

SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD
CLOSED SESSION IN-PERSON MEETING
February 2, 2012

VOTING MEMBERS PRESENT

John S. Parker, Major General (Retired), M.D., *Chair*
Georges C. Benjamin, M.D., FACP, FACEP(E), FNAPA, Hon FRSPH
John S. Bradley, M.D., FAAP, FIDSA
Nelson J. Chao, M.D., M.B.A.
David J. Ecker, Ph.D.
Emilio A. Emini, Ph.D.
Daniel B. Fagbuyi, M.D., FAAP, Major
Manohar R. Furtado, Ph.D.
Kevin A. Jarrell, Ph.D.
Steven E. Krug, M.D.
Sarah Y. Park, M.D., FAAP
Betty J. Pfefferbaum, M.D., J.D.

VOTING MEMBERS NOT PRESENT

Jane Delgado, Ph.D., M.S.

EX OFFICIO MEMBERS PRESENT

COL Bernard L. DeKoning, M.D., FAAFP, COL, Commander, U.S. Army Medical Research Institute of Infectious Diseases, U.S. Department of Defense
Heather Evans, Ph.D., Policy Analyst, Program and Planning Office, Director's Office, Chemical Science and Technology Laboratory, National Institute of Standards and Technology, U.S. Department of Commerce (*designated by Dianne Poster, Ph.D.*)
Andrew Flacks, HHS/ASPR Liaison to Veterans Health Administration, Office of Public Health and Environmental Hazards, U.S. Department of Veterans Affairs (*designated by Victoria J. Davey, Ph.D., M.P.H.*)
Bruce Gellin, M.D., M.P.H., Director, National Vaccine Program Office, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services
Rosemary Hart, J.D., Special Counsel, Office of Legal Counsel, U.S. Department of Justice
Carole Hudgings, Ph.D., Senior Advisor to the Deputy Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, U.S. Department of Health and Human Services (*designated by Hugh Auchincloss, M.D.*) (by phone)
Peter Jutro, Ph.D., Deputy Director, National Homeland Security Research Center, U.S. Environmental Protection Agency
Ali S. Khan, M.D., M.P.H., RADM, U.S. Public Health Service; Assistant Surgeon General; Director, Office of Public Health Preparedness & Response, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

George W. Korch Jr., Ph.D., Senior Science Advisor, Office of the Principal Deputy,
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of
Health and Human Services

Randall L. Levings, D.V.M., Scientific Advisor, National Center for Animal Health, U.S.
Department of Agriculture (by phone)

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

Carmen Maher, Acting Deputy Director, Office of Counterterrorism and Emerging
Threats, Office of the Commissioner, Food and Drug Administration, U.S.
Department of Health and Human Service (*designated by Luciana Borio, M.D.*)

Donald Malinowski, Ph.D., Office of the Director of National Intelligence (*designated by
Lawrence D. Kerr, Ph.D.*)

Vincent Michaud, M.D., M.P.H., Col, USAF Detailee, MC, CFS, Director, Medicine of
Extreme Environments, Office of the Chief Health and Medical Officer, National
Aeronautics and Space Administration (*designated by Richard Williams, M.D.*)

Sally Phillips, R.N., Ph.D., Deputy Director, Health Threats Resilience Division, Office
of Health Affairs, U.S. Department of Homeland Security

Bonnie Richter, Ph.D., Director of the Office of Illness and Injury Prevention Programs,
Office of Health Safety and Security, U.S. Department of Energy (*designated by
Patricia R. Worthington, Ph.D.*)

Amber L. Story, Ph.D., Deputy Division Director, Division of Behavioral and Cognitive
Sciences, National Science Foundation (by phone)

OTHER INVITED PARTICIPANTS

Susan Gorman, CDC (by phone)

David R. Howell, ASPR/OPP

Chad Hrdina, ASPR/OPP

Lisa Kaplowitz, ASPR/OPP

Michael Kurilla, NIH/NIAID

Gerald Kovacs, ASPR/BARDA

Bert Maidment, NIH/NIAID (by phone)

Nicki Pesik, CDC (by phone)

Joanna Prasher, ASPR/OPP (by phone)

Stephen C. Redd, CDC

Robin Robinson, ASPR/BARDA

Casey Wright, ASPR/OPP

Kevin Yeskey, ASPR/OPEO

NATIONAL BIODEFENSE SCIENCE BOARD

MacKenzie Robertson, Acting Executive Director

Jomana Musmar, M.S., Program Analyst (Contractor)

CALL TO ORDER, ROLL CALL, AND CONFLICT OF INTEREST RULES
MacKenzie Robertson, Acting Executive Director, NBSB

Ms. Robertson called to order the closed session of the NBSB meeting and reviewed the conflict of interest guidelines. She explained that the documents under discussion for the meeting are pre-decisional; therefore, the Board cannot provide formal recommendations on them to the Assistant Secretary for Preparedness and Response (ASPR) or the Secretary of the U.S. Department of Health and Human Services (HHS). (The review of sensitive documents and the exemption of the Board from Federal guidelines on public deliberation were discussed during the earlier, public portion of the meeting.)

WELCOME AND INTRODUCTION

John S. Parker, Major General (Retired), M.D., NBSB Chair

Dr. Parker explained that the Board has been asked for the first time to review pre-decisional documents. In doing so, the Board members would conduct discussions among the group as a whole and would not break into working groups.

OPENING REMARKS AND OVERVIEW OF ASPR REQUEST

George Korch Jr., Ph.D., Senior Science Adviser, ASPR, HHS

Dr. Korch stated that the ASPR is seeking the Board's input on planning for investments that affect a wide range of disciplines. He outlined the presentations to come from ASPR staff. Dr. Korch reiterated the request made by the ASPR, Nicole Lurie, M.D., M.S.P.H., in her December 2011 letter to the Board:

I would like the NBSB to review and evaluate the 2012 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan (SIP) during its development and near completion. Given the NBSB's previous deliberations and understanding of the PHEMCE and its mission, specifically your March 2010 report, *Where are the Countermeasures? Protecting America's Health from CBRN Threats*, I believe you are in a unique position to offer perspectives and insight in this endeavor from an independent scientific body.

HHS PHEMCE SIP FOR CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR (CBRN) THREATS (2007)

Carol D. Linden, Ph.D., Principal Deputy Director, Biomedical Advanced Research and Development Authority (BARDA), ASPR, HHS

Dr. Linden described the evolution of the PHEMCE, noting that HHS recognized the need to develop the SIP to communicate with partners, stakeholders, and the public about how it would respond to public health emergencies. The 2007 PHEMCE SIP (available online at

https://www.medicalcountermeasures.gov/BARDA/documents/phemce_implplan_041607final.pdf) focused on how HHS would allot the Project BioShield Special Reserve Funds.

Dr. Linden summarized the four goals outlined in the 2007 plan and its four pillars (the broad description of the planned steps to meet those goals). She explained the information sources that informed the development of the plan. Dr. Linden also outlined the key factors that shaped the prioritization of the plan's goals and activities. She pointed out that HHS and its partners in the Department of Homeland Security (DHS) have an integrated portfolio of research on medical countermeasures.

The 2007 SIP included a chart predicting the status of development and acquisition of medical countermeasures (MCMs) in the near-, mid-, and long-term, and Dr. Linden said progress has been made. She concluded that HHS is committed to updating the PHEMCE SIP and incorporating lessons learned.

WHERE ARE THE COUNTERMEASURES? PROTECTING AMERICA'S HEALTH FROM CBRN THREATS (2010)

John S. Parker, Major General (Retired), M.D., NBSB Chair

Dr. Parker stated that the Board's Markets and Sustainability Working Group discussed in depth the interface between industry and government around MCMs. Questions from that Working Group led the Board to review the whole Enterprise, resulting in the Board's 2010 report, *Where Are the Countermeasures? Protecting America's Health from CBRN Threats* (available online at <http://www.phe.gov/Preparedness/legal/boards/nbsb/meetings/Documents/nbsb-mcmreport.pdf>). The report identified the need for strong leadership and a good compass with three points: prioritization, synchronization, and anticipation (with input from the intelligence and research communities).

Dr. Parker summarized the findings and recommendations of the report. He concluded that the report was widely read, and he hoped that the issues raised would be reflected in the updated PHEMCE SIP.

Among the recommendations, the report identified the need for multi-year funding commitments; that issue is a growing concern as budgets get tighter. Robin Robinson, Ph.D., said he believes the importance of multi-year funding has been recognized by Congress.

HHS PHEMCE REVIEW: TRANSFORMING THE ENTERPRISE TO MEET LONG-RANGE NATIONAL NEEDS

George Korch Jr., Ph.D., Senior Science Adviser, ASPR, HHS

Dr. Korch described the events leading up to the Secretary's decision to conduct a comprehensive review of the PHEMCE, including the Board's 2010 report and the 2010 State of the Union address, in which President Obama called for initiatives to speed up the nation's response to security threats. The *PHEMCE Review: Transforming the Enterprise to Meet Long-Range National Needs* (available online at <https://www.medicalcountermeasures.gov/media/1138/mcmreviewfinalcover-508.pdf>) incorporated the findings of several commissioned white papers and input from numerous stakeholder workshops and discussions.

The report documented a strategy for forward-looking investment in MCMs for current and future threats, known and unknown. It emphasized the following key attributes, many of which reflect the thinking outlined in the Board's *Where Are the Countermeasures?* report:

- Nimble, multi-use technology and platforms
- Greater investment in regulatory innovation and enhancement of regulatory science
- New mechanisms for public-private partnerships
- More creative approaches to help MCM developers anticipate and resolve barriers to progress

Dr. Korch outlined the five major HHS-based initiatives that resulted from the comprehensive review:

- Numerous projects to improve the U.S. Food and Drug Administration's processes related to MCM development
- Plans to establish a center (or centers) for excellence in advanced MCM development and manufacturing
- Focus on increasing the number of MCMs in the pipeline and accelerating the pace of development (e.g., through the Concept Acceleration Program at the National Institute of Allergy and Infectious Diseases)
- Efforts to address the immediate needs related to pandemic influenza vaccine development
- Plans to create an independent strategic investment fund for MCM innovation

In addition, the PHEMCE established a new governing body, the Executive Senior Council, to coordinate decision-making and prioritization and created a formal, systematic approach to decision-making. It has also addressed the speed of contract finalization and developed new methods of requirement setting. The Public Readiness and Emergency Preparedness Act provided liability protection for MCM makers. The HHS Secretary supports multi-year funding and budget alignment across HHS agencies, Dr. Korch noted.

Dr. Korch also described the key agencies in the PHEMCE and the role each plays as products move from discovery to utilization. He emphasized that other Federal partners play critical roles. The Department of Defense (DoD) has systems similar to HHS for product research and development (and HHS coordinates with DoD whenever possible). The Department of Veterans Affairs shares the burden of response during an event. The DHS provides infrastructure protection as well as threat assessment and prioritization. The U.S. Department of Agriculture is critical in addressing zoonotic diseases that can affect humans.

DRAFT 2012 PHEMCE SIP

David R. Howell, Ph.D., Executive Director, PHEMCE SIP Steering Committee, Office of Policy and Planning, ASPR, HHS

Dr. Howell noted that the 2007 PHEMCE SIP called for regular updates of the SIP. The Government Accountability Office also recommended revisiting the SIP in its 2011 report, *National Preparedness: Improvements Needed for Acquiring Medical Countermeasures to Threats from Terrorism and Other Sources*. The PHEMCE Enterprise Executive Committee established an interagency SIP Steering Committee in July 2011.

Dr. Howell summarized the target audiences for the PHEMCE SIP and described proposed changes to the scope of the SIP. He outlined the overarching goals and structure. HHS aims to release the updated strategic plan in the spring and the corresponding implementation plan in the summer. Dr. Howell asked the Board to provide input on gaps and reactions to the goals and objectives as the documents are developed over the next few months.

CHARGE TO NBSB MEMBERS

George Korch Jr., Ph.D., Senior Science Adviser, ASPR, HHS

Dr. Korch clarified that while the Board is a Federal advisory committee subject to guidelines on transparency, the contents of the PHEMCE SIP should not be made public before the Secretary approves it. In the early stages of development, Board members can provide input from their perspectives as individual representatives of science, industry, public health, and other fields. When the strategy is released to the public, the Board can choose whether to provide a more in-depth review.

Dr. Korch summarized some of the areas the updated PHEMCE SIP should address. He explained that the NBSB is an ideal group to provide input, because it is familiar with the Enterprise and MCM issues, its members have expertise in key areas of concern, and it can provide thoughtful, unbiased analysis in a rapid fashion.

The proposed process for review of the PHEMCE SIP draft is to hold a closed teleconference in late February, possibly followed by another teleconference (which could include an update from the ASPR on the status of the document).

DISCUSSION

John S. Parker, Major General (Retired), M.D., NBSB Chair

Members raised concerns about identifying national security vulnerabilities in a public document. Dr. Korch agreed that it is necessary to strike a balance between the need to engage stakeholders and the need for secrecy. The 2007 PHEMCE SIP identified gaps. However, Dr. Korch believed it also signaled that the United States is doing more than any other country in the world to develop MCMs—a message that should serve as a deterrent. He added that resource constraints require the PHEMCE to clarify MCM development priorities.

In response to members, Dr. Korch noted that the SIP sets policy goals and forms the basis for each agency to direct its investments. It is not a procurement or spending plan. Dr. Parker clarified that once the SIP is released to the public, the Board can make specific comments and recommendations; in the meantime, the Board can provide valuable insight through its discussion.

It was noted that decision-making on prioritization requires intelligence that spells out the threats. Dr. Korch said the intelligence community cannot provide a clear list of threats and their likelihood. Thus, HHS and its partners must determine how to meet MCM needs in the most efficient, effective manner. There was some discussion about whether the SIP should include specific timelines and deliverables. The Board members unanimously agreed to accept the task of reviewing the draft PHEMCE SIP and providing input.

Following continued discussion about prioritization in relation to the likelihood of threats, it was emphasized that the SIP is intended to provide strategic direction for developing MCMs for all hazards, including those not yet recognized. A well-crafted and nimble strategic plan should define processes that can apply to any situation. The Board can be particularly helpful in identifying gaps or oversights in the draft SIP and in determining whether the SIP communicates clearly to stakeholders. It can offer input on whether the objectives linked to the goals are realistic and speak to the overall needs of the SIP.

NEXT STEPS

John S. Parker, Major General (Retired), M.D., NBSB Chair

Dr. Parker reiterated that the Board accepted the task of reviewing the draft PHEMCE SIP. Jomana Musmar announced that the Board would meet by teleconference for the next closed session under the Government in Sunshine Act, on February 28, 2012. She also noted that Federal Register Notices will be published announcing all closed sessions scheduled under the Act. Board members who are in the Washington, D.C., area are welcome to join the NBSB staff for the teleconference. Meeting details will be sent to members by e-mail.

ADJOURNMENT

Ms. Robertson thanked the participants and adjourned the meeting at approximately 5 p.m.