BioShield Stakeholders Workshop

September 25 – 26, 2006

Crystal Gateway Marriott
Arlington, Virginia

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

TABLE OF CONTENTS

EXECUTIVE SUMMARY

WORK SESSION 1: PHEMCE STRATEGY FOR CBRN THREATS – STAKEHOLDER RESPONSE

Specific versus Broad Spectrum or Fixed versus Flexible Defenses *4*
Domestic versus International *4*
Traditional, Enhanced, Emerging, and Advanced Threats *5*
Medical versus Non-Medical Countermeasures *5*
Prevention/Mitigation versus Treatment *6*
Relative Hierarchy of CBRN Threat Classes *6*
First Available versus Next Generation Medical Countermeasures *7*
Acute versus Chronic Effects *7*
General versus Special Populations *7*
Addressing Top Priority versus All Threats *8*

WORK SESSION 2: PUBLIC HEALTH CONSEQUENCES AND MEDICAL COUNTERMEASURE RESEARCH, DEVELOPMENT, AND UTILIZATION — STAKEHOLDER RESPONSE

U.S. Government Interactions and Dialogue with External Stakeholders *9*
Medical Countermeasures Research and Development Pipeline *9*
Leveraging Experiences in Addressing Emerging Infectious Disease Threats such as Pandemic Influenza to Inform Approaches to CBRN Threats *10*
Acquisition Process and Policy under Project BioShield *10*
Reciprocal Influences between Medical Countermeasure Development and U.S. Government CONOPS *11*
Establishment and Prioritization of Medical Countermeasures Requirements *12*

APPENDICES

1. BioShield Stakeholders Workshop Attendance *14*
2. Strategic Policies *16*
3. BioShield Stakeholders Workshop Agenda *19*

BIOSHIELD STAKEHOLDERS WORKSHOP

September 25-26, 2006

"We will work closely with other departments and agencies to streamline and make more effective the current BioShield interagency governance process. We will make this process more transparent and work to educate the public and industry about our priorities and opportunities. As part of this, HHS will convene an outreach meeting with these external stakeholders later this year."

HHS Secretary Michael O. Leavitt
Testimony before the United States Senate Committee on Health, Education, Labor, and Pensions
March 16, 2006

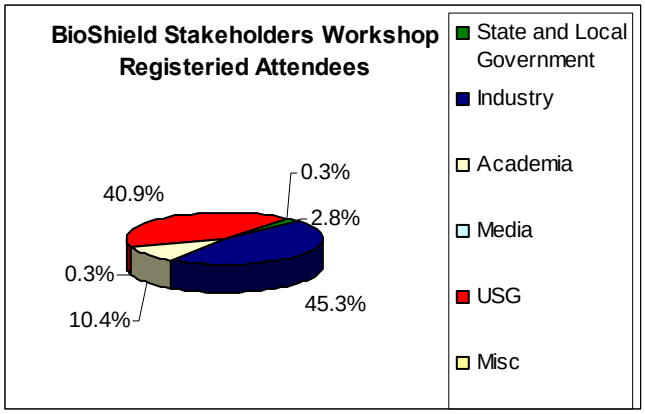
GOALS

The BioShield Stakeholders Workshop was held on September 25-26, 2006, to fulfill the promise made by Secretary Leavitt before the Senate Committee on Health, Education, Labor, and Pensions to improve transparency and educate BioShield Stakeholders. The goals of the BioShield Stakeholders Workshop were:

1. To provide its attendees with insight into the current interagency governance process for implementing the Project BioShield Act of 2004; and
2. To provide individual stakeholders with an opportunity to help guide the future implementation of Project BioShield by providing input into the draft *Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for Chemical, Biological, Radiological, and Nuclear (CBRN) Threats* (*HHS PHEMCE Strategy*). The HHS PHEMCE Strategy was published in the Federal Register as a draft for comment on September 8, 2006.

ATTENDEES

The Workshop provided insight into HHS activities to integrate biodefense requirements, across the full range of threat agents, with advanced development and procurement of medical countermeasures and provided an opportunity for non-federal stakeholders to provide feedback to HHS. The over 400 participants who either attended in person or participated in the Workshop via live webcast represented the pharmaceutical and biotechnology industries, professional societies, state and local public health organizations, the academic research and development community, public interest groups, stakeholder federal agencies, and Congress.



PROGRAM OVERVIEW

The BioShield Stakeholders Workshop was opened by HHS Secretary Michael O. Leavitt and included a series of briefings by federal government officials, external stakeholder panels, and a number of breakout sessions to facilitate interactive dialogue on the HHS PHEMCE Strategy, HHS implementation of the Project BioShield Act of 2004, and a variety of other topics related to public health emergency preparedness for CBRN threats.

The draft HHS *PHEMCE Strategy for CBRN Threats* was developed under the leadership of the HHS Office of the Biomedical Advanced Research and Development Authority (BARDA; formerly the Office of Public Health Emergency Medical Countermeasures) within the Office of the Assistant Secretary for Preparedness and Response (ASPR; formerly the Office of Public Health Emergency Preparedness). The *HHS PHEMCE Strategy* defines the principles and strategic objectives guiding HHS medical countermeasure research, development, and acquisition priorities.

The purpose of the Project BioShield Act of 2004 (Project BioShield) is to accelerate the research, development, acquisition, and availability of effective medical countermeasures for CBRN threats. The Special Reserve Fund (SRF), a discretionary reserve of $5.6 billion for the advanced development and purchase of priority medical countermeasures over 10 years, was authorized under Project BioShield to support this mission.

Secretary Leavitt's Keynote Address at the BioShield Stakeholders Workshop highlighted HHS accomplishments in improving public health emergency preparedness and indicated areas needing improvement that are the focus of current HHS efforts. The Secretary's keynote was followed by addresses from key representatives of the Homeland Security Council, the Department of Defense, the Department of Homeland Security, and the leaders of the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA) on issues related to the HHS Public Health Emergency Medical Countermeasures Enterprise, including Project BioShield.

The Stakeholders Workshop also included a series of panels with representatives from Industry, the Academic and Scientific Community, and Medicine and Public Health. These panel discussions addressed diverse topics, such as ways to improve risk management within the public-private partnership of medical countermeasure development, special challenges that will need to be addressed during CBRN disasters, perspectives on the role of the public health community, and the need for cooperation and coordination between Federal response efforts and those at the state and local level. The program also included intense breakout sessions in which Workshop attendees participated in facilitated discussions on a wide variety of themes related to public health emergency preparedness.

KEY THEMES

HHS has made great progress in preparing the nation to face a CBRN attack. Medical countermeasure research and development grew from $53 million in 2001 to $1.8 billion in 2006. Eight contracts had been awarded as of September 2006, using a total of $1.9 billion of the BioShield Special Reserve Fund to acquire critical medical countermeasures for the Strategic National Stockpile. However, HHS must continue to strive towards further improvements in preparedness for a CBRN attack. In order to achieve this goal, HHS must become a better business partner to industry and increase the speed and transparency with which the Department conducts business with its external stakeholders. HHS invited all stakeholders to work together in good faith towards achieving the goal of improved public health emergency preparedness.

In addition to the Workshop, the draft *HHS PHEMCE Strategy* published in the Federal Register provides an opportunity for stakeholder feedback on the implementation of Project BioShield and future activities under the HHS PHEMC Enterprise. The *HHS PHEMCE Strategy,* finalized in March 2007 following

incorporation of stakeholder feedback, was critical in laying the foundation for the *HHS PHEMCE Implementation Plan* that HHS released in April 2007. The *HHS PHEMCE Implementation Plan* was based on the principles and objectives contained in the *HHS PHEMCE Strategy* and was prioritized with near-, mid-, and long-term goals for medical countermeasure research, development, and acquisition. This two-step strategic process will enable HHS to be a more predictable partner to industry and allow private industry to plan their business models to meet USG needs.

FOSTERING A PUBLIC-PRIVATE DIALOGUE

In order to leverage the high degree of expertise represented by the participants of the conference, HHS actively encouraged participants to contribute feedback and insight during the two breakout sessions and during the multiple plenary session question and answer periods. Participants provided the government with vital insights on the themes of the *HHS PHEMCE Strategy* as well as broader issues relating to public health emergency preparedness.

Stakeholders focused particularly on the need for improved dialogue between the government and its external partners, increasing the resources available to meet the challenge of improving national preparedness for a CBRN attack, and encouraging a creative approach to meeting the challenges of public health emergency preparedness in a variety of areas. In addition to discussing each of the themes of the *PHEMCE Strategy*, stakeholders provided valuable feedback on diverse topics, including:

- The research and development pipeline;
- The acquisition process and policy under Project BioShield;
- Leveraging experiences in emerging infectious diseases to counter CBRN threats;
- Issues surrounding the deployment and utilization of medical countermeasures; and
- Prioritization of medical countermeasures requirements.

The final *HHS PHEMCE Strategy* reflected these critical inputs, as well as those comments received through the *Federal Register*.

FOR MORE INFORMATION

Major themes captured during the Stakeholder Work Sessions follow this summary. To find out more about the BioShield Stakeholders Workshop, please see our website at http://www.hhs.gov/aspr/ophemc/. The website provides a wide range of information on the BioShield Stakeholders Workshop, including the videocast of the plenary sessions, presentation slides, and the final HHS *PHEMCE Strategy* and *HHS PHEMCE Implementation Plan for CBRN Threats*. The website also includes additional information on Project BioShield, including the 2006 *Project BioShield Annual Report to Congress.*

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 BioShield@hhs.gov.

UPCOMING EVENTS

The BioShield Stakeholders Workshop, which will be referred to as the Public Health Emergency Medical Countermeasure (PHEMC) Enterprise Stakeholders Workshop in the future, will be an annually occurring event. The next PHEMC Enterprise Stakeholders Workshop is planned for July 31-August 2, 2007. Information on this event is also posted on the BARDA Website at http://www.hhs.gov/aspr/ophemc.

BIOSHIELD STAKEHOLDERS WORKSHOP
September 25-26, 2006

WORK SESSION 1
PHEMCE STRATEGY FOR CBRN THREATS – STAKEHOLDER RESPONSE

Stakeholders were divided into five breakout sessions. Each breakout session consisted of five or six tables, and each table was asked to discuss two questions from a predetermined set of ten strategic policy questions posed in the draft PHEMCE Strategy published in the Federal Register on September 8, 2006. The full text of each question can be found in Appendix 2. A selection of the major stakeholder views expressed in response to each question is presented below.

Specific versus Broad Spectrum or Fixed versus Flexible Defenses

Benefits of Specific, Broad-spectrum, Fixed, or Flexible Defenses: Some participants supported the specific ("one bug, one drug") approach, which has been used with children's vaccination schedules. However, it is unclear how this approach would translate to addressing the radiological, nuclear, and chemical threats. Such a strategy would need to address the issues of drug resistance and vaccine specificity for biological threat agents, as well as pre-existing disease or age considerations. Some participants thought that an "all-hazards" approach is needed, where appropriate, to identify common countermeasures that can be used for multiple hazards.

The benefits of narrow-target development are the greater feasibility and likelihood of bringing the products to market. Broad-spectrum pharmaceutical medical countermeasures are likely to be more appropriate for radiological/nuclear and chemical threats than for biological threats. Emphasizing fixed defenses will likely result in a greater number of products, although any flexible defenses that are successful could ultimately prove more useful. The *HHS PHEMCE Strategy* should seek to improve the development and acquisition of near-term, broad-spectrum solutions using available technologies.

Developmental/Regulatory Challenges: Achieving the "one bug, one drug" goal will require a time-consuming—and therefore expensive—process. However, the biology of microorganisms is a major barrier to developing broad-spectrum countermeasures. A regulatory agency is likely to expect testing for all potential targets of such a broad-spectrum countermeasure, therefore developmental costs will be a barrier to developing flexible defenses.

New Acquisition Approaches: New acquisition approaches are necessary that acknowledge the need for significant basic, investigator-initiated research as the precursors to advanced medical countermeasure development. Although the federal government has many acquisition models for acquiring conventional, narrowly defined products, there are few examples of acquisition processes for nonconventional products outside the DoD's Defense Advanced Research Products Agency.

Domestic versus International

International Countermeasure Development: Some participants thought that planning to use mainly domestically manufactured countermeasures was reasonable, although the meaning of "domestic" was not entirely clear. Would a domestically-owned company with overseas manufacturing facilities be considered in the domestic category? However, others noted that many drugs (and most vaccines) are only produced overseas. Biodefense is an international concern and an international effort is required to address it. In addition, the risks inherent in utilizing international manufacturing capabilities vary between countries depending on the status of their relationship with the United States and are not uniform world-

wide. Modern transportation options mean that the need for international shipping would be at most a minor barrier

Challenges to International Procurement: A lack of understanding of international health regulations might have a negative effect on U.S. efforts to maintain adequate capacity and supply. It is critical to ensure that agents can be brought into the United States in time to treat those exposed to a threat. In addition, the supply chain, logistics, and import and/or export control issues involved in moving large amounts of materials overseas and the associated ethical and/or humanitarian issues need to be addressed. Product liability and intellectual property rights must be addressed in the context of international law. Communication between stakeholders is critical in this regard.

Domestic vs. International Needs: The U.S. Government needs to provide clear information as to how public dollars are spent to address domestic vs. international needs. The U.S. Government also needs to ensure that there is a plan in place for handling an event overseas in advance of that event. The U.S. should leverage international demand for products and support international marketing of U.S.-made biodefense products. The government should clearly communicate its decisions as to international product marketing to the pharmaceutical industry to enhance the industry's ability to make business planning decisions.

Traditional, Enhanced, Emerging, and Advanced Threats

Proposed Classification Scheme: Some participants thought that the four categories seemed reasonable for classifying biological agents. However, others argued that this approach could constrain the thinking of developers. For example, categorizing anthrax as a traditional threat could limit consideration of new anthrax strains that are more difficult to treat.

Threat Assessments: It was unclear how the threat assessments for various agents are derived, how different threat agents rank in priority, or how these priorities are determined. Medical countermeasure development and acquisition should be driven by clear-headed risk analysis of attack likelihood and/or agent use feasibility, rather than on nightmare scenarios of what the "enemy" is thought to possess.

Threat-Based Medical Countermeasure Development: Without a material threat determination (MTD) or an explanation of the government's planned concept of operations (CONOPS), private industry will be uncertain of the government's commitment to develop countermeasures for a given agent. Broad-based solutions have a lower barrier because a market exists beyond biodefense; thus, a solution-based approach might be better than an agent-based approach. Nonmedical countermeasures and strategies should also be developed to balance the overall approach.

Medical versus Non-Medical Countermeasures

Focus on Medical Countermeasures: "Medical" and "non-medical" need to be more explicitly defined. For example, it is unclear which category applies to handwashing or diagnostics. Also, it is not clear whether HHS is responsible for non-medical countermeasures, and if so, for which ones. With these caveats however, participants agreed that overall it is logical to place a high priority on developing medical countermeasures to increase preparedness. It is also important however to identify non-medical countermeasures that complement medical countermeasure strategies. Supportive care for example is a critical component of medical preparedness, particularly in those cases where the "ideal" medical countermeasure does not yet exist.

Requirements for Implementation: Developing countermeasures without planning for distribution and utilization could be as disastrous as having a threat detection system without a clear response system. Implementation plans for medical countermeasures should include methods for consistent dissemination of appropriate and accurate information to the public, as well as defined, organized CONOPs. Medical

countermeasures need to be concurrently developed and integrated with the CONOPS to ensure effective utilization. All stakeholders (e.g., responders, planners, developers, and scientists) need to be truly integrated into the planning process. Communication between different stakeholders is critical, particularly between product developers and those who are engaged in policy development and response planning.

Prevention/Mitigation versus Treatment

Prevention versus Treatment: The distinctions between "pre-" and "post-event" and "pre-" and "post-exposure" need to be clarified. Given these caveats, for certain threats a focus on prophylaxis may be preferable. For most threats, post-exposure treatments are more realistic, given the risk/benefit equation that considers potential side effects in unexposed populations. The *HHS PHEMCE Strategy* and *HHS PHEMCE Implementation Plan* should specifically define what issues are considered in determining the cost–benefit analysis.

Countermeasure Development and Prioritization: Post-exposure medical countermeasures are currently not largely available and should be developed. Post-exposure prophylaxis would need to be in the form of a pill or intramuscular injection and treatments should, ideally, be outpatient. Standards for safety and efficacy of countermeasures differ depending on whether a countermeasure is to be used for treatment or prophylaxis and whether it is to be used prior to or after an event. Acceptable risks for healthy populations are low, especially for pre-exposure prophylaxis.

No clear criteria are available to inform companies if the government is interested in pre-event or post-event countermeasures. The delay in revealing government medical countermeasure priorities delays industry's ability to ramp up production and development. Although Project BioShield provides incentives to companies to develop either preventive or treatment measures, it does not provide any assurance that these measures will be purchased. The appropriate balance of prevention and treatment modalities should be based on a cost–benefit analysis, including underlying costs to providing healthcare surge capacity that will be needed to support any medical countermeasure utilization program. The decision-making process should broadly engage stakeholders from industry and regulatory agencies, as well as other partners. The overall HHS strategy for short-, mid-, and long-term medical countermeasures should be developed and communicated across all threats.

Small companies are often unable to develop responses to government procurement requests due to the resources and opportunity costs involved in government contracting. Companies require regular, informal access to regulatory experts to help ensure that product proposals correctly address government needs. Access to critical threat agents and nationally standardized assays is often limited. Other possible barriers include the lack of surge capacity for manufacturing, lack of communication, and lack of government leadership, especially with respect to legal/intellectual property issues.

Relative Hierarchy of CBRN Threat Classes (Biological versus Chemical versus Radiological/Nuclear)

Relative Hierarchy: Some participants supported an emphasis on biological threats because biological attacks offer a longer treatment time window than chemical and radiological threats, and because biological threats were felt to affect more people and be more catastrophic than chemical or radiation threats. In addition, previous medical countermeasure development experience provides a working structure in the biological threat area. It was noted, however, that there are important differences between contagious/infectious biological threats and biological toxins.

Some participants however argued that more emphasis should be placed on radiological, nuclear, and chemical threats and that the hierarchy should be influenced by the current state of the art, the likelihood of an attack with a given agent, the number of people potentially affected, and the potential economic

costs. Given that the effectiveness of medical intervention for any particular threat may be greatly influenced by the particular circumstances of an event, a broad vision is required in determining where the biggest impact may be found. As HHS prioritizes, it should consider whether other measures (such as public health measures, physical agent security, or rapid detection) could address a specific threat.

First Available versus Next Generation Medical Countermeasures

Appropriate Balance: Some participants thought that the program should focus on the development of next-generation medical countermeasures, although countermeasures that could be stockpiled quickly should also be considered. Decisions will need to be made on a case-by-case basis. Others suggested that new drug development be performed in parallel with production and/or enhancement of older products.

First-available countermeasures may have significant drawbacks in terms of short shelf life and reduced stability. Rapid cycles in the biotechnology industry however can discourage investment in next-generation countermeasures. Furthermore, in spite of the technical risks associated with new product development, few financial incentives are available for companies to develop next-generation countermeasures. The U.S. Government needs to clarify which product aspects are most important to them in a next generation product (e.g., stability, room temperature storage, ease of delivery, etc.). Government requirements for next-generation medical countermeasures should be based on regular evaluations of long-term strategies, but it is not clear how and when such evaluations will occur or whether industry partners will be involved in these evaluations. The operational aspects of medical countermeasures should be reviewed to determine if better deployment of existing medical countermeasures would obviate the need for next-generation products.

Ensuring Production Capacity: Investments can be made in production capacity that could be ramped up as needed while a small stockpile is produced and stored for immediate distribution in case of an event. In addition, the animal models required to develop critical products must be supported to ensure timely approval of next-generation medical countermeasures. Communication lines with the government need to be simplified for transmitting new ideas.

Acute versus Chronic Effects

Focus on Acute versus Chronic Effects: Given limited resources, the focus on acute effects seems appropriate; however, chronic effects should not be overlooked. Requirements for addressing chronic effects should be predicated on prompt recognition and appropriate management of acute effects. The priority for guiding investment in responding to acute versus chronic effects should be further defined. In addition, the balance of priorities between chronic and acute effects needs to be clarified for biological category A, B, and C agents; radiological and/or nuclear; and chemical threat countermeasures.

Challenges in Treating Acute Effects: Difficulties in detection and diagnosis and a short therapeutic window after exposure are challenges to treating acute effects. Available medical countermeasures should be inventoried and a real-time tool should be developed to obtain immediate access to this information. An inventory of private-sector assays also needs to be available in real time, with appropriate safeguards to ensure protection for developers/manufacturers from industrial sabotage or loss of proprietary information.

General versus Special Populations

Approach to Special Populations: The focus should be on general populations but the needs of special populations should be addressed in the development of next-generation products. The needs of special populations should be included in response planning and each population should be considered for its specific needs. The government and industry should identify ways to develop products that meet the

needs of both the general population and special populations. In particular, funding and incentives are needed to support the development of medical countermeasures for children, the elderly, pregnant women, and disabled populations. For certain threats, specific populations may be the ones at highest risk.

It is not clear how countermeasures will be provided to populations that do not speak English or who have no transportation to the medical countermeasure distribution sites. First responders will need to know how to treat patients for whom the countermeasures are not indicated; for example, children could be exposed to a threat but the only therapy available might not be indicated for them.

Ethical Issues: When setting policy, the U.S. Government needs to take into account the ethical implications of allocating resources for special populations. If the goal of the U.S. Government is to save the largest number of lives, then this should be clearly stated. A broader public discussion of these issues is warranted.

Countermeasure Development: Many medicines are not tested in special populations. Testing experimental drugs in special populations raises ethical as well as technical considerations and could be prohibitively expensive. Incentives for special population studies do not exist and would be needed to attract pharmaceutical companies to this area. For some countermeasures, the route of administration may be different in special vs. the general population, and the resources associated with developing additional medical countermeasures delivery routes can be burdensome to private industry. Regulatory direction from the FDA is also needed, especially as to data required under the "Animal Rule" for special populations.

Addressing Top Priority versus All Threats

Countermeasure Development Challenges: The amount of funding currently available is not adequate to execute all priorities. Although under the BioShield Act of 2004 payment can only be made for delivery of final product, companies would prefer payments for achieving milestones as well.

PHEMCE Strategy for CBRN Threats: should address indemnity, liability, and intellectual property concerns, which are very important to businesses, especially when considering platform technology development. In addition, companies need information on the procurement lifespan of countermeasures to forecast revenue, personnel needs, and other resources.

Easy-to-Develop Medical Countermeasures: Easy-to-develop countermeasures for lower priority threats might be overlooked if too much emphasis is placed on the highest priority threats. Priorities are currently based on perceived threats, which can potentially change. A policy is needed to ensure that easy-to-develop countermeasures for lower priority threats are considered for development.

WORK SESSION 2
PUBLIC HEALTH CONSEQUENCES AND MEDICAL COUNTERMEASURE RESEARCH, DEVELOPMENT, AND UTILIZATION — STAKEHOLDER RESPONSE

Stakeholders were again divided into five breakout sessions. Each breakout session had five or six tables, and each table was asked to discuss one issue out of a set of six issues. A selection of the major stakeholder views expressed in response to each issue is presented below.

U.S. Government Interactions and Dialogue with External Stakeholders

Importance of Communication at Various Stages: Communication with external stakeholders was proposed early in the procurement process, even before the release of a draft Request for Proposals (RFP). Once an RFP is released communication between the government and industry is limited by procurement rules. However, some discussions at this time can ensure that the government understands industry capability and that those submitting proposals understand government needs. For example, RFPs often require a response within 45 days, but this may not be long enough for submitting proposals on basic research and development work. Potential partners should be solicited to help determine the appropriate time needed to respond to announcements. More education and communication for non-traditional contractors would also be helpful. Many people in academia and industry would benefit from a workshop about the basics of the Federal Acquisition Regulations.

Role of the Public: Proactively engaging the public during the planning process will be important for effective communication. Public comments early in the process are necessary for developing policies that take the public's voice into account. The lack of public and patient advocates at the current workshop shows that the public is not engaged in the process and the Federal Register is not known widely enough to obtain broad public input. Therefore, new forms of communication, such as town hall meetings and surveys, might be needed to enhance the dialogue with the public.

Communicating with and Navigating Government Agencies: The primary government agency for medical countermeasure stakeholder relations needs to be clarified. The federal government needs to facilitate communication between different government organizations and help stakeholders navigate through government organizations to quickly find and work with appropriate points of contact. To facilitate communication with and navigation of government organizations, the government could establish a question-and-answer hotline, a clearinghouse for answers to questions, and/or well-defined points of contact.

Role of FDA: Participants recommended that the FDA proactively set requirements that are more flexible than the standard regulatory strategies in place and that the FDA hold a workshop to better clarify their roles in the medical countermeasure development process.

Medical Countermeasures Research and Development Pipeline

Federal Agency Role: The relationship between NIH and HHS funding should be clarified and the associated gaps and time delays should be identified. The government should also clarify the process used to define the responsibilities of all agencies involved, how these agencies are funded, and whether the funding is appropriated in line with the *HHS PHEMCE Strategy* and *HHS PHEMCE Implementation Plan*.

Risks of Development: Additional partnerships and more risk sharing between government and industry are needed in threat assessment and requirements development. Government and industry should form groups that share information regarding specific agents (e.g., smallpox and tularemia). Very substantial cash outlays are involved in running Phase 3 clinical trials and the capital and development costs of

countermeasures should be factored into the government's equations. Support is needed from private investors for the capital costs associated with creating new technologies, but the Project BioShield legislation does not sufficiently encourage investors to participate. Investors need to know the market size and have a clear understanding of the market opportunity. BioShield is helpful in establishing a framework for these investments, but it is hoped that legislation currently under discussion will go even further.

Industry Participation: Participants also noted the lack of biodefense companies willing to contribute to a critical mass of resources for research; and, consequently, the lack of interest in continually developing or improving products. It was felt this may be assisted by increasing the talent, competition, and financial commitment to carrying the *HHS PHEMCE Strategy* forward.

Leveraging Experiences in Addressing Emerging Infectious Disease Threats such as Pandemic Influenza to Inform Approaches to CBRN Threats

Using Pandemic Flu as a Model: To determine whether pandemic flu is a good model for PHEMCE planning, more information is needed on national, local, and industry planning for pandemic influenza and how it compares to the universe of CBRN threats. Spending for an emerging infectious disease, such as a pandemic flu, is handled differently than for CBRN threats. The influenza model applies more to biological threats than chemical or radiation and/or nuclear threats because of the incubation time for biological agents. However, the phases involved in product development for all types of threats are similar and the countermeasures for influenza and other threats have some similarities. Experiences to be leveraged should not be limited to emerging infectious disease threats but should also include other events, such as natural disasters.

Lessons Learned: Lessons learned from influenza include how to incentivize development of and prepare utilization plans for antivirals and treatments. The CDC's surveillance programs for identifying influenza outbreaks might be useful for other communicable diseases (e.g., smallpox). However, the CDC needs more diagnostics and ways to recognize epidemics. Cross-agency communication is critical and has been a handicap in past disaster responses, so a uniform and centralized approach is needed to disseminate information on threats throughout the country.

Role of HHS: Because the response to any threat is ultimately executed at the local level, consistency needs to be maximized in preparing for future CBRN threats. HHS should gather information on city and state medical countermeasure stockpiles and strategies and should issue emergency preparedness guidelines as a first step in minimizing variability at the local level. Although not recommended as mandates, guidelines of "best practices" could be helpful to local planners.

Medical Countermeasures Delivery: Investment in strategies to facilitate HHS implementation of products is critical. Delivery technologies for agents should be leveraged to make new countermeasures easier to distribute and more likely to be used. Most vaccines are administered as injections at physicians' offices; however, for a pandemic event or large-scale biological warfare, better delivery methods will be needed. The development of new delivery methods explored for flu might be exploited for other new vaccines.

Acquisition Process and Policy under Project BioShield

Short and long-term Acquisition Strategies: In the short term, platform technologies should be developed and process validation is needed for new technology. Short-term strategies could also focus on new indications for existing products. For the mid- and long term, HHS should establish clear requirements so that industry can focus its efforts with reduced risk. The long-term strategy includes basic science efforts that will take time to develop into mature technologies. Long-term strategies depend on the viability of private companies through the 2023 timeframe, and the private sector needs to know that the government has a long-term commitment to the program.

Access to Infrastructure: Small companies need access to pilot and/or small-scale good laboratory practice (GLP) facilities, animal facilities, and manufacturing capabilities. The plan should specify how access would be provided to critical infrastructures, such as facilities, animal models, and workforce training. HHS should engage different stakeholder groups to develop the necessary infrastructures. The *HHS PHEMCE Strategy* or *HHS PHEMCE Implementation Plan* should explain how the infrastructure for medical countermeasures development will be funded, perhaps with support from several agencies, as well as who will identify the needs and whether diagnostics development needs will be included in supported infrastructure. Clinical manufacturing resources for the production of medical countermeasures (e.g., good manufacturing practice [GMP] facilities at NIH) exist within HHS but their availability is largely unknown to industry. The process for using these government programs and their availability needs to be communicated to industry to support the development of new products. Even with the availability of these resources, industry partners' manufacturing facilities will be needed to complete the production of new countermeasures.

Animal Models: A list of acceptable animal models for medical countermeasures for each threat should be provided. Animal models do not exist for many threats and medical countermeasures. The lack of appropriate models is a problem at both the development and regulatory stages. The availability of appropriate models would reduce the time required to bring medical countermeasures to market. Also, streamlining and better defining the two-animal rule would improve industry's ability to develop new agents.

Current R&D Portfolio: The HHS strategy is to determine where gaps exist and support research and development to fill the gaps. Barriers exist to transitioning from basic research to advanced development, and planning is needed to overcome these barriers. Requirements should be identified early in the research and development pipeline to allow coordination and management of countermeasure development paths. To determine the requirements, CONOPS is needed early on, and the requirements could depend on what the private sector can deliver. Increased clarity and guidance are needed, especially with regard to the definition of a "usable product" that is acceptable to the government.

A complete inventory of products and their relative position along the research and development pipeline must be compiled from government agencies and industry. A gap analysis should be performed on the pipeline inventory to better inform strategic plans. Such information could enable industry to decide whether to make agents *de novo* or to modify existing products in the pipeline. This analysis could also help transition products between government and industry for development, clinical testing, and acceleration of deployment.

Compressed Development Timeframe: Quick action is needed in developing medical countermeasures. For example, it often takes 2 years after an RFI or RFP is released for the contract to be awarded. This timeframe should be compressed so that industry can develop countermeasures in an optimal manner.

Disincentives: The plan to develop medical countermeasures with a long shelf life that will only rarely need to be procured is likely to be viewed as a disincentive by industry, as is the limited quantities often purchased by the government. To increase industry participation in countermeasure development, the strategy should include more incentives such as sustaining the production of countermeasures through the long term.

Reciprocal Influences between Medical Countermeasure Development and U.S. Government CONOPS

CONOPS Development and Updating: Overarching CONOPS for particular threat scenarios should be developed based on what exists and what is desired but not available, with a separate CONOPS for each medical countermeasures category. Requirements documents should identify objectives and thresholds. CONOPs should also be established to facilitate the refinement of requirements and to inform early-stage

findings. The CONOPS must take into account the appropriate timeframes for countermeasure responses. The DoD's procedures for long-term planning chould serve as a model for the PHEMCE.

CONOPS need to be updated and revised at specified intervals, and whenever a new countermeasure is added to the formulary, through continued dialog and discussions with internal and external stakeholders. Medical consequence models must take into account response operations, including realistic assumptions of public behavior in disasters. It is clear that the critical role of CONOPs puts a tremendous burden on CDC – additional resources and support will be needed to support these requirements.

Product Specifications: HHS should consider the overall cost–benefit implications of end-user requirements such as safety, supply chain, cost, and shelf life. A standard list of questions should be developed to address storage conditions, dose frequency, and other variables so that as HHS develops RFPs, the same types of issues are addressed in each RFP, although they could be weighted differently.

Communications: HHS should indicate the information sensitivity and level of clearance required for countermeasure development. In doing so, it needs to weigh the benefits of providing full information to researchers against the possible costs of disclosing vulnerabilities. Potential pre-exposure, exposure, and post-exposure scenarios should be distributed to the community. Spokespersons who are credible and understandable should be identified.

Special populations should be educated on how to respond with individual medical countermeasures. The audiences (businesses; consumers; and federal, state, and local governments) for this information should be considered, and advisory panels should be created with representation from these sectors. In addition, stakeholder groups should be established in each threat area to keep industry informed of changing requirements, CONOPS, and environments. The U.S. Government must be clear about how it makes decisions related to product distribution and communicate those plans in advance.

Establishment and Prioritization of Medical Countermeasures Requirements

Threat Prioritization: When DHS developed its initial threat determinations, the process was not perceived as transparent and the results not sufficiently specific. That analysis addressed the threats but did not describe the potential numbers of people affected (e.g., morbidity and mortality). More communication with industry about threat scenarios, even if this information is restricted to threat-specific industry members, would help provide an incentive to develop medical countermeasures.

Priority Duration: HHS is approaching priorities for medical countermeasures in a relatively conservative way, but unforeseen events and technology breakthroughs could affect priorities. It is not clear how sustainable the priorities are or whether they are fixed for a certain period of time. The *HHS PHEMCE Strategy* or *HHS PHEMCE Implementation Plan* should specify whether the number of priorities is limited, how frequently the priorities are reconsidered, and how the agency will prioritize countermeasures based on cost, ease of use, and other factors.

Medical Countermeasure Availability and Use: It is unclear how HHS will determine the amounts of available medical countermeasures not in the SNS. A continuous, dynamic, simple, and flexible process is needed for information exchange so that the government can better plan for surge capacity. An industry advisory board would be helpful to facilitate interaction among industry, government, and academia. The government should also develop an acquisition strategy and a plan for marketing RFIs.

Distribution procedures should be developed for stockpiled countermeasures for diverse or multi-locality events. In addition, backup and evacuation plans are needed. Plans should also be made to adjust distribution of countermeasures to those exposed. It is not clear who will determine who has been exposed or how this determination will be made, especially if those who have been exposed evacuate the affected area. The government should also develop a plan to inform those in the affected area who are unaffected that they are fine and explain why they are not receiving scarce countermeasures. In addition,

the strategy needs to explain how companies with products in the SNS will communicate and coordinate with the government to follow up and obtain data on product efficacy and how the product is used and delivered.

APPENDIX 1

BioShield Stakeholders Workshop Attendance

Summary:

Industry	144 attendees
U.S. Government	130 attendees
Academia	33 attendees
State/Local Government	9 attendees
Media	1 attendee
Miscellaneous	1 attendee

Organizations/Agencies:

20/20 GeneSystems Inc.
American Association for the Advancement of Science
American Association of Blood Banks
Acambis, Inc.
Alliance for Biosecurity
Alnylam Pharmaceuticals
ALung Technologies
American Medical Association
American Academy of Pediatrics
American Society for Microbiology
ANSER Analytic Services
Applera Corporation
Applied Biosystems
Association of Public Health Laboratories
Association of State and Territorial Health Officials
Auburn Health Strategies, LLC
Avecia
Battelle Biomedical Research Center
Battelle Memorial Institute
Bavarian Nordic
Berlex, Inc.
Biotechnology Industry Organization
Bioavailability Systems
BioFactura, Inc.
BioRosettex/Sarnoff
BIOSAFE Inc.
Booz Allen Hamilton
Cangene Corporation
Cellerant Therapeutics Inc.
Center for Biosecurity/University of Pittsburgh Medical Center
Cornerstone Government Affairs
Chimerix, Inc.
Citigroup
Cleveland BioLabs, Inc.
Columbia University
Commissioned Officers Association of the U.S. Public Health Service
Congressional Research Service
Constellation Technology
CytoPulse Sciences Inc.
Dalrymple & Associates, LLC
Delaware Health and Social Services
Duke University Medical Center
Duramed Pharmaceuticals, Inc.
Dynport Vaccine Company LLC
Dyonyx
Elusys Therapeutics
Executive Office of the President
Emergent BioSolutions
Office of the Vice President
Office of Science and Technology Policy
Fabiani & Company
Fleming & Company Pharmaceuticals
Foley Hoag LLP
Four Seasons Ventures
Functional Genetics Inc.
General Dynamics
GenPhar Inc.
GenVec Inc.
George Washington University
GlaxoSmithKline
Global Secure Systems Corp.
Great Lakes Research Center of Excellence
Hematech Inc.
Hollis-Eden Pharmaceuticals
Homeland Security Council
Human Genome Sciences
Humanetics Corp.
Innovative Decisions, Inc
Innovative Emergency Management Inc.
ImmuneRegen Biosciences, Inc.
Invitrogen
Iomai Corporation
Kaketsuken
Kimbell & Associates
Linda Jenckes & Associates
Lovelace Respiratory Research Institute
Massachusetts State Laboratory/Association of Public Health Laboratories

McKenna Long & Aldridge LLP
Midwest Research Institute
Maryland Institute for Emergency Medical Services Systems
Mitretek Systems
Morgan Lewus & Bockius LLP
Nanoviricides
National Association for State EMS Officials
National Center for Disaster Preparedness
National Conference for State Legislators
North Dakota Department of Health
New Jersey Department of Health and Senior Services
New York City Department of Hygiene and Mental Health
New York State Department of Health
Ohio Emergency Management Association
Omrix Biopharmaceuticals
Osiris Therapeutics Inc.
Pfizer Inc.
Pharm Athene, Inc.
Policy Directions Inc.
Preston Gates Ellis & Rouvelas Meeds LLP
PRTM Management Consultants
Royal Danish Embassy
Sanofi Pasteur, Inc.
Science Applications International Corporation
Social & Scientific Systems, Inc.
Spectrum Research LLC
Steris Corporation
System Planning Corporation
T. Dean Reed Company
The Housman Group
Trudeau Institute
Tunnell Consulting
U.S. Department of Defense
- Armed Forces Radiology Research Institute
- Chemical Biological Medical Systems
- Joint Program Executive Office–Chem Bio Defense
- Military Vaccine Agency
- Office of Secretary
- Uniformed Services University of the Health Sciences
- U.S. Army
- U.S. Army Medical Research Institute of Infectious Diseases

U.S. Department of Energy
- Oak Ridge National Laboratory

U.S. Department of Health and Human Services
- Centers for Disease Control and Prevention
- Food and Drug Administration
  - Center for Biologics Evaluation and Research
  - Center for Drug Evaluation and Research
  - Office of Counter-Terrorism and Emergency Coordination
  - Center for Devices and Radiological Health
- Health Resources Services and Administration
- National Institutes of Health
  - National Institute of Allergy and Infectious Diseases
  - Division of Allergy and Immunology, and Transplantation
  - Division of Microbiology and Infectious Diseases
- Office of the Secretary
  - Office of Public Health Emergency Preparedness
  - Office of Medicine, Science, and Public Health
  - Office of Plans and Emergency Operations
  - Office of Public Health Emergency Medical Countermeasures

U.S. Department of Homeland Security
- National Biodefense Analysis and Countermeasures Center
- National Disaster Medical System

U.S. Department of State
- Bureau of Oceans and International Environmental and Scientific Affairs
- International Health Affairs

U.S. House Committee on Homeland Security
U.S. Senate Budget Committee
U.S. Senate Committee on Health, Education, Labor, and Pensions
U.S. Senate Subcommittee on Bioterrorism and Public Health Preparedness
University of Maryland
- Center for Health and Homeland Security
- Greenebaum Cancer Center
- School of Medicine

U.S. Medicine
University of Rochester Medical Center
URS Corporation
University of Texas Medical Branch
VaxGen, Inc.
Vical Inc.
Virginia Bioinformatics Institute
Virginia Department of Health
Xoma LLC

APPENDIX 2
Strategic Policies

Several critical policy issues were used to guide creation of the *HHS PHEMCE Implementation Plan for CBRN Threats*. These policies addressed both the development and acquisition of medical countermeasures to threat agents. These ten strategic policies, as laid out in the draft *PHEMCE Strategy* and discussed in Work Session I of the BioShield Stakeholder Workshop, included:

1. **Relative Hierarchy of CBRN Threat Classes (Biological versus Chemical versus Radiological/Nuclear)**
   The *PHEMCE Implementation Plan* will address the relative value of medical countermeasures across all classes of threat agents. There is general consensus that the greatest potential for medical mitigation exists for biological threat agents. However, HHS also envisions identifying significant, though more limited, opportunities for MCM for radiological, nuclear and chemical threats.

2. **Addressing Top Priority versus All Threats**
   While our primary goal is to prevent the health effects of an attack with WMD, we recognize that despite our best efforts we will not be able to develop and acquire medical countermeasures to prevent and reduce adverse health effects against all threats in all places at all times for all people. Consequently, the *PHEMCE Implementation Plan* will consider all CBRN threats weighing costs, risks, and benefits such as their relative priority, feasibility of use in an event, and cost to mitigate with MCM and non-MCM to develop the best strategy. Recognizing the scope of the threats and the limited resources, the investments will focus on the top priorities for medical mitigation. Where possible, HHS will aim to develop and acquire medical countermeasures that have the potential to address multiple threats, particularly for lower priority threat agents.

3. **Traditional, Enhanced, Emerging, and Advanced Threats**
   There are four classes of biological threat agents: traditional, enhanced, emerging, and advanced (or engineered) threats. These are defined, briefly as:
   - Traditional Agents: naturally occurring microorganisms or toxin products with the potential to be weaponized and disseminated to cause mass casualties (e.g. anthrax, smallpox, etc.). This includes all Category A, B and C agents.
   - Enhanced Agents: traditional agents that have been modified or selected to circumvent current countermeasures. For example, an enhanced agent could be a bacterial pathogen that is modified to confer resistance to an antibiotic.
   - Emerging Agents: naturally occurring organisms that are newly recognized or anticipated to present a public health threat. Recent examples of emerging agents include Severe Acute Respiratory Syndrome (SARS) and West Nile Virus.
   - Advanced Agents: novel organisms that have been engineered or newly generated in the laboratory. Ongoing advances in biotechnology are believed to enable the engineering of novel organisms that could be targeted to completely bypass our countermeasures and might even be mistaken as naturally occurring emerging agents.

   The *PHEMCE Implementation Plan* will address traditional, enhanced, emerging, and advanced (engineered) threats and develop the best strategy to mitigate risk within time and cost constraints. HHS will continue to support a robust basic research program that will aim to develop broad-spectrum solutions using technologies that enable more flexible next generation interventional concepts and to consider approaches and technologies derived from the commercial drug development sector to support the biodefense mission. However, it is anticipated that near- and mid-term acquisition programs will continue to focus on addressing specific high priority threats with specific medical countermeasures. We will work closely with the intelligence community to ensure that our priorities are consistent with intelligence assessment of the threats most likely to be faced by our nation.

4. **Medical versus Non-medical Countermeasures**
HHS will work closely with interagency partners and in concert with national strategies and directives to guide and coordinate our medical countermeasure efforts with the other aspects of our homeland security strategies and missions to maximize synergies and minimize any gaps in our national defenses. Specifically, the *PHEMCE Implementation Plan* will take into consideration the use of non-medical countermeasures when establishing priorities to complement the use of medical countermeasures.

5. **Specific versus Broad Spectrum or Fixed versus Flexible defenses**
As is true in the broader biodefense context, a key challenge to the Implementation Plan will be to define the optimal balance between fixed and flexible defenses.[1] While static defenses and the so-called "one bug-one drug" approach can be justified for top priority threat agents such as anthrax, with well-recognized potential for catastrophic medical and economic consequences, the uncertainties associated with the CBRN threat environment require that the *PHEMCE Implementation Plan* be as flexible as possible, to allow for the best approach for protection of our nation's citizens. Therefore, HHS will support the development of flexible MCM while recognizing that, at least for the immediate future, some agents will require agent-specific MCM.

6. **Prevention/Mitigation versus Treatment**
The *PHEMCE Implementation Plan* will address both medical prevention and treatment alternatives and develop the best strategy considering both costs and benefits. The term "cost" in this case goes beyond simple immediate expenditure of funds to also include weighing future opportunity costs. For example, if the United States government purchases a medical countermeasure in the short term it may then miss the opportunity to buy a more effective medical countermeasure in the future due to budgetary constraints. In addition, a medical countermeasure that has a more expensive cost upfront, may be more valuable in the long term if it meets the criteria in utilization during a crisis, that is, easily self administered, no cold-chain storage, or broad spectrum with respect to threat mitigation. As with the definition of costs, benefits also go beyond the simple definition of "curing disease" and include concepts such as overall lifecycle of the medical countermeasure including storage, utilization and deployment.

For civilian populations, it is anticipated that, aside from some of the top priority threats, a post-event strategy will be adopted. Pre-event MCM (e.g. vaccines) are appropriate for high priority threats and when pre-event MCM are justified. Therapeutics/diagnostics or the use of post-exposure prophylaxis following an event will be the preferred strategy for all other threats. From this perspective, vaccines that provide post-exposure efficacy will be of interest.

7. **Acute versus Chronic Effects**
The *PHEMCE Implementation Plan* will give priority to addressing the acute (immediate to weeks time frame) medical/public health outcomes resulting from CBRN threat agents.

8. **First Available versus Next Generation**
The *PHEMCE Implementation Plan* will address both currently available and next generation medical countermeasures and will regularly evaluate on a case-by-case basis strategies for long-term maintenance and/or replacement of medical countermeasures in the SNS. Currently available medical countermeasures will be considered for acquisition if they meet immediate, critical needs and may be effectively deployed under current preparedness plans. Investment to meet particular threats will not however be a singular event, but rather an ongoing process that synchronizes the lifecycle requirements of currently stockpiled medical countermeasures with on-going research and development efforts. This synchronization should ensure that, as current

[1] Relman DA. Bioterrorism – Preparing to Fight the Next War. NEJM, 2006; 354(2):113-115, 2006. In the context of defense against biological threats, a fixed defense is a medical countermeasure intended for use against a specific organism and not useful in scenarios that employ a different organism.

stockpiles age and decline, more appropriate, next generation products will be available for acquisition consideration.

9. **General versus Special populations**
   The *PHEMCE Implementation Plan* will address the needs of both general and special populations such as children, the elderly, pregnant women, persons with immunocompromised conditions and persons with disabilities that may impact the efficacy of, or the ability to access, MCM. Given limited available resources, priority will be given to those medical countermeasures that will prevent and treat adverse health effects to the greatest number of individuals. However, efforts will continue to be made to find creative solutions for providing treatment and mitigation of high priority threats to all populations.

10. **Domestic versus International**
    The *PHEMCE Implementation Plan* will focus on the domestic medical countermeasure needed to protect the homeland, while recognizing that in a global emergency these resources may be utilized by the USG to meet critical international needs and the need to protect the homeland, to the extent feasible, under the framework of the International Health Regulations (2005) that will go into force in June 2007. Additionally, the Implementation Plan will call out and address those instances in which domestic manufacturing capacity is critical to national security.

Appendix 3

BioShield Stakeholders Workshop Agenda

September 25—Day 1

8:00–8:30 AM	On-site Registration
8:00 AM–5:30 PM	"Help Desk" Informational Booths Available
	Opening Session
8:30–8:35 AM	**Welcome and Introduction of ASPHEP** ***Dr. Carol Linden***, Acting Principal Deputy Director, Office of Public Health Emergency Medical Countermeasures, Office of Public Health Emergency Preparedness, Department of Health and Human Services
8:35–8:40 AM	**Introduction of Secretary** ***RADM Craig Vanderwagen***, Assistant Secretary for Public Health Emergency Preparedness, Department of Health and Human Services
8:40–9:00 AM	***Secretary Michael O. Leavitt***, Department of Health and Human Services
9:00–9:20 AM	***Dr. Rajeev Venkayya***, Special Assistant to the President for Biodefense, Homeland Security Council, Executive Office of the President
9:20–9:40 AM	***Ms. Ellen Embrey***, Deputy Assistant Secretary of Defense for Force Health Protection and Readiness, Department of Defense
	Session I **Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for Chemical, Biological, Radiological, and Nuclear (CBRN) Threats**
9:40–10:10 AM	**Introduction to HHS PHEMC Enterprise and the PHEMCE Strategy** ***RADM Craig Vanderwagen,*** Assistant Secretary for Public Health Emergency Preparedness, Department of Health and Human Services
10:10–10:30 AM	***Dr. Elias A. Zerhouni*,** Director, National Institutes of Health, Department of Health and Human Services
10:30–10:50 AM	***Dr. Andrew C. von Eschenbach***, Acting Commissioner, U.S. Food and Drug Administration, Department of Health and Human Services
10:50–11:10 AM	***Dr. Julie L. Gerberding***, Director, Centers for Disease Control and Prevention, Department of Health and Human Services
11:10–11:30 AM	Break
	11:30 AM–1:15 PM **Stakeholder Panels**
11:30–12:00 PM	**Panel 1: Industry** Moderator: ***Dr. Monique K. Mansoura*,** *Acting Deputy Director for Policy, Planning and Requirements, Office of Public Health Emergency Medical Countermeasures, Office of Public Health Emergency Preparedness, Department of Health and Human Services* ♦ ***Chris Colwell***, Director, Healthcare Regulatory Affairs, Biotechnology Industry Organization (BIO) ♦ ***Tom McKenna,*** Chair, Health Emergency Response Work Group, Pharmaceutical Research and Manufacturers of America (PhRMA) ♦ ***Mark Leahey***, Executive Director, Medical Device Manufacturers Association (MDMA) ♦ ***Janet Trunzo,*** Executive Vice President, Technology and Regulatory Affairs, AdvaMed

12:00–12:30 PM	**Panel 2: Academia/Science** Moderator: ***Dr. Carol Linden***, *Acting Principal Deputy Director, Office of Public Health Emergency Medical Countermeasures, Office of Public Health Emergency Preparedness, Department of Health and Human Services* ♦ ***Dr. Tara O'Toole***, CEO and Director, the Center for Biosecurity of the University of Pittsburgh Medical Center ♦ ***Dr. Debra Anderson***, Associate Director, Great Lakes Biodefense Research Center of Excellence ♦ ***Dr. Paul Okunieff***, Centers for Countermeasures against Radiation; Chairman, Department of Radiation Oncology, University of Rochester Medical Center

12:30–1:15 PM	**Panel 3: Medicine and Public Health** Moderator: ***Dr. Gerald Parker***, *Principal Deputy Assistant Secretary, Office of Public Health Emergency Preparedness, Department of Health and Human Services* ♦ ***Dr. James J. James***, Director, Disaster Preparedness, American Medical Association (AMA) ♦ ***Nancy L. Hughes***, Director of the Center for Occupational and Environmental Health, American Nurses Association (ANA) ♦ ***Dr. Georges Benjamin***, Executive Director, American Public Health Association (APHA) ♦ ***Dr. Paul E. Jarris***, Executive Director, Association of State and Territorial Health Officials (ASTHO) ♦ ***Dr. Michael Fraser***, Deputy Executive Director, National Association of County and City Health Officials (NACCHO)
1:15–2:45 PM	LUNCH
2:45–4:45 PM	**Work Session I: PHEMCE Strategy for CBRN Threats—Stakeholder Response** Focus Areas: ♦ Specific versus Broad Spectrum or Fixed versus Flexible Defenses ♦ Domestic versus International ♦ Traditional, Enhanced, Emerging, and Advanced Threats ♦ Medical versus Nonmedical Countermeasures ♦ Prevention/Mitigation versus Treatment ♦ Relative Hierarchy of CBRN Threat Classes (Biological versus Chemical versus Radiological/Nuclear) ♦ First Available versus Next Generation ♦ Acute versus Chronic Effects ♦ General versus Special Populations ♦ Addressing Top Priority versus All Threats
4:45–5:45 PM **NETWORKING/SOCIAL HOUR**	
6:00 PM	ADJOURN

September 26—Day 2

8:00 AM–5:00 PM	"Help Desk" Informational Booths Available
8:00–8:10 AM	**Welcome and First Day Review** ***RADM Craig Vanderwagen*****,** Assistant Secretary for Public Health Emergency Preparedness, Department of Health and Human Services
	Session II **CBRN Threats and Medical/Public Health Consequences**
	Session Chair: ***Dr. Carol Linden,*** Acting Principal Deputy Director, Office of Public Health Emergency Medical Countermeasures, Office of Public Health Emergency Preparedness, Department of Health and Human Services
8:10–8:30 AM	**Chemical, Biological, Radiological, and Nuclear Threat Assessments** ***Dr. John Vitko Jr.,*** Director, Chemical and Biological Division, Science and Technology Directorate, Department of Homeland Security
8:30–8:50 AM	**Medical/Public Health Consequence Modeling** ***Dr. Peter Highnam*****,** Office of Public Health Emergency Medical Countermeasures, Office of Public Health Emergency Preparedness, Department of Health and Human Services
8:50–9:10 AM	**Medical Countermeasures in a Public Health Emergency** ***Dr. R. Tom Sizemore III*****,** Deputy Director Operations, Office of Preparedness and Emergency Operations, Office of Public Health Emergency Preparedness, Department of Health and Human Services
9:10–9:30 AM	**Threat Surveillance/Detection and Medical Countermeasure Utilization and Deployment** ***CAPT Dan Sosin*****,** Senior Advisor for Science and Public Health Practice, Coordinating Office for Terrorism, Preparedness and Emergency Response, Centers for Disease Control and Prevention, Department of Health and Human Services
9:30–10:00 AM	**Session II Q and A** Panel of plenary speakers will answer written and oral questions from audience
10:00–10:20 AM	BREAK
	Session III **Medical Countermeasure Research, Development, and Acquisition**
10:20–10:30 AM	Session Chair: ***Dr. Jerome Donlon,*** Principal Science Advisor, Office of Public Health Emergency Medical Countermeasures, Office of Public Health Emergency Preparedness, Department of Health and Human Services
10:30–10:50 AM	**NIH Biodefense Research and Development Priorities/Programs** ***Dr. Michael G. Kurilla*****,** Director, Office of Biodefense Research Affairs, the Division of Microbiology and Infectious Diseases; Associate Director, Biodefense Product Development, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services
10:50–11:10 AM	**The Role of the U.S. Food and Drug Administration in Biodefense** ***RADM Boris Lushniak*****,** Assistant Commissioner, Counterterrorism Policy, Office of Counterterrorism Policy and Planning, Office of the Commissioner, U.S. Food and Drug Administration, Department of Health and Human Services
11:10–1:30 PM	**Establishing and Prioritizing Medical Countermeasure Requirements for Chemical, Biological, Radiological, and Nuclear (CBRN) Threats** ***Dr. Monique K. Mansoura*****,** Acting Deputy Director for Policy, Planning, and Requirements, Office of Public Health Emergency Medical Countermeasures, Office of Public Health Emergency Preparedness, Department of Health and Human Services
11:30–11:50 PM	**Acquisition Process, Programs, and Policy under Project BioShield** ***Dr. Carol Linden*****,** Acting Principal Deputy Director, Office of Public Health Emergency Medical Countermeasures, Office of Public Health Emergency Preparedness, Department of Health and Human Services

11:50–12:30 PM	**Session III Q and A** Panel of plenary speakers will answer written and oral questions from audience
12:30–2:00 PM	LUNCH
2:00–4:00 PM	**Work Session II: Public Health Consequences and Medical Countermeasure Research, Development, and Utilization—Stakeholder Response** Focus Areas: ♦ U.S. Government Interactions and Dialogue with External Stakeholders ♦ Medical Countermeasures Research and Development Pipeline ♦ Leveraging Experiences in Addressing Emerging Infectious Disease Threats such as Pandemic Influenza to Inform Approaches to CBRN Threats ♦ Acquisition Process and Policy under Project BioShield ♦ Reciprocal Influences between Medical Countermeasure Development and USG Utilization Needs and Concept of Operations (CONOPS) ♦ Establishment and Prioritization of Medical Countermeasure Requirements
	Closing Session
4:15–4:25 PM	**Medical Countermeasure Development and Acquisition—Path Forward under the PHEMCE Strategy:** ***Dr. Carol Linden*,** Acting Principal Deputy Director, Office of Public Health Emergency Medical Countermeasures, Office of Public Health Emergency Preparedness, Department of Health and Human Services
4:25–4:30 PM	**Closing Remarks** ***Dr. Gerald Parker*,** Principal Deputy Assistant Secretary, Office of Public Health Emergency Preparedness, Department of Health and Human Services
4:30 PM	WORKSHOP ADJOURNS