

SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD
PUBLIC TELECONFERENCE
February 10, 2010

VOTING MEMBERS PRESENT

Patricia Quinlisk, M.D., M.P.H., *Chair*
Stephen V. Cantrill, M.D.
Roberta Carlin, M.S., J.D.
Albert J. Di Rienzo
Kenneth L. Dretchen, Ph.D.
John D. Grabenstein, R.Ph., Ph.D.
James J. James, Brigadier General (Retired), M.D., Dr.P.H., M.H.A. (not available for vote)
John S. Parker, Major General (Retired), M.D.
Andrew T. Pavia, M.D.
Eric A. Rose, M.D.
Patrick J. Scannon, M.D., Ph.D.

VOTING MEMBERS NOT PRESENT

Ruth L. Berkelman, M.D.
Thomas J. MacVittie, Ph.D.

EX OFFICIO MEMBERS PRESENT

Peter Emanuel, Ph.D., Policy Analyst, Office of Science and Technology Policy,
Executive Office of the President
Bruce Gellin, M.D., M.P.H., Director, National Vaccine Program Office, Office of the
Secretary, Office of Public Health and Science, U.S. Department of Health and
Human Services
Rosemary Hart, 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
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
Boris D. Lushniak, M.D., M.P.H., Rear Admiral, Assistant Surgeon General, U.S. Public
Health Service, 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 S. Williams, M.D.*)
John Skvorak, D.V.M., Ph.D., COL, Commander, U.S. Army Medical Research Institute
for Infectious Diseases, U.S. Department of Defense

STAFF OF THE NATIONAL BIODEFENSE SCIENCE BOARD

Leigh Sawyer, D.V.M., M.P.H., CAPT, U.S. Public Health Service, Executive Director
Donald Malinowski, M.S., Program Analyst
Jomana Musmar, M.S., Contractor
MacKenzie Robertson, Program Analyst
Carolyn Stevens, Executive Assistant

CALL TO ORDER AND CONFLICT OF INTEREST RULES

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), Captain, U.S. Public Health Service (USPHS), U.S. Department of Health and Human Services (HHS)

CAPT Sawyer called the public teleconference to order at 2:05 p.m. EST. She called the roll, provided a brief overview of the NBSB, and reviewed conflict of interest rules. CAPT Sawyer said all of the documents presented for discussion at this meeting are available online at www.hhs.gov/aspr/omsph/nbsb/100210-nbsb-meeting.html.

AGENDA OVERVIEW

Patricia Quinlisk, M.D., M.P.H., Chair, NBSB

Dr. Quinlisk reviewed the agenda and commended CAPT Sawyer and the NBSB staff for organizing the teleconference despite the Federal government closure and inclement weather.

REPORT OF THE MEDICAL COUNTERMEASURES (MCM) MARKETS & SUSTAINABILITY (M&S) WORKING GROUP (WG)

John D. Grabenstein, R.Ph., Ph.D., and John S. Parker, M.D., Major General (Retired), Co-Chairs

Dr. Grabenstein thanked NBSB staff, especially Don Malinowski and David Noll, Ph.D.(2007-2009), for their assistance in developing the report "Optimizing Industrial Involvement with Medical Countermeasure Development." Dr. Grabenstein briefly summarized the contents of the report, noting that the only major change since the MCM M&S WG members last reviewed the document is the addition of an executive summary provided to the NBSB members and public in advance of the meeting today.

Discussion

Andrew Pavia, M.D., called the report detailed, thoughtful, and very helpful. He suggested the executive summary be edited to include more of the key considerations described in the report, as many people will only read the summary. For example, in calling for more Federal funding for medical countermeasures (MCMs) development, Dr. Pavia suggested explaining that Federal funding has been not only inadequate but also inconsistent, as noted in the report. The NBSB staff and members agreed that such editorial changes to the executive summary could be made without an additional round of formal approval by the Board, as long as the changes reflect concepts and recommendations already spelled out in the report.

Dr. Quinlisk asked for clarification of the term “allied governments” in the recommendation “The U.S. Government should expand MCM markets to include State and local first-responders and allied governments.” Dr. Grabenstein said the term referred to treaty-allied governments, such as NATO. Dr. Quinlisk asked that the wording be revised to sound more inclusive of State and local emergency/first responders as well as allied State government agencies and Federal and international partners.

Dr. Grabenstein suggested some additions to the report in response to comments sent by Disaster Mental Health Subcommittee member David Schonfeld, M.D., and representatives of the American Academy of Pediatrics and the National Commission on Children and Disasters (see Appendix):

- In the Overview, add that the scarcity of MCMs for pediatric populations is especially troubling.
- In the future MCM review, revise Table 1 to indicate those products for which a pediatric dose has been identified and those threats for which a pediatric product is available.
- In the subsection Assessment of the MCM Enterprise and its Stakeholders, add the sentence, “Further, the unique needs of children for MCMs have not received adequate attention or effort,” and cite data from the National Commission on Children and Disasters.
- In the Conclusion, noting the need for licensed chemical/biological/radiological/nuclear MCMs for both adults and children.
- Revise the executive summary to reflect the changes regarding the importance of addressing pediatric issues.

Roberta Carlin, M.S., J.D., supported addressing pediatric changes and asked whether specifying MCM issues for people with disabilities would be appropriate. Dr. Grabenstein said the report seeks to focus on issues of markets and sustainability, and pediatric concerns are unique in that they pose particular market-related issues to pharmaceutical development.

Public Comment

CAPT Sawyer read the public comments received via email prior to opening the line for additional public comment (comments are found at end of summary).

Steve Brozak of StormBio said he sees a disconnect in the perception of how businesses work with government. Those companies that know how the systems work do well, but those that don’t “get a bloody nose” when they try to work with the government and are unlikely to try again, especially those that are publicly traded. He applauded the Markets & Sustainability Working Group’s (M&S-WG’s) effort but suggested getting anonymous input from CEOs on the problems they have faced and how government could do better.

Tom Zink of St. Louis University School of Public Health said State departments of homeland security and emergency response are hampered by the fact that vaccines are

not included as appropriate countermeasures on the Federal Emergency Management Agency's Authorized Equipment List nor its Standardized Equipment List. He said the lists are periodically updated but the process is slow and doesn't make much sense. Local emergency responders, State and urban homeland security agencies and others are unable to obtain grant funds for items not included on those lists. Adding vaccines to those lists would not only improve preparedness but could also improve vaccination rates in general, said Mr. Zink. He asked that NBSB thoroughly review the Authorized Equipment List and the Standardized Equipment List and recommend including vaccines.

Michael Eichberg of Achoagen says the experience of his company in working with the government on several projects does not seem to be reflected in the report's discussion of problems related to market size and market incentives. He indicated that the Strategic National Stockpile includes many antibiotics (which are seen as top-priority MCMs) that were developed without any government investment because a commercial market for such products exists. Mr. Eichberg said the government perceives that a commercial market exists for any antibiotic with broad-spectrum activity and therefore sees no need to provide incentives to spur their development. He asked how the M&S -WG had considered the nature of dual-use agents within the existing market.

Dr. Grabenstein responded that the M&S -WG did not conduct a random survey of all biopharmaceutical company CEOs but did collect data from some, and the problems they identified are included in the Inventory of Issues Constraining or Enabling Industrial Involvement with MCM Development (provided in the appendix of the report). He asked for more comments on specific issues not addressed in the Inventory, noting that comments may be submitted to NBSB via its website at www.hhs.gov/aspr/omsph/nbsb/.

Dr. Grabenstein noted that equipment lists are mentioned in the Inventory and are at the heart of the recommendation that the Federal government expand MCM markets to include State and local first-responders and allied governments. He added that in the case of dual-use agents, the commercial market helps propel the development of MCMs. Dr. Pavia noted that not all commercial uses are very profitable (e.g., antibiotics for hospital-acquired infections), but NBSB encourages development of dual-use agents. He believed the issue may be discussed in more depth in the upcoming review of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE).

David Gilbert of the Infectious Diseases Society of America said that in the area of antibacterials, dual use is a must for industry to have substantial incentive to proceed. His organization hopes to see more enthusiasm for developing antibiotics to fulfill unmet needs. He said the report does not clearly identify the potential for leadership from the National Institute of Allergy and Infectious Diseases in pulling together stakeholders to look for new targets and treatments.

Vote on Report, "Optimizing Industrial Involvement with Medical Countermeasure Development"

Following a motion by Dr. Grabenstein (seconded by Dr. Parker), the Board voted unanimously in favor of the following:

Recommendations

- NBSB adopts the M&S -WG Report, “Optimizing Industrial Involvement with Medical Countermeasure Development,” with the changes discussed (clarify “allied governments,” incorporate pediatric concerns, edit the executive summary).
- NBSB recommends that the M&S -WG, having completed its charge, stand down.

SECRETARY SEBELIUS’ CALL FOR THE REVIEW OF PHEMCE

NBSB Charge from the ASPR

Nicole Lurie, M.D., M.S.P.H., Assistant Secretary for Preparedness and Response, HHS

Dr. Lurie thanked NBSB for its efforts and said the M&S -WG’s report is very much appreciated, especially in light of the upcoming PHEMCE review. She explained that Secretary Sebelius charged her with conducting the PHEMCE review for several reasons. First, if some of the biggest and best manufacturers in the world could not produce the H1N1 vaccine as quickly as it was needed, how can the nation pin its plans for the development of countermeasures on the capacity of small startup biotech firms, which are the companies primarily involved in such work? Second, the Department has been frustrated with the inability to move forward on a next-generation anthrax vaccine. Dr. Lurie and Secretary Sebelius feel that the slow pace of countermeasures development may stem from the fact that the moving parts are not aligned to produce success.

To address concerns, the PHEMCE review has multiple components. The first is a synthesis of what is known. To manage the volume of information, HHS commissioned a set of white papers and requested the Institute of Medicine (IOM) convene a workshop to discuss them. (The workshop was originally scheduled for February 10–11, 2011, but has been postponed to the week of February 22 because of the weather.) One paper evaluates methods to create a robust pipeline of products for advanced development—in other words, the best ways to procure the science. A second paper considers the market forces and incentives that affect the government’s ability to meet preparedness goals.

Another paper analyzes the current procedures for stockpiling, distributing, and dispensing countermeasures. NBSB has provided insight on two areas related to this topic. First, behavioral issues related to MCMs, such as acceptance of the countermeasure, are critically important and may drive the delivery mechanisms. We would not want to be in a situation where we had a more aggressive disease than H1N1 and 50 percent of the public will not accept the countermeasure, said Dr. Lurie. Also, NBSB has highlighted the needs of special populations, such as children and pregnant women that should be addressed in the PHEMCE review.

Dr. Lurie thought NBSB would be particularly helpful in looking at issues of leadership, accountability, and strategic management overall for the PHEMCE. Along those lines, another paper will present case studies on countermeasures, some of which were successful, some of which were not. Dr. Lurie asked NBSB to:

- convene a workshop to look at strategic management, leadership, and accountability, using the case studies paper as a springboard, and
- write a report of its findings for the Secretary that synthesizes the issues and challenges facing the enterprise.

Dr. Lurie said the work of NBSB, IOM, ASPR staff, and others would be combined in a report that is due to Secretary Sebelius by March 31, 2010. With such a short timeline, she said, she expects that recommendations might not be fully fleshed out in the report and that the report likely would not contain detailed strategies. She acknowledged that the request requires a great deal of work and thanked NBSB for taking it on.

Finally, Dr. Lurie praised the work of NBSB's Disaster Mental Health Subcommittee, which informed the Department's H1N1 response. In addition, the Subcommittee's recommendations greatly enhanced the mental health component of the Department's response to the earthquake in Haiti in January—for people in Haiti, for response workers traveling to Haiti, and for Haitians in the United States.

NBSB Response to ASPR Request

Patricia Quinlisk, M.D., M.P.H., Chair, NBSB

Dr. Quinlisk thanked Dr. Lurie for providing clear goals and direction on how the Board can assist the Department. Dr. Pavia asked Dr. Lurie to identify (from her experience) the types of expertise that NBSB should call on to help it evaluate leadership, accountability, and management issues. Dr. Lurie suggested mapping out each component of the enterprise and its relationship to the end goal to determine who is accountable for what, what incentives motivate each participant, and how the goals and incentives align. Quality improvement principles can help to identify measures and metrics and illuminate how systems adapt to their surroundings. Dr. Lurie emphasized that the issues in the biodefense industry are not unique to that industry.

A number of public health threats exist, and countermeasures are needed to address them quickly, said Dr. Lurie. One question to consider is whether the PHEMCE strategy should focus on specific threats or products with broader uses. Developing products with commercial applications decreases the investment costs to the government, she noted. The case studies paper should be helpful in evaluating strategies. That paper should be available in time for the upcoming IOM meeting.

Patrick J. Scannon, M.D., Ph.D. asked how national security concerns affect prioritization and leadership in the development of MCMs. Dr. Lurie responded that a major public health threat, such as a severe pandemic, could destabilize the government and thus pose a national security threat. Thus, she suggested considering MCM development in that context. She hoped that lessons could be drawn from across sectors. She hoped the paper on the research pipeline would look beyond security to other areas that have addressed similar scientific challenges. Dr. Grabenstein encouraged the public to weigh in via the NBSB website on the ASPR's charge to the Board.

Discussion

Drs. Grabenstein, Parker, and Scannon have already discussed preliminary steps and suggest that NBSB form a new Working Group to address the charge of the ASPR. Dr. Parker recommended the new group have co-chairs so that one person is not saddled with too much work. Dr. Scannon suggested determining at the outset what issues to address immediately in time for the report due to the Secretary March 31 and what other issues could be discussed later. Dr. Pavia recommended the new group quickly identify the larger questions to address, then seek feedback from Dr. Lurie to confirm it is on the right track. Dr. Lurie responded that, given the short timeframe, she hoped NBSB's review could at least highlight the major areas where change is needed. She also suggested NBSB draw on all its experience and information gathered to date.

CAPT Sawyer explained the process by which previous Working Groups had been formed: All voting members and ex officio members are invited to participate. Those who are interested meet to select a chair(s) and determine how to develop the response to the charge. Ex officio members can designate a representative to join the group who can provide needed expertise. The group can invite other experts within and outside the Federal government to take part. After further discussion, the Board agreed to the following:

- Drs. Grabenstein, Parker, and Scannon will serve as co-chairs of the new MCM Working Group.
- CAPT Sawyer will request more staff resources to support the MCM Working Group.
- The MCM Working Group will hold its initial meeting by teleconference on February 16.
- All Board members and ex officio members will be invited to join the Working Group.

Dr. Scannon pointed out that the Board's report is due to Dr. Lurie on March 26. CAPT Sawyer said the April 2010 NBSB public meeting had been rescheduled for March 26. The draft report compiled by the MCM Working Group will be posted on the website as soon as it is available prior to the public meeting for public comment on March 26.

WRAP UP AND ADJOURN

Dr. Quinlisk reminded participants that Dr. Lurie had also asked the Board to consider new issues to address for the future. However, given the scope of the effort required to address the PHEMCE review over the next six weeks, Board members agreed to table that discussion for future consideration. The meeting was adjourned at approximately 4 p.m. EST.

APPENDIX: Written Public Comments

From: Shriver, Mark [<mailto:mshriver@savechildren.org>]
Sent: Monday, February 08, 2010 10:58 AM
To: Krug, Steve; David.Schonfeld@cchmc.org; Quinlisk, Patricia
Cc: laird@aap.org; Christopher.Revere@ACF.hhs.gov
Subject: RE: NBSB report on Medical Countermeasures
Dear Dr. Quinlisk,

I greatly appreciate David's request and the continued support of Steve and the AAP. I also sincerely appreciate the ongoing support of the NBSB for the work of the Commission and vice-versa.

The challenges surrounding medical countermeasures for children will not be addressed unless they are called out specifically and confronted directly by the Federal government. The report being developed by the NBSB presents a great opportunity to bring these challenges into the light. I hope the NBSB agrees and will augment the report to devote more attention to children.

Warmly,

Mark

-----Original Message-----

From: Krug, Steve [<mailto:skrug@childrensmemorial.org>]
Sent: Mon 2/8/2010 12:24 AM
To: 'David.Schonfeld@cchmc.org'; 'pquinlis@idph.state.ia.us'
Cc: 'laird@aap.org'; 'Christopher.Revere@ACF.hhs.gov'; Shriver, Mark
Subject: Re: NBSB report on Medical Countermeasures

Dr. Quinlisk,

I'd like to echo David's comments. The development and deployment of appropriate medical countermeasures for children is an area of great concern for the American Academy of Pediatrics and we stand ready to assist you and the NBSB towards addressing this important issue in the report.

Steven Krug, MD
Chair, AAP DPAC

----- Original Message -----

From: David Schonfeld <David.Schonfeld@cchmc.org>
To: pquinlis@idph.state.ia.us <pquinlis@idph.state.ia.us>
Cc: laird@aap.org <laird@aap.org>; Christopher (ACF) Revere <Christopher.Revere@ACF.hhs.gov>; Krug, Steve; mshriver@savechildren.org <mshriver@savechildren.org>
Sent: Sun Feb 07 15:08:08 2010
Subject: NBSB report on Medical Countermeasures
Dear Dr. Quinlisk,

As a member of the Disaster Mental Health Subcommittee of the NBSB, I recently received a copy of the draft report from the NBSB regarding optimizing industrial involvement with medical countermeasure development and was glad to see that the NBSB included mention of the need to consider the unique needs of developing medical countermeasures for children (page 17, under the 7th recommendation). As a member of both the National Commission on Children and Disasters (NCCD) and the Disaster Preparedness Advisory Council (DPAC) of the American Academy of Pediatrics, I know that this has been one of the top concerns for both groups. If it is still possible, I think it would strengthen the report a good deal if further discussion of the unique needs of children as it relates to the unique barriers for pediatric countermeasure development (which go above and beyond the financial, institutional, and regulatory

barriers already present for adult countermeasures) to either add a paragraph to the report to discuss this further and/or insert a citation to reference the interim report to the President and Congress released in October 2009 of the National Commission (which already includes some language on this topic). We had the opportunity to meet with Dr. Lurie several days ago in her office to underscore the unique needs of children as it relates to medical countermeasures and to urge ASPR and others in the federal government to devote the attention to this issue it most definitely deserves (but frankly has not received to date). I know from my participation within the meetings of the NBSB that the Board as a whole, and you personally, understand and appreciate the importance of the unique needs of children. I am not sure, though, that the rest of the federal government is "on the same page."

I have copied Mark Shriver and Chris Revere (Chair and Executive Director respectively) of the National Commission on Children and Disasters and Steve Krug, MD and Laura Aird (Chair and AAP staff respectively) of the Disaster Preparedness Advisory Council of the AAP. We all stand ready to assist you and the NBSB with the preparation of any language that may be added to this important report.

Thanks in advance for your assistance.

Sincerely,

David

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