local level, although *planning* for dissemination of these products should occur at the local level. The federal government should be responsible for the stockpiling and distribution of products to the states and tribes.

Rights vs. Responsibilities: An appropriate balance must be struck between states' rights and states' responsibilities. State (and local) governments should request help from the federal government when they feel they need it. For example, in Israel, the government pays for and distributes gas masks to its citizens, whereas France has decided that individuals must provide their own. In general, the federal government must do for individuals what they cannot do for themselves.

Local Role:

Partnership: Planning for the dissemination of products and information should occur at the local level, in coordination with the state or tribal governments. Partnerships within society need to be strengthened (e.g., between governments, medical schools, hospitals, and laboratories). The federal government cannot and should not coordinate every aspect of preparedness, but it can develop and disseminate standardized templates for programs, products, and messages.

*Are there examples of federal partnerships
with state, local, and tribal authorities that work well?
Examples of partnership efforts that could be improved?*

Positive Partnerships:

State of Florida: Florida has excellent joint training programs that involve the state, medical schools, CDC, and agencies responsible for child welfare. The Florida partnership could serve as a model for other states, which would help to guarantee consistency among state programs.

Weapons of Mass Effect (WME) Teams: The national Domestic Preparedness Program is a success in training first responders (i.e., law enforcement agencies, fire departments,

emergency medical services, emergency planners, and healthcare personnel) for a joint emergency response to weapons of mass effect.

TOPOFF Exercises: The Top Officials (TOPOFF) National Exercise Series is an example of successful partnerships among federal, state, and local entities. The program involves hundreds of domestic and international organizations, ranging from government agencies to private industry and nonprofit organizations. Lessons learned also have applications for response and recovery for major natural disasters.

Pandemic Influenza Planning: It was felt that most states had their own plans before the *HHS Pandemic Influenza Implementation Plan* was released. States took responsibility for their own pandemic planning instead of waiting for federal guidance. This action facilitated the building of relationships among first responders *before* a potential event rather than after the fact. Additionally, the Institute for Entrepreneurship and Innovation at Stanford University has developed a curriculum for pandemic planning that uses community coordinators.

Partnership Efforts That Need Improvement:

Interoperation Communication: Interoperation communication between federal, state, tribal and local governments needs to be improved. Communication between states must also be improved as each state now individually interprets guidance from federal agencies.

Procurement Programs: Improvement also is needed in programs in which the federal government procures products but states perform the “pull-through” and dissemination. What is the incentive for companies to develop drugs if the government will not purchase medical countermeasures until after 2013 according to the *HHS Pandemic Influenza Implementation Plan* timeline? States need guidance concerning the products that are available and the means of dissemination. The federal government’s messages are sometimes ambiguous, which leads to inconsistency among the states. One example involves the guidance provided for block grants. Additional communication is needed in working partnerships that involve the federal government’s purchasing drugs at reduced rates that are not available to states and local governments.

Need for Better Communication and Coordination: Two-way communication also is lacking in the CDC Laboratory Response Network, and issues of exclusivity tend to lock out local government bodies. In addition, effective partnerships should include social organizations, such as churches, business groups, civic groups, professional groups and neighborhood associations. The Association of State and Territorial Health Officials can provide coordination of efforts among states. Communication and coordination between states and the federal government will decrease confusion about roles and increase compliance.

Military Role: Another problem concerns the military response, which is to lock down and focus on the national security threat instead of determining ways to help the civilian population. The military also refuses to provide storage for relief supplies. The role of the military in domestic emergency response should be examined and communicated before an event.

How should authorities balance medical countermeasure preparation for likely-but-lower-consequence events versus unlikely-but-catastrophic events?

All-Hazards Preparedness: A baseline of preparedness allows for easy adaptability for different situations. One basic plan can be adapted to cover all hazards. Too much emphasis on specific (e.g. biological) threats is counterproductive. The public should be educated on preparedness

in general (i.e., the common elements in response to all disasters) so that people can prepare themselves for any and all eventualities.

Need for Definitions: Clearer definitions are needed for the terms “likely,” “unlikely,” high-risk,” and “low-risk.” Objective evidence on which to base analysis is not being shared with planners at the state and local levels. Additional data in available databases will help to measure the severity of catastrophes, although modeling rather than measuring might be a more valuable way to address this issue.

Financial Considerations: The amount of medical countermeasures that states can purchase depends on the amount of money they can allocate to that purchase. Perhaps emergency preparedness grants should be written with a view to doing “the greatest good for the greatest number of people” instead of focusing on specific quantities of money.

*What is the role of individual public preparedness
for pandemic influenza and/or CBRN threats?*

Public Need for Information and Education: In order to take responsibility for preparedness, individuals must be able to access reliable information. The federal and state governments should disseminate information to the public about preparedness via well-publicized Web sites and grassroots campaigns at churches and schools. Individuals need far more information and education if they are to take control of their own preparedness or serve as monitors for public agencies. Social marketing and media involvement are needed in preparing for disasters because public health agencies lack funds for outreach and cannot rely on volunteers for this role. The media also can help to disseminate a model of a home preparedness kit. A real concern involves inducing panic in individuals versus encouraging compliance with guidelines. More discussion is needed on distribution plans and individual responsibilities. Industry needs more information about the various plans and documents and where they can be found. A central point of contact is needed to guide industry through the various plans and programs.

Public Health and Law Enforcement Needs: Individuals who work in public health and law enforcement will need guidelines for how to protect their own families in the case of threats to the public health and welfare. Better training is needed for the families of first responders as well as first responders themselves. Also, first responders need more money for training as well as equipment and supplies. Preparedness guidelines also are needed regarding ways to back up financial and medical records.

Vulnerable Populations: Not all local governments are equally proactive in providing individuals with information, and not all individuals are able to use the information provided. There are major gaps in planning for vulnerable populations. Likewise, preparedness supplies should be affordable for low-income families.

*Are there any additional comments, questions, or issues
that should be considered?*

More consideration should be given to how to handle “the worried well” in the event of a pandemic influenza or CBRN event.

More vaccine production should take place in the United States.

Infrastructure issues must be considered.

The issue of intellectual property must be handled with more clarity.

WORK SESSION 3
Incentivizing Private Industry to Support CBRN Medical Countermeasure Preparedness

*What incentives can be offered to private industry for medical countermeasure research and development?
What concerns might prevent industry's full participation in this effort?*

Lengthen Funding Timelines: The government funding timeline is insufficient to allow industry to develop its products. Companies need to know that funding will be secure throughout the development cycle. Contracts should be issued on a multiyear basis rather than an annual basis. The government should make long-term commitments so that companies know what to expect and can operate under a realistic timeframe that allows for sustainable growth. (See *Work Session 1, Question 1: BARDA Funding.*)

Clarify Intellectual Property and Indemnification Issues: Companies need to know who really owns the product and the idea. Because the government invests in research and development, it deserves a return on its investment. The return on investment in biodefense activities is the benefit of the product to society as well as taxes paid on company profits and employee compensation—in short, the creation of a new industry. The return for the company rests in its intellectual property. BARDA must also clearly demonstrate its commitment to reduce liability for the product developer. (See *Work Session 1, Question 1: Indemnification.*)

Market Expansion: More definition is needed to identify the exact market for stakeholders' products. If the government is the only buyer of medical countermeasure products, this limits the market, preventing companies from obtaining private capital. Companies are concerned that BARDA alone cannot translate into a business plan for them. The Government should find another way (beyond RFPs for government requirements only) to involve industry in the production of medical countermeasure products.

Improve the RFP Process: Companies need more guidance through the RFP process. Improved federal interagency coordination is needed. For example, there is regulatory uncertainty related to FDA product reviews. Government assumptions are currently unclear. The whole process should be simplified and made less burdensome and costly to companies. Timely awards of RFPs are needed; it is difficult for companies to wait for awards when the timing is uncertain. Also, BARDA should release numerous RFPs to increase access to the federal government market.

Fund Early-Stage Projects: Funding should be increased for novel, high-risk projects and associated processes in the earliest stages of development. The government should also diversify its grant awards to include funding of logistical activities.

Review the Topic of Animal Model Development: This topic should be reviewed specifically during the time of preclinical studies. More than two species of animals might be ultimately used depending on the complexity of the study. Money is available for animal model development, but serious consideration must be given regarding the most effective utilization of this money.

*Is the risk to the federal government/private industry
being appropriately shared/managed?
What is the appropriate balance, and what action would achieve it?*

Shared Risk: Industry bears an unfair share of the risk involved in drug development. BARDA's milestone payments help by reducing risks to companies, but other processes increase risks. The risk/reward ratio is not balanced, which is why companies are not engaging. BARDA needs to take on more risk. DoD has a better model than HHS in terms of development of products; Federal Acquisition Regulations stipulate a cost-type contract in which DoD bears all of the risk for cost on research and development contracts. HHS should fund early and mid-stage development up to 100 percent, thereby sharing more fairly in the investment process.

Market Expansion: BARDA is not doing enough to establish the market for countermeasure drugs. There is currently no commercial market for CBRN drugs. Companies are investing too much capital given the small amount of government funding and the small market. At a minimum BARDA should issue more RFPs. The \$100 million cutoff in the *HHS PHEMCE Implementation Plan for CBRN Threats* essentially eliminates interest in projects below that amount.

Company Size Considered: The government should determine appropriate levels of risk differently for small companies than for large companies. Cost-sharing, indemnification, cost-saving, and cost overruns should be approached differently depending on the size of the provider company. Currently, available funding does not leave sufficient room for error. The maximum award might ultimately be insufficient to support the program if mid-course corrections are required.

Administrative Risk: Lack of coordination among NIH, FDA, BARDA and other federal agencies is an administrative risk companies face. Industry is exposed to risk when messages and programs change from agency to agency and when the government can discontinue a program at a late stage of development. Small companies, in particular, need a person they can contact in each key agency for explanations of BARDA or NIAID processes and to obtain additional clarity (without crossing ethical boundaries). The government must take responsibility for this risk. For example, NIH is funding projects in the pipeline that do not match BARDA's top priorities; this needs to be examined. FDA must be more consistent. Its three review centers (Center for Biologics Evaluation and Research; Center for Drugs Evaluation and Research; Center for Devices and Radiological Health) each issue different messages. FDA and BARDA must clarify and unify their messages.

*Does the HHS PHEMCE Implementation Plan for CBRN Threats
and/or the targets identified in it
effectively allow for private industry business planning?*

Lack of Long-Term Commitment, Clarity, and Specificity: The plan is a step in the right direction, but companies cannot use it to develop a business plan. It lacks granularity and detail, it does not refer to volume of medical countermeasures required, and there is not enough information on the timing of RFPs to help companies prepare. An example of a lack of detail is the plan's reference to funding in broad categories: \$1-\$100 million or \$100+ million. Additionally, the focus of the plan is on getting products into the stockpile instead of on sustainability over time (i.e., how to keep factories producing). The plan raises question about the "political will" needed for its full implementation. It shows a limited strategic vision; instead, it focuses on current problems and shows a lack of commitment to long-term countermeasures. Long-term budget and political commitments should be established and must be adhered to. Companies require more information on committed, rather than

projected, funding, and they also need reassurances on the continuity of funding and program commitment. The NIH and BARDA plans should be consistent with each other and currently the NIH pipeline does not match what BARDA is requesting.

The plan also lacks clarity; in particular, it contains poorly defined indications in radiation, prophylactics versus therapeutics, prioritization of threats, and doses sought. The required stage of product development to be funded by a particular agency is unclear.

WORK SESSION 4
Medical Countermeasure Concept of Operations:
Making the Connection Between Development and End-User Utility

*At what stage in medical countermeasure development
is it critical to consider end-user utility
of medical countermeasures in a public health emergency?*

Defining End User: There will no doubt be multiple end users for medical countermeasures. Healthcare providers, public health departments, or the military might be the end providers for therapeutic countermeasures, but the person who receives the countermeasure is also an end user. FDA defines the patient as the end user. The product utility depends on who uses it, when it is used, and where it is used. Furthermore, medical countermeasures are not limited to therapeutic drugs or even vaccines but could include diagnostics and computer software.

Earlier is Better: Earlier is better for the consideration of end-user utility and enhanced communications between product developers and the appropriate agencies. The exact guidance will depend largely on the countermeasure under development. For example, considerations for medical countermeasures such as prophylactics and therapeutic drugs will differ from those for diagnostics and software applications.

Early answers to questions about product issues such as storage and packaging, and the dissemination of information and the product itself, would help guide and speed the development of drugs and vaccines. For software and computer products, issues such as compatibility and interface should be addressed.

End-User Involvement During Development: End-user involvement might be desirable at the earliest stages of development, such as once proof-of-concept studies are complete but additional data is still needed to determine product safety. A successful product can be defined as one that is both effective and able to be used and/or administered on a practical level. At the same time, the risk is that potentially valuable products might be excluded from development if they are deemed impractical by the end user at an early stage of development.

End-User Education: Both healthcare providers and the public need education about what countermeasures are available and how they will be used. Both groups must be informed about the risks and benefits of products in order to obtain true informed consent.

End-User Input: End users targeted by product and software presentations need input on how to choose a product. For example, approved subject experts such as those used in the federal procurement process should provide advice on product selection.

What forums would be most effective in supporting dialogue between medical countermeasure developers and the end users in the public health community?

Internet Forums: The development of an Internet forum could encourage dialogue between agencies and end users and allow for the collection of information after an incident. All of the parties involved would have to agree on the responsibility for the site and the specifics about what information to include and how to share it.

Interagency Working Groups: Interagency working groups should be established to increase dialogue between medical countermeasure developers and end users. Such groups often lack an industry component; therefore, industry, first responders, health providers, and end users should all be included.

Other Forums: Town Hall meetings are another useful source of input regarding medical countermeasures. Stronger connections to state and local governments also will prove useful.

What is needed to ensure that medical countermeasures are supportable by present or future distribution capabilities at the federal, state, local, or tribal level?

Distribution Capabilities: Better integration and communication among stakeholders will be essential to support distribution capabilities on all levels. Special consideration must be given to differences in socioeconomic status, geography, and culture. Vulnerable populations, including children, must be addressed.

Clear-cut, consistent protocols are essential, as are diagnostic and patient triage tools. Drills and outreach efforts are essential to ensure the community's awareness and trust and to guarantee that both civilians and providers are educated. In addition, an established infrastructure for distribution of medical countermeasures is critical. Another relevant issue is climate differences among distribution areas.

Strategic National Stockpile: Regulations associated with the Strategic National Stockpile are a concern, particularly limitations involving rotation and shelf life extension. The rotation of antivirals for first responders is not allowed, and state and local public health officials do not want strategic drugs designated as "for government use only."

Post-Incident Data Collection: A nationwide electronic medical records system might eventually exist. In the meantime, discussion is needed about how to collect data after a disaster in order to record what occurred. A common formal mechanism to collect information would be extremely helpful. After an incident, surveillance and monitoring information must also be collected. This collection is a critical matter, but the larger question involves who will do it.

Long-Term Effects of Countermeasures: The long-term effects of medical countermeasure intervention must not be overlooked. For example, the swine flu vaccination program was a lesson in public health that should not be repeated.

WORK SESSION 5
**Technological Innovations to Improve Medical Countermeasure Response
and to Meet the Challenge of Novel and Emerging Threats**

How should BARDA define innovation?

Possible Definitions: An innovation can be viewed as something brand new or as an old technology applied in a new way (e.g., flu cell cultures for the production of vaccines). The term “innovation” also might apply to a new platform rather than a specific product.

The concept of innovation also can be applied to translational ideas rather than to science for the sake of science. A basic research advancement or a new way to take advantage of known technology might be considered an innovation (e.g., a new adjuvant to extend a vaccine injection).

Innovation also applies to product development, engineering, shelf life extension methods, and discovering something really new, for example, a vaccine de jour technology. BARDA will need to determine if it will focus on platforms or specific products, and if it will support development at the concept stage or even earlier.

*What are ways to promote innovation
that BARDA should be aware of or utilize?*

Monetary Incentives: Support should be given for clinical trials (phase 0/1). BARDA should provide funding, in more flexible RFPs, for development of diagnostics and biomarkers. Grants should be made for long-term product development with better guidance and flexibility. More research funding incentives and security are needed for the fragile, new biodefense industry.

Other Incentives: FDA should institute changes that allow for intelligent flexibility of the animal rule. Technology watching and searches also would encourage innovation. PHEMCE should discuss ranking, workshops, and prioritization of techniques by consensus. More discussion is needed on dual civilian uses of biodefense products in non-emergency conditions (e.g., broad spectrum antivirals).

Information and Longer Timelines: BARDA should make clear how can a developer can talk to BARDA or exchange information. Establishing longer product development timelines and providing companies with more information on risks, cost/benefits, and procurement contract details could improve medical countermeasures. Government and research organizations should consider how they can work together and understand each other.

*What technological innovations exist
that could improve current medical countermeasures?*

Examples of Technological Innovations: Immune boosters, credit card radiation detectors, and home detectors for poisons and infectious agents could result in early detection and prophylaxis.

Stockpiling of Products: Improving storage methods and increasing the longevity of countermeasure products could result in medical countermeasure improvements.

What technological innovations exist that could provide the flexibility to meet novel or emerging threats?

Examples of Technological Innovations: Monoclonal antibody technologies can be used for diagnosis or treatment. Quick detection technologies allow for more rapid discovery of the virus causing the infection. Flash-to-bang engineering solutions can tackle new problems. Flexible solutions are preferable to the one-bug-one-drug approach.

Further Suggestions: FDA approval should be obtained for a specific platform rather than product by product (e.g., the seasonal flu vaccine). Multiple contracts and/or agencies should work on one particular drug to avoid interruptions in supplies. One way to boost mass production and distribution is to conduct sociological research on special populations (e.g., children, the elderly) to ensure delivery of what people actually need.

APPENDIX 1

HHS PHEMC Enterprise Stakeholders Workshop Attendance

Summary

	Number of <u>Attendees</u>
Industry	188
Federal government	154
Academia	24
Healthcare Provider/First Responder	18
State/Local/Tribal Government	15
Other	6
Media	<u>1</u>
Total	410

Organizations and Agencies

4SC AG	Buchanan Ingersoll & Rooney
Acambis, Inc.	Cambridge Biostability, Ltd.
Accuthera, Inc.	CanadaNews International
Achaogen, Inc.	Canadian Department of National Defense
Adamas Pharmaceuticals, Inc.	Cangene Corporation
Alliance for Biosecurity	Center for Biosecurity of the University of Pittsburgh Medical Center
American College of Emergency Physicians	Chimerix, Inc.
American Dental Association	Civitas Group, LLC
American Medical Association	Cleveland BioLabs, Inc.
American Nurses Association	Cloudburst Consulting Group, Inc.
American Public Health Association	College of American Pathologists
American Red Cross	Columbia University
AML	Computer Sciences Corporation
Analytic Services Inc.	Congressional Quarterly, Inc.
ANSER, Inc.	Corcoran College of Art and Design
Apro Bio Pharmaceutical Corp.	Countervail Corporation
Arnold & Porter, LLP	Crucell Holland BV
Association of Public Health Laboratories	CSL Behring
Association of Schools of Public Health	CUBRC, TriBioMed
Association of State and Territorial Health Officials	CytoGenix, Inc.
Aton Pharma, Inc.	Dalrymple & Associates, LLC
Auburn Health Strategies, LLC	Development Technologies International, Inc.
Avecia Biotechnology, Ltd.	Duke University, Southeast Regional Center of Excellence for Emerging Infections and Biodefense
Baker Donelson	Dynavax Technologies
Baltimore City Health Department	DynPort Vaccine Company, LLC
Battelle	DYONYX
Bavarian Nordic, Inc.	Eli Lilly and Company
Baxter BioScience, Vaccines	Elusys Therapeutics, Inc.
Baxter Healthcare Corporation	Emergent Biodefense Operations
Bayer HealthCare Pharmaceuticals	Emergent Product Development
BMERS	Emisphere Technologies, Inc.
BIO (Biotechnology Industry Organization)	European Commission Delegation
BioCryst Pharmaceuticals, Inc.	Fabiani & Company
BioFactura, Inc.	Fairfax County Health Department
Booz Allen Hamilton, Inc.	
Brownstein Hyatt Farber Schreck	

Fleming & Company, Pharmaceuticals
 Flu Wiki
 Framework Therapeutics, LLC
 Functional Genetics
 GenPhar, Inc.
 George Washington University
 Georgia Department of Human Resources, Division of Public Health
 GexGroup, Inc.
 Goldbelt Raven, LLC
 Gryphon Scientific
 Heyltex Corporation
 Humabs, LLC
 Hyman, Phelps & McNamara, P.C.
 iJET Intelligent Risk Systems
 ImmunoBiology Limited
 Implicit Bioscience, Inc.
 Infectious Diseases Society of America
 Innovative Emergency Management, Inc.
 Institute for Defense and Homeland Security
 Integrated Warehousing Solutions, LLC
 Iomai Corporation
 Johns Hopkins Applied Physics Laboratory
 JRH Associates, Inc.
 Kaketsuken
 Kimbell & Associates
 Kirkpatrick & Lockhart Preston Gates Ellis, LLP
 Lewis-Burke Associates, LLC
 Logical Images, Inc.
 Lovelace Respiratory Research Institute
 McKenna Long & Aldridge, LLP
 Merck Vaccine Division
 Moldex Metric, Inc.
 Morgan, Lewis & Bockius, LLP
 Mystic Pharmaceuticals, Inc.
 National Association of City and County Health Officials
 Nanotherapeutics, Inc.
 NanoViricides, Inc.
 National Congress of American Indians
 National Hospice and Palliative Care Organization
 New York City Department of Health and Mental Hygiene
 NexBio, Inc.
 Nova Southeastern University College of Osteopathic Medicine
 Office of the County Attorney, Montgomery County, MD
 Oklahoma State Department of Health
 ORC Worldwide
 PanThera Biopharma, LLC
 PharmAthene, Inc.
 PolyMedix, Inc.
 ProCell Corporation
 PRTM Management Consultants
 Quintiles Public Health & Government Services
 Rhode Island Department of Health
 Robinson Consulting
 Roche Laboratories, Inc.
 RTI International
 RxBio, Inc.
 SAFC Carlsbad
 Science Applications International Corporation (SAIC)
 Sanochemia Corporation
 Sidley Austin, LLP
 SIGA Technologies, Inc.
 Southwest Research Institute
 SRI International
 St. Jude Children's Research Hospital
 Stormbio, Inc.
 Texas Department of State Health Services
 The Endocrine Society
 The Housman Group
 The JF Group
The Star-Ledger
 Thomson Scientific
 Tunnell Consulting
 Tunnell Government Services Group
 University of Alabama at Birmingham
 University of Hawaii
 University of Louisville
 University of Maryland
 Center for Health and Homeland Security
 School of Medicine
 University of Michigan
 University of Missouri
 University of Rochester
 University of Southern California
 University of Texas Medical Branch
 U.S. Department of Agriculture
 U.S. Department of Commerce
 U.S. Department of Defense
 Armed Forces Radiobiology Research Institute
 Army Medical Department Activity
 Army Medical Research Institute of Chemical Defense
 Army Medical Research Institute of Infectious Diseases
 Chemical Biological Medical Systems
 Defense Threat Reduction Agency
 Medical Identification and Treatment Systems
 Military Vaccine Agency
 Navy Bureau of Medicine and Surgery
 Office of the Secretary of Defense for Health Affairs
 U.S. Department of Energy
 U.S. Department of Health and Human Services
 Center for Medicare and Medicaid Services
 Centers for Disease Control and Prevention
 Food and Drug Administration
 Health Resources and Services Administration
 National Institutes of Health
 Office of the Assistant Secretary for Preparedness and Response
 Office of the Inspector General
 Office of Public Health and Science
 U.S. Department of Homeland Security
 Office of Health Affairs

U.S. Department of Veterans Affairs
U.S. Executive Office of the President
 Homeland Security Council
 Office of Management and Budget
U.S. Government Accountability Office
U.S. House of Representatives
 Office of Representative Doris Matsui
U.S. Library of Congress
 Congressional Research Service
U.S. Senate
 Homeland Security and Governmental Affairs Committee
 Office of Senator Richard Burr
UT-Battelle, LLC
Valeant Pharmaceutical
VAXINNATE Corporation
Vical Incorporated
Washington Hospital Center
Washington Strategic Consulting
West Coast Biologicals
XOMA (US), LLC
Yale New Haven Center for Emergency Preparedness and
 Disaster Response

APPENDIX 2

HHS PHEMC Enterprise Stakeholders Workshop

Agenda



HHS Public Health Emergency Medical Countermeasures (PHEMC) Enterprise Stakeholders Workshop

The Fairmont Hotel Washington
Washington, DC

July 31–August 2, 2007



Day One – July 31, 2007

- 8:00 – 8:25am **WELCOME AND OPENING SESSION**
Carol D. Linden, Ph.D.
Principal Deputy Director and Acting Director, Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services
- RADM W. Craig Vanderwagen, M.D.*
Assistant Secretary for Preparedness and Response, Department of Health and Human Services
- Secretary Michael O. Leavitt*
Department of Health and Human Services
- 8:25 – 8:45am **PANDEMIC AND ALL-HAZARDS PREPAREDNESS**
RADM W. Craig Vanderwagen, M.D.
Assistant Secretary for Preparedness and Response, Department of Health and Human Services
- 8:45 – 9:00am **BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA) IMPLEMENTATION**
Carol D. Linden, Ph.D.
Principal Deputy Director and Acting Director, Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services
- 9:00 – 9:15am **NATIONAL STRATEGY FOR MEDICAL COUNTERMEASURES AGAINST WEAPONS OF MASS DESTRUCTION**
Rajeev Venkayya, M.D.
Special Assistant to the President for Biodefense, Homeland Security Council, Executive Office of the President
- 9:15 – 9:30am **NATIONAL INSTITUTES OF HEALTH'S CBRN MEDICAL COUNTERMEASURE ACTIVITIES**
Anthony S. Fauci, M.D.
Director, National Institute of Allergy and Infectious Diseases
National Institutes of Health, Department of Health and Human Services
- 9:30 – 9:45am **CENTERS FOR DISEASE CONTROL AND PREVENTION'S CBRN MEDICAL COUNTERMEASURE ACTIVITIES**
Greg Burel
Acting Director, Division of Strategic National Stockpile
Centers for Disease Control and Prevention, Department of Health and Human Services
- 9:45 – 10:00am **FOOD AND DRUG ADMINISTRATION'S CBRN MEDICAL COUNTERMEASURE ACTIVITIES**
Andrew C. von Eschenbach, M.D.
Commissioner, Food and Drug Administration, Department of Health and Human Services

10:00 – 10:15am **DEPARTMENT OF HOMELAND SECURITY ADDRESS**

Jeff Runge, M.D.

Acting Assistant Secretary for Health Affairs and Chief Medical Officer, Department of Homeland Security

10:15 – 10:30am **DEPARTMENT OF DEFENSE, CHEMICAL AND BIOLOGICAL DEFENSE PROGRAM:
CBRN MEDICAL COUNTERMEASURES PROGRAM**

Jean D. Reed

Special Assistant to the Secretary of Defense for Chemical Biological Defense and Chemical Demilitarization Programs, Department of Defense

B R E A K 10:30 - 10:50

10:50 – 11:10am **INDUSTRY PANEL**

Moderator: Monique K. Mansoura, Ph.D.

Acting Deputy Director for Policy, Planning, and Requirements

Office of Biomedical Advanced Research and Development Authority

Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

Chris Colwell

Director, Healthcare Regulatory Affairs, Biotechnology Industry Organization (BIO)

Del Persinger

Senior Vice President and Chief Financial Officer, Pharmaceutical Research and Manufacturers of America

11:15 – 11:35am **ACADEMIA/ SCIENCE PANEL**

Moderator: Carol D. Linden, Ph.D.

Principal Deputy Director and Acting Director, Office of Biomedical Advanced Research and Development Authority

Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

Tara O'Toole, M.D., M.P.H.

Chief Executive Officer and Director, Center for Biosecurity of the University of Pittsburgh Medical Center

Debra Anderson, Ph.D.

Associate Director, Regional Biocontainment Laboratory

Department of Veterinary Pathobiology, University of Missouri

Paul Okunieff, M.D.

Center for Medical Countermeasures Against Radiation

Chairman, Department of Radiation Oncology, University of Rochester Cancer Center

11:40 – 12:00pm **MEDICINE AND PUBLIC HEALTH PANEL**

Moderator: Gerald W. Parker, D.V.M., Ph.D., M.S.

Principal Deputy Assistant Secretary

Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

James J. James, M.D., Dr.P.H., M.H.A.

Director, Center for Disaster Preparedness and Emergency Response, American Medical Association

Nancy L. Hughes, M.S., R.N.

Director, Center for Occupational and Environmental Health, American Nurses Association

Georges C. Benjamin, M.D.

Executive Director, American Public Health Association

12:05 – 12:25pm **STATE, LOCAL, AND TRIBAL RESPONSE PANEL**
Moderator: Kevin Yeskey, M.D.
 Deputy Assistant Secretary and Director, Office of Preparedness and Emergency Operations
 Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

James S. Blumenstock, M.A.
 Chief Program Officer, Public Health Practice, Association of State and Territorial Health Officials

Jack Hermann
 Project Director for Public Health Preparedness, National Association of County and City Health Officials

Robert Holden
 Director, Emergency Management and Radioactive Waste Programs, National Congress of American Indians

2:00 – 3:30pm **BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA) IMPLEMENTATION**

<i>Group A1</i>	<i>Location: Ballroom I</i>
<i>Group A2</i>	<i>Location: Ballroom II</i>
<i>Group A3</i>	<i>Location: Lord Culpeper Room</i>

FEDERAL PARTNERSHIP WITH STATE, LOCAL, AND TRIBAL AUTHORITIES IN PREPAREDNESS AND RESPONSE

<i>Group B1</i>	<i>Location: Alice Longworth Room</i>
<i>Group B2</i>	<i>Location: Benjamin Latrobe Room</i>

INCENTIVIZING PRIVATE INDUSTRY TO SUPPORT CBRN MEDICAL COUNTERMEASURE PREPAREDNESS

<i>Group C1</i>	<i>Location: Decatur Room</i>
<i>Group C2</i>	<i>Location: Lindens Suite, Third Floor</i>

MEDICAL COUNTERMEASURE CONCEPT OF OPERATIONS: MAKING THE CONNECTION BETWEEN DEVELOPMENT AND END USER UTILITY

<i>Group D1</i>	<i>Location: Potomac Suite, Third Floor</i>
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TECHNOLOGICAL INNOVATIONS TO IMPROVE MEDICAL COUNTERMEASURE RESPONSE AND TO MEET THE CHALLENGE OF NOVEL AND EMERGING THREATS
Group E1 *Location: Dumbarton Suite, Third Floor*

B R E A K 3:30 - 3:50

3:50 – 3:55pm **OPENING**
RoseMary Mann
 Contracting Officer, Office of Biomedical Advanced Research and Development Authority
 Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

3:55 – 4:25pm **FEDERAL ACQUISITION REQUIREMENTS (FAR) 101 AND BARDA CONTRACTING**
Brian Goodger, M.S.
 Contracting Officer, Office of Biomedical Advanced Research and Development Authority
 Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

4:25 – 4:40pm **NATIONAL INSTITUTES OF HEALTH RESEARCH AND DEVELOPMENT ACQUISITION PROCESSES**
Charles Grewe
 Director, Office of Acquisitions, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases
 National Institutes of Health, Department of Health and Human Services

4:40 – 4:55pm **CENTERS FOR DISEASE CONTROL AND PREVENTION, DIVISION OF THE STRATEGIC NATIONAL STOCKPILE ACQUISITION PROCESSES**

Steven A. Adams, M.P.H.

Deputy Director, Division of Strategic National Stockpile
Centers for Disease Control and Prevention, Department of Health and Human Services

4:55 – 5:10pm **MEDICALCOUNTERMEASURES.GOV (A STAKEHOLDER PORTAL)**

Matthew Lawlor, Ph.D.

Program Analyst, Presidential Management Fellow
Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

5:10 – 5:30pm **Q AND A**

Day Two – August 1, 2007

8:00 – 8:10am **WELCOME**

Carol D. Linden, Ph.D.

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

8:10 – 8:30am **NATIONAL PANDEMIC INFLUENZA PLAN**

Kenneth Staley, M.D., M.P.A.

Director for Biodefense Policy, Homeland Security Council, Executive Office of the President

8:30 – 8:45am **HHS PANDEMIC INFLUENZA IMPLEMENTATION PLAN – PROGRESS TO DATE**

ADM John O. Agwunobi, M.D., M.B.A., M.P.H.

Assistant Secretary for Health, Department of Health and Human Services

8:45 – 9:00am **NATIONAL VACCINE PROGRAM OFFICE'S PANDEMIC INFLUENZA PLAN IMPLEMENTATION ACTIVITIES**

Bruce Gellin, M.D., M.P.H.

Director, National Vaccine Program Office, Department of Health and Human Services

9:00 – 9:15am **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE IMPLEMENTATION ACTIVITIES**

Gerald W. Parker, D.V.M., Ph.D., M.S.

Principal Deputy Assistant Secretary
Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

9:15 – 9:30am **NATIONAL INSTITUTES OF HEALTH'S PANDEMIC INFLUENZA IMPLEMENTATION ACTIVITIES**

Roland A. Levandowski, M.D.

Chief, Influenza, SARS and Other Viral Respiratory Diseases Section, Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases, National Institutes of Health, Department of Health and Human Services

9:30 – 9:45am **CENTERS FOR DISEASE CONTROL AND PREVENTION'S PANDEMIC INFLUENZA PLAN IMPLEMENTATION ACTIVITIES**

CAPT Stephen Redd, M.D.

Influenza Team Lead, Coordinating Center for Infectious Diseases
Centers for Disease Control and Prevention, Department of Health and Human Services

9:45 – 10:00am **FOOD AND DRUG ADMINISTRATION'S PANDEMIC INFLUENZA PLAN IMPLEMENTATION ACTIVITIES**

Mark Goldberger, M.D., M.P.H.

Medical Director for Emerging and Pandemic Threat Preparedness, Center for Biologics Evaluation and Research
Food and Drug Administration, Department of Health and Human Services

10:00 – 10:15am **DEPARTMENT OF DEFENSE PANDEMIC INFLUENZA ACTIVITIES**

LTC Wayne E. Hachey, D.O., M.P.H.

Director Preventive Medicine, Office of the Assistant Secretary of Defense (Health Affairs)
Force Health Protection and Readiness, Department of Defense

B R E A K 10:15 - 10:35

10:35 – 11:15am **PANDEMIC INFLUENZA ANTIVIRAL DRUG STOCKPILE PARTNERING PANEL**

Moderator: Arthur Y. Elliot, M.D., Ph.D.

Senior Program Manager, Antivirals, Pandemic Influenza Preparedness
Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

Dominick Iacuzio, Ph.D.

Medical Director, Hoffman-La Roche, Inc.

Adam Kesselman

Relenza Global Product Director, GlaxoSmithKline

Susan C. Penfield, M.D.

Manager, Infectious Disease Control Unit, Texas State Department of Health

Stephen S. Morse, Ph.D., F.A.A.M., F.A.C.E.

Founding Director & Senior Research Scientist, Center for Public Health Preparedness
National Center for Disaster Preparedness; Assoc. Professor, Columbia University, Mailman School of Public Health

11:20 – 12:00pm **PANDEMIC INFLUENZA MEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT PANEL**

Moderator: Benjamin Schwartz, M.D.

Senior Science Advisor, National Vaccine Program Office, Department of Health and Human Services

Daniel R. Perez, Ph.D.

Assistant Professor, Virginia – Maryland Regional College of Veterinary Medicine
University of Maryland, College Park

David Spiro, Ph.D.

Assistant Investigator, Viral Genomics, J. Craig Venter Institute

Richard J. Whitley, M.D.

Professor of Pediatric Infectious Diseases, University of Alabama School of Medicine

L U N C H 12:00 - 1:30

1:30 – 1:50pm **CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR THREAT ASSESSMENTS**

John Vitko, Ph.D.

Director of Biological and Chemical Countermeasures, Science and Technology Directorate
Department of Homeland Security

1:50 – 2:10pm **MEDICAL AND PUBLIC HEALTH CONSEQUENCE MODELING: CBRN THREATS AND PANDEMIC INFLUENZA**

Peter Highnam, Ph.D.

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

2:10 – 2:30pm **USING MODELING FOR MEDICAL COUNTERMEASURE GAP ANALYSIS: THE PANDEMIC INFLUENZA EXAMPLE**

CAPT Ann Knebel, R.N., D.N.Sc., F.A.A.N.

Deputy Director for Preparedness Planning, Office of Preparedness and Emergency Operations
Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

2:30 – 2:50pm **SURVEILLANCE AND SITUATIONAL AWARENESS**

Pamela S. Diaz, M.D.

Senior Medical Advisor, Division of Bioterrorism Preparedness and Response
Coordinating Center for Infectious Diseases, Centers for Disease Control and Prevention
Department of Health and Human Services

2:50 – 3:00pm Q AND A

B R E A K 3:00 - 3:20

3:20 – 3:50pm **ROLES IN SELECT AGENT USE: U.S. DEPARTMENT OF AGRICULTURE AND CENTERS FOR DISEASE CONTROL AND PREVENTION**

Lee Ann Thomas, D.V.M., M.S.

Director, Animals, Organisms, Vectors and Select Agents
National Center for Import and Export, U.S. Department of Agriculture

Rob Weyant, Ph.D.

Director of the Division of Select Agents and Toxins
Coordinating Office for Terrorism, Preparedness and Emergency Response
Centers for Disease Control and Prevention, Department of Health and Human Services

3:50 – 4:05pm **NATIONAL INSTITUTES OF HEALTH - SUPPORTING INVESTIGATOR RESEARCH WITH SELECT AGENTS**

Paula Strickland, Ph.D.

Director, Office of International Extramural Activities, National Institute of Allergy and Infectious Disease
National Institutes of Health, Department of Health and Human Services

4:05 – 4:20pm Q AND A

4:20 – 4:40pm **FOOD AND DRUG ADMINISTRATION'S (FDA) ROLE IN MEDICAL COUNTERMEASURE DEVELOPMENT**

RADM Boris Lushniak, M.D., M.P.H.

Assistant Commissioner, Office of Counterterrorism Policy and Planning
Food and Drug Administration, Department of Health and Human Services

4:40 – 5:30pm **Q&A WITH THE FDA**

Cynthia L. Kelley, M.S.

Senior Advisor for Counterterrorism/Medical Countermeasures
Center for Biologics Evaluation and Research, Food and Drug Administration
Department of Health and Human Services

Rosemary Roberts, M.D.

Director, Office of Counter-Terrorism and Emergency Coordination
Center for Drug Evaluation and Research, Food and Drug Administration
Department of Health and Human Services

Alberto Gutierrez, Ph.D.

Deputy Director, Office of *In Vitro* Diagnostic Device Evaluation and Patient Safety
Center for Devices and Radiological Health, Food and Drug Administration

Department of Health and Human Services

Day Three – August 2, 2007

- 8:00 – 8:10am **WELCOME**
Carol D. Linden, Ph.D.
Principal Deputy Director and Acting Director, Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services
- 8:10 – 8:25am **MEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT PIPELINE – CBRN THREATS**
Michael Kurilla, M.D., Ph.D.
Director, Office of Biodefense Research Activities, Division of Microbiology and Infectious Diseases
Associate Director for Biodefense Product Development, National Institute of Allergy and Infectious Diseases
National Institutes of Health, Department of Health and Human Services
- 8:25 – 8:40am **MEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT PIPELINE – PANDEMIC INFLUENZA**
Carole Heilman, Ph.D.
Director, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases
National Institutes of Health, Department of Health and Human Services
- 8:40 – 8:55am **DEPARTMENT OF DEFENSE TRANSFORMATIONAL MEDICAL TECHNOLOGIES INITIATIVE (TMTI)**
COL David G. Jarrett, MC, USA
Deputy Special Assistant and Medical Director, Chemical Biological Defense Programs
Department of Defense
- 8:55 – 9:10am **ANIMAL MODEL DEVELOPMENT**
Judith Hewitt, Ph.D.
Research Resources Program Officer, National Institute of Allergy and Infectious Diseases
National Institutes of Health, Department of Health and Human Services
- 9:10 – 9:25am **HHS CBRN MEDICAL COUNTERMEASURE ACQUISITIONS – A FORECAST**
Monique K. Mansoura, Ph.D.
Acting Deputy Director for Policy, Planning, and Requirements
Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services
- 9:25 – 9:40am **PANDEMIC INFLUENZA PHARMACEUTICAL AND NON-PHARMACEUTICAL MEDICAL COUNTERMEASURE ACQUISITIONS – A FORECAST**
Robin Robinson, Ph.D.
Acting Associate Director, Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

9:40 – 10:00am Q AND A

B R E A K 10:00 - 10:20

- 10:20 – 10:40am **Indemnification/Liability Protections under the Public Readiness and Emergency Preparedness (PREP) Act**
Dan Barry, J.D.
Deputy Associate General Counsel, Office of the General Counsel, Department of Health and Human Services
- 10:40 – 11:00am **Intellectual Property Issues in Medical Countermeasure Development**
Julie A. Muroff, J.D.
Senior Attorney, Office of the General Counsel, Public Health Division
National Institutes of Health Branch, Department of Health and Human Services

11:00 – 11:20am **New Provisions under BARDA**
Michael Goulding, J.D.
Attorney, Office of the General Counsel, Department of Health and Human Services

11:20 – 11:30am Q and A

LUNCH 11:30 - 1:00

1:00 – 1:20pm **NATIONAL RESPONSE PLANNING (EMERGENCY SUPPORT FUNCTION-8)**
Kevin Yeskey, M.D.
Deputy Assistant Secretary and Director, Office of Preparedness and Emergency Operations
Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

1:20 – 1:35pm **CBRN MEDICAL COUNTERMEASURES IN FEDERAL RESPONSE PLANNING**
CAPT Ann Knebel, R.N., D.N.Sc., F.A.A.N.
Deputy Director for Preparedness Planning, Office of Preparedness and Emergency Operations
Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

1:35 – 1:50pm **PANDEMIC INFLUENZA MEDICAL COUNTERMEASURES IN FEDERAL RESPONSE PLANNING**
Keith Holtermann, Dr.P.H., M.B.A., M.P.H., R.N.
Office of Preparedness and Emergency Operations
Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

1:50 – 2:05pm **STRATEGIC NATIONAL STOCKPILE UTILIZATION AND DEPLOYMENT**
Greg Burel
Acting Director, Division of Strategic National Stockpile
Centers for Disease Control and Prevention, Department of Health and Human Services

2:05 – 2:20pm **FEDERAL COOPERATION WITH STATE, LOCAL, AND TRIBAL RESPONSE**
Christa-Marie Singleton, M.D., M.P.H.
Associate Director for Science, Division of State and Local Readiness
Centers for Disease Control and Prevention, Department of Health and Human Services

2:20 – 2:30pm Q AND A

BREAK 2:30 - 2:45

2:45 – 3:05 pm **MEDICAL COUNTERMEASURE DEVELOPMENT AND ACQUISITION: THE PATH FORWARD UNDER THE HHS PANDEMIC INFLUENZA PLAN**
Benjamin Schwartz, M.D.
Senior Science Advisor, National Vaccine Program Office, Department of Health and Human Services

3:05 – 3:30 pm **MEDICAL COUNTERMEASURE DEVELOPMENT AND ACQUISITION: THE PATH FORWARD UNDER THE HHS PHEMCE IMPLEMENTATION PLAN FOR CBRN THREATS**
Carol D. Linden, Ph.D.
Principal Deputy Director and Acting Director, Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

APPENDIX 3

HHS PHEMC Enterprise Stakeholders Work Session Questions

GROUP A

BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA) IMPLEMENTATION

BACKGROUND INFORMATION

On December 19, 2006, President George W. Bush signed into law the Pandemic and All-Hazards Preparedness Act (Public Law 109-417), referred to as PAHPA. Title IV of PAHPA established the Biomedical Advanced Research and Development Authority (BARDA) within the Department of Health and Human Services (HHS) to facilitate the research, development, and acquisition of medical countermeasures for chemical, biological, radiological, and nuclear (CBRN) threats and emerging infectious diseases, including pandemic influenza. BARDA establishes systems that encourage and facilitate the development of innovative biomedical products, including vaccines, therapeutics and diagnostics, as well as technologies to meet the challenges of CBRN agents and emerging infectious diseases, including pandemic influenza, in support of HHS Public Health Emergency Medical Countermeasures Enterprise (HHS PHEMCE) priorities.

QUESTIONS TO BE DISCUSSED AT EACH TABLE

1. The draft *BARDA Strategic Plan for Medical Countermeasure Research, Development, and Procurement* was released on June 20, 2007. What comments or concerns do you have as HHS moves forward to finalize this Strategic Plan?
2. The first *HHS PHEMCE Implementation Plan for CBRN Threats* was released this year. This Plan identifies top priorities for medical countermeasure research, development, and acquisition programs that HHS has determined, in collaboration with interagency partners, to have the greatest potential to improve public health emergency preparedness. Does this Plan and/or the targets identified within it effectively allow for private industry business planning?
3. Using its advanced research and development authority, BARDA seeks to strengthen HHS' efforts to bridge the *valley of death* funding gap that exists between the research and early development and the acquisition of medical countermeasures for the Strategic National Stockpile (SNS). What barriers exist that may prevent achievement of this goal?
4. Outreach to and transparency with all stakeholders is necessary for effective collaboration with public and private sectors in the domestic and international medical product development communities, including academia, industry, and federal, state, and local governments. These efforts serve as an opportunity to maximize the transparency of HHS priorities, to solicit feed-back, and to discuss implementation of future medical countermeasure advanced development and acquisition programs. What are additional avenues HHS should pursue in reaching out to stakeholders?
5. What comments or questions do you have about the assigned topic? Are there any additional issues that should be considered?

GROUP B
FEDERAL PARTNERSHIP WITH STATE, LOCAL, AND TRIBAL AUTHORITIES
IN PREPAREDNESS AND RESPONSE

QUESTIONS TO BE DISCUSSED AT EACH TABLE

1. What should be the role of the federal government in medical countermeasure efforts in preparation for and response to natural or manmade public health emergencies (e.g., chemical, biological, radiological or nuclear (CBRN) attacks or pandemic influenza)? What should be the role of state, local, and tribal authorities?
2. Are there examples of federal partnerships with state, local, and tribal authorities that work well? Examples of partnership efforts that could be improved?
3. How should federal or state/local/tribal authorities balance medical countermeasure preparation for likely but lower consequence events versus unlikely but catastrophic events?
4. What is the role of individual public preparedness for pandemic influenza and/or CBRN threats?
5. What comments or questions do you have about the assigned topic? Are there any additional issues that should be considered?

GROUP C
INCENTIVIZING PRIVATE INDUSTRY
TO SUPPORT CBRN MEDICAL COUNTERMEASURE PREPAREDNESS

QUESTIONS TO BE DISCUSSED AT EACH TABLE

1. What is required to incentivize private industry to participate in medical countermeasure research and development? What concerns might prevent private industry from fully participating in this effort?
2. Is risk to the federal government/private industry being appropriately shared and/or managed? If not, what is the appropriate balance and what actions by either the Department of Health and Human Services (HHS) and/or private industry would achieve it?
3. The first *HHS PHEMCE Implementation Plan for CBRN Threats* was released this year. This Plan identifies top priorities for medical countermeasure research, development, and acquisition programs that HHS has determined, in collaboration with interagency partners, to have the greatest potential to improve public health emergency preparedness. Does this Plan and/or the targets identified within it effectively allow for private industry business planning?
4. What comments or questions do you have about the assigned topic? Are there any additional issues that should be considered?

GROUP D
**MEDICAL COUNTERMEASURE CONCEPT OF OPERATIONS:
MAKING THE CONNECTION BETWEEN DEVELOPMENT AND END USER UTILITY**

QUESTIONS TO BE DISCUSSED AT EACH TABLE

1. At what stage in medical countermeasure development is it critical to consider end user utility of medical countermeasures – in other words their ability to be utilized in a public health emergency?
2. What forums would be most effective in supporting dialogue between medical countermeasure developers and the end users in the public health community?
3. In the *HHS PHEMCE Implementation Plan for Chemical, Biological, Radiological and Nuclear (CBRN) Threats*, the Department of Health and Human Services (HHS) has detailed its near, mid- and long-term priorities for medical countermeasure research, development and acquisition for the highest priority CBRN threats. These medical countermeasures must be associated with effective concepts of operations. What is needed to ensure these medical countermeasures are supportable by present or future programmed distribution capabilities at the federal, state, local or tribal level?
4. What comments or questions do you have about the assigned topic? Are there any additional issues that should be considered?

GROUP E
**TECHNOLOGICAL INNOVATIONS TO IMPROVE MEDICAL COUNTERMEASURE RESPONSE
AND TO MEET THE CHALLENGE OF NOVEL AND EMERGING THREATS**

BACKGROUND INFORMATION

As required under the Pandemic and All-Hazards Preparedness Act (Public Law 109-417) passed in December 2006, the Office of the Biomedical Advanced Research and Development Authority (BARDA) seeks to promote innovation “to reduce the time and cost of countermeasure and product advanced research and development.”

QUESTIONS TO BE DISCUSSED AT EACH TABLE

1. How should BARDA define innovation?
2. What are ways to promote innovation that BARDA should be aware of or utilize?
3. What technological innovations exist that could improve current medical countermeasures?
4. What technological innovations exist that could provide the flexibility to meet novel or emerging threats?
5. What comments or questions do you have about the assigned topic? Are there any additional issues that should be considered?