

## SUMMARY MEETING REPORT

### Global Health and Security Initiative (GHSI) Public Health Emergency Medical Countermeasures Workshop

November 4-5, 2009  
Washington, D.C.

The Office of the Assistant Secretary for Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS) held a GHSI Public Health Emergency Medical Countermeasures Workshop on November 4-5, 2009 in Washington D.C. Two hundred participants from the Governments of the GHSI countries, the private sector including members from the pharmaceutical industry, and academia attended the workshop.

The goals of this workshop were to:

- a) Share information on research and development programs in GHSI countries including candidate MCMs (vaccines, therapeutics, diagnostics) in the pipeline for Chemical, Biological, Radiological/Nuclear threats and Pandemic Influenza.
- b) Explore collaboration opportunities on research and development of specific products
- c) Discuss regulatory and legal issues associated with stockpiling and using MCM including harmonization of approval pathways (e.g. Animal Rule), emergency use authorization for unapproved and off-label use of MCMs, and shelf-life extension of stockpile products
- d) Explore challenges and needs to build a sustainable global infrastructure for MCM for public health emergencies

This report is a summary of the meeting notes and proceedings.

#### DAY ONE

**8:30 a.m. – 12:30 p.m.**

#### **Plenary Session: A Sustainable Global Infrastructure for Medical Countermeasures (MCM)**

Moderator: Mary Mazanec, M.D., J.D., Deputy Assistant Secretary, Director, Office of Medicine, Science, and Public Health, ASPR, HHS

The first plenary session examined the challenges and needs to build a sustainable infrastructure for medical countermeasures (MCM) globally.

In a welcome speech, Dr. Nicole Lurie, the HHS Assistant Secretary for Preparedness and Response (ASPR), outlined the need for a global approach to the development of a sustainable infrastructure for MCM. The recent experience with H1N1 influenza, the shortages in the supply of antivirals, and the issues of vaccine availability and access worldwide, showcased the importance of having a global infrastructure for MCM.

Professor Nigel Lightfoot (U.K.), in his capacity as Chair of the GHSI Risk Management and Communications Working Group, introduced the GHSI approach to address the creation of a sustainable global infrastructure for MCM. GHSI is a forum of like-minded countries to

strengthen health preparedness and response globally to threats of biological, chemical, radio-nuclear terrorism (CBRN) and pandemic influenza.

The GHSI is interested in discussing a way forward to share MCM for several reasons. Firstly, emerging infectious diseases, pandemics, and CBRN terrorism are a global issue. Secondly, it is virtually impossible for a single country to fund research and development programs for MCM for most threat agents. Thirdly, there is an overall global shortage in the production capacity for vaccines and therapeutics for most threat agents. Finally, there are few incentives for the pharmaceutical sector to develop MCM for diseases or CBRN threats that may affect only a few people in a few countries during limited periods of time.

The next panel speakers talked about preparedness and response programs in their countries and gave a global view of these efforts:

Mr. François Salicis (FR), Project Manager for CBRN Issues in the Public Health Emergency Preparedness and Response Division within the French Ministry of Health, France, gave an overview of the French MCM research and development (R&D) program. In France, prior to 2007, several different agencies responded by CBRN threats and pandemic influenza (Ministry of Health, Ministry of Defense, Ministry of Research and other Health Agencies). The response was decentralized, and tended toward the one-bug, one-drug approach. Following the H5N1 outbreaks in 2005, some GHSI discussions on MCM and an EU Task Force on CBRN threats, in 2007 France moved towards a new paradigm of managing its MCM by creating EPRUS. The role of EPRUS is to set up a corps of health reserve personnel, and to manage the logistics of the French national stockpile to respond to health threats nationally or abroad (see presentation by Mr. Martin on the second day for additional information on EPRUS.)

Dr. Michael Kurilla (US), Director of the Office of Biodefense Research Affairs, and Associate Director for Biodefense Product Development at the National Institute of Allergy and Infectious Diseases (NIAID), within the HHS National Institutes of Health (NIH), introduced the Medical Countermeasures Program on Biodefense, Radiological/Nuclear, and Chemical Threats at NIAID. The program undertakes *in-vitro* assessment of screening activities, animal model testing, preclinical IND enabling services, GLP animal efficacy model development, reagent production, and clinical trial infrastructure support.

Dr. Carol Linden (US), Principal Deputy Director, within the ASPR Biomedical Advanced Research and Development Authority (BARDA), detailed the BARDA Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) that came into existence in late 2006. Its mission is to provide countermeasures for CBRN threats, pandemic influenza and emerging infectious diseases through product requirement setting, product development, stockpile acquisition/building, building manufacturing infrastructure and product innovation. BARDA executes 6 critical functions:

- Setting MCM requirements
- Managing advanced development of MCM
- Procuring for the stockpile
- Building infrastructure for manufacturing
- Fostering innovation
- Coordinating the entire PHEMCE

Finally, Dr. R. Kent Harding (CA), Chief Scientist at Defence Research and Development Canada, discussed the concept of forming a Canadian MCM consortium. In terms of funding, the Public Health Agency of Canada supports in-house research and partners with industry and

academic projects. With a few exceptions, the Department of National Defence supports programs up to Technology Readiness Level (TRL) 4 (this is the Proof of Concept stage, where some animal models are developed to test the desired indication of measure, and *in vivo* activity is demonstrated in the small animal models.)

One of the exceptions is the Technology Demonstration Program which supports programs through the pre-clinical stage (TRL 5). Unlike the U.S., Canada has few products that make it to the final stages of production: a gap is in the development of products beyond TRL 5/6, which impact clinical development, product licensing and post licensure activities. To bridge this gap, Canada is creating a joint-effort approach, or consortium, which currently involves the Health and Defence Departments.

The goal of the next session was to provide an overview of major initiatives in global preparedness and response to involve the sharing of MCM globally. Speakers also addressed obstacles to developing these MCM and barriers to sharing them.

Dr. Cathy Roth (WHO), Coordinator for Biorisk Reduction for Dangerous Pathogens within the World Health Organization (WHO), gave an overview of WHO's Smallpox Vaccine Bank. After the eradication of smallpox in 1979, the organization decided to augment its stockpile and garner support from those member states that still manufactured smallpox vaccine. The Two-Tier system essentially consists of a) a WHO-held Stockpile, and b) stocks held in countries which have committed a specified amount or proportion of their national stocks, to be released if required. The target is to assemble 200 million doses by coordinating pledges with Member States. Furthermore, WHO has developed an operational framework for acquisition and release of the vaccine and is working with donor countries to complete concepts of operations to share these doses in the event of a smallpox emergency.

Dr. Roth (WHO) also spoke about WHO's coordination efforts to make 2009 H1N1 vaccine available globally. The organization called for international solidarity to meet the donation target of 10 percent population coverage for countries in need. Several countries and manufacturers already pledged support. So far, they pledged a total of 178 million vaccine doses. Countries also pledged monies for the operational costs of vaccination. In July 2009, an advisory group made some important recommendations for the prioritization of the delivery of the H1N1 vaccine:

- Adults and adolescents 10 years and older should receive a single dose of vaccine,
- Where national authorities have made children a priority for early vaccination, children older than 6 months and younger than 10 years, priority should be given to the administration of the first dose to as many children as possible,
- In the absence of a specific contra-indication by the regulatory authority, any licensed pandemic vaccine can be used to protect pregnant women,
- There is a need for studies to determine dosage regimens effective in immunocompromised persons,
- When seasonal and pandemic vaccines are both inactivated, or when one is inactivated and the other is live attenuated, that they can be co-administered.

Dr. Patrick J. Scannon (US), a member of the MCM Markets and Sustainability Working Group within the National Biodefense Science Board (NBSB) gave his perspective on MCM markets and sustainability. NBSB, a Federal advisory committee, was created in 2006 as an independent body consisting of leaders from the pharmaceutical industry and others, to provide expert advice to the Secretary of HHS regarding current and future chemical, biological, nuclear and radiological agents.

The pharmaceutical industry as a whole does not have a long history of partnering with the Government. As a result, there are real and perceived barriers-to-entry that have affected industry participation in the development of MCM:

- Contracting with the USG can be slow, unwieldy, expensive and opaque.
- There is a lack of clarity and transparency from USG (procurement size, warm-base requirements, length of review, reliability of sustained funding, contract review process, rate of issuance of new proposals, requirement generation) that increase industry risk.
- There is a lengthy process to generate requirements, but with a contract in place, HHS viewed as cooperative, helpful, responsible and responsive.
- There is a perceived lack of coordination between development activities, and regulatory responsibilities remain a concern to industry.
- Industry reliance upon USG for key components of licensure submissions (disease studies, toxicology reports, access to BSL facilities) can lead to lack of accountability.
- Advanced development needs more dedicated funds, separate from BioShield procurement.
- Cost-plus-fee contracting flexibility for advanced development is appropriate for advanced development and would reduce industry risk.
- Multiyear funding with carry-over authority, with multi-year contracting authority, would signal USG commitment and increase industry sense of long-term stability.
- Bioshield expires in 2013; the program needs to be reauthorized with associated funding.
- BioShield funds should not be diverted to fund other initiatives.

Mr. John Clerici (US), Partner and Chair of Life Sciences and Public Health Preparedness Practice, within McKenna Long & Aldridge LLP, spoke on the legal and liability issues associated with international sharing of MCM. Many companies have long shied away from developing devices, vaccines and other countermeasures against naturally occurring and man-made threats to human health because of the fear of crippling litigation and findings of liability. To solve this problem in the United States, the Public Readiness and Emergency Preparedness (PREP) Act was signed into law to address this concern in 2005. The PREP Act offers targeted liability protections to those involved in the development, manufacturing and deployment of pandemic and epidemic products and security countermeasures. The Act creates a shield of immunity for claims arising out of, related to, or resulting from the administration or the use of a covered countermeasure (i.e., vaccines, countermeasures, devices and certain other products). This immunity covers a wide range of uses, including design, development, testing, manufacturing, distribution, administration, use and other activities so that the protections can be applied as broadly as possible.

**14:00 – 17:30**

### **Breakout Session I: MCM Research and Development**

In the afternoon, participants divided into several breakout rooms according to topics of choice: Pandemic Influenza, Biological Threats, Radiological/Nuclear Threats and Chemical Threats to discuss more threat-related topics of interest (a synopsis of the outcomes of these breakouts is provided on pages 5-6).

#### *Pandemic Influenza Breakout*

Moderator: Michael Perdue, Ph.D., Biomedical Advanced Research and Development Authority, ASPR, HHS

#### *Biological Threats Breakout*

Moderator: Professor Daniel Gillet, Ph.D. Deputy Chief and Coordinator, French RNBC Program, Department of Molecular Engineering of Proteins (SIMOPRO), Biology and Technology Institute of Saclay (IBiTec-S) French Atomic Energy Commission, France

#### *Radiological Nuclear Threats Breakout*

Moderator: Hilary Walker M.Sc., Ph.D., Deputy Director, Emergency Preparedness, Department of Health, United Kingdom

#### *Chemical Threats Breakout*

Moderator: Susan Cibulsky, Ph.D., Chemical Science Branch Chief, Policy, Planning, and Requirements Division, BARDA, ASPR, HHS

**18:00 – 20:00**

#### **Poster Session**

The first day ended with a poster session and reception, sponsored by the Foundation for the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) Foundation. The session had 29 posters on topics ranging from research and development programs on MCM in the United States and abroad, development of new diagnostics for MCM, sustainable influenza vaccine production capacity worldwide, and the use of animal models for testing new products, to the legal challenges of sharing MCM internationally. A list of abstracts in the web link at *To Be Posted in the Next Week*).

## **DAY TWO**

**9:30 a.m. – 10:40 a.m.**

#### **Policy Session I: Stockpile Management and Shelf-Life Extension**

Moderator: Professor Walter Biederbick, Ph.D., Center for Biological Safety, Robert Koch. Institute, Ministry of Health, Germany

The second day was divided into two sessions. The first policy session looked at how stockpiles and shelf-life extension is managed in different countries, and speakers gave their country's perspectives on the topics.

Mr. Claude-Olivier Martin (FR), Head Manager of Health Reserve Services within French Agency for Preparedness and Response of Health Emergencies (EPRUS), started the session by detailing stockpile management and shelf-life extension in France. Prior to 2007, France would buy MCM from manufacturers, having no centralized system of developing new MCM. During the 2003 outbreaks of H5N1, France started to work more closely with pharmaceutical industries to develop appropriate MCMs. In 2007, the French Government created EPRUS to control the stock of health products from manufacturing to distribution. In addition to stockpiles, France also has a reserve of health professionals. This reserve plays a critical role in a crisis situation by strengthening the medical and social structures of care as well as the durability of care.

Professor Daniel Camus (FR), Specialist on Infectious and Parasitic Diseases at the French Ministry of Health, briefed participants on France's Shelf-Life Extension Program, or SLEP, overseen by Afssaps (France's Medicine Agency). The program covers the strategic national

stockpile of 14 key pharmaceutical products including oseltamivir, various antibiotics, Tamiflu and other medications.

Dr. Greg Burel (US), Director of the Strategic National Stockpile in the then Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER now called the Office of Public Health Preparedness and Response or OPHPR) at the HHS Centers for Disease Control and Prevention (CDC), followed with information on the U.S. Strategic National Stockpile. In the United States, the CDC is responsible for the acquisition, storage, maintenance and deployment of products through the Strategic National Stockpile. The stockpile consists of a \$3.5 billion portfolio that includes antibiotics, medical supplies, antidotes, antitoxins, antiviral, vaccines and other pharmaceuticals.

Dr. Susan Gorman (US), Associate Director for Science for the Division of Strategic National Stockpile (DSNS), COTPER, within the HHS Centers for Disease Control and Prevention (CDC), detailed the cost/benefit analysis of shelf-life extension for drugs and biologics. An ever growing percentage of the SNS budget is consumed storing, maintaining and replacing the countermeasure inventory. The Shelf-Life Extension Program (SLEP) in the United States helps federal entities achieve maximum shelf-life for medical material by extending the expiration date beyond the label date, based on retesting data. SLEP also helps to reduce risk to critical infrastructure but can place a burden on manufacturers (e.g., a sole-source product).

Although SLEP has saved the U.S. Government hundreds of millions of dollars, the program may not be cost-effective for all assets. DSNS is currently determining the break-even point for all assets in its stockpile. SLEP is only available for drugs and does not include biological products. Shelf-Life extension of biologics is carried out by the HHS Food and Drug Administration (FDA) on a lot-by-lot basis.

Dr. Alan Goldhammer (US), Associate Vice President for Regulatory Affairs, at Pharmaceutical Research and Manufacturers of America (PhRMA) in the United States, gave an industry perspective of shelf-life extension. Typically, manufacturers are conservative when setting the expiry date. In addition, expiration dates are product dependent. As such, the expiration date for a solid product may be different from that of liquids. Storage conditions, such as temperature range, also play a role in setting the expiration date. PhRMA created a multi-coalition group called Rx Response. Coalition partners include the American Hospital Association, the American Red Cross, the Biotechnology Industry Organization, the Generic Pharmaceutical Association, the National Association of Chain Drug Stores and other partners. The goal of Rx Response is to support the continued provision of critical medicines to patients whose health is threatened by a severe public health emergency and as such, shelf life extension issues are part of its considerations.

**11:00 a.m. – 12:30 p.m.**

**Policy Session II: Regulatory Approval and Use of MCM**

Moderator: Maria Julia Marinissen, Ph.D., Acting Team Leader, International Partnerships and Initiatives, Office of Medicine, Science, and Public Health, ASPR. HHS

The second afternoon policy session focused on the regulatory approval and use of MCM globally. The session gave an overview of the complexity of regulating MCM at the individual country level, and thus the challenges of sharing MCM internationally.

Ms. Sabine Atzor (European Commission), Policy Officer for Consumer Goods, within the Enterprise and Industry Directorate-General of the European Commission, described the regulatory procedures for the authorization of vaccines in the European Union. There are two kinds of marketing authorizations: a central-market authorization and a national-market authorization. Central-market authorization is required for certain products, such as biotechnology processes, and allows market access to all member states. National-market authorization is more limited and is only applicable to the member state that applied. In addition, as part of pandemic preparedness planning, the European Commission (EC) and the European Medicines Agency (EMA) introduced a procedure to allow the submission and evaluation of core pandemic dossiers (for mock-up vaccines) during the inter-pandemic period leading to marketing authorizations. The vaccines can only be used during an officially declared pandemic (WHO Phase 6). The procedure foresees the fast track assessment of the data for replacing the strain in the mock-up vaccine with the recommended pandemic strain as a variation. The mock-up concept must provide proof-of-principle and safety data.

Ms. Cynthia L. Kelley (US), Senior Advisor for Counterterrorism/Medical Countermeasures at the Center for Biologics Evaluation and Research (CBER) within the FDA, presented on the Emergency Use Authorization (EUA) for MCMs in the United States. The EUA allows for the use of unapproved products and unapproved uses of approved products as the result of an incident involving a chemical, biological, or radiological/nuclear (CBRN) agent, following a declaration of emergency by the HHS Secretary.

The conditions to be met for authorizing the use of a product under an EUA are:

- The agent specified in the declaration of the emergency can cause a serious or life-threatening disease or condition;
- It is reasonable to believe that the product may be effective in diagnosis, treatment, or prevention of disease;
- There known and potential benefits of the product, when used to diagnose, prevent, or treat such a disease or condition, *outweigh* the known and potential risks of use of the product; and,
- There is no adequate, approved, and available alternative product.

Dr. David Wood (WHO) Coordinator, Quality Assurance and Standards, Immunization, Vaccines, and Biologicals at WHO, reviewed the prospects for international harmonization of the regulatory processes for MCM. The advantage of harmonizing regulatory processes would be that countries could apply the common international standards when developing and testing MCM, and as a result, share MCM amongst Member States more easily. Over the past years, WHO has been an important player in the international harmonization of the regulatory processes for MCM. The pandemic H1N1 vaccine has proven to be a useful case study to examine some of these global regulatory and safety considerations. Preparations over several years have resulted in a relatively high degree of regulatory preparedness and harmonization for pandemic influenza vaccines. However reagents to calibrate the majority of candidate vaccines using conventional potency tests were qualified only just before the initiation of clinical trials. This has delayed trials and set back the date of completion of the vaccine. Safety issues have also come to bear because there is relatively little experience with the population-wide use of adjuvanted influenza vaccines. Combining surveillance of side effects of the vaccine across countries could give a much more comprehensive picture of the safety of the vaccine.

Dr. Lida Anestidou (US), Senior Program Officer at the Institute for Laboratory Animal Research within the National Academies, described the use of animal models to assess countermeasures to bioterrorism agents. Due to the ethical *do no harm* principle, a number of therapeutics or preventatives with MCM potential cannot be tested in humans. This has led to the reliance on

animal models to develop these countermeasures. The FDA's Animal Rule is the regulatory framework for licensure of such drugs and biologics, provided that appropriate efficacy studies in animals have been conducted. The National Academies are tasked with examining the utility and relevance of such animal models for research funded by the Transformational Medical Technologies Initiative of the U.S. Department of Defense. One of the global challenges is that the Animal Rule is unique to the United States, which means that there would be many legislative and scientific hurdles before sharing MCM globally.

**14:00 – 15:30 p.m.**

**Breakout Session II: MCM research and development**

In the afternoon, the participants re-organized into several breakout rooms according to topics of choice: Pandemic Influenza, Biological Threats, Radiological/Nuclear Threats and Chemical Threats (a synopsis is provided on pages 5-6), and then in breakout roundtables, where they discussed gaps, future needs, and ways to collaborate globally on the particular threat of interest.

*Pandemic Influenza for the Breakout and Roundtable*

Moderator: Michael Perdue, Ph.D., Biomedical Advanced Research and Development Authority, ASPR, HHS

*Biological Threats Breakout*

Moderator: Professor Daniel Gillet, Ph.D. Deputy Chief and Coordinator, French RNBC Program Department of Molecular Engineering of Proteins (SIMOPRO), Biology and Technology Institute of Saclay (IBiTec-S) French Atomic Energy Commission, France

*Biological Threats Roundtable*

Moderator: Professor Nigel Lightfoot, CBE, Chief Advisor, Health Protection Agency, United Kingdom

*Radiological Nuclear Threats Breakout*

Moderator: Mary J. Homer, Ph.D., Team Lead, Division of Chemical, Biological, Radiological, and Nuclear Countermeasures, BARDA, ASPR, HHS

*Radiological Nuclear Threats Roundtable*

Moderator: Jean-René Jourdain, Pharm.D., Ph.D., Representative for International Partnerships and Cross-Departmental Activities, Directorate of Radiation Protection and Human Health, Institute for Radiological Protection and Nuclear Safety, France

*Chemical Threats Breakout*

Moderator: Susan Cibulsky, Ph.D., Chemical Science Branch Chief, Policy, Planning, and Requirements Division, BARDA, ASPR, HHS

*Chemical Threats Roundtable*

Moderator: Professor Peter Blain, C.B.E., Professor of Environmental Medicine and Director of Medical Toxicology Centre, Newcastle University and Health Protection Agency, United Kingdom

**17:00 – 17:45 p.m.**

## **Plenary Roundtable: Guidelines to Integrating Policy and Research and Development for MCM**

Moderator: Monique K. Mansoura, Ph.D., Director for Medical Countermeasure Policy, Planning, and Requirements, BARDA, ASPR, HHS

The Chairs of each of the breakout groups presented a brief summary of the major issues discussed. The main points of each of the summaries are presented below.

### **Nuclear and Radiological Threats**

- In order to work toward common preparedness and response goals, countries must first agree on key generic scenarios or do joint threat/risk assessments.
- The old approach for MCM was to develop a new drug for every threat. Now, countries have expressed the need to develop drugs that can be used for number of different threats or can have indications for more than one condition or disease (also called **multi-use+drugs**), to alleviate the financial burden and logistical challenges of developing a large number of different drugs that will only serve for a particular indication. For similar reasons, countries would like to see an increased focus on research for innovative treatments for radiation injuries.
- In order to share MCM with international partners, countries are looking to understand and harmonize EMEA and FDA requirements for market authorization. Therefore, clarification and harmonization of regulatory requirements is essential.
- Participants expressed an interest in having international R&D workshops on regular basis, with incentives and resources encouraging the research and development community to share information.
- Pharmaceutical companies also expressed a need to understand what the requirements of Governments are in terms of development, acquisition and stockpiling of MCMs and what opportunities arise there from.

### **Chemical Threats**

- In the chemical threats arena, development of better oximes (Oxime compounds are used as antidotes for nerve agents) is essential to treating organo-phosphate poisoning.
- Creating a simplified classification of hazardous chemicals would also allow first responders to better identify the exposure of victims of chemical events, and thus expedite proper treatment.
- In general, countries expressed a need for greater preparedness to chemical threats, including: development of rapid diagnosis; readiness of MCM stockpiles; development and testing of emergency plans.
- Finally, participants would like to see greater investment in the R&D portfolio for MCM to treat chemical exposures globally. They have noted that MCM research for chemical injuries lags behind that of biological agents.

### **Pandemic Influenza Threats**

- The H1N1 epidemic has provided a number of important lessons to be learned including the fact that the vaccine production process should be modernized from top to bottom, scalable (i.e., not using eggs since that limit production capacity), consistent, with high productivity and readily quantifiable.
- In order to develop new MCM quickly, the clinical trial process needs to be expedited: start earlier with more than one candidate product; develop and implement regulations for emergencies, such as pandemics; evaluate differences between Government and industrial clinical trials and identify gaps.

- Countries should revisit their assumptions and strategic plans for pandemic influenza. For example, the H5N1 epidemic has shown that, while many countries were relatively well prepared for an H5N1 pandemic in terms of stocks of antivirals, vaccines and other materials, another virus variant arose and they have had to adapt to this new strain.
- It is essential to conduct close surveillance of the H1N1 outbreak, using animal and human isolates, in order to give an accurate picture of the progress of the epidemic.
- Finally, countries would like to learn from global lessons of the current H1N1 outbreak to accelerate new technologies and reduce the time it takes to scale up vaccine production.

### **Biological Threats**

- While the U.S. infrastructure for MCM is highly integrated with strong financial support to develop a wide spectrum of solutions for biological threats, most countries do not have the same financial platform. Therefore, countries should focus on developing a smaller number of MCM that fit their most urgent needs.
- Participants have expressed an interest in having a secure venue for frank discussion of data to develop a roadmap for medical countermeasure investment. This would allow Government Senior Officials to forecast budgetary needs in the next years.
- Countries need to collaborate to deliver a report identifying recent successes and specific threats with plans to counteract biological threats globally.

Following this report-out of the breakouts sessions, Dr. Mary Mazanec (US), Deputy Assistant Secretary and Director of Office of Medicine, Science, and Public Health (OMSPH), with ASPR, closed the meeting and thanked all the participants and the workshop staff for their contributions.

**Copies of the agendas are available at:**

<http://www.blsm meetings.net/2009GHSImeetingsMCM/agenda.html>

**Copies of the participant list are available at:**

<http://www.blsm meetings.net/2009GHSImeetingsMCM/H16802PostMtgParticipantList120709.pdf>

**Copies of the most of the presentations slides are available at:**

<http://www.blsm meetings.net/2009GHSImeetingsMCM/postmeetingmaterials.html>