SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD
PUBLIC MEETING
April 28, 2011

VOTING MEMBERS PRESENT

Patricia Quinlisk, M.D., M.P.H., *Chair*
Georges C. Benjamin, M.D., FACP, FACEP(E), FNAPA, Hon FRSPH
Stephen V. Cantrill, M.D.
David J. Ecker, Ph.D.
Daniel B. Fagbuyi, M.D., FAAP
John D. Grabenstein, R.Ph., Ph.D.
Kevin A. Jarrell, Ph.D.
Thomas J. MacVittie, Ph.D. (by phone)
John S. Parker, Major General (Retired), M.D.
Betty J. Pfefferbaum, M.D., J.D. (by phone)
Patrick J. Scannon, M.D., Ph.D.

VOTING MEMBERS NOT PRESENT

Ruth L. Berkelman, M.D. (*on leave of absence*)
Jane Delgado, Ph.D., M.S.

EX OFFICIO MEMBERS PRESENT

Hugh Auchincloss, M.D., Principal Deputy Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health
Bruce Gellin, M.D., M.P.H., Director, National Vaccine Program Office, Office of Public Health and Science, U.S. Department of Health and Human Services
Peter Jutro, Ph.D., Deputy Director, National Homeland Security Research Center, U.S. Environmental Protection Agency
George W. Korch Jr., Ph.D., Acting 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 (by phone)
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 (by phone)
Carmen Maher, CDR, U.S. Public Health Service, Policy Analyst, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, U.S. Department of Health and Human Services (*designated by Luciana Borio, M.D.)* (by phone)
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.)*
Tracy Dewese Parker, Ph.D., Office of Health Affairs, U.S. Department of Homeland Security *(designated by Sally Phillips, R.N. Ph.D.)* (by phone)

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.)* (by phone)
Frank Scioli, Ph.D., Director, Division of Social and Economic Sciences, National Science Foundation
John P. Skvorak, D.V.M., Ph.D., COL, U.S. Army, Commander, U.S. Army Medical Research Institute of Infectious Diseases, U.S. Department of Defense
Daniel M. Sosin, M.D., M.P.H., FACP, CAPT, U.S. Public Health Service, Deputy Director and Chief Medical Officer, Office of Public Health Preparedness & Response, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services *(designated by RADM Ali S. Khan, M.D., M.P.H.)*

STAFF OF THE NATIONAL BIODEFENSE SCIENCE BOARD

Leigh Sawyer, D.V.M., M.P.H., CAPT, U.S. Public Health Service; Executive Director
MacKenzie Robertson, Program Analyst
Jomana F. Musmar, M.S., Program Analyst, Contractor
Brook Stone, M.F.S., LT, U.S. Public Health Service, Program Analyst

CALL TO ORDER

CAPT Leigh Sawyer, D.V.M., M.P.H., Executive Director, National Biodefense Science Board (NBSB)

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

WELCOME AND INTRODUCTION

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

Dr. Quinlisk welcomed the Board members and other participants and reviewed the agenda for the meeting (see Appendix A).

ALL HAZARDS SCIENCE RESPONSE WORKING GROUP REPORT

Stephen V. Cantrill, M.D.

On January 21, 2011, Nicole Lurie, M.D., M.S.P.H., Assistant Secretary for Preparedness and Response (ASPR) for the U.S. Department of Health and Human Services (HHS), asked that the NBSB investigate strategies to deal with knowledge gaps and research needs for improved response to future hazards and public health emergencies. In response, the Board formed the All Hazards Science Response Working Group to consider how to better incorporate scientific investigation into disaster response planning. Dr. Cantrill summarized the Working Group's efforts and its draft report, *Call to Action: Include Scientific Investigations as an Integral Component of Disaster Planning and Response*.

Scientific investigation often occurs in response to a disaster—for example, following the attacks on the World Trade Center, the identification of H1N1 influenza, the Deepwater Horizon oil spill in the Gulf of Mexico—but with little advance planning, organization, or integration. Incorporating scientific investigation into disaster response planning will benefit the victims and the responders in future public health emergencies, Dr. Cantrill said.

Dr. Cantrill described the Working Group's process, including a workshop in March with invited public and private stakeholders. The workshop participants agreed unanimously that scientific investigation should be an integral component of disaster planning and that it should be a priority.

The Working Group report put forth 10 recommendations:

1. Immediately convene Strategic Science Planning Panels, made up of leading expert government and civilian scientists, to identify research questions and knowledge gaps likely to arise during a variety of incident types, including those foreseen in Federal Emergency Management Agency (FEMA) National Planning Scenarios.

2. Add a "Scientific Response Support Annex" to the National Response Framework (NRF), and amend the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) to include the scientific response.

Dr. Cantrill strongly recommended working closely with the Department of Homeland Security (DHS), which oversees the NRF, to accomplish this recommendation.

3. Establish with leadership and staff from the Office of the ASPR an Interdepartmental Center for Scientific Investigations During Disaster Response (Center); the Center will have a dedicated staff, and its primary mission will be to anticipate, plan for, coordinate, facilitate, and evaluate scientific investigations conducted before, during, and after disasters.

The proposed Center should have full-time staff and appointed liaison staff as needed, said Dr. Cantrill. The Center would be responsible for implementing recommendations number 4–10.

4. Develop the concepts, doctrine, infrastructure, and personnel needed to begin scientific investigation and data collection rapidly in various types of incidents.

5. Integrate the Public Health Emergency Research Review Board (PHERRB) into standard operating procedures for review of research before, during, and after a disaster response.

The PHERRB could act as a Federal-level institutional review board (IRB) to facilitate some aspects of timely scientific investigation immediately after an event, Dr. Cantrill noted.

6. Appoint a liaison within the Center to the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) to facilitate review of scientific protocols required by the Paperwork Reduction Act (PRA).

Dr. Cantrill said that workshop discussions revealed lack of understanding about the requirements of the PRA and how to meet them. A liaison could help address requirements before and during events and help streamline the OMB process.

7. Establish funding mechanisms to support a rapid and robust scientific response to disasters.

The Working Group members acknowledged that funds are limited and suggested repurposing some existing funding. For example, it may be possible to have existing national centers of excellence in scientific investigation prepared to ramp up quickly in response to a disaster.

8. Integrate individuals and communities affected *by* a disaster as full partners in scientific investigations related *to* the disaster.

Dr. Cantrill stressed the importance of community-based participatory research and the need to identify and involve local leaders.

9. Standardize approaches to data collection and sharing by Federal, State, and local response organizations (and encourage the same among private and volunteer organizations), giving special attention to collection of baseline data.

Dr. Cantrill pointed out that many authorities work in isolated silos and their data are not interoperable. Also, more baseline data are needed.

10. Identify, acquire or develop, deploy, and maintain new information technology for collecting data in the field.

During the Deepwater Horizon response, use of social media for communication and of radiofrequency detection badges to track individuals came to light. Dr. Cantrill said more can be done with new technology.

Dr. Cantrill thanked the Working Group members, the workshop participants, and NBSB staff for their hard work and participation.

Discussion

Dr. Lurie said she has been thinking about ways to advance the quality of response, and improving scientific response has become a high priority. She appreciated the deliberation that went into the report and looked forward to reviewing the Board's final recommendations.

Bruce Gellin, M.D., M.P.H., pointed out that the intent of recommendation number 3, to anticipate research questions or prepare for data gathering in specific settings, for example, is not well reflected in the wording of the recommendation.

Daniel M. Sosin, M.D.—noting that he was speaking for himself and not on behalf of the Centers for Disease Control and Prevention (CDC)—suggested the Working Group revisit its conclusion that the PRA is valuable and worth the resources it commands. The PRA may not be an impediment, said Dr. Sosin, but he questioned whether a bureaucratic function managed by people who do not have expertise in the field of scientific research should have the final say on data collection. He proposed that another entity evaluate whether the PRA is necessary and valuable during emergencies.

Dr. Sosin clarified that States that conduct their own data collection outside of national efforts or without Federal funding are exempt from the PRA requirements, but they are subject to the requirements if they are collecting data in coordination with or under the direction of a Federal agency. Frank Scioli, Ph.D., of the National Science Foundation, said the PRA may impede investigations and may damage the research process. He pointed out that we cannot know the costs of *not* pursuing scientific investigation in a timely manner after an emergency. In the time it takes to comply with PRA requirements, data can become contaminated and important research opportunities lost, he added. Kevin A. Jarrell, Ph.D., said the proposed Center would help address these issues by identifying in advance subject matter experts who would coordinate efforts quickly.

Dr. Sosin noted that OMB does have mechanisms for expediting approval to achieve an almost-immediate response in some cases. He suggested looking more closely at emergency approval procedures. Dr. Cantrill offered to revise recommendation number 6 to call for an independent review of the effect of the PRA on timely scientific investigation and possible approaches for remediation.

Peter Jutro, Ph.D., stressed the need to look beyond the immediate aftermath of disaster, recognizing that advance preparation can minimize the health effects of a disaster, as can the response in the months and years that follow. He commented on the importance of distinguishing "science" from "research." The NCP's Incidence Response Teams believe they already have scientific advice built in to the process.

Dr. Jutro also said that NBSB ex officio member Franca R. Jones, Ph.D., Senior Policy Analyst for Chemical and Biological Countermeasures in the President's Office of Science & Technology Policy (OSTP), has convened a working group to look at similar issues. He suggested asking Dr. Jones to invite Dr. Cantrill or an HHS representative to present the NBSB report to the OSTP working group.

The report provides a general framework for collecting scientific data, said Dr. Scannon, but whoever implements the recommendations should pay close attention to those directly affected by the disaster and work to ensure that data collection only minimally impacts the pressing, immediate concerns of those affected. It should also be noted, Dr. Scannon added, that the nature of a disaster can evolve, as the tsunami that struck Japan evolved from a natural disaster into a nuclear emergency, for example. Thus, it's important to have flexibility in responsiveness.

Dr. Cantrill felt the report could address local IRB review more and proposed some additional language for recommendation number 8. Much discussion ensued about coordination among IRBs and what entities are involved in reviewing research involving human subjects.

Public Comments

There were no public comments.

NBSB Vote on All Hazards Science Response Working Group Recommendations

Dr. Cantrill moved and the Board unanimously supported the following:

> ***MOTION***
>
> The Board adopts the report, *Call to Action: Include Scientific Investigation as an Integral Component of Disaster Planning and Response*, with the following changes suggested and approved by the Board at the public meeting on April 28, 2011, and empowers the NBSB staff to make minor editorial changes that do not affect the recommendations.
>
> The following sentence will be added to recommendation number 6: "There should also be an independent review of the benefit versus the net loss of the effect of the Paperwork Reduction Act on a timely, emergent, scientific response, with consideration of the possible approaches for remediation."
>
> The following sentence will be added to the explanatory text for recommendation number 8: "Integration with the community should extend to local, academic, medical, and public health communities with the intent of streamlining local institutional review board approval to scientific investigations when indicated."

Finally, the Board agreed to send the final report to the HHS Secretary, simultaneously copying the ASPR so that Dr. Lurie receives the report at the same time. Dr. Lurie thanked the Board and the Working Group for the passion with which they embraced her request. She noted that during the Deepwater Horizon response, 17 different agencies were conducting some kind of investigation, and it was challenging to bring the data together in a cohesive platform. Dr. Lurie supported the idea of presenting the recommendations to the OSTP and working with the OMB, the U.S. Environmental Protection Agency, and others to put them into practice.

REFLECTIONS ON REJOINING ASPR

Richard Hatchett, M.D., Chief Medical Officer and Deputy Director, Biomedical Advanced Research and Development Authority (BARDA), HHS

Dr. Hatchett left the HHS Office of Public Health Preparedness (the predecessor to ASPR) in 2004; he went on to serve as director for Biodefense Policy on the White House Homeland Security Council before returning to BARDA recently.

While BARDA has grown much larger in the past seven years, the primary concerns have remained the same, said Dr. Hatchett: disease surveillance, emergency preparation, and response. In 2001, the head of the Office testified before Congress about creating an anthrax vaccine and a national pharmaceutical stockpile. The Office focused exclusively on domestic security, said Dr. Hatchett; pandemic disease was not yet considered an important threat, and radiological and nuclear threats were not part of the agenda for the Office of Public Health Preparedness.

Since returning to BARDA, said Dr. Hatchett, the biggest surprise is the intensity of the environment at the Office of the ASPR. In addition to what seems like an unending series of major disasters and other events, the ASPR is under relentless scrutiny from Congress, the White House, the Government Accountability Office, stakeholders, think tanks, and the press. Finding time to think strategically in that environment is a challenge, said Dr. Hatchett.

The vulnerabilities highlighted by the H1N1 pandemic in 2009 along with the change in administration offered a once-in-a-decade opportunity for meaningful change, Dr. Hatchett said, and he became devoted to the transformation of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The opportunity to implement the changes called for by the comprehensive PHEMCE review brought Dr. Hatchett back to BARDA. He emphasized two important observations about the PHEMCE review:

- The changes that resulted from the review were transformative in intent and substance, but they do not represent a rupture from the past. Rather, they represent an attempt to achieve the same goals but faster and at lower cost.
- Changing the enterprise is not a substitute for the market guarantee provided by Project Bioshield.

In hindsight, Dr. Hatchett said, it was naive to think that Project BioShield alone would solve the problem of developing medical countermeasures (MCMs), although it succeeded in creating a market guarantee. In the years since Project BioShield was established, the U.S. Government has gained a better understanding of the private sector and the challenges it faces in developing MCMs. Project BioShield works well, Dr. Hatchett emphasized; BARDA now sponsors about 60 contracts for MCMs for chemical, biological, radiological, and nuclear (CBRN) threats and is overwhelmed with proposals and requests for meetings. The pace of MCM development is accelerating dramatically.

Dr. Hatchett believes the market guarantee is working and should remain a pillar of the PHEMCE. But the PHEMCE review identified the need for strategic thinking, re-envisioning partnerships, and improving program management and administration. The latter—improving management and administration—is extraordinarily important, said Dr. Hatchett. While many have heard about the big initiatives, like the Centers for Innovation and the strategic investment efforts, other efforts are also ongoing.

For example, said Dr. Hatchett, the NBSB called for enhanced leadership with more synchronization across agencies, more discipline, and more teamwork. Now, agency heads are all fully involved in a Senior Council that has not seen so much direct engagement of high-level leaders since 2002, Dr. Hatchett noted. The unique medical and public health challenges of the past two years have led to the establishment of benchmarks for leadership and collaboration that flow into the PHEMCE.

The NBSB also called on HHS to refine its acquisitions structure and metrics to make them more accountable. Since then, the Office of the ASPR has been reorganized, establishing the Office of Acquisitions Management, Contracts, and Grants (AMCG) as an entity separate from BARDA that reports directly to the ASPR. The AMCG implemented a quality assurance program in

which it tracks proposals and automatically alerts senior officials when a time limit is exceeded. Contracts are now structured with multiple milestones. The AMCG and BARDA are instituting in-progress reviews to assess programs and evaluate deviations.

As part of BARDA's ongoing initiative to improve portfolio and program management, BARDA will map workflows to identify work breakdown structures, institute a common set of metrics across portfolios, and improve the provision of real-time information to decision-makers. Over time, this approach will allow for the development of standards that can be tracked against BARDA and industry norms. It will improve BARDA's ability to take action to address problems and, when remedies don't work, to "fail small and fail fast."

Over the past decade, we've come a long way, said Dr. Hatchett. Preparedness and response has gone through five phases of evolution:

- The dawning awareness of threats before 9-11
- The extreme reaction immediately after 9-11
- The "adolescence" of response, with some painful lessons learned (e.g., the Hurricane Katrina debacle)
- The early maturity of preparedness, with the creation of the PHEMCE and an integrated portfolio of CBRN MCMs
- The current level of maturity, evidenced by clear-eyed analysis of lessons learned, a focus on continuous quality improvement, enhanced attention to unknown threats and rapid response, an emphasis on long-term sustainability, and a commitment to private-public partnerships

Dr. Hatchett concluded that even as the mission evolves and expands, the prospects for success have never been better, and he feels privileged to lead BARDA forward.

Discussion

John D. Grabenstein, R.Ph., Ph.D., thanked Dr. Hatchett for his contributions and excellent public service. He noted that the intensity of commitment to MCM development must remain high to ensure that more products make it through the pipeline. Success is the licensed product, said Dr. Grabenstein, and there are still not that many products in the cupboard. Dr. Hatchett agreed that the enthusiasm of private companies is encouraging, but the PHEMCE review focused on how HHS can go beyond the market guarantee and smooth the way to licensure. He added that BARDA is a full partner in the $1-billion investment called for by the PHEMCE review.

ADDRESSING PEDIATRIC POPULATION ACCESS TO MCMs

George Korch Jr., Ph.D., Acting Principal Deputy, Office of the ASPR, HHS

In a letter dated 27 April 2011, the ASPR asked that the NBSB consider issues related to the use of anthrax vaccine adsorbed (AVA, BioThrax®). AVA is currently in the Strategic National Stockpile and licensed for 5-dose pre-exposure prophylaxis by healthy persons 18 to 65 years of age. It may be used in a declared emergency under an Emergency Use Authorization (EUA) for this same population as a post-exposure prophylaxis in combination with licensed antibiotics for

prevention of anthrax disease. The product would likely qualify for 3-dose post-exposure prophylaxis under an EUA. However, the pediatric population and other special populations are not covered by the EUA. Dr. Korch offered some context for the request. Recently, the Dark Zephyr Senior Officials exercise used a scenario of an anthrax attack in San Francisco, CA, and evaluated the subsequent decisions about, for example, deployment of MCMs, evacuation versus sheltering-in-place, and the airborne spread of anthrax outside the city.

The exercise revealed some knowledge gaps and raised questions about the need for a vaccine program for people who desire to continue to live in "contaminated" areas. There are no safety or immunogenicity data for AVA in pediatric populations. During an emergency, due to the lack of data, the anthrax vaccine would need to be provided to pediatric populations under an investigational new drug (IND) clinical research protocol. These factors complicate operational response and public messaging, said Dr. Korch.

The Office of the ASPR initiated discussions with the Center for Biologics Evaluation and Research (CBER) of the U.S. Food and Drug Administration (FDA), the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), BARDA, and CDC to develop possible protocols for providing anthrax vaccine to pediatric populations. The issue has been considered by other bodies, and the NBSB has previously identified the need to look at MCMs for pediatric populations. Dr. Korch said the following questions and considerations should be addressed:

- What data are needed?
- Can we address the risk-benefit equation and ethical constructs that would permit a clinical protocol now, (pre-event, to gather some data in the pediatric population), when there is no immediate threat on the horizon?
- If, following an event, an IND research protocol were established, could researchers gather and assess enough data within the 60-day antibiotic prophylaxis period to determine whether post-exposure vaccine should be used in others?
- How do we address logistic challenges? Would the clinical trial site be limited to the site of the attack or could it take place at other locations?
- Should we consider a general use protocol or a post-exposure protocol (e.g., if another attack is anticipated)?
- What other constraints could arise?

Dr. Korch reminded the participants that, for pediatric populations, clinical protocols must be especially sensitive to the benefits relative to the risk. If the risk to the pediatric subject is more than minimal, there should be a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting children's health or welfare. For pediatric studies, Federal regulations categorize protocols according to the risk and potential benefit. The same regulations require the FDA Commissioner to consult with an advisory body of experts in pertinent disciplines about a proposed pediatric protocol before approving it.

Discussion

Dr. Korch explained that other advisory groups look at similar issues, and an advisory board to the FDA Commissioner would likely review any proposed anthrax vaccine pediatric research protocol (as required by regulations). However, the NBSB is the only advisory board that focuses solely on the intersection between biodefense and product development. Regarding the threat of an anthrax attack that would affect children in the United States, Dr. Korch said that no one can say it will happen, but in a general sense, there is "chatter" about a biological attack, and anthrax is one of only a couple pathogens that are universally known. If anthrax is a "standard" biological weapon, so to speak, and you're not prepared to work through the implications of an anthrax attack, why invest in any MCM, Dr. Korch asked rhetorically.

Georges C. Benjamin, M.D., said the NBSB could address the questions raised, but deeper questions arise, such as the timing of prophylactic antibiotics or prophylactic versus post-exposure vaccination. Who should be vaccinated and when? Who determines which populations should be vaccinated? Dr. Benjamin suggested that the NBSB create an algorithm that lays out the questions and let another body address the safety and efficacy of the vaccine.

Dr. Korch noted that only certain military personnel, who are deemed at high-risk of exposure to anthrax, receive prophylactic vaccination. If more data were available about safety and immunogenicity, he said, authorities would have more information on which to base decisions. At present, adults can be vaccinated under an EUA in a declared emergency, but children would need to receive the vaccine under IND, with informed consent. Dr. Benjamin said that if vaccine were available for adults, public health providers would also give it to children. Dr. Korch responded that the supply would be limited and controlled by the government, which at present does not allow for vaccinating children, under an EUA. Further, providers would be setting themselves up should the vaccine later be proven not to be safe in children. Dr. Korch agreed that an algorithm of questions would be useful.

Participants discussed the basis for the current protocols for prophylactic antibiotics and post-exposure vaccine, including the efficacy of the vaccine in adults. Dr. Jarrell asked whether studies could be conducted among populations where natural anthrax exposure still occurs relatively frequently. Daniel B. Fagbuyi, M.D., noted that in some countries where U.S. soldiers are deployed (e.g., Iraq), public health providers do treat children for anthrax exposure, so it may be possible to conduct trials in other countries, if the condition is sufficiently frequent.

Dr. Fagbuyi stressed the importance of getting stakeholder input in advance to ensure that target populations will take part in protocols and public health efforts once they are developed. Dr. Korch agreed. He noted that some effective tools to prevent or treat anthrax may be available, and the question- remains how to provide access or remove barriers to treating children. Dr. Scannon emphasized that educating the American public is a key challenge to vaccine acceptance and uptake. Dr. Korch pointed out that not only would an anthrax attack present different logistic challenges, it would be associated with different parental perceptions and communication challenges than other vaccines possess. None of the participants were aware of any vaccine found to be safe in adults that was not safe for children.

To outline the problem, Dr. Grabenstein walked through a research scenario under the currently accepted procedures. He concluded that beginning an IND clinical protocol for children immediately after an attack would result in several hundred children being treated with both antibiotics and vaccine in trials for several months while a million other children who were potentially exposed to anthrax await treatment with antibiotics alone pending the results of the trials. Both Dr. Korch and CDR Carmen Maher of the FDA's Office of Counterterrorism and Emerging Threats, Office of the Commissioner (OCET) said that the FDA recognizes the need to streamline protocol procedures in the face of an emergency—for example, by shortening the informed consent form.

Cynthia Kelley of CBER, FDA noted that if it were not possible to get safety and immunogenicity data on the use of the anthrax vaccine in children before an anthrax event, it is likely that FDA would provide access to antibiotics and AVA to people under 18 years of age under an IND protocol with informed consent. Parents would be asked to volunteer their children for follow-up evaluation so that safety and some immunogenicity data could be gathered that would possibly facilitate use of the anthrax vaccine under an EUA either later in the same event or in a future event.

David J. Ecker, Ph.D., said we should anticipate that children will get the vaccine through some mechanism in an emergency; therefore, we should consider some approach to getting data that can be extrapolated to this and other vaccines. Dr. Korch responded that the ASPR would like more input on whether we should we look at general approaches for all MCMs or look specifically at AVA in a specific scenario? He favored the latter, because people appreciate examples on which to base future decision-making. Board members agreed to consider the issue further and determine how to respond to the ASPR's request.

CONCLUSION

CAPT Sawyer thanked all of the participants and Board members, especially Dr. Cantrill for his efforts and for presenting the Working Group's findings. She also gave special thanks to the NBSB staff for their hard work. The next public NBSB meeting is scheduled for September 22–23, 2011. Dr. Quinlisk thanked all the participants and adjourned the meeting at approximately 3:00 p.m.

Appendix A

NBSB NATIONAL BIODEFENSE SCIENCE BOARD

Public Meeting
Thursday, April 28, 2011
Washington Plaza Hotel
10 Thomas Circle Northwest
Washington, DC 20005

10:15 a.m. – 10:45 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 *Patricia Quinlisk, M.D., M.P.H.* *Chair, National Biodefense Science Board*
10:45 a.m. – 11:45 a.m.	**All Hazards Science Response Working Group Report** *Stephen Cantrill, M.D.* *Chair, All Hazards Science Response Working Group* *National Biodefense Science Board*
	Discussion
11:45 a.m. – 12:00 p.m.	**Public Comment**
12:00 p.m. – 12:15 p.m.	**NBSB Vote on All Hazards Science Response Working Group Recommendations** *Patricia Quinlisk, M.D., M.P.H.*
12:15 p.m. – 1:15 p.m.	**Lunch on Your Own**
1:15 p.m. – 1:45 p.m.	**Addressing Pediatric Population Access to Medical Countermeasures** *George Korch Jr., Ph.D.* *Acting Principal Deputy* *Office of the Assistant Secretary for Preparedness and Response* *U.S. Department of Health and Human Services*
	Discussion
1:45 p.m. – 2:30 p.m.	**Reflections on Rejoining ASPR** *Richard Hatchett, M.D.* *Chief Medical Officer and Deputy Director* *Biomedical Advanced Research and Development Authority* *U.S. Department of Health and Human Services*
	Discussion
2:30 p.m.	**Wrap Up and Adjourn** *Patricia Quinlisk, M.D., M.P.H.*