MEETING MINUTES
of the
NATIONAL BIODEFENSE SCIENCE BOARD
A FEDERAL ADVISORY COMMITTEE FOR THE
OFFICE OF THE SECRETARY OF THE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Teleconference
March 26, 2008
Washington, DC 20201
2:00 PM to 3:00 PM EST

National Biodefense Science Board
Members Present

VOTING MEMBERS
Patricia Quinlisk, M.D., M.P.H., *Chair*
Ruth L. Berkelman, 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
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
Peter Jutro, Ph.D., National Homeland Security Research Center, U.S. Environmental Protection Agency
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
Ken Staley, M.D., M.P.A., Homeland Security Council, Executive Office of the President

EX OFFICIO MEMBERS DESIGNEE
Shawn L. Fultz, M.D., M.P.H., VHA Office of Public Health and Environmental Hazards, U.S. Department of Veterans Affairs

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

National Biodefense Science Board, Disaster Medicine Working Group
Members Present

NBSB VOTING MEMBERS
James J. James, Brigadier General (Retired), M.D., Dr.P.H., M.H.A., *Co-Chair*
*Stephen V. Cantrill, M.D., *Co-Chair*
Albert J. Di Rienzo
Kenneth L. Dretchen, Ph.D.

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EX OFFICIO MEMBERS DESIGNEE
Shawn L. Fultz, M.D., M.P.H., VHA Office of Public Health and Environmental Hazards, U.S. Department of Veterans Affairs

OTHERS
David Marcozzi, M.D., MS-CL, FACEP, Director, Emergency Care Coordination Center, Office of Preparedness and Emergency Operations, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services
Jonathan Ban, Office of Policy Strategic Planning, and Communications, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

*****Stephen V. Cantrill, M.D., *Co-Chair*, was not able to participate in the teleconference however, he did concur with the Working Group recommendations.

Roll Call and Welcome

The teleconference was called to order at 2:02 PM by CAPT Leigh A. Sawyer, D.V.M., M.P.H., 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) who serves as the Designated Federal Official for this Federal Advisory Committee. Notice of the meeting was posted in the Federal Register, Volume 73, No. 49, Wednesday March 12, 2008 (p.13238). CAPT Sawyer welcomed all of the participants to the second Public Meeting of the National Biodefense Science Board (NBSB).

Roll call of the NBSB members and the NBSB Disaster Medicine Working Group members was taken by Donald Malinowski. CAPT Sawyer also noted the attendance of Susan B. Spring, Ph.D., who would act as rapporteur for the meeting.

Dr. Sawyer reviewed the Conflict of Interest (COI) Rules that are applicable to the NBSB. She noted that the document titled, "Standards of Ethical Conduct for Employees of the Executive Branch" has been received by all Board members, who, as Special Government Employees, are subject to conflict of interest laws and regulations therein. Annually, or sooner when situations change, Board members provide information about their personal, professional, and financial interests. This information will be used to assess real, potential, or apparent conflicts of interest that would compromise members' ability to be objective in giving advice during Board meetings. Board members must be attentive during meetings to the possibility that an issue may arise that could affect or appear to affect their interests in a specific way. Should this happen, it will be asked that the affected member recuse himself or herself from the discussion by refraining from making comments and leaving the room. Board members have been invited to direct any questions to Board Management.

CAPT Sawyer then provided background information on the NBSB. She stated that the National Biodefense Science Board was authorized by the Pandemic and All-Hazards Preparedness Act (PAHPA), and provides expert advice and guidance to the Secretary on scientific, technical and other matters of special interest to the department regarding activities to prevent, prepare for and respond to adverse health effects of public health emergencies resulting from current and future chemical, biological, nuclear and radiological agents. The Board held its inaugural meeting on December 17 and 18, 2007. At the conclusion of the meeting, the Board voted to establish four working groups. One of these is the NBSB Disaster Medicine Working Group (DM-WG) the work of which will be part of this meeting.

CAPT Sawyer noted that on March 4, 2008, the U.S. Department of Health and Human Services (HHS) Secretary, Michael Leavitt, signed the amended Charter of the NBSB which allows the Board to deliberate on, and form working groups to address matters that extend beyond the specific matters with which the NBSB was charged in the original Charter to include duties concerning public health emergency preparedness and response.

CAPT Sawyer stated that the purpose of this public meeting is for the Board to consider the assessment of the Disaster Medicine Working Group's review of the proposed Federal Education and Training Interagency Group (FETIG) draft charter. The Board will provide recommendations to the Secretary regarding the Federal Education and Training Interagency Group draft charter and the coordination of core curricula, training, and education for public health and medical disaster preparedness.

CAPT Sawyer reviewed the meeting agenda format. Following completion of the roll call and welcome, there would be an introduction of the NBSB Disaster Working Group by Dr. James James, the co-chair of that group. Dr. David Marcozzi, Director, Emergency Care Coordination Center, OPEO, ASPR, HHS

would then provide an introduction to the Federal Education and Training Interagency Group (FETIG). Dr. James would then follow with the recommendations of the NBSB Disaster Medicine Working Group on the FETIG Draft Charter. Dr. Patricia Quinlisk, Chair, NBSB would lead a discussion of the NBSB members on the Working Group recommendations related to the FETIG charter. The public comment period would begin at 2:40 and remain open for ten minutes. The public teleconference center would moderate this session. Public participants with prepared comments would be introduced in order of joining the call. Participants with a question directed to the Board would notify the moderator who would then place them in the queue. Those making public comments needed to identify themselves by stating their name and affiliation prior to making their statement or asking their question. The time for comments and questions would be limited to three minutes per speaker. Following the public comments, the NBSB would vote on the Working Group recommendations. There would be concluding remarks by Dr. Quinlisk following which CAPT Sawyer would adjourn the meeting.

Introduction of the NBSB Disaster Medicine Working Group

Dr. James indicated that the Disaster Medicine Working Group (DM-WG) was established by the NBSB during the inaugural meeting in December 2007. The Working Group, in consultation with HHS, has identified several areas that allow the Working Group to contribute to the important mission of the Office of the Assistant Secretary for Preparedness and Response and to its accomplishment by that Office. Broadly, these areas focus on HHS's efforts around education and training with regards to disaster preparedness and to the provision of mass casualty care. Dr. James indicated that as one of the co-chairs, he is leading the working group in area of training and education and that the other co-chair, Dr. Stephen Cantrill, will lead the group in the area of mass casualty care.

Dr. James added that in the short time that the DM-WG has been engaged, they have seen commendable and considerable openness and forthrightness and willingness to work with the private and public sector on the part of all of the many federal partners. He hoped that this teleconference will be the first of a number that will follow and that will increase this collaboration between the public sector, represented by the federal partners, and the private sector members of the NBSB.

Dr. James stated that the Working Group's approach will be aligned with Homeland Security Presidential Directive-21 (HSPD-21). He indicated that one of the most important individuals in this education and training effort is Dr. David Marcozzi, Director, Emergency Care Coordination Center, Office of Preparedness and Emergency Operations, in ASPR at HHS. Dr. Marcozzi is a member of the DM-WG. Dr. James stated that he and Dr. Marcozzi have been working together on the issues of education and training as related to the DM-WG as well as some other areas.

Before turning the meeting over to Dr. Marcozzi, Dr. James summarized Dr. Marcozzi's background. He indicated that Dr. Marcozzi is a graduate of Boston College and St. George's University School of Medicine. He completed his Emergency Medicine Residency at Brown University, where he served as Chief Resident. He also holds a Masters of Health Sciences in Clinical Leadership from Duke University School of Medicine. Prior to coming to HHS, Dr. Marcozzi worked for the United States Senate Subcommittee on Bioterrorism and Public Health Preparedness where he assisted in drafting the *Pandemic and All-Hazards Preparedness Act* (PAHPA). Dr. James stated had the privilege and pleasure of working with Dr. Marcozzi during the PAHPA development process.

Dr. James indicated that Dr. Marcozzi would present an introduction of the Federal Education and Training Interagency Group (FETIG), a group focused on education and training for medical disaster preparedness and response and public health. Dr. James stated that following the presentation he would present the NBSB with the DM-WG recommendations regarding the charter for the FETIG.

Dr. James reiterated his commendation of HHS and the federal partners for their openness in this important endeavor.

Introduction of the Federal Education and Training Interagency Group (FETIG)

Dr. David Marcozzi, Director, Emergency Care Coordination Center, Office of Preparedness and Emergency Operations, greeted the participants and indicated that he would discuss the name, authorities, function, and structure of the FETIG and the role of the NBSB in relation to the FETIG. He indicated that he has no stake in the name, FETIG, which was easy to derive and captured the group's mission.

The authority for the FETIG is derived from Section 304 of the Pandemic and All-Hazards Preparedness Act (P.L. 109-417). Section 304 looked to establishing a core curriculum and training along three tracks, a medical and clinical track, a public health track and a laboratory track. Recently in October 2007, HSPD-21 was issued and provided further guidance in the area of education and training.

Dr. Marcozzi noted that PAHPA created an opportunity to…build upon and standardize the preparedness education foundation established [to date] through various programs at the Federal, State, and local levels. And in so doing, integrated, interdisciplinary, and consistent public health and medical response curricula, rooted in community need, will be available to practitioners and universities/colleges.

Dr. Marcozzi cited three sections of HSPD-21 which are particularly relevant to the FETIG.

Paragraph 37 requires that the secretaries of the five lead agencies to build on Section 304 of PAHPA to "develop a mechanism to coordinate public health and medical disaster preparedness and response core curricula and training across executive departments and agencies, to ensure standardization and commonality of knowledge, procedures, and terms of reference within the Federal Government that also can be communicated to State and local government entities, as well as academia and the private sector."

Paragraph 38 goes on to clarify that the "Secretaries of Health and Human Services and Defense, in coordination with the Secretaries of Veterans Affairs and Homeland Security, shall establish an academic Joint Program for Disaster Medicine and Public Health housed at a National Center for Disaster Medicine and Public Health at the Uniformed Services University of the Health Sciences" (USUHS which is located in Bethesda, MD). Dr. Marcozzi noted that the remainder of Paragraph 38 provides more detail about how that program should be defined.

Dr. Marcozzi indicated that the FETIG seems particularly to subsume the goal of Paragraph 32 of HSPD-21 which indicates that: "The Secretary of Health and Human Services, in coordination with the Secretaries of Defense, Veterans Affairs, and Homeland Security, shall ensure that core public health and medical curricula and training developed pursuant to PAHPA address the needs to improve individual, family, and institutional public health and medical preparedness."

Dr. Marcozzi indicated that the seven functions of the FETIG are consistent with the legislation (PAHPA) and with HSPD-21 as related to the development of a core curriculum. These functions are:

1. Design a Center of Excellence in Disaster Medicine and Public Health Preparedness
2. Serve as a coordinating mechanism for preparedness and response core curricula, training, and education
3. Ensure standardization and commonality
4. Provide policy and strategic guidance

5. Ensure interagency coordination
6. Develop and propagate training and education
7. Facilitate research and the translation of research findings to public health practice

Dr. Marcozzi noted that there are multiple government agencies that have interacted in the effort to develop the FETIG charter. The goal was to develop a charter that achieved the requirements of HSPD-21 and PAHPA, that could be supported by the federal partners, and that could clear the five lead agencies at the Executive Secretariat level.

The participating agencies are the following:

1. U.S. Department of Defense (DoD)*
2. U.S. Department of Health and Human Services (HHS)*
3. U.S. Department of Homeland Security (DHS)
4. U.S. Department of Veterans Affairs (DVA)
5. U.S. Department of Transportation (DOT)
6. U.S. Department of Agriculture (USDA)
7. U.S. Agency for International Development (USAID)
8. U.S. Department of State (DOS)
9. U.S. Department of Education (DOE)
10. U.S. Department of Labor (DOL)
11. Others as defined by the FETIG

The first two agencies, DoD, HHS are the co-chairs (*) and the first five are defined as the lead agencies.

The role of the NBSB in the process is two-fold:

1. Review and comment on the draft FETIG Charter.

2. Prepare a white paper defining Disaster Medicine and how to effectively engage academics, professional societies and the private sector in the creation of competency-based education and training curriculum, identifying which stakeholders should be involved in the development of the curriculum.

At this point, the goal is to engage the NBSB early in the FETIG charter process. Subsequently, the NBSB will prepare the white paper related to engaging the private sector.

Dr. Marcozzi then turned the meeting back to Dr. James for the Disaster Medicine's Working Group's recommendation on the draft FETIG charter.

Recommendations on the Federal Education and Training Interagency Group (FETIG) Draft Charter

Dr. James stated that the DM-WG of the NBSB was asked to review and comment on the draft charter for the FETIG.

The DM-WG wanted to thank HHS for actively soliciting input from the NBSB and the DM-WG. The early engagement of the NBSB is a clear sign that HHS is interested in engaging stakeholders in the development of public health and medical disaster preparedness and response core curricula, training, and education.

The DM-WG noted that, in general, the Charter is a reasonable initial step in the process of the U.S. government's efforts in the development of public health and medical disaster preparedness and response core curricula, training, and education. The DM-WG shared HHS's sense of urgency related to this initiative and encouraged other departments to expeditiously sign the Charter.

In the DM-WG review of the draft Charter, they identified three areas where they wanted to make recommendations. These are as follows:

1. The DM-WG believes the current charge of the FETIG, with its broad focus on Public Health and Medical Disaster Preparedness and Response is overly broad.

   The DM-WG recommends the FETIG charter be focused on Disaster Medicine, and aspects of Public Health that are related to Disaster Preparedness.

2. The DM-WG recognizes that the draft FETIG charter includes a statement regarding soliciting external advice, consultation, and recommendations; however, the Working Group believes, as drafted the FETIG charter does not clearly commit engagement of non-federal stakeholders.

   The DM-WG recommends the FETIG charter clearly define the role and mechanism for non-federal stakeholder engagement in the development of the core curriculum.

3. The DM-WG is concerned the FETIG charter as drafted, implies that the Joint Program in disaster medicine and public health is going to be responsible for carrying out the activities of the FETIG. The draft charter, by listing the establishment of the Joint Program over emphasizes its role in these activities.

   The DM-WG recommends the FETIG Charter be revised to clarify the responsibilities of the FETIG and the role of the Joint Program.

He suggested that the Board work through the recommendations one by one and provide comments on each recommendation. Dr. James then turned the meeting over to Dr. Quinlisk, Chair of the NBSB.

NBSB Discussion

Dr. Quinlisk then led the discussion on the DM-WG's recommendations on the draft FETIG charter. She noted that HSPD-21, and trying to deal with issues surrounding disaster preparedness had led to the charter of the FETIG which the NBSB has been asked to review. The NBSB comments will go to HHS Secretary Leavitt as the NBSB's advice on this issue. Dr. Quinlisk suggested considering each recommendation in order.

The comments on DM-WG Recommendation 1 (*The DM-WG recommends the FETIG charter be focused on Disaster Medicine and aspects of Public Health that are related to Disaster Preparedness*.) were as follows:

Dr. Ruth L. Berkelman thanked Dr. James and the Working Group and Dr. Marcozzi for their efforts. She wanted clarification as to how Recommendation 1 would actually impact the FETIG. It appeared to her that Recommendation 1 was trying to narrow the scope of public health. Dr. James replied that the DM-WG's concern was just the opposite. The DM-WG felt that leaving the wording as "public health" made the mission too broad. The target of both the HSPD-21 and DM-WG is disaster medicine and

preparedness. The DM-WG felt that the FETIG, would be better focused on those particular subsets of public health (disaster medicine and those aspects of public health relating to disaster preparedness) rather than getting into areas that while they are important, are not pertinent to the work at hand.

Dr. Grabenstein indicated that the problem may be that the phrase "public health" does not make a good adjective. It seems that the name of the Joint Program, Joint Program for Disaster Medicine and Public Health, is clearer in this respect. Perhaps the charter could include another sentence that simply sets the scope of the DM-WG suggestion or the follow-on words of the FETIG could be changed to match those of the Joint Program.

Dr. Berkelman indicated that she wanted to be sure that public health was kept in the medicine aspects as well. There is a need to make sure that the medical care providers and the public health-side are linked very firmly. Dr. James assured her that public health will be a prominent player and will always have an equal footing with medicine in the DM-WG. Dr. Berkelman also indicated that it seems that some of the preparedness programs are being directed by individuals trained who are well-trained primarily in emergency medicine and that she would like to see a more integrated approach.

The comments on DM-WG Recommendation 2 (*The DM-WG recommends the FETIG charter clearly define the role and mechanism for non-federal stakeholder engagement in the development of the core curriculum*.) were as follows:

Ms. Roberta Carlin stated that she concurred with the need to tighten-up the language. Additionally, she wanted to be sure that disability and special needs populations were included in the process.

Dr. Andrew Pavia stated that Recommendation 2 was an incredibly important recommendation and he endorses it. From Dr. Marcozzi's presentation, it seemed that the next step that would be taken would be to define how to get non-federal stakeholders involved in the NBSB DM-WG. That approach sounded very helpful and useful to him, but Dr. Pavia felt that the charter needs to be amended to clearly spell out the responsiveness to and the involvement of stakeholders.

Dr. James concurred with Dr. Pavia's statements. He clarified that there are two parts to Recommendation 2. One aspect, on which he is already working with HHS, is to expand the DM-WG to include input from others in academia and in public health; these types of leaders are needed to help inform the process. The other aspect, which addresses Dr. Pavia's first point, is that there not be just a verbal intention of input from the private sector, but that there be a mechanism to ensure it.

Ms. Carlin suggested that consideration be given to adding wording that would "ensure and enforce" the involvement of the non-federal sector.

The comments on DM-WG Recommendation 3 (*The DM-WG recommends the FETIG Charter be revised to clarify the responsibilities of the FETIG and the role of the Joint Program*.) were as follows:

Dr. Grabenstein enquired about the relationship of the FETIG and the Joint Program Director; particularly whether the FETIG acts as an advisory group to the Joint Program or whether the Director of the Joint Program works for the FETIG. Dr. James indicated that the DM-WG was concerned that although there is to be a balance between the FETIG and Joint Program, the Joint Program has not yet been defined. It is kind of a chicken and egg issue in that it will be hard to define the Joint Program until the work of the FETIG gets underway.

Dr. Marcozzi indicated that the first step of this effort is to develop a mechanism to coordinate all of the federal agencies, including a mechanism to engage the stakeholders. The second step would be defining how the FETIG, which has the role of coordination, evolves to providing either oversight or input into the Joint Program at USUHS. The language within the HSPD regarding the Joint Program and its establishment at the National Center is meant to be consistent and uniform with regard to how the National Center and Joint Program are the one entity that allows for coordinating the process of the core curriculum for federal emergency preparedness and training. Dr. Marcozzi stated that he preferred not to get into more detail on the nomenclature of National Center or Joint Program at this time.

Dr. James indicated that the basis of the DM-WG recommendation is to clarify the FETIG language to reflect Dr. Marcozzi's statement.

Noting no additional comments from the NBSB members on the DM-WG recommendations, Dr. Quinlisk turned the meeting over to Dr. Sawyer. Dr. Sawyer requested a roll call of individuals who may have joined the teleconference subsequent to the first roll call at the beginning of the teleconference. Such a roll call was taken.

Public Comment

CAPT Sawyer turned the meeting over to the teleconference company moderator who provided instructions to the public participants about using the teleconference system for making comments.

Dr. John D. Malone, Pacific Northwest National Laboratory and Member, Infectious Disease Society of America (IDSA) Bioemergencies Task Force stated that he was speaking for the IDSA. As a professional organization, IDSA is looking forward to offering their expertise in bioterrorism, specifically, but also in the broader context of response to all types of hazards. He wanted to encourage the group to consider network centric theory for dealing with complex situations that arise during their future work. He stated that he had some specific ideas in this area and was looking forward to providing advice.

There being no additional public comments, CAPT Sawyer turned the meeting back to Dr. Quinlisk.

NBSB Voting

Dr. Quinlisk described the process for voting on each of the DM-WG recommendations on the FETIG draft charter. Each recommendation was read and the 12 voting members of the NBSB in attendance were asked to indicate "yes" or "no" on the recommendation.

The NSBS voted unanimously 12-0-0 in favor of Recommendation 1.

Before voting Recommendation 2, Dr. Quinlisk noted that during the discussion two points had been raised. One was to ask for a further description of the roles that the working groups and other non-federal stakeholders might play in this process. The second was adding language to "ensure and enforce" engagement of the non-federal stakeholders. Dr. Quinlisk suggested surveying the NBSB members to determine if they wanted to vote on the language of Recommendation 2 as stated by the DM-WG or wanted to add additional language. 11 of the 12 members indicated that they preferred to vote on the language as put forth by the DM-WG.

The NSBS voted unanimously 12-0-0 in favor of Recommendation 2.

The NSBS voted unanimously 12-0-0 in favor of Recommendation 3.

Dr. Quinlisk asked for clarification that these recommendations would go to the Secretary, HHS as advice from the NBSB. Dr. Sawyer indicated that they would.

Concluding Remarks

Dr. Quinlisk thanked all of the participants, HHS staff and the NBSB. She indicated that she hoped that these recommendations would make both the FETIG and Joint Program stronger and that the DM-WG will be able to have a mechanism to formally get advice from non federal stakeholders.

Dr. Sawyer added her thanks to all of the participants. She indicated that the next public meeting of the NBSB will be June 18-19, 2008 in Arlington, VA. Information about that meeting will be posted on the NBSB Website. The NBSB Website also has the minutes and rosters of the Board. The presentations made by Dr. Marcozzi during this teleconference will also be posted there. The Website can be accessed by using a search engine to find NBSB or directly at www.hhs.gov/aspr/omsph/nbsb.

Adjournment

Dr. Sawyer then adjourned the teleconference at 2:58 PM EST.