**SUMMARY REPORT**
**of the**
**NATIONAL BIODEFENSE SCIENCE BOARD**
**June 18, 2008**

**Sheraton National Hotel**
**900 South Orme Street**
**Arlington, VA 22204**

**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. (by phone)
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. (by phone)
Eric A. Rose, M.D.
Patrick J. Scannon, M.D., Ph.D.

**EX OFFICIO MEMBERS PRESENT** (or designee)
Richard E. Besser, M.D., Coordinating Office for Terrorism Preparedness and Emergency Response, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services
Michelle M. Colby, D.V.M., M.S., Office of Science and Technology Policy, Executive Office of the President
Lawrence Deyton, M.D., M.S.P.H., Chief Public Health and Environmental Hazards, U.S. Department of Veterans Affairs (Shawn Fultz, designee**)**
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
Lawrence (Larry) D. Kerr, Ph.D., National Counterproliferation Center, Office of the Director of National Intelligence
Carol D. Linden, Ph.D., 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, Office of the Commissioner, Food and Drug Administration, U.S. Department of Health and Human Services

Willie May, Ph.D., National Institute of Standards and Technology, U.S. Department of Commerce (Diane Poster, designee)
Carter Mecher, M.D., Homeland Security Council (by phone)
Diane Berry, Ph.D., Office of Health Affairs, U.S. Department of Homeland Security
Timothy R. Petty, Deputy Assistant Secretary for Water and Science, U.S. Department of the Interior
John P. Skvorak, Colonel, D.V.M., Ph.D., U.S. Army Medical Research Institute for Infectious Diseases, U.S. Department of Defense

**EX OFFICIO MEMBERS NOT PRESENT**
Joseph Annelli, D.V.M., Animal and Plant Health Inspection Service, U.S. Department of Agriculture
Hugh Auchincloss, M.D., National Institute of Allergy and Infectious Diseases, National Institutes of Health, U.S. Department of Health and Human Services
Maryanna Henkart, Ph.D., Directorate for Biological Sciences, National Science Foundation
Claudia A. McMurray, Ph.D., Environmental and Scientific Affairs, U.S. Department of State
Patricia A. Milligan, R.Ph., C.H.P., U.S. Nuclear Regulatory Commission
Richard S. Williams, M.D., Office of the Chief Health and Medical Officer, National Aeronautics and Space Administration
Patricia R. Worthington, Ph.D., Office of Health and Safety, U.S. Department of Energy

**STAFF OF THE NATIONAL BIODEFENSE SCIENCE BOARD**
Leigh Sawyer, D.V.M., M.P.H., CAPT, U.S.P.H.S., Executive Director
Ian Berke, Ph.D., Science Policy Fellow
Donald Malinowski, M.S., Program Analyst
David Noll, Ph.D., Science Policy Fellow
Carolyn Stevens, Executive Assistant
Brook Stone, M.F.S., LTJG, U.S.P.H.S., Program Analyst

## WELCOME AND INTRODUCTION

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

CAPT Sawyer welcomed the Board members and the public to the meeting and briefly summarized the formation and work of the Board to date. Dr. Quinlisk also welcomed the Board members.

## OPENING REMARKS

**Gerald W. Parker, D.V.M., Ph.D., M.S., Principal Deputy Assistant Secretary for Preparedness and Response, HHS**

Dr. Parker thanked the Board members for contributing their time and expertise and gave particular recognition to the chair for her dedication to the Board. He noted that the United States led talks with Canada, Mexico, the United Kingdom, France, Germany, the European Commission, and the World Health Organization (WHO) in which it was agreed that medical countermeasures are a key component of public health security that warrants international cooperation and commitment. Also, HHS is sponsoring a Global Health Security Initiative Workshop on medical countermeasures on September 23 in Arlington, VA.

Dr. Parker gave an overview of the Board's agenda. He described his role as ensuring that the HHS advisory boards with complementary missions—e.g., the NBSB, the Institute of Medicine's Forum on Medical and Public Health Preparedness for Catastrophic Events, and similar boards of the Department of Defense (DoD) and the Federal Emergency Management Agency (FEMA)—are aware of each others' efforts. He added that the Assistant Secretary for Preparedness and Response will testify at a hearing on preparedness for radiological and nuclear events and HHS is working on a National Health Security Strategy, for which input from the Board is critical.

**BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA)**
**Robin Robinson, Ph.D., Deputy Assistant Secretary and Director, BARDA, ASPR**

The presentation delivered by Dr. Robinson focused on the U.S. Department of Health and Human Services (HHS) Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) for medical countermeasures for chemical, biological, radiological, and nuclear (CBRN), pandemic influenza, and emerging infectious disease threats. BARDA's role in the Enterprise was presented.

Dr. Robinson noted that BARDA is considering how individuals, businesses, and health care organizations could use stockpiling of medical countermeasures to address potential inequities in availability and timing of delivery should the Strategic National Stockpile be inadequate in a public health emergency. Home-stockpiling is one concept that takes advantage of individuals' interest in personal preparedness and desire for self-reliance.

The HHS Centers for Disease Control and Prevention (CDC) germinated the idea of home-stockpiling when it sponsored the concept of personal supplies of antibiotics for anthrax in 2004. In 2006, the CDC conducted a pilot-test sending medical toolkits (also known as MedKits) to consumers in St. Louis. CDC found that 97% of those who received the MedKits followed the instructions for storage and potential use correctly.

Since 2007, BARDA has been considering a MedKit containing antibiotics against anthrax as well as influenza antivirals that would be an adjunct to community mitigation measures. HHS has drafted home-stockpiling guidance for antimicrobials and is drafting guidance on home use of antivirals for pandemic influenza.

Dr. Robinson said several manufacturers are planning label comprehension, compliance, and simulation studies of existing influenza antivirals, as well as conducting market research, with an eye toward licensing an antiviral MedKit for use by the general adult public in mid-2010, with kits specifically for elderly and pediatric populations to follow. Computer modeling suggests that the MedKits may have a limited impact on their own but may ameliorate the effects of national antiviral stockpile depletion. BARDA will begin its own studies later this year and, if appropriate will conduct testing during the annual influenza season.

Similarly, BARDA is looking at an antimicrobial MedKit for anthrax. It has compliance data from the CDC-sponsored, St. Louis pilot project and is planning a palatability study this year (i.e., evaluating the feasibility of crushed pills taken with food for people who cannot swallow pills). BARDA has issued a request for proposals to study label comprehension for doxycycline. At least seven manufacturers of generic antibiotics have expressed interest in conducting market research and manufacturing of these products. The CDC has drafted advisory guidance for physicians and consumers on the use of doxycycline for home-stockpiling. HHS is considering antibiotics against anthrax as a preventive measure for target populations. For example, U.S. Postal Service workers may receive antibiotics under emergency use authorization as early as December 2008. HHS and the U.S. Department of Homeland Security (DHS) are also considering emergency use authorization for first responders and emergency care providers. Home antibiotic MedKits for the general public could be licensed by the end of 2009.

Other changes reflect BARDA's new perspective. Advanced development efforts are at work and being extended to address emerging diseases. The Pandemic and All-Hazards Preparedness Act (PAHPA) modified BioShield for stockpile acquisitions. Market sustainability for medical countermeasures is being evaluated. BARDA is considering how successful innovations can be translated to other products and how it can help industry move forward. It is supporting combined extramural/intramural research efforts, such as mix-and-matching adjuvants and antigens from different companies. The office is also looking at new approaches to boost manufacturing infrastructure, such as using defunct or swing spaces for manufacturing and facilitating partnerships between large manufacturers and small biomedical firms.

Of the challenges BARDA faces, funding is the biggest, Dr. Robinson said—particularly funding advanced development of CBRN and pandemic influenza medical countermeasures. The organization has expanded rapidly and anticipates experiencing growing pains. It is seeking to hire more public health, scientific, and technical experts. Coordination with military operations and end users remains a challenge, as does support for intramural programs.

Dr. Robinson posed the following questions for consideration by the Board:

- Should pre-pandemic influenza vaccination be expanded?
- Should the pandemic influenza medical countermeasures portfolio include pneumococcal and streptococcal vaccines? Should staphylococcal vaccines be

developed?
- What is the right mix of shared responsibility for influenza antivirals for pandemic prophylaxis?
- Should prime-boost vaccination strategies for BARDA medical countermeasures be offered before an event? Should they be commercially marketed?
- Are there better ways to prepare other than stockpiling?
- What are the emerging infectious diseases on the horizon?
- Is home-stockpiling of medical countermeasures a safe and effective preparedness measure?

Dr. Robinson noted that all-hazards preparedness is fed by the integration of efforts to combat seasonal influenza while preparing for both possible pandemic influenza and CBRN events. He added that he hopes BARDA's strategic plan will be finalized in time for the stakeholders workshop sponsored by PHEMCE on September 24–26 in Arlington, VA.

**DISCUSSION**

Peter Jutro, Ph.D., asked whether BARDA's Federal focus was exclusively on HHS and DHS first responders and emergency care providers, or whether Dr. Robinson was only using those agencies as illustrative examples. Dr. Robinson then asked for suggestions from the Board about whom else, including personnel from other Federal agencies, should be included in an emergency use authorization (EUA) order for prophylactic antibiotics.

Ruth Berkelman, M.D., asked about international efforts around pre-pandemic influenza vaccine expansion. Dr. Robinson replied that some manufacturers are in favor of pre-event use of stockpiles and WHO is evaluating the concept. The risks and benefits from a public health standpoint must be assessed. For example, Dr. Robinson noted, what data would be needed to make the decision to administer vaccine before the event?

In response to a question from Patrick Scannon, M.D., Ph.D., about integrating research portfolios across agencies, Dr. Robinson said HHS, DoD, and other departments have established memoranda of understanding in support of the "one portfolio" approach. He said he would have more concrete details for the Board in the fall on efforts to promote synergy in research and development.

Albert Di Rienzo asked whether any BARDA initiatives are looking at sophisticated screening techniques to complement the therapeutic approaches. Dr. Robinson answered that BARDA works with CDC, which has more expertise in screening.

**BIOSURVEILLANCE**
**Kenneth L. Dretchen, Ph.D., NBSB**

Dr. Dretchen explained that the Board Working Group charged with evaluating medical countermeasures and public health biosurveillance established two subgroups, one on

medical countermeasures, one on public health biosurveillance . He added that Homeland Security Presidential Directive 21 (HSPD 21) called for the development of a nationwide robust integrated biosurveillance capability through the creation of a National Biosurveillance Strategy. To prevent a duplication of effort, the subcommittee on public health biosurveillance decided to "stand down." Dr. Daniel Sosin, who is heading the effort to create the National Biosurveillance Strategy, graciously agreed to present an update of his office's activities to date to the NBSB.

### UPDATE ON HOMELAND SECURITY PRESIDENTIAL DIRECTIVE 21 FEDERAL BIOSURVEILLANCE WORKING GROUP ACTIVITIES

**CAPT Daniel M. Sosin, M.D., M.P.H., F.A.C.P., Director, Biosurveillance Coordination Unit, Coordinating Office for Terrorism Preparedness and Emergency Response, CDC, HHS**

CAPT Sosin provided a draft of the National Biosurveillance Strategy to the Board, adding that biosurveillance and situational awareness are complementary to the goals of PAHPA. HSPD 21 called on HHS to create a national system for communication and provided more support for CDC to take a national lead in human health biosurveillance. The effort acknowledges the need not just for better communication of electronic data but also improving human connections and the flow of data among government agencies, clinicians, medical practices, and the private sector.

CAPT Sosin described the charge to the CDC to develop the next-generation biosurveillance system via its Biosurveillance Coordination Unit, which seeks to improve overall situational awareness of public health threats, improve the flow of information, and enhance characterization of urgent public health threats through integration of information. The unit has established a Federal advisory committee with diverse membership to ensure State and local public health entities have their voices heard. The finalized National Biosurveillance Strategy will go to DHS on October 31. By December 31, the unit will produce an operational plan with an implementation strategy for a national biosurveillance system.

CAPT Sosin outlined the mechanisms by which CDC is gathering input from stakeholders to determine what they need from a biosurveillance system. He described the scope and guiding principles of the draft strategy, including identifying the functional requirements and current capabilities of existing systems. Among the challenges CDC faces is a shortage of skilled workers to collect and integrate data.

CDC sees potential for enhancing global biosurveillance capability and connectivity and is working effectively with international organizations to develop standards for sharing information. CAPT Sosin pointed out that in other countries, unstructured data (e.g., media reports) have been a useful source of information, and CDC seeks to explore how such data could be gathered.

CAPT Sosin asked the Board to consider what role it would be willing to play in helping CDC as it takes its next steps toward a national biosurveillance strategy. These steps

include identifying user needs, exploring innovative technologies for surveillance and communication, incorporating information from previous studies, evaluating legal and privacy considerations, engaging health information technology and enterprise architecture efforts, integrating operational plans from key programs, establishing performance measures, and identifying research and development priorities.

**DISCUSSION**

John Parker, M.D., asked how CDC provides incentives to State and local public health departments and others to act on the CDC's goals. CAPT Sosin acknowledged that CDC is open to suggestions from stakeholders but recognizes that financial resources are a significant limiting factor. The draft strategy does not spell out the value proposition for State and local governments of working with CDC on a national biosurveillance system, but future iterations may address that issue. CAPT Sosin said the strategy will evolve and incorporate the priorities of the next administration. At present, CDC's goal is to create an environment that allows the agency to gather input and put forth the principles of standardized, integrated information.

Dr. Berkelman pointed out the lack of uniformity in the quality of information on death certificates and the need for an electronic death registry. CAPT Sosin emphasized the need for collaboration among agencies at all levels to identify key strategies and leverage existing resources toward this goal.

CAPT Sosin added that some States and communities have developed innovative systems and tools to collect information and provide feedback to the clinical community. CDC seeks recommendations from the Board and others on how it should identify and evaluate existing model programs.

Dr. Dretchen said the Board's working group on biosurveillance will work with CDC to build bridges with domestic and international entities to develop compatible frameworks for gathering information.

## OVERVIEW OF ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS (ASTHO) GUIDANCE DOCUMENT

**Susan Cooper, M.S.N., R.N., Commissioner, Tennessee Department of Health**

Ms. Cooper described recent draft guidance published by ASTHO on planning for pandemic influenza in at-risk populations. The development of the guidance was unusual in that it not only included stakeholders and experts but also held meetings to engage the general public in its deliberations, soliciting input from at-risk populations and those who provide services to them. Moreover, the group applied a unique methodology by defining "at risk" as those who would be affected by the consequences associated with a pandemic. CDC sponsored the group's work, marking the first time such national guidance has been developed outside of CDC.

The ASTHO guidance identifies factors that increase a person's risk of being affected by pandemic influenza, recognizing that the factors may be related to social, economic, or health- impacts. Factors include economic disadvantage (e.g., lacking resources to stockpile supplies or stay home from work), absence of a support network (e.g., lack of alternative to daycare for children, travelers), the need for support to accomplish daily activities (e.g., physical or developmental disabilities, difficulty hearing or seeing), and difficulty reading, speaking, or understanding English.

The guidance document identifies five critical areas that public health entities should address in preparing for pandemic influenza among at-risk populations:

- Collaboration with and engagement of at-risk populations
- Identifying at-risk populations
- Communications with and education of at-risk populations
- Provision of services (clinical and non-clinical)
- How to test, exercise, measure, and improve preparedness

Ms. Cooper summarized the content of the guidance document. She recommended that the public health community adopt ASTHO's factors-based approach to defining who is at risk and emphasized the importance of including people at risk in policy development. Who is at risk varies at the State, city, and county level, she noted. While communication is vital, more attention is needed to ensure messages are delivered appropriately and in a timely manner. Public health entities must consider how to craft messages so individuals can clearly distinguish between general health information and an urgent call to action. Among the suggestions provided by the guidance document is identifying community leaders to deliver a message in person, going door-to-door if necessary.

In terms of provision of clinical and non-clinical services, Ms. Cooper said, the guidance document encourages a broad view to identify the barriers that would arise during a pandemic. For example, a person with well-controlled diabetes who loses access to health care providers or pharmacy services may be unable to maintain his health. Moreover, a pandemic will overwhelm the public health system, and providers should consider how they can adapt their roles to meet the changing needs of their community in an emergency.

Ms. Cooper said the guidance includes a number of tools used to evaluate public health system response. The Homeland Security Exercise and Evaluation Program is one mechanism that could be tailored for use with at-risk populations. The guidance also includes proposed timelines for implementing preparedness plans that are based on the severity and phase of the pandemic.

Ms. Cooper listed a number of key recommendations arising from the guidance document, primarily related to collaboration, prioritization, and communication. An interim guidance document will be released publicly in mid-July. Implementation activities involving senior public health officials begin in August and continue through

2009. Ms. Cooper emphasized that the ASTHO document provides guidance to State and local agencies but does not establish requirements that they must meet.

### DISCUSSION

Richard Besser, M.D., of the CDC praised ASTHO's approach and said CDC is considering adapting the guidance document to address all hazards.

### PUBLIC COMMENT

Susan Chu, Executive Director of the ReadyMoms Alliance, applauded ASTHO's efforts, saying State and local public health organizations need such guidance. She asked for more clarification of the concept of identifying those at risk of consequences of pandemic influenza but not at elevated risk of infection. She added that if communities are called on to close schools during a pandemic, many children whose families have difficulty finding alternative child care would be at risk. Ms. Chu wondered how agencies could avoid exacerbating that risk yet move swiftly to act in the best interest of the community. She posed the question of which populations public health efforts should seek to care for first: the most vulnerable or the largest and easiest to address? She believes that public health efforts build resilience within communities by first empowering the largest populations at least risk to care for themselves.

Ms. Chu emphasized that closing schools during a pandemic will have a major impact on parents and kids, yet parents have been left out of the policy making process. She encouraged public health proponents to seek input from stakeholders outside the usual organizations.

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

Dr. Pavia said the working group identified two primary tasks:

- Evaluate the process and coordination of scientific and funding decisions across HHS to ensure that there is thoughtful development of a coordinated strategy
- Assess the capabilities of HHS advisory bodies to review and provide rapid advice on emerging data and issues such as vaccine efficacy, adverse events related to antivirals, vaccines, or real-time epidemiological data; develop recommendations for improved rapid evaluation and response

Agencies across HHS were asked to describe their strategic planning processes; Dr. Pavia's slides summarized the responses from the National Institute of Allergy and Infectious Diseases (NIAID), the Food and Drug Administration (FDA), and CDC.

In assessing the roles of various HHS advisory bodies, the working group determined that only the Advisory Committee on Immunization Practices has experience providing rapid evaluation and response. Dr. Pavia listed advisory committees that provide both specific

and general expert advice to HHS on matters of science and policy. The working group raised considerations about the timing of advisory body recommendations—that is, expert scientific consensus may be needed in weeks, not the months or even years it can take for a committee's recommendations to make their way through existing processes. With a number of bodies focusing on a wide range of topics, expertise may be spread out across various committees and an individual committee may have gaps in expertise. Without some overarching coordination among bodies, advice may not be effective and timely if it is too narrowly focused or reaches too limited an audience .

Dr. Pavia described instances in which advisory bodies played a role during a public health crisis and one situation in which a more responsive advisory process would have been beneficial. He called on the Board to consider whether an advisory board is needed specifically to evaluate emerging data and provide recommendations during a public health crisis.

**ACTION ITEM**

At a future meeting, the Board will consider the need for an advisory group that can provide expert advice to the Secretary of HHS during an emergency.

## PERSONAL PREPAREDNESS

**Robin Robinson, Ph.D., Deputy Assistant Secretary and Director, BARDA, ASPR**

Dr. Robinson explained that some public health emergencies (e.g., wide-area release of aerosolized *Bacillus anthracis*) would require timely mass chemoprophylaxis to prevent catastrophic loss of life, but few, if any, municipalities are prepared for such events. HHS recognizes that some citizens may wish to reduce their dependency on public agencies by stockpiling prescription drugs at home. Board members were provided two draft letters—one intended for health care providers and the other for consumers—that provide guidance on home storage of antimicrobial drugs (specifically doxycycline). Dr. Robinson noted that doxycycline (among other antibiotics) is approved for post-exposure prophylaxis against anthrax but prescription in anticipation of a bioterrorism incident could be considered an off-label use of the drug.

Dr. Robinson raised several questions regarding home-stockpiling of antimicrobials:

- Is this approach a needed threat preparedness measure?
- Is home-stockpiling a viable component of personal preparedness?
- Does this approach increase the possibility of antibiotic resistance emergence?
- How fast can the Strategic National Stockpile deliver antimicrobials?
- Would the general public use antimicrobials they had stockpiled? What would be the overall impact of such use?

As described earlier, HHS is in the early phases of developing an antibiotic MedKit that could be available for the general population, and the CDC has drafted advisory letters to health care providers and consumers on home-stockpiling.

In closing, Dr. Robinson described a potential scenario in which an anthrax attack affected a city of 3 million people. Under existing capabilities, it was estimated that all available drug would be dispensed within 4-6 days of the attack and 660,000 people would have died within 6 days of the attack if surge response with antibiotic dispensing does not occur promptly.

**DISCUSSION**

Richard Besser, M.D., of the CDC noted that the issues surrounding dispensing and distributing antibiotics in the event of a large-scale anthrax attack are formidable. He emphasized that the CDC does not support the concept of home-stockpiling right now outside of a licensed MedKit. However, the CDC drafted guidance to health care providers and consumers to ensure that they have good information on the safe storage and use of antibiotics if they are being prescribed for home stockpiling.

Dr. Besser pointed out that the CDC does support personal preparedness. He noted that in contrast to a typical prescription of pills in a bottle, the CDC antibiotic MedKits contain doxycycline and ciprofloxacin in a special envelope printed with large warnings about their use; the envelopes include patient information on when to use the drugs, and that information is based on CDC data about how people use and store medicines in their homes. The CDC's pilot project found that 97% of those who had a MedKit were able to locate it 4–6 months after they received it in the mail. They also felt more secure having this in their home and were willing to pay for the kits.

However, we know from extensive research that antibiotics, drugs designed to treat specific bacterial infections, are frequently misused by the public and taken for the treatment of viral infections. Misuse of drugs by the public is one of the primary factors promoting the development of antibiotic resistance. Given the paucity of new antibiotics being developed, we must treat antibiotics as a scarce, limited national resource. A home-stockpiling program should maximize the likelihood that the drugs would be stored correctly and would be available during an emergency.

Dr. Besser urged the Board and BARDA to consider several issues before moving forward. It is important to consider home-stockpiling not just through the biodefense lens, but also through the broader lens of public health. In the broader public health context, would encouraging individuals to request antibiotics from their health care providers affect the utility of these drugs for other conditions? Antibiotic resistance is a real concern. Doxycycline has been found to encourage resistance to other agents. CDC has begun to see a rise in resistance to doxycycline since its introduction as a drug used to treat methicillin-resistant *Staphylococcus aureus* (MRSA). In 2001, no strains of group A streptococcus in the Active Bacterial Corps Surveillance system were resistant to tetracycline (a drug related to doxycycline). In 2006, 15% of strains were resistant to tetracycline. To ensure that doxycycline remains effective against MRSA we must ensure that it is not misused. The home-stockpiling proposal must be considered in light of other strategies to combat antibiotic resistance, Dr. Besser said. He was an active

participant in the development of the Federal Plan to Combat Antimicrobial Resistance. The Federal government needs to ensure that as we move forward, our actions are consistent with that plan.

Dr. Besser continued that the medical and public health communities are in the middle of a complicated debate, weighing the competing benefits of science and public policy. Without buy-in from both communities, the public may not warm to the idea of home-stockpiling, and the approach would not be effective without broad uptake.

Dr. Besser added that a home-stockpiling policy would have to address safety issues, such as the possibility of overdose, allergic reaction, use by children, side effects, effects of outdated products, and proper disposal of expired drugs. It would have to address accessibility for at-risk and vulnerable populations, for example, those who cannot afford to pay for the drugs. It would have to take into account regulatory requirements of the Food and Drug Administration (FDA), specifically, whether home-stockpiling is equivalent to over-the-counter use of a prescription drug. The policy would also have to address how to recover, replace, and dispose of expired drug supplies in people's homes.

Boris Lushniak, M.D., M.P.H., of the FDA also emphasized the difference between the MedKit and an individual's prescription bottle. The FDA and HHS have identified a path forward for a potential MedKit that, if approved, by the FDA, could be marketed for use in the home setting. This path requires that the MedKit undergo the FDA's drug approval process. Home-stockpiling of individually prescribed medications, however, is a very different issue and clearly raises all the concerns about safety and inappropriate use discussed by Dr. Besser.

Dr. Lushniak noted that there are concerns about the instructions and labeling given to patients in the draft guidance. If the instructions recommend the drug for a new indication, or different indication than that for which it was approved, there could be concerns regarding mislabeling or off-label usage. While health care providers may prescribe drugs off-label, significant liability issues may arise if the Federal government is seen as encouraging off-label use. Even providing home preparation instructions for pediatric populations or for people who cannot swallow pills could be considered re-labeling and therefore problematic under FDA regulations.

Finally, Dr. Lushniak said the FDA has concerns about the wording of the draft guidance. It should be precise and state clearly that individuals may wish to consult with their health care providers; however, it should avoid suggesting that individuals do so or raising expectations that their health care providers will write them a prescription if they ask for one.

Kenneth Dretchen, Ph.D., expressed concern about the possible misuse of prescription drugs stored at home. He pointed to incidents during the first Gulf War in the early 1990s in which Israelis who had home medicine kits, including autoinjectors, as countermeasures for chemical attacks received false alarms; as a result, several children suffered from atropine poisoning. He also said a recent label comprehension study

indicated that two thirds of those surveyed did not correctly interpret the instructions "take two tablets twice a day." If home-stockpiling efforts were to move forward, Dr. Dretchen said, the labeling must be clear and simple.

James James, M.D., Dr.PH., M.H.A., emphasized the importance of relying on science to make recommendations. He noted that there was no evidence that ciprofloxacin is superior to doxycycline in treating anthrax, yet ciprofloxacin was the drug of choice during anthrax scares in the United States. Dr. James said a large-scale anthrax attack occurred in Russia in 1979, and evidence from that incident should be reviewed carefully. He also said the efficacy of vaccination should be evaluated.

Albert Di Rienzo wondered how the "signal" to use the drug would be communicated. He also called for evaluation of new technologies that could help identify when drug vials are opened unnecessarily.

John Grabenstein, R.Ph., Ph.D., said that if home-stockpiling is intended to address the barriers to timely distribution, perhaps a wider network of small-scale distribution centers should be considered instead.

Andrew Pavia, M.D., noted that the draft guidance would be construed by the public as a recommendation for home-stockpiling, no matter how neutral the message is intended to be. He pointed out that people who have antibiotics in their homes tend to use them frequently and at their own discretion. Dr. Pavia raised concerns that confusing and premature advice on this issue could have lasting negative effects on the public's trust in the public health system, eroding the ability to communicate successfully in the future.

Ruth Berkelman, M.D., added that prescription drugs are often misused and noted that instruction sheets are likely to be separated from a bottle of pills without special packaging. She noted the difference between a permissive strategy (e.g., allowing but not advocating health care providers to prescribe prescription drugs for home-stockpiling) and a pro-active strategy, and queried whether government release of instruction sheets would be perceived as a pro-active strategy. She felt the MedKit approach should be taken into consideration along with other strategies.

John Parker, M.D., stated that he considered individual preparedness a major part of national preparedness and reiterated others' concerns about the safety of expired drugs and the costs of the drugs. He added that providing antibiotics could create a false sense of security as well as an opportunity to engineer an anthrax bacterium that is less sensitive to the drug. Dr. Parker said the military has experience with "just-in-time" distribution that should be considered. He suggested considering alternative distribution tactics, such as using pharmacies as distribution points and extending product life expectancy. Dr. Parker also strongly suggested that the documents intended to go to physicians and individuals should conform to and be tested using the CDC "Red Book" guidance on risk communication. He also pointed out that there are issues related to differences between the Federal and State jurisdictions concerning prescribing regulations that need to be considered.

Jon Krohmer, M.D., of DHS (sitting in for Diane Berry, Ph.D.) said his agency is looking at ways to address distribution concerns. He supports the concept of personal preparedness, noting that people routinely seek out preventive measures when traveling overseas, for example. Dr. Krohmer said home-stockpiling could be a component of individual readiness.

Patrick Scannon, M.D., Ph.D., observed that the Board should deliberate carefully on this matter, weighing the issues of safety and security.

The public was invited to comment, and Julie Hantman of the Infectious Diseases Society of America agreed that any guidance from HHS would be construed as a recommendation for home-stockpiling. She asked for clarification about the threat of anthrax to support the notion that the benefits of home-stockpiling outweigh the risks. She echoed concerns about eroding the public's trust in government and the public health system, alluding to previous government recommendations regarding smallpox vaccination and the use of duct tape to protect from a chemical attack. She asked for more public discussion and a coherent public health policy that takes into account post-exposure treatment, vaccination, and other approaches.

Gerald Parker, D.V.M., Ph.D., M.S., Principal Deputy Assistant Secretary for Preparedness and Response, pointed out that the draft guidance prepared by the CDC was provided to the Board for their information and should not be construed as recommendations, although he conceded that such misinterpretation is a risk. He said that the draft guidance is an effort to provide guidelines to those already requesting and prescribing antibiotics for home-stockpiling; under those circumstances, he asked, "Doesn't the CDC have a responsibility to provide guidance for safe and responsible use?" Neither the timeline for clearance of the documents nor the plan for disseminating them have been determined. Dr. Robinson added that the agency would appreciate input from the Board on the draft guidance but plans to move forward with the documents and its other studies unless the Board has strenuous objections.

Stephen Cantrill, M.D., said the draft guidance is written at too high a reading level for the general public, that it contains inaccuracies, and that it should be translated into other languages. Eric Rose, M.D., added that the draft guidance is poorly written and raises concerns about conflicts with FDA regulations. Dr. John Parker suggested that the CDC follow its own Red Book guidance on risk communication and appropriate development and testing of guidance.

Dr. Grabenstein categorized the Board's comments into several areas that should be addressed before any program promoting personal preparedness is undertaken: The draft guidance is not ready as presented and needs revision to address misuse, concerns about antibiotic resistance, product expiration dates, and readability. Graphics should be added to help those of low literacy. The consumer document might be reformatted to provide a one-page summary, followed by additional detail. Any public communication should emphasize the responsibility of health care providers to minimize misuse through

effective patient counseling and that the antibiotics should only be used when explicit instructions from their own local public health officials are provided. Further, the home stock-piling concept should be subject to research on label comprehension, compliance to instructions, and palatability, just as the MedKits are.

Patricia Quinlisk, M.D., M.P.H., added that health care providers need to be informed about the potential medicolegal issues that could arise with the off-label use of individually prescribed antibiotics for home-stockpiling.

#### RECOMMENDATION

The Board recommends that a working group be formed to address personal preparedness measures.

#### ACTION ITEM

Because all the voting members of the Board indicated a desire to take part in a personal preparedness working group, the staff will convene a conference call of the Board on personal preparedness, with further logistics of working group membership to be determined.

#### RECOMMENDATION

The Board recommends that the Secretary take the comments made at this meeting by Board members and others into consideration before proceeding with the personal preparedness measures described or the CDC draft guidance.

#### ACTION ITEM

The NBSB staff will send the Secretary the relevant discussion points on personal preparedness from this meeting, excerpted from the meeting summary.

## MEDICAL RESPONSE/PREPAREDNESS FOR RADIOLOGICAL/NUCLEAR EVENT
**Thomas MacVittie, Ph.D., NBSB**

Dr. MacVittie introduced two HHS representatives who had been invited to give overviews to the Board on their respective offices' efforts around radiological and nuclear response.

### PREPAREDNESS AND PLANNING FOR RADIOLOGICAL AND NUCLEAR EVENTS
**C. Norman Coleman, M.D., Senior Medical Advisor, Office of Preparedness and Emergency Operations, and Associate Director, Radiation Research Program, HHS**

Dr. Coleman described the exercises and models used in preparing a response to a radiological or nuclear event. He pointed out that lessons learned in these efforts—for

example, preparing for an improvised nuclear device—are broadly applicable to other hazards. He gave examples of how modeling could be used to give insights on the potential scope of an event and help planners anticipate immediate, near-term, and long-term needs.

Dr. Coleman said efforts are underway to identify and map every potential medical care center for treatment of radiological exposure. Because of limited resources, should there be a large event, the Federal government relies on pre-organizing as much as possible, designating who would be accountable for various aspects of response, said Dr. Coleman. For example, the proposed Virtual Strategic National Stockpile would require local organization with Federal coordination. Dr. Coleman said his office's playbooks are very useful in identifying all the steps in a scenario, and planners can use them to create their own algorithms for response. Dr. Coleman also indicated that investment is needed to establish a laboratory network for hematology, cytogenetic biodosimetry, and radionuclide bioassay.

Clinicians need easy access to specific, relevant information during an event. Dr. Coleman recommended the National Library of Medicine's website on radiation event medical management (http://www.remm.nlm.gov/) as a good source for background information that provides education and can also guide management decisions. He encouraged response planners to take a systems approach and work with others on scenarios so that in case of a real event, there are mechanisms in place to facilitate a timely, effective response.

### CURRENT STRATEGIES AND FUTURE CHALLENGES TO THE DEVELOPMENT OF MEDICAL COUNTERMEASURES FOR RADIOLOGICAL AND NUCLEAR EVENTS

**Richard J. Hatchett, M.D., Associate Director for Radiation Countermeasures Research and Emergency Preparedness, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health, HHS**

HHS's strategic approach to the development of medical countermeasures for radiological and nuclear events heavily emphasizes applied research and product development. In terms of product development, Dr. Hatchett said, NIAID is configured to provide support services and testing facilities as well as assistance in navigating the regulatory process (although not all services that NIAID is capable of providing are currently being utilized).

The primary area of focus is the development of medical countermeasures for acute radiation syndrome. The greatest challenge, Dr. Hatchett pointed out, is the high cost of developing effective medical countermeasures. Better diagnostic tools are also needed. The Federal government has allotted some resources to these efforts, but biotechnology and pharmaceutical companies are facing uncertain economic times, fragmented markets, and declining research and development productivity, which have created strong disincentives for primary investments in biodefense countermeasures. Federal government investments to date have not been sufficient to overcome the lack of true markets for such products, Dr. Hatchett said.

Dr. Hatchett described techniques to push product development forward that take account of such realities. For example, the NIAID Radiation Countermeasures Program has emphasized developing products that have dual utility. The NIAID program has also attempted to reduce barriers to entering the market by seeking out promising companies, providing expertise in radiobiology and animal models, conducting efficacy studies performed in compliance with standards of good laboratory practice (GLP) in government facilities and at government expense, and lending support during the regulatory process. The rationale for providing such services and expertise is to reduce the investment of time, energy, and resources required on the part of private-sector partners in the hope of increasing corporate interest in countermeasures development.

Dr. Hatchett stated that many companies have articulated that they find government contracts cumbersome and unattractive from a business perspective. Consequently, Federal agencies may be able to facilitate partnerships by eliminating some of the administrative burden—for example, by limiting the use of contracts and cooperative research and development agreements (CRADAs), relying on less complicated agreements, and generally allowing companies greater flexibility than contract mechanisms typically afford. The Federal government can address the regulatory challenge companies face by developing and providing vetted animal models, conducting efficacy trials in animals at government expense, and sharing government expertise on FDA requirements and processes.

Dr. Hatchett concluded that while radiological and nuclear threats differ from other weapons of mass disaster (WMD) threats in certain ways, the challenge of developing medical countermeasures is identical in that development costs are high, markets for such products are limited, lifecycle costs are substantial, and the regulatory pathway is not well defined. He suggested that many of the solutions the NIAID Radiation Countermeasures Program has evolved to address these challenges may be transferable to efforts to develop biological and chemical countermeasures as well.

## WORKING GROUP UPDATE—U.S. GOVERNMENT MEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT PROCESSES FOR CBRN AGENTS

**Patrick J. Scannon, M.D., Ph.D., Chair, Medical Countermeasure Research and Development Processes Working Group, NBSB**

Dr. Scannon said the working group is seeking areas of overlap between HHS and DoD biodefense efforts that would affect policy planning and the selection and development of a research portfolio. He said integration between the two departments is evident at various levels and in different ways. For example, HHS and DoD jointly acquired smallpox and anthrax vaccine stockpiles. The two have coordinated some product development lines so that each can focus on a specific area. The working group is encouraged by the progress toward developing medical countermeasures for chemical threats.

Dr. Scannon said he is particularly pleased with the high-level integration occurring as a result of the Enterprise Governance Board, a policy-driven interagency effort, and the work toward a national biodefense medical countermeasures portfolio. The Enterprise Governance Board includes HHS, DoD, the Department of Veterans Affairs (VA) and DHS. It will ensure that policies are coordinated and executed at the program level. The parallel structure of research efforts and workflow of HHS and DoD appears to work well for medical countermeasures, as both agencies recognize their common and unique requirements.

The working group believes the development of medical countermeasures requires unprecedented cooperation and integration across the Federal government that, in turn, requires increased and sustained funding, Dr. Scannon said. The working group plans to continue its assessment efforts to better understand the process of advanced development and how DoD and HHS could further integrate their efforts.

**WORKING GROUP UPDATE—MARKETS AND SUSTAINABILITY**
**John Parker, M.D., Chair, Markets and Sustainability Working Group, NBSB**

Dr. Parker said the Federal government's process for medical countermeasures development requires more steps than the private-sector approach. The Federal government first looks in-depth at needs and requirements. Different agencies have different areas of focus. But both the government and private sector should be working throughout with the FDA to anticipate and address regulatory issues.

The working group is looking at barriers to product development identified by industry representatives. For companies that are not regularly involved in government contracting, the process is slow, unwieldy, expensive, and opaque. Most of the problems lie in getting started: requests for proposals are difficult to interpret, contract language lacks clarity, the review process is mysterious, and the duration of the start-up process is difficult for small companies to sustain (especially if they must have facilities and personnel in place before they receive any government funding).

The private sector perceives a lack of coordination in development activities and regulatory approaches, Dr. Parker said. For example, companies are concerned about inconsistencies in how the so-called animal efficacy rule applies and different definitions of "emergency use" by different government agencies. In fact, companies are seeking clear, consistent guidance from FDA on applying the animal rule (i.e., the use of animal studies to demonstrate product efficacy when human testing is not acceptable) to studies of CBRN countermeasures. Dr. Parker said that companies that develop relationships with FDA early in their process fare better than those that do not.

Dr. Parker said another significant factor that requires attention is industry reliance on the Federal government to supply key components of licensure submissions, such as disease studies and toxicology reports. This dependency can lead to a lack of accountability. In addition, demand currently outstrips the Federal government's capabilities.

The working group believes more Federal funding is needed to support advanced development of countermeasures and that funding must be long-term and sustained with multi-year appropriations. Advanced development would also benefit from more flexibility in contracting as well as a commitment on the part of the Federal government to product acquisition and lifecycle management. Industry cooperation is required, Dr. Parker said, and incentives need to be built in to the process.

Dr. Rose added that the biodefense industry is nascent, and only one company has made a profit as a publicly traded company. The private sector may be reluctant to invest in product development because it senses that the government has focused on development without committing to acquisition. Dr. Lushniak noted that the private sector shares responsibility for developing new animal models and validating existing ones, which will help FDA better implement the animal rule.

**WORKING GROUP UPDATE—DISASTER MEDICINE**
**James James, M.D., Dr.P.H., M.H.A , Co-Chair, Disaster Medicine Working Group, NBSB**
**Stephen Cantrill, M.D., Co-Chair, Disaster Medicine Working Group, NBSB**

This working group focuses on two areas: 1) education and training and 2) mass casualty care. Dr. James, the lead for education and training, said the working group evaluated the charter of a new HHS advisory body, the Federal Education and Training Interagency Group (FETIG), which will coordinate medicine and public health disaster preparedness and response education and training. The working group supports the FETIG charter, Dr. James said, but believes it should focus more narrowly on disaster medicine, clearly delineate the role of non-Federal stakeholders in developing a disaster medicine core curriculum, and clarify the roles and responsibilities of a proposed national joint program in disaster medicine. These recommendations were forwarded to HHS Secretary Michael Leavitt for consideration. Dr. Quinlisk read out loud the letter she received from Secretary Leavitt that morning thanking the Board for its recommendations and wishing the Board well at its meeting.

The working group is also preparing a white paper that will define disaster medicine and how to create a competency-based curriculum for education. The first draft will be circulated among Board members for comment; the second draft will be widely disseminated for input from the public and private sector. Dr. James hoped the third draft would be ready for final Board review at the November NBSB meeting.

**ACTION ITEM**

After the draft document on disaster medicine is disseminated to Board members, the Disaster Medicine Working Group will hold a conference call to gather input from the Board on the document.

Dr. Cantrill, the lead for mass casualty care, said a meeting is scheduled for June 19 to further review the report prepared by a contractor evaluating the National Disaster

Medical System. The working group hopes to present recommendations on the National Disaster Medical System for the Board's consideration at the November NBSB meeting.

**INTRODUCTION—SUBCOMMITTEE ON DISASTER MENTAL HEALTH**
**Patricia Quinlisk, M.D., M.P.H., Chair, Subcommittee on Disaster Mental Health; Chair, NBSB**

Dr. Quinlisk said that HSPD 21 acknowledged the impact of the "worried well" on the public health system during a crisis and recommended evaluating the mental health response to disaster. To do so, the Board is establishing the Disaster Mental Health Subcommittee, which will develop mechanisms for protecting, preserving, and restoring individual and community mental health in catastrophic settings. It will also focus on mental health education, messaging, and communication. Dr. Quinlisk will chair the Board, and Daniel Dodgen, Ph.D., Director of the Office of At-Risk individuals, Behavioral Health and Human Services Coordination within ASPR, will serve as Executive Director.

The subcommittee includes three other NBSB voting members and five NBSB *ex officio* agency representatives plus 14 invited experts. The inaugural meeting of the subcommittee is June 19–20.

**BIOSECURITY CONCERNS RELATED TO THE SYNTHESIS OF SELECT AGENTS—AN UPDATE ON THE ACTIVITIES OF THE NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY (NSABB)**
**Amy Patterson, M.D., Executive Director, NSABB; Director, Office of Biotechnology Activities, Office of Science Policy, Office of the Director, National Institutes of Health, HHS**

Dr. Patterson defined the "dual use" issue: despite the many benefits of advanced life sciences research, it can be used in ways that violate national security. She summarized the calls to address dual use with new biosecurity measures that recognize the potential for misuse and the need to strike a balance in oversight so that we don't jeopardize scientific inquiry. NSABB was established to recommend a strategy for efficient, effective oversight of dual-use life sciences research. Dr. Patterson outlined the membership, charge, and methodology of NSABB. She described the primary concerns identified by the group and the document it presented to the Federal government in June 2007, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (www.biosecurityboard.gov).

Ultimately, Dr. Patterson said, the framework stresses the importance of cultivating a culture of awareness and responsibility throughout the research lifecycle, ensuring that dual use is considered upfront at the same time and with the same weight as issues of stewardship and integrity, and not just at the time of publication of results. Because research is dynamic, re-evaluation of research for potential dual use may be necessary. On July 15, 2008, the U.S. Government will hold a workshop consultation to solicit input

from the scientific community and the public on the oversight framework proposed by the NSABB. The U.S. Government is also engaged in international discussions regarding dual-use life sciences, including roundtables co-sponsored by WHO.

The issue of biosecurity of synthetic genomics has arisen with the rapid advances in technology and the availability of DNA sequence data. NSABB was charged with assessing the potential concerns about misuse and the possibility that synthetic genomes could be misused. The NSABB document *Addressing Biosecurity Concerns Related to the Synthesis of Select Agents*, published in December 2006, found that 1) infectious viruses and select agents can be created with synthetic genomes, and 2) the technology is available but the processes require significant technical skill and scientific knowledge. Synthetic nucleic acids are easily acquired, Dr. Patterson said, and in a rapidly expanding, predominately private industry, there are no best practices for recordkeeping or sequence tracking. A number of rules and guidelines govern acquisition and use of select agents, but, overall, the applicability of these regulations in the realm of synthetic genomics is unclear.

NSABB also found variation in the interpretation and application of laws and regulations governing select agents. Current screening tools are not optimal, and more databases and software are needed, Dr. Patterson said. Current approaches to assessing biosafety are based on knowledge of the parent agent; improving both safety and security will require better understanding of the function and behavior of an agent on the basis of it genomic sequence.

The NSABB report *Addressing Biosecurity Concerns Related to the Synthesis of Select Agents* offers a number of recommendations, including increasing awareness among investigators and service providers about the agents they work with, developing additional guidance and tools to screen orders, engaging in international dialogue about oversight and scrutiny, and updating biosafety guidelines to address emerging synthetic biologics and genomics.

The U.S. Government's response to NSABB's recommendations was favorable and, as a consequence, a number of related policy initiatives are underway across Federal agencies. NSABB is currently finalizing its report addressing biosecurity concerns raised by synthetic biology but concluded from workshops and other input that the field is nascent and the framework proposed for dual-use research is adequate to encompass synthetic biology at this time.

**DISCUSSION**

Dr. Dretchen pointed out that some smaller universities and research centers contract out the functions of institutional biosafety committees and institutional review boards. Therefore, personnel at those universities and centers don't necessarily see the guidance and information that NSABB provides.

A voting member stressed the importance of not discouraging research when no decisions have been made about a national policy or implementation of the proposed framework for dual use. He did not want to alarm investigators without providing them with tools to manage the potential concerns. Dr. John Parker suggested that attempts to control import and exports of select agents should avoid using lists of agents and should seek to establish a single point of entry.

## FUTURE ACTIVITIES OF THE BOARD
**Patricia Quinlisk, M.D., M.P.H., Chair, NBSB**

CAPT Sawyer reminded the Board that it has agreed to host a session during the Stakeholders Workshop on September 25.

### ACTION ITEM

Staff will convene a conference call of the Board to determine what its session at the September Stakeholders Workshop should cover. The initial steps of the Disaster Mental Health Subcommittee may be considered as a topic for the presentation.

## WRAP-UP
**Patricia Quinlisk, M.D., M.P.H., Chair, NBSB**

Dr. Quinlisk thanked the ASPR staff for bringing issues such as personal preparedness to the Board for consideration. CAPT Sawyer said HHS is grateful for the Board's input. Dr. Quinlisk thanked the Board members for their time and input and the NBSB staff for their work in facilitating the meeting. She adjourned the meeting at 5 p.m. Wednesday, June 18, 2008.

## SUMMARY OF RECOMMENDATIONS AND ACTIONS
### RECOMMENDATIONS
**Personal Preparedness**

The Board recommends that a working group be formed to address personal preparedness measures.

The Board recommends that the Secretary take the comments made at this meeting by Board members and others into consideration before proceeding with the personal preparedness measures described or the CDC draft guidance.

### ACTION ITEMS
**Working Group Update—Pandemic Influenza**

At a future meeting, the Board will consider the need for an advisory group that can provide expert advice to the Secretary of HHS during an emergency.

**Personal Preparedness**

Because all the voting members of the Board indicated a desire to take part in a personal preparedness working group, the staff will convene a conference call of the Board on personal preparedness, with further logistics of working group membership to be determined.

The NBSB staff will send the Secretary the relevant discussion points on personal preparedness from this meeting, excerpted from the meeting summary.

**Working Group Update—Disaster Medicine**

After the draft document on disaster medicine is disseminated to Board members, the Disaster Medicine Working Group will hold a conference call to gather input from the Board on the document.

**Future Activities of the Board**

NBSB staff will convene a conference call of the Board to determine what its session at the September Stakeholders Workshop should cover. The initial steps of the Disaster Mental Health Subcommittee may be considered as a topic for the presentation.