SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD
April 22–23, 2009
Hyatt Regency, Arlington, VA

VOTING MEMBERS PRESENT

Patricia Quinlisk, M.D., M.P.H., *Chair*
Ruth L. Berkelman, M.D.
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.
Thomas J. MacVittie, Ph.D.
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.

EX OFFICIO MEMBERS PRESENT (or designee)

Diane Berry, Ph.D., Chief Scientist, Director, Threat Characterization and Countermeasures, Office of Health Affairs, U.S. Department of Homeland Security (by phone)
Daniel Fletcher, Ph.D., Office of Science and Technology Policy, Executive Office of the President *(designated by Michelle Colby, D.V.M., M.S.)*
Bruce Gellin, M.D., M.P.H., National Vaccine Program Office, Office of the Secretary, Office of Public Health and Science, U.S. Department of Health and Human Services
Rosemary Hart, Office of Legal Counsel, U.S. Department of Justice
Peter Jutro, Ph.D., National Homeland Security Research Center, U.S. Environmental Protection Agency
Boris D. Lushniak, M.D., M.P.H., Rear Admiral, Assistant Surgeon General, 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.)*
Diane Poster, National Institute of Standards and Technology, U.S. Department of Commerce *(designated by Willie May, Ph.D.)*
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.)*
Daniel Sosin, M.D., M.P.H., Coordinating Office for Terrorism Preparedness and Emergency Response, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services *(designated by Richard E. Besser, M.D.)*

STAFF OF THE NATIONAL BIODEFENSE SCIENCE BOARD
Leigh Sawyer, D.V.M., M.P.H., CAPT, U.S.P.H.S., Executive Director
Erin Fults, Scientific/Technical Writer
Rayshawn Holmes, Junior Analyst
Donald Malinowski, M.S., Program Analyst
Amanda Richardson, Ph.D., M.S., Science Policy Fellow
MacKenzie Robertson, Program Analyst
Carolyn Stevens, Executive Assistant
Brook Stone, M.F.S., LTJG, U.S.P.H.S., 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., Chair

Dr. Quinlisk welcomed the Board members and the public. She said that RADM William C. Vanderwagen, M.D., the first Assistant Secretary for Preparedness and Response (ASPR), has remained engaged with the Board. In March and April, RADM Vanderwagen asked the Board for input on use of pre-pandemic influenza vaccine currently in the U.S. Strategic National Stockpile (SNS), use of telehealth as it applies to public health emergency and disaster medical response**,** and fostering more engagement of manufacturers in product development. The Board's Working Groups are deliberating on all of these issues.

OPENING REMARKS: PAST, PRESENT, AND FUTURE
RADM William C. Vanderwagen, M.D., ASPR, U.S. Department of Health and Human Services (HHS)

RADM Vanderwagen pointed out that although ASPR has responsibility for the whole preparedness enterprise, others coordinate various aspects of the enterprise. For example, the National Institutes of Health (NIH) takes the lead on research; the Food and Drug Administration (FDA) manages licensure and regulatory issues; the private sector contributes to product innovation and development; and the Centers for Disease Control and Prevention (CDC), in concert with communities, coordinates product delivery.

The expertise of the Board will be critical in helping HHS better understand and prioritize some of the challenges ahead. The three issues identified over the past few months by ASPR (pre-pandemic vaccination, telehealth, and product development) will be important for the incoming HHS Secretary, RADM Vanderwagen stressed. He was confident that Secretary nominee Gov. Kathleen Sebelius would bring the right combination of skills to the job.

RADM Vanderwagen reported that there appears to be a move to consolidate the Homeland Security Council and the National Security Council to address both domestic

and international security concerns under one guiding authority. He said interested parties may need to make an extra effort to ensure that biological threats receive appropriate attention from a combined Security Council. He added that HHS is poised to play a more prominent role in the National Security Council and as such will continue to rely upon the Governance Board of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to inform HHS and Interagency decisions on medical countermeasure preparedness.

The challenge that lies ahead, RADM Vanderwagen noted, is to communicate to the public and policymakers that the goals of national health security and preparedness align with those of health care reform.

DISCUSSION

Andrew Pavia, M.D., asked RADM Vanderwagen to describe the top unmet needs of ASPR that he plans to discuss with the new Secretary. RADM Vanderwagen summarized three priorities: increased investment in advanced development; continued support for community and individual preparedness; and communication with international partners to address concerns, share lessons learned, and provide assistance to developing countries.

Dr. Pavia asked whether emerging threats such as drug resistance should be added to the research portfolio of the Biomedical Advanced Research and Development Authority (BARDA). RADM Vanderwagen responded that BARDA's priorities for advanced development include broad-spectrum antibiotics in the short term and consideration of vaccines against *Staphylococcus* and tuberculosis in the long term.

FACTS AND QUESTIONS: HHS' ROLE IN BIODEFENSE AND NATIONAL SECURITY

Tara O'Toole, M.D., M.P.H., C.E.O., Director, Center for Biosecurity, University of Pittsburgh Medical Center

Dr. O'Toole said the recommendations of the National Biosurveillance Advisory Subcommittee were not yet finalized, so she focused her remarks on the need to raise the profile of biodefense concerns in public policy. As director of the independent Center for Biosecurity, Dr. O'Toole has been advocating for more Congressional funding of advanced development of countermeasures. She said that while there is some appreciation of the need for hospital preparedness and biosurveillance, policymakers are confused and under-informed about the nature and urgency of biothreats. Dr. O'Toole said many people have unrealistic expectations of the intelligence community's ability to provide specific, tactical information on a looming biological threat. She added that the intelligence community presents ambiguous information to policymakers. In Congress, she said, the absence of intelligence is perceived as an absence of threat.

Further, Dr. O'Toole complained of a lack of scientific literacy among policymakers and called on Board members to educate their representatives. In addition, policymakers do not appreciate the potential power of rapid advancements in biotechnology.

Many policymakers approach biothreats in the same way they approach nuclear threats and therefore believe that prevention is the most important tactic, said Dr. O'Toole. But prevention is not a reliable method for biosecurity, and it has been difficult to make policymakers understand that locking dangerous pathogens up is not the answer, Dr. O'Toole pointed out. The only recent experience with biothreat was the anthrax event of 2002, she noted, and that event was not sufficient to convey the magnitude of threat the United States may face.

Dr. O'Toole believes HHS lacks the resources to carry out its responsibility to assess and prepare for biological threats. Recent assessments of national security point to lethargy and dysfunction across Federal agencies that focus too much on their own interests and not enough on the needs of the country as a whole, she said. Issues of biosecurity suffer from these shortcomings, said Dr. O'Toole, and are likely to suffer further as attention turns to health care reform. As evidence, Dr. O'Toole pointed to the underfunding of BARDA.

To address these problems, Dr. O'Toole offered three suggestions:

1. Improve the public's and the government's understanding of biothreats and how to counter them.
2. Develop and test detailed plans for responding to biothreats and do so in a transparent manner, sharing the results with Congress.
3. Link budgets more closely to goals and budget in longer cycles to allow for better planning.

DISCUSSION

Patrick J. Scannon, M.D., Ph.D., asked for suggestions on improving understanding among Congress members. Dr. O'Toole recommended more open discussion among career professionals within agencies and Congressional staff. She suggested addressing the hot topic of food safety. Ruth L. Berkelman, M.D., felt that not all of those directly involved in preparedness efforts fully appreciate the nature and urgency of biothreats. Dr. O'Toole agreed and suggested more education for governors. She also said funding mechanisms could be used to enhance emergency preparedness in general while improving the ability to respond to biothreats at the local level.

John D. Grabenstein, R.Ph., Ph.D., noted that some money allocated for the BioShield project was redirected, which is troublesome. Dr. O'Toole said Congress did not appreciate the real costs of research and development, and manufacturers are becoming discouraged with the lack of funding. She pointed to enormous progress in influenza vaccine development that may transform the potential for a global pandemic into a manageable event. That work provides an example of how significant investment in biosecurity research can drive down the costs of medicines and vaccines in this country and others.

Dr. Scannon pointed out that in addition to money, research takes a great deal of time. Dr. O'Toole agreed but said BARDA has worked to decrease the time from research to production.

Dr. Pavia asked for advice on addressing some of the built-in barriers, such as the inability of scientists to talk directly with Congress, limits on multiyear funding, and the inability to fund an overall mission. Dr. O'Toole emphasized the importance of leadership in facilitating communication and cooperation.

PUBLIC COMMENT

Anil Diwan of NanoViricides Inc. said that from a manufacturer's perspective, the concept of advanced development is not clearly defined and is not well supported by NIH or the National Institute for Allergy and Infectious Diseases (NIAID). Dr. O'Toole said clarity around advanced development is improving between BARDA and NIAID. She advocated for a single research portfolio on countermeasures under the purview of HHS. Current Federal investment is not sufficient to provide results, Dr. O'Toole said, and most of the funding goes to basic research.

George Korch of ASPR called for a systems approach to improving the research enterprise. For example, FDA needs more funding for infrastructure to support animal research. He said BARDA is evaluating bottlenecks and barriers across the enterprise. Dr. O'Toole agreed, but said even more is needed. She recommended massive investment in biotechnology research and development that would create jobs, further the science, and result in extremely useful products for the whole world.

Richard Jaffe of the Office of the Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense and Chemical Demilitarization said DoD and HHS maintain separate research portfolios because countermeasures may be developed for different purposes. However, the two agencies have formed a panel to ensure an integrated, national portfolio that identifies gaps, targets investment, and eliminates duplication of effort. He pointed out that if research efforts are consolidated, the whole research enterprise suffers if Congress cuts funding to a given effort. Dr. O'Toole countered that Congress may be less likely to cut funding for a program that has widespread impact, adding that we can no longer afford to focus on protecting department priorities.

HEALTH INFORMATION TECHNOLOGY (HIT)

Kathleen Fyffe, Special Assistant, Office of the National Coordinator for Health Information Technology (ONCHIT), HHS
Judy Sparrow, Senior Policy Analyst, ONCHIT, HHS

Ms. Fyffe announced that David Blumenthal, M.D., was named the National Coordinator for HIT. The goal of ONCHIT is to develop a nationwide HIT infrastructure that ensures privacy and security of patient health information, improves quality of care, reduces the cost of care, improves coordination of care, and enhances information exchange among health care providers. Effective HIT systems will improve public health efforts and facilitate research, said Ms. Fyffe.

Ms. Sparrow explained that ONCHIT is establishing two new Federal advisory committees: the HIT Policy Committee and the HIT Standards Committee. The HIT Standards Committee is scheduled to meet in May. Ms. Sparrow described the proposed membership requirements for both committees. She explained that the Policy Committee will make recommendations to ONCHIT on policies for standards, implementation, specifications, and certification, while the Standards Committee will focus on developing or recognizing interoperable standards.

Ms. Sparrow pointed out that the American Recovery and Reinvestment Act of 2009 (ARRA, also known as the Federal stimulus package) includes about six grant programs for HIT.

DISCUSSION

Dr. Scannon asked whether ONCHIT envisions electronic health records (EHRs) assisting with early identification of biological threats in the United States. Ms. Sparrow pointed out that population health is a high priority for ONCHIT. Dr. Berkelman noted that CDC collects data electronically through the BioSense program.

Albert J. Di Rienzo asked whether ONCHIT would address front-end problems such as data acquisition and interoperability between systems. Ms. Fyffe responded that ONCHIT is heavily involved in such issues, noting that a pilot project to exchange patient records electronically between the Social Security Administration and MedVirginia is helping to assess and overcome real barriers. She pointed out that the National Committee on Vital Health Statistics will hold public hearings April 28–29 on meaningful use of HIT.

Dr. Quinlisk hoped that ONCHIT would keep in mind that some rural areas still need help getting access to technology. Ms. Fyffe said ARRA includes substantial funding to expand broadband access. She said she would look into whether ARRA also includes funding for purchasing technology. Ms. Fyffe noted that the ARRA calls for States to map out their current broadband access, which will provide important information to ONCHIT.

PUBLIC COMMENT

Cheryl Vos of the Federation of American Scientists asked for opinions on recent reports that the American public is not convinced that EHRs will help decrease health care costs. Ms. Fyffe said ONCHIT will try to make the case that HIT is a tool that can help bring costs down. Stephen V. Cantrill, M.D., said he believes HIT will help improve care but is skeptical about its cost-effectiveness. Mr. Di Rienzo pointed out that the cost savings may be indirect, e.g., manifesting in fewer medical errors or improved productivity.

NATIONAL COMMISSION ON CHILDREN AND DISASTERS

Mark K. Shriver, Chair
Christopher Revere, Executive Director

Mr. Shriver explained that the Commission was formed in response to recent events that

underscored how national, state, and local emergency response plans overlook children, which he characterized as "benign neglect.: Children make up 25 percent of the population, he noted, but their needs are usually lumped in with those of vulnerable populations. The Commission was created through bipartisan Congressional action to conduct a comprehensive assessment of children's needs in disaster preparedness, response, and recovery. The Commission will make preliminary recommendations to the President and Congress in October 2009 and finalize its recommendations with broad stakeholder input by October 2010.

Mr. Shriver noted that the Commission has already met with Federal policymakers at several agencies who recognize that few planning efforts have included specific steps to address children's needs. The Commission is also reaching out to state and local stakeholders and will hold a national stakeholders meeting in January 2010.

The Commission has identified two opportunities for collaboration with the Board: 1) development of medical countermeasures for children and 2) mental health and long-term recovery. In terms of countermeasures, Mr. Shriver would like to see an advance effort to support off-label use of drugs for children in an emergency (loosely referred to as pre-emergency use authorization [EUA]). Development of a pre-EUA would enable the HHS Secretary and FDA to respond more quickly to the needs of children during declared public health emergencies. In terms of the development of medical countermeasures for children, currently, PHEMCE prioritizes the needs of the general population first, thus stacking the deck against development of countermeasures for children, because treating children typically is more expensive than treating adults, said Mr. Shriver. The Commission is considering a recommendation that a new advisory body to the HHS Secretary be created, with a specific focus on pediatric countermeasures. Mr. Shriver said he also sees an opportunity for the Commission to work collaboratively with the Federal Emergency Management Agency (FEMA) and HHS in creating a national, long-term recovery framework that would address the mental health needs of children, as well as other health and human services needs.

Mr. Shriver concluded that the Commission should not be alone in representing the needs of children. He sees the role of the Commission as pushing children's needs to the forefront and expressed strong interest in collaborating with the Board in these efforts.

DISCUSSION

James J. James, Brigadier General (Retired), M.D., Dr.P.H., M.H.A., asked whether the Commission had considered proposing changes to the Stafford Act. Mr. Revere said the Commission is gathering input from various community and advocacy organizations to determine what revisions to the legislation would be practical, but he admitted that Congress is often reluctant to revise the Act. The Commission is also evaluating the roles of Federal agencies in community recovery to assess whether other agencies should provide services that the Federal Emergency Management Agency (FEMA) is not well equipped to carry out. Mr. Shriver pointed out that disaster case management is an area in which it is necessary to put systems in place rapidly after a disaster. He noted that in

Texas, families have waited for months for disaster relief services while the State works out a contract with the Federal government, which he called "outrageous."

In terms of medical countermeasures for children, Mr. Revere said the Commission is working with ASPR to raise the profile of children's needs in the context of PHEMCE contracts. The Commission and the American Academy of Pediatrics will ask FDA to consider label changes and developing a pre-EUA that allows for use of certain medical countermeasures in children. Mr. Revere hoped that support from the Board, among others, would help further that cause.

Boris D. Lushniak, M.D., M.P.H., of FDA pointed out that the lack of data in pediatric populations about dosing and adverse events is a key barrier to allowing an EUA that includes children. Eric A. Rose, M.D., asked FDA to give some guidelines on what kind of pediatric data would be acceptable and how it could be gathered. Dr. Lushniak pointed out the difficulty of getting data on safety and efficacy of treating rare or nonexistent diseases in children. Subpopulations, however, may offer an opportunity to gather data, he noted. For example, an emergency department that treats a number of children with pesticide poisoning could provide insight into best practices for addressing a nerve agent, although it's debatable whether such data would be sufficient for an EUA. Mr. Shriver said the upcoming meeting with the FDA is a good first step in recognizing the unique needs of children.

Dr. Pavia suggested that the arrival of a new FDA Commissioner and the new Congress may create an opportunity to change legislation and regulations that would facilitate or incentivize development of products for children. Mr. Revere agreed and said he thinks there is some willingness in Congress to look closely at the issues. The Commission is looking both at regulations to allow use of existing products in the SNS in children and funding to create new products for children. Bruce Gellin, M.D., M.P.H., pointed out that the regulatory system is set up to protect children from the dangers of clinical trials. Dr. Lushniak added that regulators have sought to encourage manufacturers to conduct more research involving children but with little success. He said people on all sides of the issue need to agree on what kinds of clinical trials in children would be acceptable.

Dr. Berkelman noted that failure to address parents' mental health recovery needs can have a strong impact on children. Mr. Shriver agreed and said case management might be a mechanism to address the needs of the whole family. He added that the Commission is pushing to implement best practices in case management before the beginning of the next hurricane season.

Thomas J. MacVittie, Ph.D., pointed out that all research and development in the area of radiological and nuclear threats focuses on young adults, because there are no animal models to support research in pediatric or elderly populations. The issue gets pushed aside, he said, and more money is needed to address it. Mr. Shriver agreed to raise the issue to the Commission. Dr. Grabenstein suggested the Commission develop a priority

list of countermeasures for which pediatric dosing should be addressed or for which the least data exist. Mr. Shriver appreciated the suggestion, as the Commission seeks to produce tangible and specific deliverables in its short lifespan.

NATIONAL HEALTH SECURITY STRATEGY

Brian Kamoie, J.D., M.P.H., Director, Office of Policy, Strategic Planning, and Communications, ASPR, HHS

Mr. Kamoie described the framework of the National Health Security Strategy. Within the context of four overarching goals—prevention, protection, response, and recovery—the strategy will document objectives, capabilities, and alignment with target capabilities of the Department of Homeland Security. Once the strategy is finalized, an implementation plan will be developed that describes specific activities and candidate investments.

Mr. Kamoie said legislation requires that the strategy include performance measures to assess health security efforts. ASPR surveyed HHS and identified 948 existing performance measures related to preparedness. Staff is now categorizing them and determining which should be included in the strategy. Most address countermeasures and medical response. Measures may need to be developed for community involvement and cultural competence. In addition, the performance measures must be based on evidence, and Mr. Kamoie said much work must be done to achieve that goal.

The Homeland Security Council convened an interagency meeting to discuss the draft strategy, and some external advisory groups have also reviewed it. ASPR is in the process of holding stakeholder meetings and incorporating feedback. The final strategy will be submitted to Congress at the end of 2009, and the schedule allows time for the new Secretary to weigh in.

DISCUSSION

Mr. Kamoie explained that stakeholder meetings so far have included State and local health responders and public health officials, people involved in preparedness, and representatives of nonprofit organizations (including advocates for the disabled), among others. Some first responders and planners have emphasized that they expect the Federal government to identify the priorities and leave the implementation to the responders. They are seeking strong, consistent guidance, said Mr. Kamoie. Questions have been raised about how the strategy relates to health care reform efforts, especially in the current economic climate. Mr. Kamoie said he would provide the Board with the dates for future stakeholder meetings; participants can take part by teleconference, if desired.

Dr. Grabenstein felt the strategy should be directive and raised concerns that the current draft, as described, may focus too much on delivery. Mr. Kamoie said the strategy seeks to provide explicit statements of expectations at every level. However, because the strategy is not tied directly to grant funding, it can only encourage, not require, that the expectations be met.

John S. Parker, Major General (Retired), M.D., said a series of documents is needed to

support personal preparedness at the grassroots level. Mr. Kamoie said ASPR will consider how the Board's efforts in that area can be incorporated into the strategy.

Dr. Pavia noted the complexity of public health response mechanisms and asked whether the strategy will seek to simplify the mechanisms or make them more effective. Mr. Kamoie responded that the strategy provides an opportunity for the health security community to become part of a larger national strategy. He said the strategy will be updated every four years, but this first version should try to address the complexity of the system as a whole. There has been discussion about integrating grant programs to better support national goals. Mr. Kamoie said that once Federal priorities are clearly outlined in the strategy, Federal agencies should communicate with each other and with Congress about how grant mechanisms can serve those priorities.

In response to a question about the division of authority, Mr. Kamoie said the strategy promotes teamwork but recognizes the complexity of jurisdictional authority within States.

NBSB RECOMMEDATIONS ON DISASTER MENTAL HEALTH

Daniel Dodgen, Ph.D., Director, Office of At Risk Individuals, Behavioral Health, and Human Services Coordination, ASPR, HHS; Executive Director, Disaster Mental Health Subcommittee

Dr. Dodgen said that in response to the recommendations on disaster mental health, his office is surveying Federal partners to determine what they are doing that speaks to the recommendations, what they could do if they had more funding or authority, and what they could do with minimal additional funding. Responses to date have been thoughtful. He will provide the Board with his office's assessment of the responses when it is completed.

COUNTERMEASURES: UNITED STATES POSTAL SERVICE (USPS) AND EUA UPDATE

Matthew Minson, M.D., Senior Medical Officer for Strategic Initiatives, Office of Policy, Strategic Planning, and Communications, ASPR, HHS

Dr. Minson gave the Board an overview of the USPS-specific home stockpiling EUA signed in October 2008 and the work it has facilitated in allowing the postal carriers to assist public health officials in the state of Minnesota and the Twin Cities by supporting delivery of medical countermeasures (antibiotics) in an Cities Readiness Initiative (CRI)-related emergency. He pointed out that many people had expressed concern about the risks for abuse or misuse inherent in home use of any material. However, he noted, the risk had to be considered in the context of failed delivery of antimicrobial prophylaxis following a large-scale, widely disseminated, aerosolized anthrax attack and the catastrophic morbidity and mortality that could occur if current public health distribution, dispensing, and delivery mechanisms were not adequate to ensure that all of the population of an affected city began prophylaxis in time. Examples of routine misuse and their relation to endorsed first aid kits were recounted. This included acetaminophen in first-aid kits, and recognized the need to balance risks and benefits.

Through modeling, BARDA has determined that the USPS could be used to deliver medical countermeasures to homes quickly, which could reduce the total number of casualties in a CRI-related event. To begin preparing for such an effort, a Determination of Threat was signed by the Secretary of DHS and a public health emergency declaration was signed by the Secretary of HHS in 2008. A request for an EUA was processed and signed by the Commissioner of the FDA in October 2008. Minneapolis and St. Paul had expressed a desire and were determined to be prepared adequately to begin operationalizing their USPS plan. To enable operations to go forward, three conditions for USPS engagement were satisfied: provision of personal protective equipment in accordance with requirements of the Occupational Safety and Health Administration, an agreement by law enforcement to provide physical protection, and provision of antibiotics for the carrier volunteers and their household members in advance of the event. The antibiotics will be provided in the form of MedKits containing doxycycline for anthrax exclusively. USPS carriers have been supportive of the idea once they were assured that their families would have MedKits in their homes (to allay concerns that the carriers but not their families would have access to countermeasures). Dr. Minson said the Minnesota State Patrol and Department of Health anticipate the project will be operational by July 2009. An additional 15 cities have expressed interest to the USPS in exploring and establishing such programs.

Dr. Minson said DHS and HHS are discussing with FDA a potential EUA that would enable first responders to stockpile countermeasures. First responders have indicated that they understand the risks of such stockpiling but support the concept. However, many questions of authority and accountability that would need to be addressed in an EUA have yet to be resolved. Additionally, because the dosing and ingestion instructions related to the dispensing of prophylaxis medication at a point of dispensing (POD) would be different than approved prescription information given for an unrelated anthrax exposure, use of the medication would be considered off-label and would require an EUA. Dr. Minson said a national summit in March on pre-EUA concerns and the SNS resulted in a good discussion about the mechanisms of distribution, dosages, and off-label use. (Pre-EUA involves preparation of data and information that could be used to support an EUA should the need arise.)

DISCUSSION

Dr. Minson clarified that the EUA distribution is currently limited to pharmaceutical countermeasures. He acknowledged that postal carriers could become targets as a result of the project, and local and State law enforcement agencies are working with USPS in cities where the project is moving forward.

Dr. Minson said a number of groups in HHS are looking at policies and technology to provide input on what could be used to support an EUA. He noted that the 2008 Top Officials' (TOPOFF) exercise in national preparedness included how to process an EUA. Dr. Grabenstein suggested that literature reviews on specific topics could be conducted in advance, and Dr. Minson added that assessment of operations could also be undertaken in advance.

Dr. Dretchen asked where HHS stands on pediatric dosing of existing antibiotics against anthrax. Dr. Minson said there is a requirement on providing guidance when translating the antibiotics from pill form into an elixir suspension for children. Specific discussion of suspension would be a stockpile question. It was likely because of considerations about the expiration date of a suspension, variations in dosing, etc., in a multiple-city, CRI-type event some crushing and reconstituting would be anticipated. Dr. Dretchen added that families would need clear instructions on how create a suspension.

Dr. MacVittie asked whether antibiotic treatment for acute radiation syndrome is addressed by the EUA. Dr. Minson noted that the EUA is specifically limited to doxycycline for anthrax delivered to USPS carriers and their household members in advance and in the context of the CRI. However, questions about using an EUA to support stockpiling other countermeasures are important and reasonable for pre-EUA discussion.

Dr. Rose called for a formal process to determine when pre-EUA data are complete and mature. The process would evaluate what criteria should be met, what data should be assembled, what information is needed, and how information should be disseminated so that an EUA could be approved if needed. Dr. Lushniak cautioned that criteria for EUA are very strict and that "pre-EUA" is a fuzzy concept. He said there would be no way to create a formula or criteria for pre-EUA data without legislation or some kind of modeling. As it stands, said Dr. Lushniak, the pre-EUA process is in everybody's hands and new data are incorporated as they become available. He added that pre-EUA data gathering falls on top of the workload already assigned to FDA staff with no additional resources or support.

Dr. Scannon asked how carriers would determine which type of anthrax prophylaxis would be distributed to which people. Dr. Minson clarified that the distributed MedKits would be for volunteer carriers and would have instructions for individuals; in addition, advance screening would identify whether they are candidates for the enclosed medication. Those individuals who should not take the medication provided would be directed to a POD for alternative prophylaxis.

The value of the USPS delivery to residences is that it would decrease the number of people who must leave their homes and travel to PODs to obtain prophylaxis. The USPS volunteer carriers would distribute doxycycline to individual residences. For those individuals that could not take doxycycline, there would still be a need for them to travel to a POD. Public messaging efforts would reinforce the instructions on when to use the kits delivered.

WORKING GROUP UPDATE—PANDEMIC INFLUENZA
Andrew T. Pavia, M.D., Chair, Pandemic Influenza Working Group, NBSB

Dr. Pavia said the group is focusing on the prospect of pre-pandemic vaccination and is convening a task force to gather input from subject matter experts. The task force will address two primary questions, both related to changing the existing Federal policy on pre-pandemic influenza vaccine in the SNS:

1) The current strategy calls for vaccination when a pandemic is deemed imminent. Should the timing of use of pre-pandemic vaccine be revised? If so, what considerations should be addressed and under what conditions should the vaccine be used? Should HHS support and require large clinical trials to inform pre-event use of stockpiled pre-pandemic influenza vaccine before an event occurs? Dr. Pavia noted that the efficacy of the current strategy is unknown.
2) The current strategy would provide pre-pandemic vaccination to 20 million essential workers to ensure functioning of the critical infrastructure. Should the population covered be revised? If so, who should be covered? Should HHS support and require large clinical trials of pre-pandemic influenza vaccination in populations other than healthy adults?

Dr. Pavia reminded the Board that novel adjuvants have potential to expand the capacity of existing pandemic vaccine for H5N1 virus, but there are no data on the use of adjuvants with other strains.

The task force convened by the Working Group will meet June 18–19, 2009; the Working Group is determining the membership, which will involve liaisons from other Federal advisory committees, subject matter experts, State and local public health representatives, and international experts. Initial meetings will be structured to facilitate frank, open discussion among the task force members. When the proceedings are presented to the Board, the public will be invited to give input. Dr. Pavia anticipated that public engagement efforts would be needed to ensure public support for the task force's recommendations.

WORKING GROUP UPDATE—DISASTER MEDICINE WORKING GROUP
Stephen V. Cantrill, M.D., Chair

The Disaster Medicine Working Group will convene in the near future a task force to develop a strategy for use of telehealth in public health emergencies and medical disasters. Dr. Cantrill noted that HHS convened a Working Group under ASPR to inventory telehealth efforts, and he hoped that document would be shared with the NBSB telehealth task force and could be a starting point for a comprehensive strategy.

RADM Vanderwagen identified three specific issues to be addressed by the task force: 1) congruence between EHRs used by the National Disaster Medical System and those of private entities; 2) technology interoperability for emergency support functions; and 3) current applications and innovative response strategies in public health and disaster response, specifically remote consultation, countermeasures, patient tracking, compensation, and confidentiality.

Dr. Cantrill will chair the task force; the membership is currently being determined. The Working Group is gathering background information. The goal is to provide the Board with a document for consideration within nine months of the first meeting of the task force.

WORKING GROUP UPDATE—MARKETS AND SUSTAINABILITY

John D. Grabenstein, R.Ph., Ph.D., Co-Chair, Markets and Sustainability Working Group, NBSB

Dr. Grabenstein said that RADM Vanderwagen requested the Board's input on "identifying and achieving the ways and means needed to develop and sustain fuller engagement by biotechnology and pharmaceutical industries to support our vital national security mission." Dr. Grabenstein reiterated how pharmaceutical products normally reach the commercial market and contrasted that with the pathway for medical countermeasures, in which the Federal government defines the market.

Dr. Grabenstein described various challenges from the industry's perspective and summarized the key points in the development pipeline where the system is stressed. In particular, he noted early contracting requirements, lack of regulatory coordination, funding instability, and the slow pace of discovery and advanced development as areas of concern.

The Working Group has drafted an inventory of issues that constrain or enable industry involvement. Dr. Grabenstein emphasized that the inventory is not ranked and price considerations are not included. Rather, the inventory brings together all of the issues and proposals identified by all the advisory bodies who have addressed the topic.

Dr. Grabenstein outlined the structure of the inventory, noting, for example, that the BARDA Centers for Excellence may offer an example of centralized development and manufacturing, which could mitigate some of the financial risks of vaccine development. He stressed that development of medical countermeasures is critical to national security and therefore merits stable, long-term funding, including adequate funding to support FDA review and consultation, as well as unprecedented cooperation across government and with industry.

If the Board agrees that the inventory is useful, the Working Group will seek public comments and additional input from stakeholders. He asked for suggestions on how to use the inventory to support national security goals.

DISCUSSION

Dr. Grabenstein noted that several former Congressional staffers gave input on potential solutions to include in the inventory. Dr. Parker noted that the inventory lays out the problems in a manner that may help Congress better understand them.

Dr. Scannon emphasized the importance of taking a new approach to development of countermeasures and the need for more and better cooperation among Federal agencies. He suggested that the Working Group look more closely at how well agencies and divisions are working together to use resources efficiently and streamline processes.

Dr. MacVittie pointed to some advantages in the development of countermeasures for radiological and nuclear threats. First, there's a potential commercial market for such products, including an international market. Second, the NIAID created a center at the

University of Maryland to develop countermeasures that incorporates both clinical research and regulatory components. Third, products have potential application in the area of chemical threats. Dr. Grabenstein noted that Federal funding and policy should take into account dual-use opportunities but also assist with development when dual use is not likely. Dr. Berkelman noted that ARRA funding for regional Centers for Excellence for biodefense may offer an opportunity for partnership.

Dr. Pavia recommended identifying some performance measures and asking HHS to evaluate the proposed performance measures within a specified period (e.g., 12 months) of receiving the inventory from the Board. Dr. Rose suggested the Working Group begin prioritizing the items in the inventory and determining costs once the inventory is vetted. He also recommended disseminating the report at an upcoming BARDA meeting of stakeholders.

Board members agreed that the inventory should be posted for public comment.

> ***ACTION ITEM***
> *NBSB staff will determine the appropriate mechanism for gathering public comment on the draft document, "Inventory of Issues Constraining or Enabling Industry Involvement."*

WORKING GROUP UPDATE—PERSONAL PREPAREDNESS

Ruth L. Berkelman, M.D., Co-Chair, Personal Preparedness Working Group

Dr. Berkelman said the Working Group would like to engage HHS in further discussion about the status of its proposed MedKits and home stockpiling recommendations. The group seeks to address personal preparedness from a broad perspective that includes preparedness for all hazards, not just biothreats, and takes into account the needs of vulnerable populations.

Dr. Berkelman said current preparedness efforts focus on first responders and more attention is needed to address community needs. She said it has been difficult to identify a single point of contact within HHS who is responsible for personal preparedness initiatives across the agency. The Working Group believes HHS should place a higher priority on personal preparedness and ensure that it has the authority and resources to address it, acknowledging that DHS plays a significant role.

The Working Group is drafting a letter to the Secretary recommending that personal preparedness be a higher priority for HHS and indicating that the Board is interested in revisiting the issue of home stockpiling.

DISCUSSION

Dr. Scannon pointed out that personal preparedness factors into every aspect of the biodefense effort, including how we think about delivering medical countermeasures. He noted that integration of effort is important. Dr. Parker felt HHS should take the lead in creating high-level guidance on personal preparedness so that the public is not mislead or underserved by commercial interests. Dr. Quinlisk stressed the need to maintain a

safety net in all cases. Dr. Berkelman noted that individual preparedness combined with community-level preparedness and safety nets create a firm foundation for community resiliency.

Dr. Pavia said that philosophical and political concerns inevitably affect any discussion that involves balancing public health issues, government authority, and personal responsibility. However, the Board should try to avoid polarizing the issues around personal preparedness.

Mr. Di Rienzo stated that a comprehensive approach to preparedness includes not just MedKits and medical countermeasures but also education and communication. Dr. James felt that personal preparedness should be the Board's highest priority, and efforts should recognize that getting even half of the population better prepared for an emergency greatly improves the country's safety net.

Dr. Rose asked what kind of scientific research could be conducted to inform efforts. While effectiveness of personal preparedness efforts may be impossible to demonstrate, he noted, research can improve the safety of preparedness measures. Alternative or advanced packaging approaches may be one area to study. For example, drug packaging can include advanced sensors that indicate when the package may have been opened inappropriately. Dr. Quinlisk said the Disaster Mental Health Subcommittee identified the need for more research on individual behavior in response to threats. Dr. Berkelman said the Working Group anticipates hearing from DHS about its research and identifying gaps in the research agenda. Dr. Pavia noted that there is some international experience but it is hard to extrapolate to U.S. settings.

Dr. James said there is substantial qualitative research on preparedness. He added that the U.S. military has evaluated preparation for adversity. Dr. Berkelman agreed that much could be learned from DoD and also from local public health departments where communities have experienced disasters.

PUBLIC COMMENT

Monique Mansoura, Ph.D., of BARDA, said HHS looks at exposure to applications of medical countermeasures as a measure of effectiveness. A key determinant of the effectiveness of MCMs for post-exposure prophylaxis or treatment is the duration of time between exposure to the threat agent and administration of the MCM.

ACTION ITEM

For the next meeting, the Board will consider including a presentation on recent research on personal preparedness.

WRAP-UP

Dr. Quinlisk thanked the Board members, presenters, and staff for their efforts. The next Board meeting is scheduled for September 24–25, 2009.