SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD
PUBLIC MEETING
March 26, 2010

VOTING MEMBERS PRESENT
Stephen V. Cantrill, M.D., Acting Chair
Ruth L. Berkelman, M.D. (by telephone)
Roberta Carlin, M.S., J.D.
Albert J. Di Rienzo (by telephone)
Kenneth L. Dretchen, Ph.D.
John D. Grabensteini, R.Ph., Ph.D.
James J. James, M.D., Dr.P.H., M.H.A., Brigadier General (Retired)
Thomas J. MacVittie, Ph.D.
John S. Parker, M.D., Major General (Retired)
Eric A. Rose, M.D.
Patrick J. Scannon, M.D., Ph.D.

VOTING MEMBERS NOT PRESENT
Andrew T. Pavia, M.D.
Patricia Quinlisk, M.D., M.P.H.

EX OFFICIO MEMBERS PRESENT
Hugh Auchincloss, M.D., Principal Deputy Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health
Michael D. Amos, Ph.D., Biosciences Advisor, National Institutes of Standards and Technology, U.S. Department of Commerce
Deanna Archuleta, Deputy Assistant Secretary for Water and Science, U.S. Department of the Interior
Rosemary Hart, J.D., Special Counsel, Office of Legal Counsel, U.S. Department of Justice
Kerri-Ann Jones, Ph.D., Assistant Secretary of State for Bureau of Oceans and International Environmental and Scientific Affairs, U.S. Department of State
Peter Jutro, Ph.D., Deputy Director, National Homeland Security Research Center, U.S. Environmental Protection Agency
Boris D. Lushniak, M.D., M.P.H., RADM, U.S. Public Health Service; Assistant Surgeon General, Assistant Commissioner, Office of Counterterrorism and Emerging Threats, Office of the Commissioner, Food and Drug Administration, U.S. Department of Health and Human Services
Vincent Michaud, M.D., M.P.H., Director, Medicine of Extreme Environments, Office of the Chief Health and Medical Officer, National Aeronautics and Space Administration (designated by Richard Williams, M.D.)
CALL TO ORDER

CAPT Leigh Sawyer, D.V.M., M.P.H., Executive Director, National Biodefense Science Board (NBSB), Office of the Assistant Secretary for Preparedness and Response (ASPR), CAPT, U.S. Public Health Service (USPHS), U.S. Department of Health and Human Services (HHS)

CAPT Sawyer welcomed the Board members and reviewed the guidelines for Federal advisory boards.

WELCOME AND INTRODUCTION

Stephen V. Cantrill, M.D., Acting Chair, NBSB

Dr. Cantrill thanked the participants for coming to the meeting and reviewed the agenda (see the appendix).

Nicole Lurie, M.D., M.S.P.H., RADM, U.S. Public Health Service; Assistant Secretary for Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS)

Dr. Lurie thanked the NBSB members for taking the lead in reviewing the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The Board’s findings and recommendations on strategy and leadership of the PHEMCE will inform Dr. Lurie’s report to HHS Secretary Kathleen Sebelius. On behalf of the Secretary, Dr. Lurie thanked the Board members for their hard work, especially given the very short timeframe for developing the report. She hoped the Board’s efforts would contribute to lasting, systematic changes for a structure that needs to transform.

Dr. Lurie thanked the Board members for their continued service and welcomed both new and returning ex officio members.

Dr. Cantrill noted from a letter from Dr. Lurie to the Patricia Quinlisk, Chair, NBSB dated January 26, 2010, that the ASPR tasked the NBSB with leading the review of the PHEMCE. The ASPR requested the Board hold a workshop involving multiple stakeholders to examine the strategic management, leadership, and accountability of the PHEMCE and to issue a written report by March 26th, synthesizing into policy options the issues and challenges facing the PHEMCE. The newly developed Medical Countermeasures (MCM) Working Group (WG) held a workshop on February 25 and 26, 2010. The purpose of today’s meeting was to review and vote on the draft report of the MCM-WG, later titled, Where Are The Countermeasures? Protecting America’s Health from CBRN Threats.
Dr. Grabenstein thanked all the contributors to the draft report, noting that all of the Board members provided their expertise in the process. He thanked the ex officio members, the NBSB staff, and his co-chairs, Drs. Parker and Scannon for their efforts.

Dr. Parker noted a December 2009 address by Secretary Sebelius, in which she announced that she would launch a comprehensive review of the PHEMCE. The Secretary stated, “The ultimate goal of this review is a modernized countermeasure production process where we have more promising discoveries, more advanced development, more robust manufacturing, better stockpiling, and more advanced distribution practices.” In his January 2010 State of the Union address, President Barack Obama stated, “We are launching a new initiative that will give us the capacity to respond faster and more effectively to bioterrorism or an infectious disease—a plan that will counter threats at home and strengthen public health abroad.” These statements support the effort to assess national security preparedness, said Dr. Grabenstein.

Dr. Grabenstein summarized the key conclusions and recommendations of the report, indicating the changes suggested by the MCM WG at its meeting on Thursday, March 25, for consideration by the Board. The report revolves around four themes:

- **Prioritization:** To avoid wasting time and resources, we must focus on the most important and most fruitful work.
- **Synchronization:** Everyone needs to work together as a team.
- **Anticipation:** Greater attention should be given to doing more in advance of incidents.
- **Leadership:** Leadership ties all of the above together. Without a concerted effort to keep the emphasis on MCMs during periods of calm and peace, we will be taken by surprise, and we will regret it.

Dr. Grabenstein pointed out that the request to evaluate the strategy, leadership, and accountability of the PHEMCE came not in response to a failure, but rather reflects the administration’s focus on improving the process to protect the nation. He then proceeded to review each of the draft report's five sections and the recommendations within each section.

**Section 1: Situational Assessment**

This section concludes that U.S. Government workers involved in MCM discovery, development, acquisition, and fielding are doing good and important work. But they are not synchronized, their projects are not prioritized, and oversight from the highest levels of government is not consistent. These inefficiencies are prolonging America’s vulnerabilities. The recommendations in this section address the need for HHS, in coordination with the Department of Defense (DoD) and the Department of Homeland Security (DHS) to coordinate with the White House on the best way to protect the country, and to develop a unified strategy that reflects a cohesive set of priorities.
Section II: Strategy, Leadership, Priorities, and Accountability

This section concludes that common priorities must be identified, uniformly accepted, and adopted across agencies, so that national vulnerabilities are resolved as quickly as possible. Recommendations address the need for HHS to identify and focus efforts on three high-priority MCMs, with input from DoD and DHS that prioritizes threats. The report also recommends the ASPR be given authority over HHS efforts, with the director of the Biomedical Advanced Research and Development Authority (BARDA) serving as the MCMs portfolio director. Further, the ASPR should ensure accountability within the MCMs process.

Dr. Grabenstein emphasized that a complete list of threats and high-priority MCMs will take some time to prepare, but HHS should be able to identify the top three quickly. Dr. Dretchen said HHS has many capable leaders, but one person should be responsible for the entire PHEMCE operation, and Dr. Lurie is in an ideal position to do so. Dr. Parker added that HHS has a unique opportunity to restructure the process and establish metrics of accountability that allow for more flexibility than current structures. Mr. Di Rienzo said BARDA is not only responsible for prophylactic and therapeutic countermeasures but also for diagnostics, and that putting BARDA in charge of managing the portfolio will help focus some attention on the need for diagnostics. Dr. Grabenstein said the draft report emphasizes that, although advanced development is under-funded relative to basic research, funding for basic research is vital and should not be reduced.

Additional recommendations in the report direct HHS to prioritize research goals, product requirements, and dispensing goals in coordination with DoD, and to develop a plan to improve distribution and administration of MCMs. Dr. Grabenstein acknowledged that improved distribution and administration are vital to the successful delivery of MCMs, but said the MCM WG spent less time analyzing the specific obstacles to be overcome in that regard. Dr. Cantrill emphasized that without succeeding in the last steps of the process—distribution and administration—the whole MCMs process fails. Dr. Parker noted that the Federal government has a role to play in facilitating State and local distribution efforts, not necessarily directing them.

Much discussion centered on the best way to express that the top three priority MCMs should address threats for which there is no current MCM. Dr. Lurie asked whether the ultimate goal was to ensure that the Strategic National Stockpile (SNS) stocks all countermeasures, but consensus answer agreed that the SNS may not be the best repository for every countermeasure.

Section III: Consistent, Adequate, and Balanced Funding

This section concludes that a sustained and adequately resourced national effort must address a broad spectrum of chemical, biological, radiological, and nuclear (CBRN) threats. Additional Federal funds will be needed to provide for the required scope of MCM discovery, development, acquisition, sustainment, and fielding beyond levels historically provided by the U.S. Government. The report recommends that HHS coordinate budget requirements for MCMs across the agency’s many divisions and in
coordination with DoD. Dr. Grabenstein said HHS should ensure that all of the pieces of the process fit together, from a budget perspective, in a balanced and rational way that aligns with priorities and strategies. The report also recommends that HHS seek multi-year funding authority, and request modification and reauthorization of Project BioShield. Drs. Grabenstein, Parker, and Scannon all spoke to the need for consistent funding that reflects a long-term approach to meeting goals. Dr. Grabenstein said that, to date, those involved in the PHEMCE have done the best they could with the resources provided; a more rational approach is to determine what’s needed to achieve the goals, then request the resources to do so.

**Section IV: Function and Activity**

This section concludes that the Federal MCMs program, to date, can be characterized as a good effort conducted by talented people, but one that is poorly synchronized by HHS agencies. With adequate resources and effective leadership, however, the various entities of the U.S. Government can work together and harness the expertise of the private sector in ways similar to those used to produce aircraft carriers, land humans on the moon, and accomplish other “Manhattan Projects.” The recommendations call for: centralized advanced development and manufacturing of selected biological MCMs, plans from the Food and Drug Administration (FDA) Commissioner for high-priority review of some MCMs, revising the draft guidance on the animal rule, and identification and mitigation of the need for screening and diagnostic tests for CBRN agents that can be performed in clinical settings.

Dr. Dretchen underscored the need for revising the animal rule guidance and for developing simple, rapid, and effective diagnostic tests that are readily available. RADM Lushniak, emphasized that efforts to speed up development of diagnostic tests must still adhere to the appropriate regulatory requirements to ensure the tests are safe and effective. Furthermore, the difficulty of developing a fast-track approach to MCMs at FDA is in determining which MCMs to target, said RADM Lushniak. Dr. Grabenstein agreed, noting that the FDA proposal for high-priority review must be objective and have clear criteria. He added that the report calls for special attention to FDA resources to ensure adequate staffing as well.

Another recommendation identifies roles the ASPR should take on, in coordination with other leaders, including identifying pediatric MCM needs and pediatric dosages of existing MCMs, increasing the number of pre-emergency use authorization (EUA) dossiers for the top 20 MCMs, writing integrated response plans for three high-priority threat scenarios, and evaluating States’ plans for distribution of MCMs to vulnerable populations. Dr. Parker highlighted the importance of detailed planning and drills to identify and address gaps in response. Dr. Grabenstein pointed out that the draft report’s table on pediatric aspects of top-priority CBRN MCMs provides a quick synopsis of the status of pediatric MCMs. He added that the Office of the ASPR has a huge amount of responsibility but minimal staff to execute its responsibilities; the Board agreed to revise the text of the draft report to emphasize that the ASPR needs more resources.

The report also recommends that the National Institutes of Health (NIH) develop a plan
that aligns basic-science efforts and resources around MCMs with the prioritized research goals and product requirements. Further, HHS should work with its various divisions and with DoD to allocate limited animal resources in alignment with the prioritized goals. In addition, the report recommends funding the Countermeasures Injury Compensation Program for all covered countermeasures, and extending the filing deadline.

Discussion revolved around the transition of research from NIH to BARDA, and the distinctions between “basic-science” research and “advanced development.” There was consensus about the need to better align research with priorities and to better fund BARDA to support more advanced development.

Section V: Enhanced Communication
This section concludes that the Federal government needs to prepare threat and risk assessments suitable for public communication, to provide a basis for public engagement on the consequences of CBRN threats. The recommendations address the importance of making the case to the American taxpayers for investing in MCM research, and better communicating information to the public before and during emergencies. In conclusion, Dr. Grabenstein asked the Board to consider adding to the report a paragraph suggesting that the U.S. Government assess its emergency preparedness in terms of agricultural health (i.e., plants and animals). The Board members agreed to adding such a paragraph.

PUBLIC COMMENTS
Susan Chu, M.D., of the Ready Moms Alliance, called into the meeting and said that during the H1N1 pandemic, children were the first to be affected around the world, but the most effective countermeasures were not available until after most of the pediatric infections occurred. Around the world, it was clear that children would not be protected in case of a severe pandemic, said Dr. Chu, so a centralized approach to MCMs development should be considered.

Dr. Chu said that Europe used an approach similar to that recommended by the Board in which HHS develops “pre-EUA” dossiers on candidate MCMs. In Europe, approval of the pandemic vaccine was based on scenarios developed in 2001 which anticipated a severe pandemic with 100-percent demand for vaccine. In the case of the H1N1 vaccine, additional risk-benefit analysis was not conducted, and uptake of the vaccine was low because of public mistrust, she said. Dr. Chu called for a) robust safeguards and metrics to ensure that EUA occurs in a thoughtful manner appropriate to the specific emergency, and b) unequivocal clarification that pre-EUA consideration, in no way, can be construed as product approval.

The chair recognized Gail Cassell, Ph.D., of Eli Lilly and Company, who had chaired a workshop convened by the Institute of Medicine (IOM), to inform Dr. Lurie’s report on the PHEMCE process. Dr. Cassell thanked the Board for taking the issues raised by the IOM workshop into consideration in its draft report, and expressed her support for the recommendations. However, she cautioned the Board not to underestimate the importance of involving large pharmaceutical companies in early discovery and preclinical research, and not to focus only on small biotech companies; larger companies
have databases and expertise that can facilitate needed research. Dr. Cassell further suggested that public-private partnerships might attract larger companies more than research grants.

Dr. Cassell reminded the Board that simple diagnostic tests that can be used at the point-of-care during an emergency are difficult to develop, but are desperately needed in addition to tests that can be used at clinical, hospital, and physician office settings.

Dr. Al Romanosky of the Maryland Department of Health and Mental Hygiene, said that in his role as State preparedness coordinator, he oversees 21 sites in Maryland that store and distribute CHEMPACK containers supplied by the Centers for Disease Control and Prevention (CDC). He asked the Board to involve the Department of Justice, particularly the Drug Enforcement Administration, in evaluating the regulatory requirements at the State and local levels of MCM storage distribution, and to consider communicating those requirements. Greg Burel, director of the SNS at CDC, and Rosemary Hart of the Department of Justice, both agreed to follow up on the specific issues raised by Dr. Romanosky about licensing, oversight, security, and inventory control, among others.

DISCUSSION

Stephen V. Cantrill, M.D., Acting Chair, NBSB

The Board returned to discussion of the appropriate wording of recommendation number 19 that the NIH provide the HHS Secretary a plan for aligning basic-science resources for MCMs to the national prioritized lists of research goals and product requirements. The Board agreed to remove the term “basic-science.” Dr. James J. James asked that the report emphasize the importance of coordinating response planning across all levels of government and conducting exercises and drills. In response to Dr. Peter Jutro, the MCM WG agreed to revise the original title of the draft report (Defending America Against Chemical, Biological, Radiological, and Nuclear Threats: Leadership Matters) to reflect its focus on medicine and public health.

Dr. Scannon provided a wrap-up, stating the golden threads that weave together the report’s 23 recommendations are a unified national strategy, centralized leadership, and adequate and sustained funding. All three are essential to ensure a strong Federal response to CBRN threats, whether naturally occurring or intentional. Dr. Grabenstein moved and Dr. Parker seconded the motion. The Board unanimously supported the following:

MOTION

The Board adopts the draft report, with the changes suggested and approved by the Board at the public meeting on March 26, 2010, and empowers the MCM WG writing group to make minor editorial changes that do not affect the recommendations, including revising the title. On a roll call vote, all members present voted in favor of the motion. The final version of the recommendations as adopted follows. The full text of the report was subsequently posted at www.hhs.gov/aspr/omsph/nbsb/recommendations.html.
1. The Secretary of HHS, in coordination with Secretaries of Defense and Homeland Security, confers and coordinates with the White House on how best to protect America from CBRN threats, including the merits of establishing a position on the National Security Council (NSC) to lead the relevant National Strategy.

2. The Secretary of HHS, in coordination with Secretaries of Defense and Homeland Security, coordinates with the White House on a unifying end-to-end National Strategy to address intentional, natural, and emerging CBRN threats.

3. The Secretary of HHS promptly identifies at least three high-priority new MCMs that the Department will develop to counter CBRN threats, with target timelines. At least one of these MCMs should address radiation exposure.

4. The Secretary of HHS promptly coordinates with the Secretaries of Defense and DHS and DoD to develop prioritized lists of CBRN threats of both natural and intentional origin, to guide further prioritization of MCM efforts.

5. The Secretary of HHS empowers the ASPR as the operational MCM leader, with authority to synchronize the efforts of HHS agencies and with end-to-end oversight.

6. The Secretary of HHS tasks the ASPR to refine the HHS acquisition structure and metrics, to provide accountability for the MCM program.

7. The Secretary of HHS designates the Director of the Biomedical Advanced Research and Development Authority (BARDA) as the MCM Portfolio Director, to coordinate technical aspects of balancing the HHS MCM portfolio.

8. The Secretary of HHS promptly tasks senior HHS leaders to develop a common set of prioritized research goals, prioritized product requirements, and prioritized dispensing goals for civilian populations; and coordinates these priorities with DoD.

9. The Secretary of HHS, in consultation with the Secretary of DHS, develops a plan to overcome existing obstacles that preclude timely distribution and administration of MCMs to people in need (including children and those with limited functional ability).

10. The Secretary of HHS promptly determines the coordinated budget requirements for Fiscal Year (FY) 2011 relevant to CBRN MCM budget lines within National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID), BARDA, Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and ASPR (and in conjunction with DoD), and communicates requests for revision of the President's Budget to the Office of Management and Budget. Secretary gives special attention to FDA resource needs.

11. For FY2012 and beyond, the Secretary of HHS develops a coordinated budget request relevant to CBRN MCM budget lines within NIH, NIAID, BARDA, CDC, FDA, and ASPR (and in conjunction with DoD).

12. The Secretary of HHS develops a legislative plan to seek multi-year funding authority for CBRN MCM efforts.
13. The Secretary of HHS develops a legislative plan to seek appropriate modification and reauthorization of the Project BioShield Special Reserve Fund, before its expiration in 2013.

14. The ASPR promptly provides a plan to the Secretary of HHS to provide for centralized advanced development and manufacturing of selected biological MCMs, based on one or more public-private partnerships (PPPs) or federally funded research-and-development centers (FFRDCs).

15. The FDA Commissioner promptly provides a plan to the Secretary of HHS for designating appropriate candidate MCMs for high-priority review, with the appropriate criteria of evidence for safety and efficacy.

16. The FDA Commissioner promptly advises the Secretary of HHS on a plan to revise the draft guidance on the "animal rule."

17. The CDC, BARDA, and NIAID Directors develop a plan for the ASPR for identifying and addressing the need for screening and diagnostic tests for CBRN agents that can be performed in clinical settings, prioritized among other MCM needs.

18. The ASPR, in coordination with leaders of other relevant agencies:
   A. Identifies to the Secretary of HHS needs for additional pediatric products for the SNS.
   B. Provides to the Secretary of HHS a plan to determine pediatric dosages for at least three MCMs.
   C. Identifies to the Secretary of HHS a plan to create and maintain pre-Emergency Use Authorization (EUA) dossiers for the top 20 MCMs, in coordination with DoD.
   D. Provides to the Secretary of HHS a plan for drafting three concepts of operations for managing to write integrated response plans for three high-priority threat scenarios, to describe response from alert to MCM dispensing.
   E. Provides to the Secretary of HHS an evaluation of State-level MCM distribution plans to assess adequacy in caring for children and for individuals with functional limitations, and a plan to resolve common problems identified.

19. The NIH Director and NIAID Director provide the Secretary of HHS a plan on how to align NIH resources for MCMs to the national prioritized lists of research goals and product requirements.

20. The Secretary of HHS (working with NIH, NIAID, BARDA, and DoD) develops a plan to rationally allocate limited animal resources and facilities to CBRN animal-model development and testing in alignment with the national prioritized list of research goals.

21. The Secretary of HHS develops a plan to fund the Countermeasures Injury Compensation Program for all covered countermeasures, and to extend the filing deadline to a consistent 3-year interval.
22. The ASPR provides to the Secretary of HHS a plan to release more information on CBRN consequences to the public, as part of a sustained multi-faceted education and communication plan.

23. The ASPR provides to the Secretary of HHS a plan to make information about MCMs available to the public before and during emergencies in appropriate, accessible and alternative formats.

CONCLUSION

Stephen V. Cantrill, M.D., Acting Chair, NBSB
Nicole Lurie, M.D., M.S.P.H., RADM, U.S. Public Health Service; ASPR, HHS

Dr. Lurie said the draft report, in addition to the report finalized in February 2010, *Optimizing Industrial Involvement with Medical Countermeasure Development*, demonstrates that the Board is capable of producing incredibly meaningful work of significant value. She particularly thanked the co-chairs of the MCM WG for their work as well as the efforts of the entire Board and its ex-officio members.

Dr. Lurie hoped the report would inform a bold, transformative effort to create a better, more effective, sustainable system that maintains the components that work well while taking significant steps forward. She expressed enthusiasm and optimism for real, systemic changes. Borrowing from a folk song refrain, Dr. Lurie concluded, “The policy window is open. If not now, tell me when?”

Dr. Cantrill thanked all the participants and adjourned the meeting at approximately 11:30 a.m.
Public Meeting
Friday, March 26, 2010
8:00 AM – 12:00 PM EST

Hilton Washington DC/Rockville
1750 Rockville Pike
Rockville, MD 20852

Questions please email: nbsb@hhs.gov
http://www.hhs.gov/aspr/omsph/nbsb/

8:00 a.m. – 8:30 a.m. Call to Order, Roll Call, and Conflict of Interest Rules
Leigh Sawyer, D.V.M., M.P.H.
Executive Director, National Biodefense Science Board
CAPT, U.S. Public Health Service
U.S. Department of Health and Human Services

Welcome and Agenda Overview
Stephen V. Cantrill, M.D.
Acting Chair, National Biodefense Science Board

Remarks
Nicole Lurie, M.D., M.S.P.H
Assistant Secretary for Preparedness and Response
Rear Admiral, U.S. Public Health Service
U.S. Department of Health and Human Services

8:30 a.m. – 10:30 a.m. Medical Countermeasures Working Group Report with Recommendations: “Defending America Against Chemical, Biological, Radiologic, and Nuclear Threats: Leadership Matters”

John D. Grabenstein, R.Ph., Ph.D.
Co-Chair, Medical Countermeasures Working Group
National Biodefense Science Board

John S. Parker, M.D., Major General (Retired)
Co-Chair, Medical Countermeasures Working Group
National Biodefense Science Board
Discussion

10:30 a.m. – 10:50 a.m. Public Comment

10:50 a.m. – 11:10 a.m. Break

11:10 a.m. – 11:40 a.m. Discussion and NBSB Vote on Recommendations for “Defending America Against Chemical, Biological, Radiologic, and Nuclear Threats: Leadership Matters”
   Stephen V. Cantrill, M.D
   Acting Chair, National Biodefense Science Board

11:40 a.m. – 11:50 a.m. Next Steps
   Nicole Lurie, M.D., M.S.P.H.
   Assistant Secretary for Preparedness and Response
   Rear Admiral, U.S. Public Health Service
   U.S. Department of Health and Human Services

11:50 a.m. – 12:00 p.m. Wrap Up and Adjourn
   Stephen V. Cantrill, M.D
   Acting Chair, National Biodefense Science Board