SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD
CLOSED TELECONFERENCE
**September 17, 2012**
**1:30–3:30 p.m.**

## 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.
Jane Delgado, Ph.D., M.S.
David J. Ecker, Ph.D.
Emilio A. Emini, Ph.D.
Daniel B. Fagbuyi, M.D., FAAP
Manohar R. Furtado, Ph.D.
Kevin A. Jarrell, Ph.D.
Steven E. Krug, M.D.
Sarah Y. Park, M.D., FAAP

## EX OFFICIO MEMBERS PRESENT

Luciana Borio, M.D., Acting Director, Office of Counterterrorism and Emerging Threats, U.S. Food and Drug Administration
Kay Marano Briggs, Ph.D., Lead for Genetics and Microbiology, Ecosystems Mission Area, U.S. Department of the Interior (*designated by Lori Caramanian)*
Sam Groseclose, D.V.M., M.P.H., DACVPM, Associate Director for Science, Office of Science and Public Health Practice, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services
Rosemary Hart, J.D., Special Counsel, Office of Legal Counsel, U.S. Department of Justice
Peter Jutro, Ph.D., Deputy Director, National Homeland Security Research Center, U.S. Environmental Protection Agency
Lisa Kaplowitz, M.D., M.S.H.A., Deputy Assistant Secretary for Policy, Office of Policy and Planning, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services (*designated by George W. Korch Jr., Ph.D.*)
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
Richard A. Martinello, M.D. Acting Senior Medical Advisor, 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.)*
Dianne Poster, Ph.D., Special Assistant, Associate Director for Laboratory Programs,

Director's Office, Chemical Science and Technology Laboratory, National Institute of Standards and Technology, U.S. Department of Commerce

Marc Shepanek, Ph.D., Deputy Chief, Medicine of Extreme Environments, National Aeronautics and Space Administration *(designated by Richard Williams, M.D.)*

Robert Sorenson, Bureau of Oceans and International Environmental and Scientific Affairs, U.S. Department of State (*designated by Kerri-Ann Jones, Ph.D.*)

Joey Zhou, Ph.D., Office of Health, Safety, and Security, U.S. Department of Energy *(designated by Patricia R. Worthington, Ph.D.)*

**OTHER PARTICIPANTS**

Margaret Chamberlain, Office of Policy and Planning, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

Richard J. Hatchett, M.D., Chief Medical Officer and Deputy Director for Strategic Sciences, Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

David R. Howell, Ph.D., Office of Policy and Planning, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

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

Scott Nystrom, Ph.D., Office of Policy and Planning, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

Joanna Prasher, Ph.D., Office of Policy and Planning, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

**STAFF OF THE NATIONAL BIODEFENSE SCIENCE BOARD**

CAPT Charlotte Spires, D.V.M., M.P.H., DACVPM, Executive Director, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

Jomana F. Musmar, M.S., Program Analyst, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

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

## CALL TO ORDER, ROLL CALL, AND CONFLICT OF INTEREST RULES
**Charlotte Spires, D.V.M., M.P.H., Dipl ACVPM, Executive Director, National Biodefense Science Board (NBSB), CAPT, U.S. Public Health Service**

CAPT Spires called to order the closed session of the NBSB meeting and reviewed the conflict of interest guidelines as well as the confidentiality agreements in place. She explained that the document under discussion for the meeting is 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).

## WELCOME AND INTRODUCTION

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

Dr. Parker welcomed the Board members and ex officios and reviewed the agenda. The Board convened this closed session to review the draft (version 3.1) Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Implementation Plan (IP). Dr. Parker emphasized that he felt the draft IP is very well written and thoroughly aligned with the PHEMCE Strategy.

## PHEMCE IP: BRIEFING

### Joanna Prasher, Ph.D., ASPR, HHS, Co-Chair, 2012 PHEMCE Strategy and Implementation Plan Steering Committee

Dr. Prasher summarized efforts related to the IP since the Board's June meeting and noted that the draft is moving through the chain of review. The Strategy and IP set the course for PHEMCE for the next five years. The Strategy lays out the PHEMCE mission, scope, goals, objectives, and governance structure; the IP describes the prioritized programs and initiatives that HHS and its partners will pursue to achieve the goals of the Strategy. HHS seeks to release the IP by late October or early November.

The development of the IP began with the creation of a prioritization framework, followed by input from the Board and others. Agencies were asked to identify their priorities in relation to the framework, align their efforts with the PHEMCE goals, and describe how they would accomplish the objectives of the PHEMCE Strategy. The Steering Committee compiled the responses of the PHEMCE partners and incorporated them into the draft IP.

Dr. Prasher said that for each of the PHEMCE Strategy's four goals, the IP spells out objectives and actions to be taken, as well as providing additional detail in subsequent sections on the threat-specific or capability-based actions being pursued. She then walked the participants through the IP, summarizing the objectives and actions. Following review by the PHEMCE governance bodies, the draft IP will be vetted through the HHS clearance process and publically released. Once published, ASPR will institute PHEMCE-wide tracking mechanisms for the next five years and report progress regularly.

## NBSB FEEDBACK ON THE PHEMCE IMPLEMENTATION PLAN[1]

## BOARD MEMBER COMMENTS

### *Executive Summary and Introduction*

Dr. Parker, in agreement with the majority of Board members, said the introductory sections do a good job of defining PHEMCE succinctly; they are well written and describe how the IP aligns with the Strategy. Drs. Bradley and Emilio A. Emini, Ph.D., noted that the IP had less detail than expected; Dr. Emini said it is more of a blueprint for how implementation will occur. Dr. Ecker suggested it elaborate on how the thinking that

[1] *This summary includes some, and not all, of the discussions that took place on the September 17, 2012 closed teleconference.*

guides the PHEMCE has evolved, and added that in a traditional implementation plan, the summary would outline a few high-priority goals, related actions, and corresponding tracking measures. A clear definition of the key outcomes and metrics to measure them, said Steven E. Krug, M.D., would help to better assess whether the IP is likely to be effective. Sarah Y. Park, M.D., FAAP, suggested that the IP be reviewed from the perspective of someone outside of the field to provide further clarification.

***Goal 1 and Objectives 1.1–1.3***

Dr. Parker pointed out that the IP will be disseminated to the public and thus around the world; therefore, it must convey the elements of implementation and some milestones, but it cannot provide a lot of detail. (Jane Delgado, Ph.D., M.S., seconded that assessment.) He felt the writers balanced the competing priorities of transparency and national security appropriately. Dr. Bradley suggested that the IP state upfront that the document is not as detailed as one might expect because of the security concerns. Drs. Ecker, Emini, Chao, and Jarrell, provided comments regarding the prioritization framework, the portfolio review process, MCM multifunctionality, agency accountability, and the promotion of partnerships.

***Goal 2 and Objectives 2.1–2.2***

Dr. Ecker pointed out that the actions described for Goal 2 seem substantially similar to previous actions over the past five years. Dr. Emini stated that the IP should provide more specificity about how partner agencies (especially the FDA) will operate under the PHEMCE framework, particularly in the establishment, management, and review of portfolios. Dr. Jarrell suggested that both the Strategy and the IP be consistent and specific in their use of terminology, such as reference to "regulatory pathways" whenever applicable.

***Goal 3 and Objectives 3.1–3.4***

Dr. Ecker said the IP does a good job describing the challenges of maintaining current inventory of MCMs during tough fiscal times. Dr. Park was glad to see that State, local, territorial, and tribal efforts are recognized. Dr. Bradley said the IP states that the PHEMCE will analyze issues and make recommendations, but it is not clear which entity will act on those recommendations. He added that he would like to see the IP emphasize accountability, and that further clarification is needed when referring to certain "providers" or "end-users."

***Goal 4 and Objectives 4.1–4.3***

Several members appreciated the inclusion of pediatric populations, but some pointed out that the IP does not sufficiently acknowledge other at-risk populations (in particular, those with functional access issues, said Dr. Park). Dr. Bradley said there should be more emphasis on coordinating communication and the designation of a single point of contact in an emergency.

### *Interagency Partner Roles*

Manohar R. Furtado, Ph.D., suggested including more information on programs and funding by agencies other than NIH and BARDA (e.g., the Defense Advanced Research Projects Agency [DARPA]) and on coordination across programs and agencies. Dr. Parker also said that he would like to see the partner agency roles more explicitly defined over time.

### *Conclusion*

Dr. Krug said the IP should include more detail on how progress will be monitored and evaluated, which can be described without giving away too much information about current gaps in preparedness. Dr. Prasher agreed that more detail is needed. She said ASPR will set up the mechanisms for monitoring and evaluation and share progress updates as appropriate. Dr. Prasher emphasized that Nicole Lurie, M.D., M.S.P.H., the ASPR, takes very seriously the importance of working with PHEMCE partners to accomplish what PHEMCE says it will do.

### *Wrap-Up of Board Comments*

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

Dr. Parker pointed out that HHS does not have multi-year funding and so cannot tie funds to a long-term implementation plan. In addition, the IP cannot inappropriately signal to contractors, developers, or others how HHS intends to spend its money. Therefore, the writers will have to weigh the comments from the Board and incorporate them as they see fit.

Dr. Parker hoped the IP will state when progress will be reviewed and by whom. He suggested an appendix describing how each agency contributes to the PHEMCE.

## NBSB EX-OFFICIO MEMBER COMMENTS

Marc Shepanek, Ph.D., said he appreciated the “blueprint” concept, because lengthy documents can be problematic, and that the IP does a good job of creating accountability.

Regarding partnerships, Dianne Poster, Ph.D., said that the National Institute of Standards and Technology (NIST) will provide text for consideration about its efforts to facilitate public-private partnerships in science and technology, such as its recently established National Program Office for the Advanced Manufacturing Partnership. Similarly, NIST will contribute some examples of standards and data activity that it offers to support MCM development.

Kay Marano Briggs, Ph.D., noted that the Department of the Interior would not be a major player in the context of public health emergencies, but it does conduct surveillance and research on wildlife diseases and vaccines. As such, the Department of the Interior is prepared to contribute as needed, she said.

Robert Sorenson said the IP states an intention to develop mutual assistance agreements for sharing MCMs with particular countries. He said such agreements should be broader. Dr. Kaplowitz responded that such efforts are underway.

## NEXT STEPS

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

Dr. Parker thanked all the members and ex officios for studying and providing comments on both the draft PHEMCE Strategy and IP. On behalf of the Steering Committee and the writing team, Dr. Prasher expressed heartfelt thanks for the thoughtful comments. Jomana F. Musmar, M.S., pointed out that additional comments may be sent to NBSB mailbox at NBSB@hhs.gov.

## ADJOURNMENT

The meeting adjourned at 3:17 p.m.