SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD
CLOSED SESSION TELECONFERENCE
FEBRUARY 28, 2012

VOTING MEMBERS PRESENT

Chair, John S. Parker, M.D., Major General (Retired)
Georges C. Benjamin, M.D., FACP, FACEP(E), FNAPA, Hon FRSPH
John S. Bradley, M.D., FAAP, FIDSA
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
Betty J. Pfefferbaum, M.D., J.D.

VOTING MEMBERS NOT PRESENT

Nelson J. Chao, M.D., M.B.A.

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)*
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.)*
Rosemary Hart, J.D., Special Counsel, Office of Legal Counsel, U.S. Department of Justice
Franca R. Jones, Ph.D., Senior Policy Analyst, CB Countermeasures, Office of Science and Technology Policy, Executive Office of the President
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
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
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.)*
Amber Story, Ph.D., Deputy Division Director, Division of Behavioral and Cognitive Sciences, National Science Foundation

OTHER INVITED PARTICIPANTS
Scott Deitchman, CDC
Susan Gorman, CDC
Richard Hatchett, ASPR/BARDA
Carole Heilman, NIH/NIAID
David R. Howell, ASPR/OPP
Richard Jaffe, ASPR/OPP
Lisa Kaplowitz, ASPR
Michael Kurilla, NIH/NIAID
Bert Maidment, NIH/NIAID
Susan Coller-Monarez, S&T/DHS
Joanna M. Prasher, ASPR/OPP
Nicki Pesik, CDC
Stephen C. Redd, CDC
Tracee Treadwell, CDC
Katherine Wallace, VA
Casey Wright, ASPR/OPP

NATIONAL BIODEFENSE SCIENCE BOARD
MacKenzie Robertson, Acting Executive Director
Jomana Musmar, M.S., Program Analyst (Contractor)

CALL TO ORDER AND ROLL CALL
MacKenzie Robertson, Acting Executive Director, NBSB
Ms. Robertson called the meeting to order at 12:05 pm. She briefly discussed the standards of ethical conduct, conflicts of interest, and issues of confidentiality related to today's 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 welcomed all participants to the closed session. He reminded participants that the Strategy and Implementation Plan (SIP) goals and objectives to be discussed today pertain to HHS and the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and will be setting priorities for HHS agencies including CDC, FDA, ASPR, BARDA, and NIH. Once completed, the audience for the strategic plan will be Congress, industry, academia, state and local responders, and the general public.

DRAFT PHEMCE SIP GOALS AND OBJECTIVES DISCUSSION PERIOD[1]

I. **Goal 1 -** Board members suggested identifying the specific leadership who will take responsibility for addressing each of the overall goals. This goal should include a strategic objective on how coordination will be handled. Board members suggested that it would be useful to further define the type of modeling used, how priorities will be set, and how priorities will be communicated to other organizations.

II. **Goal 2 -** The Board suggested obtaining feedback from FDA as to whether rapid approval guidelines could be applied under the current Code of Federal Regulations. If such an approach is not possible, it may be necessary to support legislation that will allow the FDA to approve medical countermeasures (MCMs) though a different pathway. The Board said it would also be important to clarify "ownership" for the goal and address any challenges and barriers.

The Board said that for this goal to be actualized, it will be important for the FDA to understand the specifics of the strategic framework that underlies the overall MCM strategy. This will require putting in place a coordinated end-to-end strategic path with specific products and targets which will help the FDA to focus on potential regulatory challenges *a priori*.

III. **Goal 3 -** The Board suggested that the goal include the end user. In other words, there's a need to hear from the public, stakeholders and other individuals who will use the medicine. That is to say, include the whole MCM cycle. One should also consider existing successful approaches in addition to innovative ones.

IV. **Goal 4 -** The Board suggested that the goal address the need to have MCMs for pediatric and other vulnerable populations – both at the state and local levels. The Board suggested adding an objective that would explicitly consider the vulnerabilities or gaps in the stockpile (e.g. gaps in the formulation and doses for at-risk populations, especially children). There should be a clear objective of intent to narrow this gap.

It's important to note that "at-risk" individuals comprise about half of the population (children, elderly, institutionalized, those with disabilities, etc.). It should be made clear in the document that this is a large population. One should also consider adding first responders as part of the "at-risk" population. One of the goals should address the need for appropriate MCMs for first responders across the local, regional or national areas involved in an event.

Also, inventory management should include accountability so that CDC and other public health authorities can track vaccines and medicines once they are distributed to determine where they were shipped, to whom, and when they were received. At the state and local level, it's important to identify how to dispose MCMs that are left over following a

[1] *The Voting members of the Board, followed by Ex Officios, and then remainder participants were asked to provide feedback on each of the Draft PHEMCE SIP goals and objectives, followed by a discussion period. This summary includes some, and not all, of the discussions that took place on the February 28, 2012 closed teleconference.*

pandemic. This includes both dealing with the environmental impact as well as expiration issues.

Perhaps there should be an additional goal (or amend a current goal) to enhance access and limit adverse effects.

The Board added that it's not always clear who will be providing guidance to state and local stakeholders. It's also not clear who will "own" the strategy.

Open Discussion

Board members made a series of suggestions including the need to clarify which agencies will be responsible for which parts of the goals. This will help the public to better understand responsibilities. The Board also suggested having a mechanism for coordinating the activities at the PHEMCE level as an overarching goal of the document. The Board suggested that tracking adverse effects under an Emergency Use Authorization (EUA) has been identified as an overarching challenge for PHEMCE. A long-range goal would be to better achieve post-marketing surveillance during a period of exigent circumstance.

Ex Officio members said the goals will be roughly aligned with responsibility sets within PHEMCE. It was also noted that the prioritization of resources will be included in the strategy document and the details will be provided in the implementation plan.

WRAP UP AND NEXT STEPS

John S. Parker, M.D., Major General (Retired), Chair, NBSB
Dr. Parker thanked all participants and adjourned the meeting at 1:25 p.m.