NBSB NATIONAL BIODEFENSE SCIENCE BOARD

Summation of Recommendations
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March 26, 2008: Federal Education Training Interagency Group (FETIG) Charter

Following discussion by the NBSB members and public comment, the Board voted to adopt the recommendations of the Disaster Medicine Working Group below and transmitted them in a letter to the Secretary.

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

   The Disaster Medicine Working Group recommends the FETIG charter be focused on Disaster Medicine, and aspects of Public Health that are related to Disaster Preparedness.
   - This recommendation resulted in changes to the charter to reflect the wording concerns.

2. The Disaster Medicine Working Group 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 Disaster Medicine Working Group recommends the FETIG charter clearly define the role and mechanism for non-federal stakeholder engagement in the development of the core curriculum.
   - This recommendation resulted in a word change to "will" engage stakeholders.

3. The Disaster Medicine Working Group 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 Disaster Medicine Working Group recommends the FETIG charter be revised to clarify the responsibilities of the FETIG and the role of the Joint Program.
   - This recommendation was understood and will be addressed and become clear as the FETIG is institutionalized.

June 18, 2008: Individual Stockpiling of Antibiotics and Antivirals

The Board voted to send a letter to the Secretary expressing concerns about HHS's Biomedical Advanced Research and Development Authority's efforts to advance personal preparedness through individual stockpiling of antibiotics and antivirals and guidance drafted by the HHS Centers for Disease Control and Prevention for health care providers and consumers with questions regarding the home stockpiling of the antibiotic doxycycline by obtaining a prescription from a physician. The Board agreed to establish the Personal Preparedness Working Group to study the many complex considerations that would affect any personal preparedness program.

August 11, 2008: Home Stockpiling of Antibiotics

The Board voted to send a letter to the Secretary referring to the letter of concern of June 18, 2008 about personal stockpiling of antibiotics, particularly through ordinary prescriptions. The Board expressed concern that the Department was moving forward rapidly to implement individual stockpiling with the proposed posting and promotion of a question and answer document before the science was adequately examined. The Board also stressed the high risk of providing a confusing message to the public that does not have the endorsement of experts in public health, biodefense, and infectious disease, nor of the majority of medical practitioners. The Board noted that their concerns and recommendations, as well as those of other experts had not yet been adequately addressed, and urged the Secretary not to move precipitously to promote home stockpiling before the scientific questions could be answered, and the concerns of clinicians and the public health community were addressed.

September 23, 2008: National Disaster Medical System (NDMS) and National Medical Surge

The NBSB Disaster Medicine Working Group established the NDMS Assessment Panel. Following discussion by the NBSB members and the public, the NBSB voted to send the revised recommendations of the Disaster Medicine Working Group presented on behalf of the NDMS Assessment Panel. The recommendations to the Secretary from the NBSB follow:

1. Envisioning the Future: Currently NDMS is a loosely integrated "system" of a deployable medical response component to serve a limited number of patients, a patient evacuation component relying heavily on military transport capability, and a definitive care component provided by volunteer member hospitals. It does not represent an overall system to provide for the medical needs of patients at a time of national need.
    1.1. Recommendation - Develop a clear, current strategic vision for the NDMS including how it integrates with the mandate of Emergency Support Function (ESF)-8 Public Health and Medical Services and how resource sharing partnerships between the NDMS, the states and the healthcare industry might be enhanced for improved medical response during a disaster.
    1.2. Recommendation - Establish an ongoing civilian advisory group for the National Disaster Medical System and for the U.S Department of Health and Human Services (HHS) ESF-8 efforts in general. This group should meet on a regular basis and assist in the ongoing assessment and improvement of our nation's disaster medical response.
2. Integrating the Past: Multiple previous studies and after-action reports have identified opportunities for improvement in the NDMS, however, there does not appear to be an organized methodology to track and monitor attempts to address these identified issues resulting in lost opportunities to continually improve the performance of the NDMS.
    2.1. Recommendation - Establish a formal mechanism to track the implementation of recommendations and lessons-learned from appropriate after-action reports and other evaluations. This process should identify the factors which have precluded effective implementation of previous recommendations, such as insufficient staff, staff turnover, unclear responsibilities, lack of funding, etc., so that these primary issues may be addressed.
3. Strengthening the Team: Medical response personnel are one of the mission critical resources, which allows the NDMS to fulfill its mission of assisting State and local authorities in dealing with the medical impacts of major peacetime disasters.

3.1. Recommendation - Every effort should be made to achieve full staffing and operational status for all NDMS Response Teams. This includes dealing with identified issues in the following Response Team areas: concept of operations, equipment and logistics, command and control, communications and training.
3.2. Recommendation - Establish a uniform and consistent training curriculum across each of the types of volunteer teams consistent with the education and training requirements as defined under HSPD-21. These efforts must be complementary and build upon a national, standardized approach for resource typing, uniform training, field deployment and logistics support.
3.3. Recommendation - Implement an accounting/tracking system that can properly register the true capacity of non-overlapping NDMS medical response personnel who can be deployed for an event. Consideration should be given to improving the NDMS personnel capability and gap analysis for multiple specified national scenarios, including consideration of conflicting obligations and time to respond.

4. Serving the Patient: By definition members of the public will only ever interact with the National Disaster Medical System in times of incredible stress and strain to the public and the healthcare system. The NDMS needs to ensure that its procedures and policies do not add unnecessary physical, emotional or financial stresses to the individuals that it serves. Particular attention needs to be paid to smooth and efficient mass evacuation of patients from impacted areas including the continuity of patient medical information during and after transport.
4.1. Recommendation - Review and expand the definition, if necessary, of what constitutes an NDMS patient. Serious consideration should be given to including any individual evacuated across state lines (regardless of mode of evacuation) due to a disaster, who requires medical evaluation or care, to be an NDMS patient for a specified limited period of time (including long-term care patients).
4.2. Recommendation - Reimbursement for care of disaster victim patients should not be limited to just NDMS hospitals, but should include all hospitals, outpatient clinics, nursing homes, alternate care facilities, shelters, etc, wherever care is provided during the time of the event or the following impact period. Reimbursement should continue at 110% of the Centers for Medicare and Medicaid Services' rate.
4.3. Recommendation - Establish a standard patient movement concept of operation. This plan should explicitly address the needs and management of at-risk individuals including children, pregnant women, senior citizens, and individuals with medical disabilities and other special needs, in the event of a disaster or public health emergency.
4.4. Recommendation - Field usability of the NDMS Electronic Medical Record (EMR) currently under development must be the goal of primary importance for its implementation. To the degree possible, integration of the NDMS EMR platform with future patient tracking and medical resource availability systems should be encouraged. The NDMS EMR platform should use medical IT best practices and protocols that will allow the greatest degree of interoperability with existing and future EMR systems. NDMS should take the lead in defining the minimal patient data set that is required in a patient tracking system.
4.5. Recommendation - Undertake a comprehensive review of federal health-related regulations and determine how such regulations pose barriers to the efficient and effective administration of patient care during times of extreme medical need. Develop criteria to specify when health-related federal regulations should be considered for temporary suspension in areas affected by a disaster and potentially

those areas receiving the evacuated patients and convey these criteria to the healthcare community to assist in their disaster preparedness planning.

5. Engaging Partners: The complete integration of federal resources with state and local resources is problematic. The process would benefit from establishing an improved understanding of each others capabilities and needs in advance. This is felt to be a significant issue especially for the Disaster Mortuary Operational Response Teams in terms of dealing with issues such as body disposition, which remains a local responsibility.
   5.1. Recommendation - Consistent with Recommendation 1.1 the NDMS should improve and expand its efforts to build sustainable partnerships with State and local resources.
   5.2. Recommendation - Establish improved alliances between NDMS and the public/private healthcare sector to provide assistance in field care, patient transport and definitive patient care. These alliances should be designed to provide additional assets to augment NDMS operations during a time of national need.
6. Allocating Resources: It is clear that funding levels for the NDMS are inadequate to support even the current level of the NDMS operation.
   6.1. Recommendation - Every effort should be made to secure adequate, sustained, increased funding for the NDMS so it may successfully accomplish its critically important mission.
7. Moving Toward the Future
   7.1. Recommendation - The ASPR should consider this report and recommendations of the NBSB. The NBSB would respectfully request feedback at our spring / summer 2009 meeting concerning each recommendation above as to whether it has: 1) already been implemented; 2) will be implemented or 3) will not be implemented, with reasons if possible.
   7.2. Recommendation - As follow-up to the NBSB report, the HHS/ASPR should request a study by the Institute of Medicine that would assess and evaluate the current status and progress of the NDMS program and make recommendations for future directions.

October 14, 2008: Personal Preparedness and Home Stockpiling

Following discussion by the Board and public comment the Board voted to send the following recommendations of the NBSB's Personal Preparedness Working Group to the Secretary:

1. Recommendation - High-quality specific information can and should be obtained from an operational evaluation during the pre-positioning of antibiotic countermeasure programs. Collecting quantitative and qualitative information would enhance rather than detract from the operational aspects of those programs. Moreover, it would provide complementary and supportive data to that gathered in planned studies that make up the core of a new drug application (NDA) package for purpose-built antibiotic stockpiles. This recommendation should be considered for the two separate activities specified below.
   - Regarding the planned implementation of the Cities Readiness Initiative (CRI) Postal Module in Minnesota, we believe that there is extensive experience and expertise among the epidemiologists at the Minnesota Department of Health, as well as at the Centers for Disease Control and Prevention, for this activity.
   - Regarding the potential pre-positioning of antibiotics for the January 2009 Inaugural Capitol Region, we believe that there is extensive experience and

expertise among the epidemiologists within the National Capitol region, as well as at the Centers for Disease Control and Prevention, for this activity.

2. Recommendation - We recommend that operational and qualitative research be conducted in order to better understand what issues and triggers drive individual decisions to participate in personal preparedness activities and their adherence to instructions on proper storage and use of individual antibiotic caches. Lessons can be learned from disaster preparedness in high risk areas for storms (high probability, moderate to high impact) and earthquakes (low probability but possibly catastrophic impact) where personal preparedness has been emphasized for many years.
3. Recommendation - A draft HHS document, "Personal Preparedness for an Anthrax Emergency: Benefits and Risks of Home Storage of Antibiotic Drugs: Questions and Answers," was provided to the NBSB members at the August 11, 2008 teleconference. Pending review by the Personal Preparedness Working Group of the NBSB, we recommend that this draft document be considered for, modified, and used during pilot testing in programs such as the CRI Postal Module in Minnesota or any other separate program such as the January 2009 Inaugural Capitol Region program.

November 18, 2008: Protecting, Preserving, and Restoring Individual and Community Mental Health

The NBSB's Disaster Mental Health Subcommittee submitted a report and recommendations to the NBSB for deliberation and discussion by members and the public. The NBSB voted on and approved the following recommendations for transmittal to the Secretary:

1. Recommendation - Integrate mental and behavioral health into all public health and medical preparedness and response activities.

   1a. At the Federal level, coordinate mental and behavioral health service efforts through a unified concept of operations (CONOPS) that addresses pre-, intra-, and post-event phases of disaster and that includes:

   - Near real-time reach-back capacity to allow for mental and behavioral health expert input and consultation;
   - Representation of mental and behavioral health functions, including consultative and clinical roles, within operational frameworks across local, State, and national levels aligned with the National Incident Management System; and
   - Standard mental and behavioral health triage of at-risk individuals and populations linked with needs-assessment activities and surveillance of emerging health effects and behavioral risk factors.

   1b. At the national level, facilitate State-based disaster mental and behavioral health planning and operations through the following:

   - Include language on mental health, substance abuse, and behavioral health in all appropriate legislation, regulations, and grants (e.g., the Pandemic and All-Hazards Preparedness Act).
   - Integrate disaster mental and behavioral health planning and exercising into performance benchmarks of new or existing Federally-funded emergency management programs or grants.

2. Recommendation - Enhance the research agenda for disaster mental and behavioral health. Convene a working group of the Disaster Mental Health Subcommittee to review the research portfolios of Federal research funders across the U.S. government (including the NIH, AHRQ, and CDC within HHS, and other relevant Federal Departments and agencies) to identify gaps in knowledge, areas of recent progress, and priorities for

research in disaster mental and behavioral health program evaluation, early intervention, treatment for disaster-related problems, and dissemination of training in disaster mental and behavioral health interventions. Set a national agenda for this research that is supported by the Federal agencies that fund research initiatives in these areas.

3. Recommendation - Enhance assessment of mental and behavioral health needs during emergencies. Integrate epidemiological strategies to capture information for public policy and resource allocation. Utilize existing national health surveillance systems and State/local-based systems to rapidly assess and track mental and behavioral health needs and recovery processes in affected populations (e.g., the Centers for Disease Control and Prevention's research, including the Behavioral Risk Factor Surveillance System, Youth Behavioral Risk Surveillance System, National Hospital Discharge Survey, and National Health Interview Survey; the Substance Abuse and Mental Health Services Administration's National Household Drug Utilization Survey; the American Red Cross Mental Health Triage information; and local systems such as the Los Angeles County Rapid Mental Health Triage System).
4. Recommendation - Enhance disaster mental and behavioral health training for professionals and paraprofessionals: Promote psychological resilience and effective delivery of psychological support by professionals and paraprofessionals through education in disaster mental health and/or training in psychological first aid.
5. Recommendation - Promote the population's psychological resilience of individuals, families, and communities through the development of a national strategy for the integration, dissemination, and ongoing evaluation of psychological first aid.
6. Recommendation - Ensure that the needs of at-risk individuals and issues of cultural responsiveness are being addressed in all efforts of the National Biodefense Science Board: Support the development of mechanisms to ensure that the needs of vulnerable and at-risk populations and issues of cultural responsiveness are appropriately considered and served in the articulation and execution of the Board's recommendations and in public health activities related to emergency preparedness and response.
7. Recommendation - Develop a disaster mental and behavioral health communication strategy.
    - Develop mass communication messages that deliver psychoeducation, information on sources of help, and other mental and behavioral health topics related to specific hazards/threats and disaster phases.
    - Develop education and training regarding the integration of mental and behavioral health/social science principles and emergency risk communication.
    - Develop a process to identify, educate, and train a cadre of mental and behavioral health experts to serve as consultants, interviewees for Federal television/Internet broadcasts, and resources for the media.
    - Establish and enforce a policy, with respect to all disaster and emergency health issues, that:
        - Requires that, prior to soliciting/undertaking new Federally-funded communication initiatives, a review of similar and/or related activities of other Federal components will be performed and documented to ensure integration and prevent duplication.
        - Requires that all communication activities (directly operated or supported through grants, contracts, or cooperative agreements) document and ensure that they are informed by current evidence-based psychosocial factors.
8. Recommendation - Develop an accessible Internet-based communication toolkit: At present, no single Federal source consolidates communication/message research and

products developed for a variety of events (e.g., pandemic influenza, terrorism, and environmental contamination from chemical stockpile/industrial accidents). The best solution for this consolidation is the development of a Federal communication Web site.

July 17, 2009: H1N1 Countermeasures Strategy and Decision-Making: Report with Recommendations

The NBSB's Pandemic Influenza Working Group convened a meeting of experts to inform their report. Following discussions by the members and public, the NBSB voted on and approved the Report with Recommendations for transmittal to the Secretary. The key findings of the meeting and subsequent deliberations follow:

H1N1 Vaccine

- Based on available data, the NBSB recommends that HHS set a goal of having several tens of millions of doses of unadjuvanted monovalent A/H1N1 vaccine available for clinical use no later than September 15, 2009. To achieve this, HHS should pursue a simplified testing program. Additional studies may be appropriate for additional supplies in subsequent months, but time of availability seems to be the dominant criterion for vaccine decision making.
- Decades of experience with A/H1N1 influenza viruses provide a basis for selecting initial antigen quantities and dosing. If the U.S. goal is vaccine availability on the shelf in September 2009, 15-mcg unadjuvanted subunit vaccine and live attenuated intranasal vaccine for children may be a rational approach.
- If the second wave is delayed or production is slower than expected, mix-and-match studies of vaccine plus separate adjuvant may yield information that could stretch the available vaccine supply.

Antiviral & Other Therapeutic Agents

- H1N1 strains appear to be sensitive to neuraminidase inhibitors, which are effective in reducing symptoms and progression in early stage disease, and for post-exposure prophylaxis in asymptomatic exposed patients.
- If the H1N1 vaccine is not available at the time of an early wave of disease, the use of antiviral drugs for post-exposure prophylaxis should be considered. This topic was not extensively discussed at the conference.
- Evidence for effectiveness of antivirals in advanced disease is less robust; there will be no approved parenteral formulation of any influenza antiviral available that could be used by fall 2009.
- Novel antiviral drugs effective against resistant strains and advanced disease will not be available for the existing pandemic but should be developed vigorously for future pandemics.
- HHS should reassess its current and anticipated supply of approved antiviral products and other therapeutic agents (e.g., antibiotics, seasonal influenza vaccine, pneumococcal vaccines) where surge demand might overwhelm normal supply.

Diagnostics

- Public health laboratories are not equipped to meet the clinical diagnostic needs posed by the present pandemic. Assays with clinical utility should be more widely distributed among clinical-care laboratories.
- Existing rapid diagnostic tests have unacceptably low sensitivity to rule out H1N1 infection in individual patients.
- Clinical criteria will likely be the primary diagnostic tool used in the upcoming fall outbreak.
- Better diagnostic tests should be developed.

- HHS should reassess its current and anticipated supply of laboratory reagents and their availability to clinical-care laboratories.

October 14, 2009: Support for the National 2009 H1N1 Immunization Program

The Board voted to send a letter to the Secretary expressing their strong support for the National 2009 H1N1 Immunization Program, based on the overwhelming evidence that the benefits of vaccination far outweigh any potential risks. The Board strongly encouraged the early voluntary immunization of all high-risk Americans followed by the vaccination of all others who would like to be protected from this infection as the vaccine supply grows over the coming months.

November 13, 2009: Actions Public Health Officials Should Consider Taking to Prevent and Mitigate Adverse Behavioral Health Outcomes During the H1N1 Public Health Emergency

Following discussion by the members of the NBSB and the public the NBSB approved the following recommendations developed by the NBSB's Disaster Mental Health Subcommittee for transmittal to the Secretary:

1. Recommendation – The HHS should encourage state and local public health officials to invite their behavioral health authorities (both mental health and substance abuse) to meet and discuss local efforts and plans; identify constituents, including high risk and vulnerable populations; and develop steps they can take together. A current roster of state disaster mental health and substance abuse coordinators from the HHS Substance Abuse and Mental Health Services Administration is available to facilitate this process.
2. Recommendation - As part of the discussion between HHS and state and local public health officials and behavioral health officials, strategies should be developed to maintain calm at treatment sites, such as flu clinics, primary care settings, and emergency departments, in order to minimize stress for providers working at these locations. It will also be important to ensure sensitivity to emotional and behavioral needs as they emerge at vaccination sites. One strategy that has been successful is assigning mental health staff to monitor the waiting area/line and to actively communicate with persons to receive services to:
    - Provide a reassuring presence and convey that everyone will be cared for throughout the entire process;
    - Provide basic and accurate information about what to expect when they receive treatment (simple handouts, if available, are helpful);
    - Identify and intervene with persons experiencing severe psychological distress.

    A good example is the fact sheet "Maintaining Calm at the POD" developed by HHS.
3. Recommendation - In the interest of providing swift, accessible education about behavioral health considerations during this crisis, the DMH Subcommittee—with the assistance of the Office of the Assistant Secretary for Preparedness and Response—compiled a list of specific resources (including resources related to death and bereavement) that pertain to behavioral health. This is a useful tool to supplement information currently available on the HHS website, "Flu.gov". The DMH Subcommittee has distributed this resource list to behavioral health professional associations and stakeholder groups across the country as well as state public health authorities.

February 10, 2010: Optimizing Industrial Involvement in Medical Countermeasure (MCM) Development: A Report of the National Biodefense Science Board

NBSB's Medical Countermeasures Markets and Sustainability Working Group presented their report with recommendations to the Board for discussion and public comment. The Board voted to send the following recommendations to the Secretary encouraging more persistent and more innovative efforts to develop the full portfolio of MCMs needed to protect the country against CBRN events:

1. Recommendation - To harness the national industrial base, the U.S. Congress and the Executive Branch must provide adequate, consistent funding. MCM development is expensive, resource-intensive, and time-consuming, with a high level of risk. Drugs and vaccines for national biodefense have little, if any, commercial market. Several groups have proposed recommendations for federal funding levels to ensure advanced development of MCMs. Additional federal funds likely will be needed for MCM development and acquisition. Inadequate funding delays achieving the goals of MCM licensure, stockpiling, and distribution; the negative impact of inconsistent funding is even more severe.
    a. Advanced Development: The U.S. Congress and Executive Branch should provide increased dedicated funding for advanced MCM development, which is distinct from procurement funding. Because most MCMs against CBRN agents are in early stages of development, more resources for advanced development will be needed before procurement funds are required. The 10-year Special Reserve Fund for Project BioShield remains a procurement device, not an advanced-development mechanism. But no MCMs will be available to be procured, unless advanced development succeeds first.
    b. Procurement: The Project BioShield Special Reserve Fund expires in 2013 and needs to be reauthorized and fully funded. These funds should not be diverted to support other initiatives, regardless of the merit of the other purposes. The U.S. Congress should consider giving BARDA authority to reprogram 10 to 40 percent of its funds on an annual basis, to advance MCM candidates through the pipeline as efficiently as possible. The need for other improvements in BARDA's functions and authority should also be explored.
2. Recommendation - The U.S. Government must accelerate the pace of MCM development and acquisition, and optimize distribution methods. MCM discovery and development are matters of national security and, as such, are distinguished from routine research-and-development activities. National vulnerability does not end when a project is funded, but rather when MCMs are stockpiled and licensed, and an effective distribution process is in place to distribute them quickly or in advance of an event.
3. Recommendation - The U.S. Government must centralize its leadership for MCM development, procurement, and approval. Strong, coordinated leadership is important if private-sector entities are expected to risk their capital to develop MCMs against CBRN agents. This leadership, perhaps coordinated at the level of the White House or through a specified Federal entity, is needed to synchronize, prioritize, plan, integrate, and coordinate all essential MCM development activities across Federal entities, industry, and other relevant stakeholders, including not-for-profit organizations.
4. Recommendation - The U.S. Government must demonstrate long-term commitment to its industry collaborators. MCM development requires unprecedented cooperation and integration across the U.S. Government and industry. Multiyear funding with carry-over authority and multiyear contracting authority would signal durable U.S. Government commitment and increase industry's sense of long-term stability. Drug development is a

complex, long-term process. Multiyear contracting authority is essential to allow long-term planning and eliminate uncertainty about the availability of federal funds. One-year budget cycles for Federal entities (DoD is the notable exception) constrain the ability of private industry to plan coherently or execute MCM development effectively. Programs should be tied to specific national security goals and subjected to regular progress assessments. A new approach to MCM acquisition that departs from the equipment-procurement model is essential, while also ensuring financial propriety, maintenance of competition, and achievement of goals and timelines.

5. Recommendation - The U.S. Government must create, sustain, and enhance innovative partnerships with private industry. Advanced-development projects should be commissioned with innovative contracting mechanisms, such as OTAs and other flexible means. Cost-plus-fee contracting flexibility is appropriate for advanced MCM development and would reduce industry risk. The U.S. Government could explore the formation of task-specific consortia or similar assemblies of industrial talent, so the Government can request assistance from specific sub-sectors of the biopharmaceutical industry when problems arise. BARDA, FDA, and other U.S. Government entities must be willing to innovate and take risks, so they fulfill the public trust to make safe and effective MCMs available as soon as possible. Effective channels of communication among these entities also are essential.
6. Recommendation - The U.S. Government should expand MCM markets to include international partners, State, local, and tribal governments, laboratorians, and first-responders in each of these sectors. These markets are relatively small, but including them would send industry an important message that the U.S. Government is not the only market. Adding MCMs to Standardized Equipment Lists (SELs) and Authorized Equipment Lists (AELs) would allow State and local first-responders to use federal grant funds to protect these personnel against occupational hazards.
7. Recommendation - The U.S. Government must do a better job of preparing for anticipatable emergencies. By their nature, CBRN attacks are unpredictable. But some scenarios can be anticipated and it is incumbent upon the U.S. Government to plan for them. Such scenarios include the potential exposure of children to anthrax spores; therefore, the U.S. Government should undertake clinical trials to determine the appropriate pediatric dose of anthrax vaccine. Similarly, several other MCMs should be assessed for pediatric dosing. For CBRN incidents that arise before an MCM is licensed, that MCM may need to be administered under EUA status. Rather than wait until a CBRN incident occurs to assemble the scientific data needed by the FDA to issue an EUA, the U.S. Government should draft more mockup pre-EUA dossiers and data sets for the unlicensed/unapproved MCMs most likely to be needed. These preparatory activities would help establish the proper size of an MCM market and speed up distribution activities. Not to prepare in these ways runs the risk of wasting time and lives in the event of a CBRN attack.
8. Recommendation - Various departments, agencies, and entities of the U.S. Government must act in concert to ensure success. The progression of candidate MCM products from basic research through advanced development to stockpiling and distribution must be as integrated and seamless as possible. Target profiles for needed MCMs should be developed early in the development process, to avoid repeating early development steps and to streamline the progress of candidate products. FDA should enhance its processes for providing guidance to industry. The Integrated Portfolio approach recently adopted by HHS and DoD is promising, but will need sustained effort to make this concept a reality. HHS and DoD must communicate sufficiently to support both their common interests and their unique requirements.

March, 26 2010: Where are the Countermeasures? Protecting America's Health from CBRN Threats – A Report of the National Biodefense Science Board

The NBSB voted to send the report with recommendations developed by the NBSB's Medical Countermeasures Working Group to the Secretary developed following a review of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) requested by the Assistant Secretary for Preparedness and Response in a letter dated January 26, 2010. A summary of the recommendations follow, note the * designates recommendations the Board considers pivotal (5, 8, 11, 15, 19):

1. The Secretary of HHS, in coordination with Secretaries of Defense and Homeland Security, confers and coordinates with the White House on how best to protect America from CBRN threats, including the merits of establishing a position on the National Security Council (NSC) to lead the relevant National Strategy.
2. The Secretary of HHS, in coordination with Secretaries of Defense and Homeland Security, coordinates with the White House on a unifying end-to-end National Strategy to address intentional, natural, and emerging CBRN threats.
3. The Secretary of HHS promptly identifies at least 3 high-priority new MCMs that the department will develop to counter CBRN threats, with target timelines. At least 1 of these MCMs should address radiation exposure.
4. The Secretary of HHS promptly coordinates with the Secretaries of Defense and DHS to develop prioritized lists of CBRN threats of both natural and intentional origin, to guide further prioritization of MCM efforts.
5. *The Secretary of HHS empowers the ASPR as the operational MCM leader, with authority to synchronize the efforts of HHS agencies and with end-to end oversight.
6. The Secretary of HHS tasks the ASPR to refine the HHS acquisition structure and metrics, to provide accountability for the MCM program.
7. The Secretary of HHS designates the Director of the Biomedical Advanced Research and Development Authority (BARDA) as the MCM Portfolio Director, to coordinate technical aspects of balancing the HHS MCM portfolio.
8. *The Secretary of HHS promptly tasks senior HHS leaders to develop a common set of prioritized research goals, prioritized product requirements, and prioritized dispensing goals for civilian populations, and coordinates these priorities with DoD.
9. The Secretary of HHS, in consultation with the Secretary of DHS, develops a plan to overcome existing obstacles that preclude timely distribution and administration of MCMs to people in need (including children and those with limited functional ability).
10. The Secretary of HHS promptly determines the coordinated budget requirements for Fiscal Year (FY) 2011 relevant to CBRN MCM budget lines within the National Institutes of Health (NIH), the National Institute of Allergy and Infectious Diseases (NIAID), BARDA, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and ASPR (and in conjunction with DoD), and communicates requests for revision of the President's Budget to the Office of Management and Budget. The Secretary gives special attention to FDA resource needs.
11. *For FY2012 and beyond, the Secretary of HHS develops a coordinated budget request relevant to CBRN MCM budget lines within NIH, NIAID, BARDA, CDC, FDA, and ASPR (and in conjunction with DoD).
12. The Secretary of HHS develops a legislative plan to seek multiyear funding authority for CBRN MCM efforts.
13. The Secretary of HHS develops a legislative plan to seek appropriate modification and reauthorization of the Project BioShield Special Reserve Fund, before its expiration in 2013.

14. The ASPR promptly provides a plan to the Secretary of HHS to provide for centralized advanced development and manufacturing of selected biological MCMs, based on one or more public-private partnerships (PPPs) or federally funded research-and-development centers (FFRDCs).
15. *The FDA Commissioner promptly provides a plan to the Secretary of HHS for designating appropriate candidate MCMs for high-priority review, with the appropriate criteria of evidence for safety and efficacy.
16. The FDA Commissioner promptly advises the Secretary of HHS on a plan to revise the draft guidance on the ‘‘animal rule.’’
17. The CDC, BARDA, and NIAID Directors develop a plan for the ASPR for identifying and addressing the need for screening and diagnostic tests for CBRN agents that can be performed in clinical settings, prioritized among other MCM needs.
18. The ASPR, in coordination with leaders of other relevant agencies:
    a. Identifies to the Secretary of HHS needs for additional pediatric products for the Strategic National Stockpile (SNS).
    b. Provides to the Secretary of HHS a plan to determine pediatric dosages for at least 3 MCMs.
    c. Identifies to the Secretary of HHS a plan to create and maintain pre-Emergency Use Authorization (EUA) dossiers for the top 20 MCMs, in coordination with DoD.
    d. Provides to the Secretary of HHS a plan for drafting 3 concepts of operations for managing to write integrated response plans for 3 high-priority threat scenarios, to describe response from alert to MCM dispensing.
    e. Provides to the Secretary of HHS an evaluation of state-level MCM distribution plans to assess adequacy in caring for children and for individuals with functional limitations, and a plan to resolve common problems identified.
19. *The NIH Director and NIAID Director provide the Secretary of HHS a plan on how to align NIH resources for MCMs to the national prioritized lists of research goals and product requirements.
20. The Secretary of HHS (working with NIH, NIAID, BARDA, and DoD) develops a plan to rationally allocate limited animal resources and facilities to CBRN animal-model development and testing in alignment with the national prioritized list of research goals.
21. The Secretary of HHS develops a plan to fund the Countermeasures Injury Compensation Program for all covered countermeasures, and to extend the filing deadline to a consistent 3-year interval.
22. The ASPR provides to the Secretary of HHS a plan to release more information on CBRN consequences to the public, as part of a sustained multifaceted education and communication plan.
23. The ASPR provides to the Secretary of HHS a plan to make information about MCMs available to the public before and during emergencies in appropriate, accessible, and alternative formats.

September 22, 2010: Integration of Mental and Behavioral Health in Federal Disaster Preparedness, Response, and Recovery: Assessment and Recommendations

The NBSB’s Disaster Mental Health Subcommittee prepared a report (1) assessing the Department’s progress to better integrate behavioral health into emergency preparedness and response activities, and (2) topics consistent with the expertise of the NBSB members and those

believed to be relevant to the public health of the American people. Following discussion by members of the Board and the public, the NBSB voted to adopt the report and transmit the report and the five recommendations to the Secretary:

1. Recommendation - Task the U.S. Department of Health and Human Services (HHS) leadership with fully implementing the eight recommendations approved by the NBSB in November 2008 to protect, preserve, and restore individual and community mental health
2. Recommendation - Issue a common Department policy regarding disaster mental and behavioral health that encompasses the strengths and activities of Federal Agencies, and also develop a strategy to implement that policy.
3. Recommendation - Empower an office or Agency to serve as the operational leader for disaster mental and behavioral health integration within HHS.
4. Recommendation - Task senior HHS leaders to develop a set of coordinated and prioritized research goals and ensure the necessary support to reach these goals for disaster mental and behavioral health.
5. Recommendation - Create and maintain a structure by which disaster mental and behavioral health experts regularly assess progress toward integration of disaster mental and behavioral health activities.

September 22, 2010: Future of the NBSB

The Board voted to send a letter to the Assistant Secretary for Preparedness and Response (ASPR) following discussion and public comment of the NBSB's Future of the NBSB Working Group findings prompted by a letter from the ASPR dated December 11, 2009. The letter contained the following statements:

The Board agreed with the Working Group's proposal to suggest the Board address issues in the following topic areas:

Suggested Short Term Priority Areas:

1. Address the unique characteristics of at-risk populations and how these characteristics impact preparedness and emergency responses.
2. Enhancing community resilience.
3. Enhancing the use of e-health technologies for preparedness and response.
4. Improving FDA engagement with the public and private sectors on regulatory science and decision theory.

Suggested Long Term Priority Areas:

1. Provide advice on the development of the health security workforce.
2. Provide advice on the National Health Security Strategy, for example, the Biennial Implementation Plan.
3. Provide advice on both past and future performances of NDMS, and how this board can best fulfill its mission.
4. Provide advice on the inclusion of emerging infectious diseases in biodefense and health security planning
5. Address the prioritization of MCM strategic planning and requirements.
6. Assess the adequacy and integration of distribution and dispensing plans.

Next, the Working Group analyzed the existing NBSB Working Groups, discussed the membership and expertise of each member, evaluated whether the tasks and responsibilities of

each WG remain appropriate, and what, if any new tasks should be undertaken. The Board agreed with the following conclusions:

1. The current collection of NBSB Working Groups satisfies the overarching mission of the Board. We do propose changing the name of the NBSB Personal Preparedness Working Group to the Personal and Community Resilience Working Group, which addresses your request to further emphasize issues related to resilience.
2. The current expertise of the Board is sufficient. When requested, the Board is able to effectively reach out, gaining additional knowledge and expertise related to specific topics.
3. The current approach to forming and completing Working Group assignments (webinars, preparatory calls, face-to-face/teleconference meetings, etc) is successful.

In reference to the interaction of the Disaster Mental Health (DMH) Subcommittee with the NBSB, the Working Group appreciates the work the DMH Subcommittee has accomplished thus far, and is looking forward to the Subcommittee's assessment on the Department's progress to better integrate behavioral health into emergency preparedness and response activities in September. The Board would like to continue to discuss how best to further the interaction and integration of the Subcommittee with the NBSB.

In addition to the four topics the ASPR requested direct feedback on, the Future of the NBSB WG made the following suggestions and several options for potential re-nomination of current NBSB members, and the Chair position, to ensure the continued effectiveness of the Board.

1. Re-nomination/re-appointment consistent with the current NBSB Charter; almost all of the members with 2010 expiring terms have expressed interest in reappointment.
2. Propose amending the current Charter to include the staggering of current members for efficient continuity of the Board's activities. Current members rotating off would have the option for re-appointment for one or two years; with no more than three to four members rotating off in each year. This would allow for transition of only one-third or one-fourth of the members each year, rather than half in some years.
3. New members receive three-year terms, with transition of one-third each year.
4. Chair position
5. Chair should be a current NBSB member whom has served for at least one year;
6. Establishment of a vice-chair position with potential ascendance to chair.

April 28, 2011: Call to Action: Include Scientific Investigations as an Integral Component of Disaster Planning and Response. A Report from the National Biodefense Science Board

NBSB's All Hazards Science Response Working Group presented their report with recommendations to the Board for discussion and public comment. The NBSB finds that during emergencies, scientific investigations and associated pre-planning for scientific work must be a fully integrated part of the framework for disaster planning and response. In its report, the NBSB accordingly offers 10 recommendations to improve the Nation's ability to mount a comprehensive and rapid mobilization of its scientific resources in the investigative response to disasters that threaten public health.

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

2. Add a "Scientific Response Support Annex" to the National Response Framework (NRF), and amend the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) to include a scientific response.
3. Establish with leadership and staff from the Office of the ASPR an Interdepartmental Center for Scientific Investigations During Disaster Response (the Center); the Center will have a dedicated staff, and its primary mission will be to anticipate, plan for, coordinate, facilitate, and evaluate scientific investigations conducted before, during and after disasters.

The new Center would have full-time staff and additional liaison staff appointed as needed, and would have primary responsibility for the successful implementation of Recommendations 4 thru 10 of this report (which are in no particular order of priority).

4. Develop the concepts, doctrine, infrastructure, and personnel needed to begin scientific investigation and data collection rapidly in various types of incidents.
5. Integrate the Public Health Emergency Research Review Board (PHERRB) into standard operating procedures for review of research before, during, and after a disaster response.
6. Appoint a liaison within the Center to the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) to facilitate review of scientific protocols required by the Paperwork Reduction Act (PRA). There should also be an independent review of the benefit versus the net loss of the effect of the PRA on a timely, emergent, scientific response with consideration of possible approaches for remediation.
7. Establish funding mechanisms to support a rapid and robust scientific response to disasters.
8. Integrate individuals and communities affected *by* a disaster as full partners in scientific investigations related *to* the disaster.
9. Standardize approaches to data collection and sharing by Federal, State and local response organizations (and encourage the same among private and volunteer organizations), giving special attention to collection of baseline data.
10. Identify, acquire or develop, deploy, and maintain new information technology for collecting data in the field.

October 28, 2011: Challenges in the Use of Anthrax Vaccine Adsorbed (AVA) in the Pediatric Population as a Component of Post-Exposure Prophylaxis (PEP). A Report from the National Biodefense Science Board

NBSB's Anthrax Vaccine Working Group presented, by teleconference, their report with recommendation to the Board for discussion and public comment. The report describes the challenges of administering AVA to children before versus after an attack with *B. anthracis* spores. The report also includes background information, responses to four questions posed by Dr. Lurie in her April 2011 letter to the NBSB, two options for HHS consideration, and a recommendation. The NBSB debated how best to obtain scientifically valid safety and immunogenicity data about AVA PEP for children. The NBSB concluded that it would be in the best interests of children, their parents, and the United States Government to attempt to gather the safety and immunogenicity data about AVA PEP in children prior to an anthrax event, rather than to wait for a future crisis to attempt to gather that information. This issue should be referred to an appropriate review board to formally address the ethical considerations. This board should include ethicists and public representation. If the ethical considerations are adequately

addressed, HHS should develop a plan for and conduct a pre-event study of AVA in children to include a research Investigational New Drug application. HHS should submit the study protocol to one or more IRBs, and comply with the 21 CFR 50.54/45 CFR 46.407 federal review process.