SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD
CLOSED SESSION TELECONFERENCE
MARCH 29, 2012

VOTING MEMBERS PRESENT

Chair, John S. Parker, M.D., Major General (Retired)
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, Major
Manohar R. Furtado, Ph.D.
Kevin A. Jarrell, Ph.D.
Steven E. Krug, M.D.
Sarah Y. Park, M.D., FAAP

VOTING MEMBERS NOT PRESENT

Georges C. Benjamin, M.D., FACP, FACEP(E), FNAPA, Hon FRSPH
Betty J. Pfefferbaum, M.D., J.D.

EX OFFICIO MEMBERS PRESENT

Kay Marano Briggs, Ph.D., Lead for Genetics and Microbiology, Ecosystems Mission Area, U.S. Department of the Interior (*designated by Lori Caramanian)*

Jessica Chaudhary, M.D., American Association for the Advancement of Science Fellow, Office of International Health and Biodefense, U.S. Department of State (*designated by Kerri-Ann Jones, Ph.D.*)

Bernard L. DeKoning, M.D., FAAFP, COL, Commander, U.S. Army Medical Research Institute for Infectious Diseases, U.S. Department of Defense

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.)*

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

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.)*

Dianne Poster, Ph.D., Special Assistant to the Associate Director for Laboratory Programs, Director's Office, Chemical Science and Technology Laboratory, National Institute of Standards and Technology, U.S. Department of Commerce

Bonnie S. Richter, Ph.D., M.P.H., Director, 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.)*

OTHER INVITED PARTICIPANTS
Margaret Chamberlin, ASPR/OPP
Suzan Gorman, CDC
Richard Hatchett, ASPR
David R. Howell, ASPR/OPP
Richard Jaffe, ASPR/OPP
Lisa Kaplowitz, ASPR
Michael Kurilla, NIH/NIAID
Nicki Pesik, CDC
Joanna M. Prasher, ASPR/OPP
Casey Wright, ASPR/OPP

NATIONAL BIODEFENSE SCIENCE BOARD
Jomana Musmar, M.S., Program Analyst (Contractor)
Casey Wright, M.P.H., Acting Designated Federal Official

CALL TO ORDER AND ROLL CALL
Casey Wright, M.P.H., Acting Director, Div. of Policy and Strategic Planning, OPP/ASPR
Ms. Wright called the meeting to order at 1:02 pm. She briefly discussed the standards of ethical conduct, conflicts of interest, and issues of confidentiality related to the closed meeting. The meeting was then turned over to NBSB Chair, Dr. Parker.

OVERVIEW OF AGENDA AND TELECONFERENCE RULES OF ENGAGEMENT
John S. Parker, M.D., Major General (Retired), Chair, NBSB
Dr. Parker said the goal of the meeting was to obtain input from participants on the draft of the PHEMCE Strategy.

FEEDBACK ON THE INTRODUCTORY SECTION (PP 2-10) OF THE DRAFT PHEMCE STRATEGY[1]
Full Board and Participant Discussion
Board members made several suggestions to the introductory sections of the draft Strategy. Some suggestions included adding the relevant legislative changes needed to enable the FDA to have more latitude during emergencies in the regulatory arena, and that regulatory science management needs to be better reflected in the document; the strategy seems to imply that there's a way to better assist industry in navigating regulatory science but the document doesn't address some of the existing regulatory issues. For example, the regulatory system is well developed for routine drug development, but it may not work equally as well when there is limited evidence for approval.

[1] *The voting members of the Board, followed by Ex Officios, and then remainder participants were asked to provide feedback on the Draft PHEMCE Strategy portion of the SIP, followed by a discussion period. This summary includes some, and not all, of the discussions that took place on the March 29, 2012 closed teleconference.*

With regard to communication – while the CDC did a great job responding to the H1N1 epidemic – communication with the public wasn't as robust as the response itself. Communicating better and informing the American public should be critical to the mission. In addition, the document's language should be tailored so it's accessible to Congress and the American public (i.e. plain language). For example, one might want to define the term "closed pod."

It's suggested that language be included to address existing gaps. Readers should understand that there are gaps so as not to give the impression that "all is known." Metrics should also be discussed as these will help determine how measurements will be made (it's hard to be accountable if there are no metrics). In addition, a few paragraphs on the complexity of the PHEMCE be included and why collaborating is difficult at best.

With regard to special populations, it was proposed to add a graph that shows which populations the PHEMCE has responsible towards. It could be a pie chart, for example, showing that the 20 percent of the population that needs to be served are, in fact, children. It's also important to discuss allocation for critical infrastructure and first–responder/health care workers. The latter is considered a critical population because they are the first on the scene of any disaster.

Several members felt strongly that Figure 1 in the document, portraying PHEMCE partner roles, should be revised to include the following comments:

- Explain how PHEMCE has to operate to meet the objectives. In other words, how the PHEMCE structure will achieve coordination in terms of implementation and priority setting;
- While PHEMCE is at the center of the figure, it's not clear who is accountable behind PHEMCE. There's a need for better governance, especially in clarifying who will be the "CEO" or decision maker during an emergency;
- Consider having an Appendix to this figure that describes the PHEMCE structure and how it will maintain the coordination and prioritization of efforts across the constituent agencies to achieve the objectives of the strategic plan;
- Include a legend which explains acronyms (e.g. OPP, MCSR, etc.); and
- Add academia, professional societies, and industry to reflect the multitude of stakeholders involved in PHEMCE.

FEEDBACK ON THE GOALS SECTIONS OF THE DRAFT PHEMCE STRATEGY
Full Board and Participant Discussion

GOAL 1
Board members suggested that it might be useful to add some examples under this goal. It might also be useful to provide intellectual protection to support effective partnerships and incorporate beta companies. This goal should examine the regulatory processes themselves to determine if there should be fundamental changes to some of them.

It's important to support the development of tools, measurement methods, and standards to assess the validity of data that will be derived from new products undergoing the development process. Such tools are essential to enabling manufacturing improvements and to inform regulatory decision-making.

GOAL 2

Board members stressed the importance of having clear regulatory pathways, and that the public should be assured that the approval of products will not compromise important quality or safety standards. Consider having an additional objective which involves the FDA from the very beginning to make it clear how the process will move forward in order to obtain approval. Also, it might be useful to present some EUA scenarios along with some potential timelines. With regard to at risk populations, it might be important to discuss any unintended barriers in addressing the needs of such populations.

GOAL 3

Board members commented on the importance of having one clear, recognized federal agency as the lead for the American public, as well as for state and local people at the beginning of an emergency. The agency would provide appropriate guidance for the coordination of a response. Additionally, it might be useful to determine who would be the lead agency for each specific type of emergency. For example, in the area of communication, it's important to create a bidirectional flow of information (e.g. from CDC to Health Departments and Practitioners).

It might be useful to better define the types of training and education that will be provided both at the individual and collective levels. Consider including an acknowledgement that it's important to create incentives for the private sector to participate in training and education efforts.

GOAL 4

First responders and health care workers should be included as one of the at-risk populations. The strategy should reflect the fact that there are gaps in the Strategic National Stockpile, especially with regards to some at-risk populations (e.g. children). The strategies to assist the distribution of countermeasures to at-risk populations should consider factors such as location and distribution (e.g. nursing homes, schools, etc.). It might also be helpful to have metrics that reflect this distribution in the operational plan.

CONCLUSION, WRAP UP AND NEXT STEPS

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

Dr. Parker informed the group that the next meeting will take place at the end of April. The draft of the Implementation Plan will be discussed at that meeting. He thanked all participants and adjourned the meeting at 3:18 pm.