

SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD
PUBLIC MEETING
February 2, 2012

VOTING MEMBERS PRESENT

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

EX OFFICIO MEMBERS PRESENT

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.*)
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
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
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.*)
Don Malinowski, M.S., National Counterproliferation Center, Global Biological Threat
Directorate, 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.*)
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 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 L. Story, Ph.D., Deputy Division Director, Division of Behavioral and Cognitive Sciences, National Science Foundation

STAFF OF THE NATIONAL BIODEFENSE SCIENCE BOARD

MacKenzie Robertson, Acting Executive Director
Jomana F. Musmar, M.S., Program Analyst

CALL TO ORDER, ROLL CALL, AND CONFLICT OF INTEREST RULES MacKenzie Robertson, Acting Executive Director, National Biodefense Science Board (NBSB)

Ms. Robertson welcomed the participants, particularly the six new Board members and returning members, to the first 2012 meeting. She reviewed the guidelines for Federal advisory boards, as well as conflict of interest guidelines. She then introduced Dr. John Parker, the newly selected NBSB chair.

WELCOME AND INTRODUCTION

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

Dr. Parker welcomed the Board members and other participants and said the Board particularly appreciates the ex officio members for the knowledge and resources they contribute to the Board's deliberations. Dr. Parker also acknowledged Lisa Kaplowitz, M.D., M.S.H.A., of the Office of Policy and Planning within the Office of the Assistant Secretary for Preparedness and Response (ASPR) for her support of the NBSB.

ASPR PRESENTATION TO NBSB

Nicole Lurie, M.D., M.S.P.H., ASPR, U.S. Department of Health and Human Services (HHS)

Dr. Lurie thanked the Board for their efforts toward strengthening national security. She thanked the previous NBSB Chair, Patricia Quinlisk, M.D., M.P.H., for leading the Board with incredible dedication since its inception in 2007 and also CAPT Leigh Sawyer, D.V.M., M.P.H., for her efforts as the Board's previous Executive Director. She added that she is thrilled that Dr. Parker agreed to serve as NBSB chair.

Dr. Lurie noted that she began her tenure as the ASPR when the H1N1 influenza pandemic began, and a number of national and international public health challenges have occurred since. The recommendations and deliberations of the Board have made a tremendous difference for her in several areas, said Dr. Lurie.

For example, HHS appreciated the NBSB's inclusion of children in its recommendations on emergency response, mental health preparedness, and medical countermeasures (MCMs). New MCM contracts now include a requirement to develop pediatric MCMs, and a team has been established to ensure that the needs of both pediatric and obstetric populations are included in the research portfolio. Dr. Lurie thanked the Board for taking on the challenge of deliberating on the use of anthrax vaccine among children, which she called the toughest assignment to the Board so far. The Board rose to the occasion, she said, and provided a thoughtful set of recommendations. The Presidential Commission for the Study of Bioethical Issues has been tasked with considering whether and how to move forward with pediatric medical countermeasure research, including anthrax vaccine.

The Board provided recommendations on behavioral health that have been very helpful to the ASPR's work, said Dr. Lurie. As a result, HHS now has a behavioral health concept of operations to help it organize planning and strategic thinking. Considering behavioral health response, particularly for pediatric and other special populations, during and following a public health emergency is important, because how public health authorities respond on day one is vital, said Dr. Lurie.

Recommendations on integrating science into public health response efforts were also helpful. Dr. Lurie said a number of activities are underway to implement those recommendations. The Board's recommendations on the response to the H1N1 pandemic were also critically important.

Notably, the HHS Secretary requested a thorough review of the 2007 Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) and recommendations to transform it. The Board's recommendations have been "game-changing" in addressing the PHEMCE, said Dr. Lurie.

Dr. Lurie concluded that she worked in a think tank before she became the ASPR, and while she enjoys thinking through tough problems, she simply does not have enough hours in the day to deliberate in depth on all the relevant issues. She said she relies on the Board to identify and evaluate complex issues, lay out the pros and cons, and provide well-thought-out positions and recommendations.

Presentation of Certificates to Retiring Members

Dr. Lurie recognized the outgoing members of the Board and presented them with personalized certificates thanking them for their service. Stephen V. Cantrill, M.D., and Patrick J. Scannon, M.D., Ph.D., were on hand to receive the certificates in person. Ruth L. Berkelman, M.D., joined the meeting by phone. John D. Grabenstein, R.Ph., Ph.D., Thomas J. MacVittie, Ph.D., and outgoing Chair Dr. Quinlisk were unable to attend.

Swearing-In of New Members

Dr. Lurie swore in the following members of the Board:

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

- John S. Bradley, M.D., FAAP, FIDSA
- Nelson J. Chao, M.D., M.B.A.
- Emilio A. Emini, Ph.D.
- Manohar R. Furtado, Ph.D.
- Steven E. Krug, M.D.
- Sarah Y. Park, M.D., FAAP

The Board members are among the nation's preeminent experts representing scientific research, public health, industry, and academia, said Dr. Lurie, and she was excited to work with them.

Introduction of New Task to the NBSB

Dr. Lurie reiterated that the Board played a vital role in evaluating the PHEMCE, and its recommendations are being implemented. The overall PHEMCE Strategic and Implementation Plan (SIP) written in 2007 requires updating to reflect lessons learned and an expanded vision for the Enterprise. The updated strategic plan is due in late spring of 2012 and should describe what is needed to develop, stockpile, deploy, utilize, and sustain MCMs to protect the nation against public health emergencies stemming from hazards of all types.

Given its experience and track record, the NBSB is in a good position to comment on the updated PHEMCE SIP during its development and to advise the ASPR on whether the goals and objectives are on track, identify gaps, and provide other input. The PHEMCE's governing body, the Enterprise Senior Council (ESC), has given the perspective of the Federal agencies. The motivation for seeking early input from the Board is to ensure that the draft plan does not overlook key issues.

Dr. Lurie explained that the Board would have more opportunity to discuss the new assignment later in the day during a closed session. Dr. Lurie thanked the Board in advance for taking on the task and looked forward to the Board's deliberations.

Ms. Robertson reconfirmed that the PHEMCE SIP is in the very early stages of development and is a pre-decisional document. The Board members would be required to consider sensitive information that should not be released to the public; premature disclosure of the information would limit the Secretary's leeway in decision-making. Thus, the deliberations of the Board would be closed to the public under exemption 9(b) of the Government in Sunshine Act.

PUBLIC COMMENTS

In an e-mail, Jeffrey S. Milstein, Ph.D., wrote that the recent decision to temporarily "pause" avian influenza H5N1 virus studies and publication does not go nearly far enough to protect the public's health, safety, and security. The urgent necessity to minimize a major risk to the public's health and security clearly trumps the privilege of unrestricted research and communication among biological scientists and engineers. The virus has the potential to kill tens of millions of people. Dr. Milstein recommended several measures that go beyond the weak current advisory and voluntary pause and that

have been used in other areas of science and engineering. He asked that such measures be incorporated into the 2012 PHEMCE Strategy and Implementation Plan.

E. Barry Skolnick, M.S., an independent and unaffiliated technical analyst, asked that the Board evaluate the weak scientific foundation and questionable quality of current environmental surface-testing practices for biothreat agent detection. The efficacy of these methods has not been evaluated, and no microbiological surface-testing procedures have been validated scientifically, as expressly called for by the Government Accountability Office (GAO) in March 2005. Four Congressional oversight hearings and six GAO reports have raised public concerns about the adequacy of the nation's environmental-testing methods for anthrax detection indoors. A review commissioned by the Department of Homeland Security corroborates the perceived investigational inadequacies in the scientific foundation for our nation's continuing surface-testing preparedness status quo, said Mr. Skolnick.

WRAP-UP

Dr. Parker gave special thanks to outgoing Board Chair Dr. Quinlisk for the pioneering spirit in which she successfully led the Board to accomplish so much during her tenure. He also thanked Dr. Lurie for her constant support, Drs. Cantrill and Scannon for attending the meeting, and all of the outgoing members for their contributions. He praised the extensive experience of the incoming members. Finally, Dr. Parker gave special thanks to members of the public who attend the Board's meetings in person or by phone because they feel strongly about the Board's work. Public input is important and prevents the isolation and insulation that can occur among advisory boards, he said.

ADJOURNMENT

Ms. Robertson noted that information on upcoming meetings would be posted on the NBSB website (<http://www.phe.gov/nbsb>). She thanked Jomana Musmar for her hard work organizing the meeting. Ms. Robertson adjourned the meeting at 11:15 a.m.