NBSB NATIONAL BIODEFENSE SCIENCE BOARD

TUESDAY, APRIL 2, 2013

PUBLIC MEETING SUMMARY

Building 19, Room 117

Roybal Campus, Tom Harkin Global Communication Center

1600 Clifton Road, NE

Atlanta, GA

CALL TO ORDER, ROLL CALL, AND CONFLICT OF INTEREST RULES

Charlotte Spires, DVM, MPH, DACVPM

Executive Director, NBSB, CAPT, U.S. Public Health Service, U.S. Department of Health and Human Services (HHS)

CAPT Charlotte Spires called the meeting to order, provided an overview of the Federal Advisory Committee Act (FACA), reviewed the conflict of interest rules, and gave instructions to members participating by phone. Roll call was then taken.

The following NBSB members were present:

NBSB Voting Members:

- John Parker
- Georges Benjamin
- John Bradley
- Jane Delgado, *by phone*
- David Ecker, *by phone*
- Emilio Emini
- Daniel Fagbuyi
- Manohar Furtado
- Kevin Jarrell
- Steven Krug, *by phone*
- Sarah Park
- Betty Pfefferbaum, *by phone*

Ex-Officio Members:

George Korch, *by phone*

Designated Alternates:

- Carmen Maher (FDA) – designated alternate for Luciana Borio, *by phone*
- Rick Martinello (VA) – designated alternate for Victoria Davis, *by phone*
- Bonnie Richter (DOE) – designated alternate for Patricia Worthington
- Mark Shepanek (NASA) – designated alternate for Richard Williams
- Robert Sorenson (Dept. of State) – designated alternate for Kerri-Ann Ann Jones

Members were asked to identify any conflicts of interest. No conflicts of interest were identified.

WELCOME AND AGENDA OVERVIEW

John S. Parker, MD
Major General (Retired), Chair, NBSB

Dr. John Parker opened the meeting by greeting all in attendance. Dr. Parker read a letter received from Kathleen Sebelius, U.S. Secretary of Health and Human Services (HHS), dated March 4, 2013, thanking the members of the NBSB for their review of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan (SIP). He then provided an overview of the day's agenda (April 2, 2013, agenda available at the end of this summary).

PRESENTATION OF RECOMMENDATIONS: NBSB PUBLIC HEALTH AND HEALTHCARE SITUATIONAL AWARENESS (SA) STRATEGY AND IMPLEMENTATION PLAN (SIP) WORKING GROUP (WG)

Sarah Park, MD, FAAP
SA SIP WG Chair
Manohar Furtado, PhD
SA SIP WG Co-Chair

The NBSB was tasked with review and evaluation of a draft U.S. Department of Health and Human Services (HHS) Public Health and Healthcare Situational Awareness (SA) Strategy and Implementation Plan (SIP) during its development phase. As part of their task, the NBSB was asked to offer guidance and recommendations on the measurable steps to take to enhance the nation's current public health and healthcare SA capabilities. They were also asked to assess current biosurveillance activities, identify efficiencies, and make recommendations in coordination with applicable existing Centers for Disease Control and Prevention (CDC) advisory committees. (See attachments for WG membership and summary of recommendations presented by Drs. Park and Furtado).

NBSB DISCUSSION, Q AND A[1]

Dr. John Parker thanked Drs. Sarah Park and Manohar Furtado for their presentation and opened up the floor for discussion by the board members. There were a few clarifying questions posed to the presenters. Below is a summary of the feedback provided by members in attendance:

- Fusion Centers play a critical role in SA and should be further highlighted and explained.
- Situation awareness is fluid not static. Experts have to validate data at a local level on a regular and continuous basis to examine and anticipate what could happen next.

Dr. Parker made one last call for board member comments and then called for any ex-officio comments by phone, and public comments by email. There being no more comments, Dr. Parker closed the floor for discussion.

Dr. Parker thanked Drs. Park and Furtado for presenting their report to the board, and explained that this task is a portion of a two-part mandate.

[1] This section includes some, not all, of the discussions that took place at the April 2, 2013, NBSB public meeting.

NBSB VOTE ON SA SIP WG RECOMMENDATIONS
John S. Parker, MD
Major General (Retired), Chair, NBSB

Dr. Parker called for the Board's vote on the report from the SA SIP WG, and the report was unanimously approved.

Dr. Parker introduced the next speaker on the agenda, Dr. DiEuliis. Several years ago, several environmental incidents occurred – the biggest one being the oil spill in Gulf of Mexico. To respond to a disaster in real time, response teams have to learn as fast as the events are evolving. The Assistant Secretary for Preparedness and Response (ASPR), Dr. Lurie, had the idea of having people with extraordinary expertise available to come on board during an event and conduct the necessary sciences to help mitigate the circumstances. In 2010, she asked the Board to examine this concept. The NBSB developed a report to the Secretary and ASPR highly recommending that all hazards science be an important part of any preparedness and response initiative.

ALL HAZARDS SCIENCE (BY PHONE)
Diane DiEuliis, PhD
Deputy Director, Office of Policy and Planning (OPP)/ASPR

Dr. DiEuliis articulated Dr. Lurie's vision for ASPR to lead and coordinate a "Science Preparedness and Response" initiative, and in building a framework for emergency response research.

Research that happens prior to, during, and following an emergency is critical to future capacity to better prevent injury, illness, disability, and death, while supporting recovery. The NBSB report noted, "Each disaster constitutes a critical opportunity in what may be a brief window of time to conduct scientific research that could lead to improved assistance to those affected by the event, and improve capabilities for responding to future disasters." Having critical infrastructure and capabilities in place is crucial to rapid and effective response.

Several questions were posed at an all-day workshop for Federal agencies with programs in this area. The following questions were posed to the attendees:

- How do we identify scientific priorities during crises?
- What is different about doing science during crises?
- How might modeling and forecasting inform scientific priorities?
- What data should be collected, who will utilize it, and when?
- What areas of research?
    - Basic research on underlying disease mechanisms of the disaster
    - Clinical Research to better inform diagnosis and treatment
    - Social science to understand impacts on behavior
    - Operations research to improve response
    - Healthcare systems level research

It was agreed that there were some features that should be included in an initiative. It should broadly include any event with major health consequences and will likely require coordination of efforts or resources across agencies and departments. It should address important unanswered questions on health impacts that would improve future response/recovery. Moreover, many events with research response may not require a creation of a new paradigm; existing offices or

resources may be capable of meeting requirements for many events, like an outbreak investigation. This initiative is not meant to supplant currently successful science response capabilities, but rather leverage all to greater benefit.

Outside of the science research itself, there are many policy challenges in terms of how to conduct science during a response. Below are the questions to be answered around policy:

- How do we perform human clinical research rapidly while maintaining safety, ethics, and privacy?
- How do we prepare rapidly implementable protocols, surveys, etc. in advance of events?
- How can we rapidly fund science that needs to be done?
- Who will do it?
- How do we achieve overall coordination of a "science response," within the Federal Government, across levels of government, and with the academic- and business- based scientific community?

In September 2012, ASPR sponsored a workshop that was intended to be the first step to coordinating the federal interagency, which will look at all of the questions. A summarized report from that workshop is on the ASPR website. Dr. Lurie also wrote a recent article in the New England Journal of Medicine (NEJM) (http://www.nejm.org/doi/full/10.1056/NEJMsb1209510). It features many of the questions discussed during the workshop and offers insights and recommendations, as does the workshop report itself.

Shortly after the workshop, the northeast coast was hit by Hurricane Sandy. At that time, ASPR and other agencies received requests from the community regarding research proposals; ASPR worked with the New York Academy of Medicine and the Institute of Medicine (NYAM/IOM) to sponsor a meeting. The meeting was held in New York within a few weeks of Sandy to identify research priorities that could be important for recovery. There is a summary of the workshop on the NYAM's website (http://www.nyam.org/news/nyam-news/2013-03-06-1.html). Attendees agreed on a set of research priority questions that, in the event funds were available, should be researched during Sandy recovery.

After the meeting, ASPR submitted a request for supplemental funds to do research in the recovery portion of Sandy, which is ongoing. ASPR received $8.6 million for this effort. The bulk of the funding ($7.6 million) will go towards research grants focused on resilience during recovery, questions about social media and how it is being used in recovery, identifying mental health outcomes, evaluation decision-making, and a few other areas. CDC was awarded an equal amount of money to provide grants on similar topics. The remaining $1 million is to be set aside for the creation of a research dataset. ASPR is hoping to release some information very quickly to the community and to ask some of the identified questions.

Dr. DiEuliis also went over some of the progress made in implementing the NBSB's prior recommendations. One of the recommendations was to establish a "center" for Science Preparedness and Response. That center now exists in the Office of Policy and Planning (OPP) at ASPR. It has not been codified, but steps are being taken to develop an interagency framework for coordination of science research response.

Another recommendation was to create a Public Health Emergency Research Review Board, commonly referred to as the PHERRB. It was agreed that NIH should sponsor the PHERRB, which will draw on expertise from sixteen intramural Institutional Review Boards (IRB) for varied events. There has been no need to draw on the expertise as of yet; however, it has been

highlighted in the funding announcement that if a national level Institutional Review Board (IRB) is needed, National Institutes of Health (NIH) would be standing by to provide it.

In addition, there was a recommendation to standardize approaches to data collection, giving special attention to collection of baseline data. Developing a dataset per the Sandy Supplement will initially use existing datasets already collected, but ASPR envisions the research community's contributions in future. They will be engaging Office of Information and Regulatory Affairs (OIRA), and other interagency partners to understand what is available for use.

ASPR is also working with OIRA to facilitate scientific protocols, particularly surveys. The National Institute of Environmental Health Sciences (NIEHS) at NIH has agreed to work on standardized exposure surveys that could be rapidly approved in disaster events.

Next steps are to utilize the $8.6 million for research – as a pilot effort that can inform future efforts, infrastructure, organization, etc. ASPR will also continue to work on developing the interagency framework. In this effort, they will identify means to convene NYAM-type meetings rapidly in the aftermath of events to quickly identify research priorities and continue to explore frameworks for rapid funding.

Dr. DiEuliis also acknowledged Dr. Jessica Tucker, who could not be present for today's meeting but has been a driving force for all the work conducted.

DISCUSSION, Q AND A[2]

Clarifying questions asked of Dr. DiEuliis were answered. The responses are listed below:

- Public Health Emergency Research Review Board (PHERRB) Applications: To take Superstorm Sandy as an example, there is opportunity to do both pre-event planning – because one might anticipate the sorts of thing that would cause infectious diseases in the population of a large city – and then review post-event opportunities, controlling the needs with a placebo-controlled or a comparative-controlled study, respectively. The PHERRB is a very critical component to this. If, for instance, one thinks that a plague might cause an outbreak in New York City, reporting could begin to look at the effectiveness of certain antibiotics in a plague-exposed cohort of people, including children. Then one could put together a quick study. Hopefully, the study could be coordinated before an event to have the PHERRB approve very quickly, in a matter of 24, 48, or 72 hours. A protocol that would supersede the local IRBs would be critical, and perhaps there could be a plague vaccine that could be distributed in this event too. Obviously, in an emergency situation, you would not be able to have all the local IRBs meet to give consent to the PHERRB. The PHERRB would have to take precedent, so that the PHERRB rulings would be accepted by everyone.
- Displaced People: In disasters like Hurricane Katrina, people are displaced. Research was conducted during that event, but after the event people could not be found for follow-up regarding long-term health consequences. There was a concern of whether this has been addressed. Dr. DiEuliis commented that there were steps being taken to address tracking issues and agencies responsible for that work but would also consult the Recovery Office to get more details.

[2] This section includes some, not all, of the discussions that took place at the April 2, 2013, NBSB public meeting.

- Evidence-Based Science: There are many great plans, great ideas, but a lot of these are not based on evidence. Also, the federal IRB will be a tremendous resource, particularly for entities that do not have an IRB process. Moreover, there will need to be pre-work conducted to have institutions relinquish control of their IRBs in the midst of a public health emergency to a federally approved process or protocol.
- Enhancing Existing Capabilities: Any efforts that can be undertaken to understand a particular population or anticipated disaster type will help expedite response processes. Modifying existing processes like electronic data, electronic medical records, or handwritten records is already difficult on a day-to-day routine. Trying to do that during a disaster response will only be harder. We are beginning to anticipate what will be needed for a disaster response and the disaster's effects on existing processes by obtaining the data elements available and securing the right input. Also, work with other entities that are doing similar functions. Consider reaching out to existing networks, like the Critical Care Network, Oncology Research Networks, Emergency Care Research Networks, etc, to support the process of data collection in the case of a disaster.

Dr. DiEuliis responded that a network of clinical centers across NIH to do research would be leveraged for data collection during an emergency. There are several institutes at NIH that conduct emergency research. NIH has also recently created a virtual institute that brings together all research portfolios; there may be opportunities to build clinical standards for data collection in their research paradigms. ASPR has also funded a contract to explore standard baseline elements in different scenarios that can be adapted. Scenarios include nuclear exposure, influenza pandemic, etc. The contract was awarded to Massachusetts General Hospital. A team is putting together baseline data elements for consideration, and the results of those efforts will be communicated to the NIH institutes mentioned for utilization.

- There's an opportunity to take work that has already been conducted around data collection in pediatrics and tweak it further to be applied to public health emergencies versus its current day-to-day critical illness usage.
- There should be a legal review on community consent, community consent with interdiction, community consent on gathering data, and community consent on minimal-risk and advance-risk protocols. This is vital during an emergency response, such as administering a vaccine in the midst of a pandemic.

Dr. DiEuliis was thanked for her presentation.

HHS ADOPTION OF NBSB REPORTS FROM THE DISASTER MENTAL HEALTH (DMH) SUBCOMMITTEE
Daniel Dodgen, PhD
Director, Division for At-Risk Individuals, Behavioral Health and Community Resilience (ABC)
OPP/ASPR

The NBSB Disaster Mental Health (DMH) Subcommittee was established under the Authority of Homeland Security Presidential Directive (HSPD)-21, "Public Health and Medical Preparedness" and signed by the President, on October 18, 2007. In June 2008, the NBSB convened the DMH Subcommittee.

In September 2010, the DMH Subcommittee's first set of recommendations were approved by the NBSB and presented to the HHS Secretary. The report and recommendations focused on four key topic areas:

- Framework Issue 1: Integration of Mental and Behavioral Health into Public Health and Medical Preparedness and Response Activities
- Framework Issue 2: Research Agenda
- Framework Issue 3: Training in Disaster Mental and Behavioral Health
- Framework Issue 4: Communications Strategy

In response to Framework Issue 1, several activities by HHS have occurred. The HHS Disaster Behavioral Health Concepts of Operation (CONOPS) was developed and approved on December 2011. Implementation is ongoing. The Federal Disaster Behavioral Health Group (FDBHG) is convened during all Emergency Support Function (ESF) 8 responses to ensure and enhance departmental and partner collaboration, information sharing, and coordination of mental and behavioral health issues and activities. ASPR's Division of At-Risk Individuals, Behavioral Health and Community Resilience (ABC) National Disaster Medical System (NDMS) leadership, and mental health responders developed additional protocols and job aides for inclusion in all-hazards operations documents detailing the role of behavioral health liaison officers for response command staff, as well as the role of behavioral health liaison staff to the Emergency Management Group (EMG). Also developed were protocols for behavioral health force protection of HHS responders to be implemented by NDMS and the Office of Force Readiness and Deployment (OFRD). Furthermore, HHS facilitated the deployment of a behavioral health safety officer during the Sandy Hook school shooting for responder behavioral health force health protection.

ASPR has been convening quarterly Behavioral Health and Community Resilience Preparedness Forums since April 2012 and has conducted stakeholder/subject matter expert interviews on preparedness best practices and gaps to inform priorities and future activities including content recommendations for an invitational Community Resilience Listening Session to be held in May 2013. HHS has also developed a planning guidance on Psychiatric Patient Movement for regional, state, and local planners. ASPR's ABC Division served as the primary point of contact for the ASPR Disaster Leadership Group (DLG) in response to the Deepwater Horizon Oil Spill. The Division provided subject matter expertise, recommendations, and guidance to policy makers on addressing the behavioral health needs of those affected. ABC provided a behavioral health liaison officer for the Secretary's Operation Center (SOC) during Superstorm Sandy and the Sandy Hook school shooting to ensure that behavioral health was an integrated aspect of the disaster and emergency response.

To address training in disaster mental and behavioral Health, ASPR and NDMS leadership created and implemented a plan to make Psychological First Aid exposure training available to

all NDMS responders. To date, greater than 2000 individuals have been trained. In collaboration with National Association of City and County Health Officials (NACCHO), HHS is conducting training for ASPR supervisory level staff on application of PFA principles to leadership. NIEHS is developing a worker resilience-training curriculum through a funding opportunity provided by the Substance Abuse and Mental Health Services Administration (SAMHSA) and with ASPR and The National Institute for Occupational Safety and Health (NIOSH) collaboration and participation. ASPR ABC and NDMS leadership are developing core competencies and training standards for behavioral health force protection for HHS responders deployed through ASPR. ASPR is promoting Facebook applications, like bReddi and the Lifeline Project, to promote connectedness and educate the public about preparedness, resilience, and recovery strategies.

SAMHSA, CDC, and ASPR continue to develop fact sheets, guidance documents, web-enabled training, information and blog posts, and webinars to promote and enhance behavioral health preparedness, response, and recovery.

OVERVIEW OF COMMUNITY RESILIENCE ISSUES

Daniel Dodgen, PhD
Director, Division for At-Risk Individuals, Behavioral Health and Community Resilience (ABC)
OPP/ASPR

Dr. Dodgen's second presentation addressed resilience in national policy and plans, such as the National Health Security Strategy of the United States of America 2009 (NHSS), the National Preparedness Goal First Edition, September 2011, the Public Health Capabilities, and grant alignment in the Public Health Emergency Preparedness (PHEP) cooperative agreement, and Hospital Preparedness Plan (HPP).

The meaning of resilience varies depending on the sector in which it is being defined. For example, in physics, it is the capability of a material to return to equilibrium after a displacement. In psychology, resilience is an individual's tendency to cope with stress and adversity. Community resilience includes a broad, complex, and inter-related set of factors that may predict and build resilience.

Resilience is a multi-sector endeavor. No sector alone is sufficient to support resilience. Connecting sectors, such as physical, health, ecological, organizational, psychological, economic, and social is central to building resilience.

Community Resilience is one of two goals of the NHSS and is defined as the sustained ability of communities to withstand and recover, in both the short and long term, from adversity. The NHSS instructs us to "refocus the patchwork of public health and medical preparedness, response, and recovery strategies in order to ensure that the nation is prepared for, protected from, and resilient in the face of health threats or incidents with potentially negative health consequences".

Community Health Resilience is a subset of overall resilience that helps to focus on the variables that health and social services can best influence. The pre-event status of health and social services in a community can predict resilience. It involves human resilience and infrastructure resilience. Moreover, social connectedness has the potential to reinforce resilience significantly. Public health, health care, and social services are deeply interwoven with other sectors, and in most communities are important nodes of social connectedness and community infrastructure; infrastructure resilience includes healthcare system and public health infrastructure.

To address resilience, CDC has developed the Composite of Post-Event Well-being (CoPE-WELL) Initiative; it is intended as a predictor of pre- and post-event functioning and well-being. Resilience is conceptualized as a latent variable that mediates post-event functioning. CoPE-WELL is working to develop a model of community resilience and post-event functioning at the population level through composite indices or use of proxy measures. It requires identifying data regularly collected at the national, state, and local levels that could compose a viable index. The composite will be computed at the county level for all U.S. counties. The Initiative will be housed at Johns Hopkins Bloomberg School of Public Health.

Strategically promoting resilience is more than just doing sector-specific jobs well. It includes health promotion and is concerned with improving the underlying health of communities and strength of service systems. It looks ahead to improve recovery and aims to improve resilience for future events through mitigation and preparedness. ASPR's efforts bring together policy, science, and emergency operations.

NBSB DISCUSSION, Q AND A[3]

Below is a summary of clarifications provided by Dr. Dodgen, including comments from the Board:
Dr. Dodgen stated that a number of programs are beginning to be implemented related to mental health and disasters. Ensuring local health department inclusion is very much a part of the work. He said he would be meeting soon with an ASPR disaster preparedness advisory group to talk about continued integration of children into disaster preparedness programs. Dr. Dodgen solicited the group's thoughts on possible partners at the local level. He also asked for board members that could provide input to participate in an upcoming meeting between NACCHO and ASPR and provide an update on what individuals are doing at the local level.

- At the local level, Dr. Fagbuyi serves on the committee working with RAND on pediatric issues, which ensures that the pediatric community's voice is being heard regarding children and resilience.
- Hearing that the local level involvement and partnerships may be lacking is concerning. This leads to issues around redundancy, with people unaware that they are working on similar topics in parallel. At Sandy Hook, the media highlighted the strain on local law enforcement, but what was not highlighted was the trauma to the community's mental health. So there is convergence between some hospital preparedness experts at the local, state, and federal at HHS, ASPR, and CDC. Resilience is one of the measures that state and local health departments must achieve, and a lot of active national work is taking place. There are many opportunities for engagement at the national, state, local, and jurisdictional level.

Dr. Dodgen provided some further clarity on ASPR's work in this area and reinforced that ASPR welcomes input on areas that may require more attention and the promising practices and great work being done by state and local partners.

- Dr. Kaplowitz expressed an interest in helping to facilitate the work that is already happening at the state and local levels. She challenged members of the Board, who are with or work with local and state health departments, to think about work that could be done in the policy arena to assist with this facilitation, streamline processes, and minimize redundant efforts.

[3] This section includes some, not all, of the discussions that took place at the April 2, 2013, NBSB public meeting.

PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES REPORT ON MEDICAL COUNTERMEASURES FOR CHILDREN (BY PHONE)

Lisa M. Lee, PhD, MS

Executive Director, Presidential Commission for the Study of Bioethical Issues (PCSBI)

Dr. Lee presented on the recent report from the PCSBI, titled, "Safeguarding Children: Pediatric Medical Countermeasure Research," released on March 19, 2013.

Dr. Lee provided a timeline of events related to the Bioethics Commissions' study of medical countermeasures (MCMs) research with children. In early 2011, the U.S. government conducted a preparedness exercise, which simulated an anthrax attack on a U.S. city, about the size of San Francisco. After the exercise, it was estimated that eight million people would be affected, including nearly two million children. The current plan is to provide antibiotics and Anthrax Vaccine Adsorbed (AVA) in the event of an emergency. There are no data about pediatric use of AVA.

In October 2011, the NBSB recommended that the U.S. government conduct pre-event clinical studies to gain safety and immunogenicity data on the pediatric use of AVA, following a full ethical review. In January 2012, the Bioethics Commission received a request from HHS Secretary Sebelius for a thorough review of the ethical considerations of conducting clinical trials of MCMs with children. She also requested the inclusion of ethical considerations in the specific case of conducting a pre- and post-event study of AVA post exposure prophylaxis (PEP) with children.

The government has the duty to protect children from undue research risk as well as the duty to protect children by being prepared for an attack to the extent that it is possible. Research with children is unique because children are legally and ethically unable to consent. They cannot accept research risks on behalf of others. As a vulnerable population without the ability to consent, additional protections for children in research are vital.

Pre- and post-event pediatric MCM studies are ethically distinct. In a pre-event study, the children are healthy and there is no potential for direct benefit for participants. But in a post-event study, children have already been exposed, and there is the possibility for direct benefit or generalizeable knowledge.

Ethical considerations were grounded in several factors:

- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-1979)
    - *The Belmont Report*
    - *Research Involving Children*
- Four ethical principles: Respect for persons, beneficence, justice, democratic deliberation
- Current regulations for conducting pediatric research
    - Pediatric research subject to local IRB approval
    - Pediatric research requiring national review—higher risk without prospect of direct benefit (Section 407)
- Central tenet: Pediatric research should be allowed only when it poses minimal risk, unless:
    - There is the prospect of direct benefit to individual research participants, or
    - Generalizeable knowledge about research participants' condition will be produced

Dr. Lee then provided an overview of the Commission's recommendations.

There were several challenges identified with regard to pre-event research. In a pre-event situation, the attack has not occurred and no one is sick. The event has unknown likelihood of occurring, and the hope is to never need to use the results of the research. Four recommendations addressed pre-event pediatric MCM research.

- Recommendation 1 states that pre-event pediatric MCM research should pose no more than minimal risk except under extraordinary circumstances. Minimal-risk research is research that has no greater risk than that faced by a healthy child, in daily life, or during a routine medical examination. Excess risk is capped at a minor increase over minimal risk, with no substantial risk to health or well being.

- Recommendation 2 states that before beginning pre-event pediatric MCM studies, testing with younger adults must be completed to identify, understand, and characterize research risks. This would include completing all prior ethically sound testing, such as modeling, testing in animals, and testing in the youngest adults. Moreover, if pediatric research is to be conducted, progressive age de-escalation should be employed.

In the pre-event application to AVA, the Commission states that before the ethical pre-event pediatric AVA trials can be considered, further steps must be taken, which include additional minimal-risk research with adults, such as dose-sparing, safety, and immunogenicity studies.

Section 407 is an exception to the general rules, where research offers no prospect of direct benefit but a potential risk is greater than minimal. Under Section 407, the Secretary, after consultation with a panel of experts, must determine that the research presents a reasonable opportunity to address a serious problem, and will be conducted in accordance with sound ethical principles. Provisions are made for parental permission and meaningful child assent.

- Recommendation 3 states that if minimal risk study is impossible, pre-event pediatric MCM research should proceed to a national-level review only if it poses no more than a minor increase over minimal risk. There should be no substantial risk to health or well-being, and research posing greater risk should not be approved.

In its report, the Bioethics Commission specified Section 407's existing regulatory requirements in an ethical framework to guide such a national-level review.

- Recommendation 4 states that national-level reviewers should apply the Bioethics Commission's ethical framework to pre-event pediatric MCM research that poses greater than minimal risk, but no more than a minor increase over minimal risk.

In the specific instance of a pre-event AVA study, if minimal risk research is impossible, a research proposal should proceed to a national-level review under Section 407 only where risk is capped at a minor increase over minimal risk. The Commission's specified ethical framework for the Section 407 review should be applied in such a national-level review.

Post-event studies might offer the prospect of direct benefit or yield generalizeable knowledge about the participants' condition, but there are scientific and logistical challenges in a post-event scenario.

- Recommendation 5 states that post-event pediatric MCM research should be planned in advance and conducted when untested or minimally tested MCMs are administered to children in an emergency.

- Recommendation 6 states that when there are no pediatric data on an MCM that will be provided to children in an emergency, it should be provided under a treatment investigational new drug application (IND) and studied concurrently under an investigator IND. This should include pre-IND consultation and approval, and rigorous pediatric research protections should be applied.

In the post-event application to AVA in the event of an anthrax attack, a treatment IND already exists and is held by Food and Drug Administration (FDA) and CDC, allowing for broad access to AVA for children. The FDA and CDC are collaborating on a nested protocol for research and surveillance to understand immunogenicity and reactogenicity to the vaccine. Both mechanisms require IRB approval and other research protections.

NBSB DISCUSSION, Q AND A[4]

Below is a summary of clarifications provided by Dr. Lee, including comments from the Board:

A question was posed to Dr. Lee about the ambiguity in defining minimal or greater than minimal risk, and how it was determined whether AVA was minimal risk or greater than minimal risk. Regarding minimal risk, Dr. Lee responded that the CDC has provided evidence around the safety of AVA. It would be possible to do an analysis of the vaccine that affects young adults. Data so far show that young adult vaccine reactions are quite similar to other adult vaccine reactions. Minimal risk is defined as risk similar to that found in daily life, but this does not mean risk-free. If evidence can be gathered that AVA research is minimal risk with the youngest adults, i.e., persons 18 years old, it might not be an enormous difference to say it is minimal risk with the oldest children, i.e., persons 17 years old. If risk can be characterized in the youngest adults, it might then be inferred to the next oldest age group. There are no barriers to doing minimal-risk research with children given that other aspects of the study are done ethically. Research can then continue backwards step-by-step and look at other ages so long as an inference of minimal risk can be made to progressively younger age groups.

A question on the potential adverse effects of vaccines was posed to Dr. Lee. She replied that children's reactions have the potential to be very different from adults, and it is unknown whether AVA given to a 5-year-old will have the same effect as when given to a 25-year-old. This is an area that might be explored through a process of careful age de-escalation. By looking at the youngest adult, the 18-year-old, could it be inferred that the adverse events would be the same for the 17-year-old? If it can, and once that research with 17-year-olds is completed, then the level of research risk with a 17-year-old might be inferred to the risk of research with a 16-year-old. The range where there would likely be uncertainty in inferring risk is in key developmental stages, from post-pubescent to pre-pubescent years for example. Scientists doing the research, other experts, and the IRBs have to make that determination. The thought is to proceed through age de-escalation through age groups that are close in range and infer minimal risk –not to proceed immediately to a wider range, like 1 to 18-year-olds.

[4] This section includes some, not all, of the discussions that took place at the April 2, 2013 NBSB meeting.

Dr. Parker concluded by saying both boards have done a tremendous job. There is a greater understanding of the challenges that lie ahead. There is opportunity for research, and the two boards have an obligation to make sure funding is available to do the research needed to protect the community as a whole.

He then thanked Dr. Lee for taking the time to provide her presentation.

PUBLIC COMMENT

Two comments were submitted by email from the public, which were very similar context. Comments were from Pauline Cantwell and Lisinka Ulatowska. They expressed that research involving children should not be done in any circumstance. They were very affronted that anyone would contemplate research involving children.

No other public comments were received.

AFTERNOON SESSION WRAP-UP AND CONCLUSIONS

John S. Parker, MD
Major General (Retired), Chair, NBSB

After thanking supportive staff for their work, Dr. Parker shared his perspective on the day's agenda. He expressed his satisfaction with the deliberations, and thanked the group for their hard work.

CONCLUSIONS AND ADJOURN

Charlotte Spires, DVM, MPH, DACVPM
Executive Director, NBSB

CAPT Spires echoed Dr. Parker's sentiments, and adjourned the meeting at 4:00 pm.

NBSB NATIONAL BIODEFENSE SCIENCE BOARD

Public Meeting Agenda
Tuesday, April 2, 2013
9:30 am – 4:00 pm
Centers for Disease Control and Prevention (CDC)
Building 19, Room 117
1600 Clifton Road, N.E., Roybal Campus, Atlanta, GA 30329
Call-in: 877-680-3342, Passcode: 7227330

9:30 am – 9:40 am	**Call to Order, Roll Call, and Conflict of Interest Rules** Charlotte Spires, DVM, MPH, DACVPM Executive Director, NBSB CAPT, U.S. Public Health Service U.S. Department of Health and Human Services **Welcome and Agenda Overview** John S. Parker, MD, Major General (Retired) Chair, NBSB
9:40 am – 10:00 am	**Presentation of Recommendations: NBSB Public Health and Healthcare Situational Awareness (SA) Strategy and Implementation Plan (SIP) Working Group (WG)** Sarah Park, MD, FAAP, WG Chair Manohar Furtado, PhD, WG Co-Chair
10:00 am – 10:30 am	**NBSB discussion, Q and A**
10:30 am – 10:45 am	**Public Comment**
10:45 am – 11:00 am	**NBSB Vote on SA SIP WG Recommendations** John S. Parker, MD, Major General (Retired) Chair, NBSB
11:00 am – 11:15 am	**15 minute BREAK**
11:15 am – 11:45 am	**All Hazards Science (*by phone*)** Diane DiEuliis, PhD Deputy Director, Office of Policy and Planning (OPP)/ASPR Jessica Tucker, PhD, Senior Adviser, OPP/ASPR
11:45 am – 12:00 pm	**NBSB discussion, Q and A**
12:00 pm – 1:00 pm	**LUNCH**

1:00 pm – 1:45 pm	**HHS Adoption of NBSB Reports from the Disaster Mental Health Subcommittee** Daniel Dodgen, PhD Director, Division for At-Risk Individuals, Behavioral Health and Community Resilience OPP/ASPR **Overview of Community Resilience Issues** Daniel Dodgen, PhD Director, Division for At-Risk Individuals, Behavioral Health and Community Resilience OPP/ASPR
1:45 pm – 2:00 pm	**NBSB discussion, Q and A**
2:00 pm – 2:30 pm	**Presidential Commission on the Study of Bioethical Issues Report on Medical Countermeasures for Children (*by phone*)** Lisa M. Lee, PhD, MS Executive Director, Presidential Commission for the Study of Bioethical Issues U.S. Department of Health and Human Services
2:30 pm – 3:00 pm	**NBSB discussion, Q and A**
3:00 pm – 3:15 pm	**15 minute BREAK**
3:15 pm – 3:30 pm	**Public Comment**
3:30 pm – 3:45 pm	**Afternoon Session Wrap-Up and Conclusions** John S. Parker, MD, Major General (Retired) Chair, NBSB
3:45 pm – 4:00 pm	**Conclusions and Adjourn** Charlotte Spires, DVM, MPH, DACVPM Executive Director, NBSB

4:00 pm – 5:00 pm **NBSB ADMINISTRATIVE MEETING**

DEPARTMENT OF HEALTH & HUMAN SERVICES **Office of the Secretary**

Office of the Assistant Secretary for
Preparedness & Response

National Biodefense Science Board
Washington, D.C. 20201

April 2, 2013

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Sebelius:

In a letter dated June 7, 2012, Dr. Nicole Lurie, Assistant Secretary for Preparedness and Response (ASPR), tasked the National Biodefense Science Board (NBSB) with review and evaluation of a draft U.S. Department of Health and Human Services (HHS) Public Health and Healthcare Situational Awareness (SA) Strategy and Implementation Plan (SIP) during its development phase. As part of their task, the NBSB was asked to offer guidance and recommendations on the measurable steps to take to enhance the nation's current public health and healthcare situational awareness capabilities. In response, the NBSB has developed a brief report including a succinct list of overarching concepts with high-level recommendations for HHS guidance during the development phase of the draft SA SIP.

The NBSB was also asked to assess current biosurveillance activities, identify efficiencies, and make recommendations in coordination with applicable existing Centers for Disease Control and Prevention (CDC) advisory committees. The NBSB looks forward to coordinating with the new CDC advisory committee on biosurveillance when it is formally stood up to fully and appropriately respond to this portion of their task.

In their report, the NBSB identified six overarching concepts that require particular emphasis and inclusion in the developed SA SIP:

1. Assurance of a common and unified strategy among all stakeholders involved in public health and healthcare situational awareness efforts, with the scopes of both public health and healthcare situational awareness to be explicitly defined.
2. Identification of the specific questions to be answered in support of both public health and healthcare situational awareness.
3. Recognition that the system for data coordination must integrate the expertise and experience from across all levels and sectors.
4. Bidirectional communication of government agencies with all stakeholders, public and private.
5. Caution in developing common technological systems for situational awareness and biosurveillance such that the valuable complexities of some existing systems are not reduced or lost.
6. Establishment of functional standards for data reporting to promote a common understanding of the target systems and capabilities.

The NBSB also strongly emphasized the need to designate an oversight authority to assure compatibility, consistency, continuity, coordination, and integration of all the disparate systems and data requirements. Therefore, the NBSB recommends that the Secretary of HHS designate a central situational awareness authority for coordinating all public health and healthcare situational

awareness data that have already been collected, processed, and analyzed from respective agencies on a national level.

The designated authority will play an essential and central coordinating role for the successful execution of the following specific recommendations:

1. Consulting with existing internal and external expert resources;
2. Continuing current system interoperability and integration efforts;
3. Determining and clarifying what and how data regarding zoonotic, agricultural, and other potentially public health impacting events should be communicated and integrated into the situational awareness system;
4. Remembering and evaluating the lessons from previous events and emergencies to inform priorities and decision-making;
5. Ensuring and/or facilitating adequate funding, resources, and staffing for systems sustainability; and
6. Integrating public health as the Emergency Support Function (ESF)#8 into the intelligence community for data sharing and monitoring.

The NBSB hopes that you find the NBSB's evaluation of our nation's public health and healthcare situational awareness helpful, and encourages the Department to take the recommendations into thoughtful consideration during their development of the SA SIP.

Sincerely,

/s/ John S. Parker

John S. Parker, MD, Major General (Retired)
Chair, National Biodefense Science Board

Enclosures
An Evaluation of Our Nation's Public Health and Healthcare Situational Awareness: A Brief Report from the National Biodefense Science Board.

cc: Nicole Lurie, MD, MSPH, Assistant Secretary for Preparedness and Response

An Evaluation of Our Nation's Public Health and Healthcare Situational Awareness: A Brief Report from the National Biodefense Science Board

April 2, 2013

In a letter dated June 7, 2012, Dr. Nicole Lurie, Assistant Secretary for Preparedness and Response (ASPR), tasked the National Biodefense Science Board (NBSB)[1] with review and evaluation of a draft U.S. Department of Health and Human Services (HHS) Public Health and Healthcare Situational Awareness (SA) Strategy and Implementation Plan (SIP) during its development phase. As part of their task, the NBSB was asked to offer guidance and recommendations on the measurable steps to take to enhance the nation's current public health and healthcare situational awareness capabilities.[2] The NBSB was also asked to assess current biosurveillance activities, identify efficiencies, and make recommendations in coordination with applicable existing Centers for Disease Control and Prevention (CDC) advisory committees. At their June 26, 2012, public meeting in Washington, DC, the NBSB formally accepted this task from the ASPR.[3]

The NBSB formed the Situational Awareness (SA) Strategy and Implementation Plan (SIP) Working Group (WG) to obtain a range of stakeholder views on this topic. The SA SIP WG comprises NBSB voting members, NBSB ex officios, invited federal experts, and invited representatives from multiple areas including: state and local government, industry, public health, epidemiology, preparedness, emergency management, information exchange, veterinary medicine, and agriculture.[4] This WG focused on responding to the situational awareness portion of the task. The NBSB looks forward to coordinating with the new CDC advisory committee on biosurveillance when it is formally stood up to fully and appropriately respond to the second portion of their task.

The WG held a series of teleconferences and webinars to gather further data, deliberate, and comment on a draft public health and healthcare situational awareness framework, presented by HHS. This draft, evaluated by the SA SIP WG, includes a consolidation of key topics and substantive elements of existing situational awareness and biosurveillance documents to be used as a starting point towards the development of the draft SA SIP.[5] Using the draft framework, the WG felt it was critical to develop a brief and succinct list of overarching concepts with high-level recommendations to provide guidance during the development phase

[1] See Appendix A for NBSB Charter and Roster.
[2] See Appendix B for task letter from the ASPR to the NBSB.
[3] Please visit the NBSB June 2012 meeting page, available at http://phe.gov/Preparedness/legal/boards/nbsb/meetings/Pages/120625meeting.aspx. To view the June 26, 2012 NBSB Public Meeting Webcast, please visit http://services.choruscall.com/links/aspr120626.html.
[4] See Appendix C for the NBSB SA SIP WG Roster.
[5] See Appendix D for the list of Federal planning documents that are relevant to public health and healthcare situational awareness.

of the draft SA SIP, and in anticipation of the reauthorization of the 2013 Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA).[6]

The NBSB held a public meeting on April 2, 2013, in Atlanta, GA, to consider, deliberate, and vote on the recommendations presented by the SA SIP WG. Following discussion by the members and the public, the NBSB voted on, and unanimously approved the transmittal of the recommendations in this report to the Secretary of HHS and ASPR for consideration.

In an effort to enhance current public health and healthcare situational awareness capabilities, the NBSB offers the following overarching concepts and key recommendations to help guide HHS in the development of the draft HHS SA SIP:

The following overarching concepts require particular emphasis and inclusion in the developed SA SIP:

1. Assurance of a common and unified strategy among all stakeholders involved in public health and healthcare situational awareness efforts, with the scopes of both public health and healthcare situational awareness to be explicitly defined.

    a. The NBSB proposes that the scope of public health situational awareness encompasses: surveillance for existing and emerging public health threats (biological, chemical, radiological) domestically and abroad, whether through monitoring for changes in trends of current disease or signals of new diseases, and whether originating in human health or elsewhere (e.g., animal health); and real-time awareness of the capacity to provide routine as well as emergency public health interventions.

    b. The NBSB proposes that the scope of healthcare situational awareness comprises: real-time awareness of the capacity to provide routine as well as emergency healthcare, whether in regular practice or during a crisis.

2. Identification of the specific questions to be answered in support of both public health and healthcare situational awareness. These questions will determine what data types (e.g., electronic, digital, and mobile) and sources (e.g., human, animal, environmental) are required, and how broad or narrow the focus should be, both in terms of level of data as well as timeline (i.e., pre-, during, and/or post event).

3. Recognition that the system for data coordination must integrate the expertise and experience from all levels and sectors of subject matter individuals and agencies that review and analyze the raw data, i.e., processed data, rather than just collect the raw data from those agencies.

[6] President Obama signed the 2013 PAHPRA into legislation on March 13, 2013. Please visit: http://www.whitehouse.gov/briefing-room/signed-legislation

4. Bidirectional communication of government agencies with all stakeholders, public and private.

5. Caution in developing common technological systems for situational awareness and biosurveillance such that the valuable complexities of some existing systems are not reduced or lost, nor should the complexities of a new system exceed or burden the capability of others.

6. Establishment of functional standards for data reporting to promote a common understanding of the target systems and capabilities.

Key Recommendation:

The NBSB strongly emphasizes the need to designate an oversight authority to assure compatibility, consistency, continuity, coordination, and integration of all the disparate systems and data requirements. Therefore, the NBSB recommends that the Secretary of HHS designate a central situational awareness authority for coordinating all public health and healthcare situational awareness data that have already been collected, processed, and analyzed from respective agencies on a national level; the authority will also have the responsibility to recommend corrective actions to improve situational awareness, including, the standardization of common operating procedures.

A central situational awareness coordination authority will require close collaboration with multiple federal partners to ensure appropriate synthesis of recommendations and decisions regarding potential threats, and the identification of "signals" above the background "noise," so arising incidents are recognized quickly and accurately. Establishing a central portfolio management group, under the authority, would also help coordinate between all biosurveillance activities conducted by various agencies to oversee alignment, identify any overlap of situational awareness activities and objectives, and make necessary recommendations.[7]

The designated authority will play an essential and central role for the successful execution of the following specific recommendations:

1. **Consulting with existing internal and external expert resources, by:**
    a. Reaching out to multiple sources, including states, private industry, and international models, especially to evaluate and potentially adopt and/or adapt existing innovative conceptual and technological approaches that may offer greater operational efficiency; and

[7] The coordination by the portfolio management group refers to an effort to inform agencies of overlapping projects, not to regulate project review and funding.

b. Identifying the roles and relationships of jurisdictional authorities and levels (i.e., state, local, territorial, and tribal) and how those systems are linked or may link and evolve to form a cohesive network, providing a nationally meaningful perspective.

2. **Continuing current system interoperability and integration efforts, by:**
    a. Implementing and leveraging standardization of data elements to promote interoperability;
    b. Promoting systematic planning at all levels and among all areas, public and private, to facilitate uniform data collection and utilization;
    c. Recognizing state and local systems and their interoperability horizontally and vertically on a national level, especially with regard to system compatibility and information sharing;
    d. Supporting ongoing preparedness capabilities for emergency response and operations at all levels and in public health and healthcare;
    e. Working with the Office of the National Coordinator for Health Information Technology (ONC) to actively endorse and facilitate the concept of a nationwide capability for public health and healthcare data exchange as described via electronic real-time health records, scrubbed of patient identifiers but linkable such that systems are interoperable and can be utilized not only to provide potential early aberrant signals but to inform healthcare status and capacity; and
    f. Building a system that integrates knowledgeable and skilled people interpreting the data and technology to provide validation and, as accurate as possible, early signals.

3. **Determining and clarifying what and how data regarding zoonotic, agricultural, and other potentially public health impacting events should be communicated and integrated into the situational awareness system, by:**
    a. Determining the scope of zoonoses as it relates to human health versus animal health surveillance; and
    b. Identifying which agencies/organizations will communicate to the oversight authority.

4. **Remembering and evaluating the lessons from previous events and emergencies to inform priorities and decision-making, by:**
    a. Recognizing the dynamic nature of situational awareness and the need to constantly assess and evolve the process and contributing systems; and
    b. Determining the type of high-level priority data essential for decision making for situations that are common among certain types of events (e.g., for flu season or other disease occurring over a period, data regarding vulnerable populations, vaccine—if one available—efficacy, regional/local incidence, morbidity and mortality).

5. **Ensuring and/or facilitating adequate funding, resources, and staffing for systems sustainability, by:**
    a. Further investing in critical infrastructure: human, equipment, and technology; and
    b. Facilitating and encouraging the strengthening of infrastructure by addressing processes and issues that could serve as roadblocks.

6. **Integrating public health as the Emergency Support Function (ESF)#8 into the intelligence community for data sharing and monitoring, by:**
    a. Incorporating public health expertise in Fusion Centers[8] to promote information sharing and partnership in the interests of both preventing and mitigating public health threats as well as assuring national security; and
    b. Recognizing the critical role of public health epidemiologists and investigators in: providing public health intelligence to validate events and their course; protecting the public's health without compromising individual confidentiality; providing strategic analysis; and enhancing current practices and systems.

[8] "A fusion center is a collaborative effort of two or more agencies that provide resources, expertise and information to the center with the goal of maximizing their ability to detect, prevent, investigate, and respond to criminal and terrorist activity." - Baseline Capabilities for State and Major Urban Area Fusion Centers (October 2008)

APPENDIX A
NBSB Charter and Roster

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

CHARTER

NATIONAL BIODEFENSE SCIENCE BOARD

Authority

The National Biodefense Science Board (hereafter referred to as the Board) was established under Section 402 of the Pandemic and All-Hazards Preparedness Act (P.L. 109-417) (codified at Section 319M of Title III of the Public Health Service Act (42 U.S.C. 247d-7f), as amended) and Section 222 of the Public Health Service Act (42 U.S.C. § 217a). The Board is governed by the Federal Advisory Committee Act (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees.

Objectives and Scope of Activities

The Pandemic and All-Hazards Preparedness Act, signed into law on December 19, 2006, directs the Secretary of the U.S. Department of Health and Human Services (hereafter referred to as the Secretary) to establish the Board to provide expert advice and guidance to the Secretary on scientific, technical and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary and/or the Assistant Secretary for Preparedness and Response (hereafter referred to as the ASPR) on other matters related to public health emergency preparedness and response.

Description of Duties

The Board shall advise the Secretary and/or ASPR on current and future trends, challenges, and opportunities presented by advances in biological and life sciences, biotechnology, and genetic engineering with respect to threats posed by naturally occurring infectious diseases and chemical, biological, radiological, and nuclear agents. At the request of the Secretary and/or ASPR, the Board shall review and consider any information and findings received from the working groups established under 42 U.S.C. 247d-7f(b). At the request of the Secretary and/or ASPR, the Board shall provide recommendations and findings for expanded, intensified, and coordinated biodefense research and development activities. Additional advisory duties concerning public health emergency preparedness and response may be assigned at the discretion of the Secretary and/or ASPR.

Agency or Official to Whom the Committee Reports

The Committee provides advice to the Secretary of the Department of Health and Human Services (HHS) and/or the Assistant Secretary for Preparedness and Response.

Support

Coordination, management, and operational services shall be provided by the Office of the Assistant Secretary for Preparedness and Response (ASPR).

Estimated Annual Operating Costs and Staff Years

The total estimated annual cost for operating the Board is $1,217,476.00. Management of the Board is estimated to require 4 annual person years of support at an annual cost of $614,034.00. Operating costs, including compensation and travel expenses for Board members, will be approximately $603,442.00 per year.

Designated Federal Officer

ASPR will select a fulltime or permanent part-time Federal employee to serve as the Designated Federal Officer (DFO) to attend each Committee meeting and ensure that all procedures are within applicable statutory, regulatory, and HHS General Administration Manual directives. The DFO will approve and prepare all meeting agendas, call all of the Committee and subcommittee meetings, adjourn any meeting when the DFO determines adjournment to be in the public interest, and chair meetings when directed to do so by the official to whom the Committee reports. The DFO or his/her designee shall be present at all meetings of the full committee and subcommittees.

Estimated Number and Frequency of Meetings

The Board shall meet at least twice annually and may be convened on an as-needed basis, at the call of the Secretary and/or ASPR or the Designated Federal Official. The Board may hold such hearings, sit and act at such times and places, take such testimony and receive such evidence, convene conferences and workshops, as the Board considers advisable to carry out its duties. Meetings shall be open to the public except as determined otherwise by the Secretary and/or ASPR, in accordance with the Government in the Sunshine Act (5 U.S.C 552b(c)) and the Federal Advisory Committee Act. Notice of all meetings will be given to the public.

Duration

Continuing

Termination

Notwithstanding section 14 of the Federal Advisory Committee Act, the Board shall terminate five years after the date on which it was established. Therefore, the National Biodefense Science Board will terminate five years after the date on which the charter is filed. The 5-year period may be extended by the Secretary and/or ASPR for one or more additional 5-year periods if the Secretary and/or ASPR determines that any such extension is appropriate.

Membership and Designation

The Board shall consist of 13 voting members, including the Chairperson; additionally, there may be non-voting ex officio members. Members and the Chairperson shall be appointed by the Secretary from among the Nation's preeminent scientific, public health and medical experts, as follows: (a) such Federal officials as the Secretary determines are necessary to support the functions of the Board, (b) four individuals from the pharmaceutical, biotechnology and device industries, (c) four academicians, and (d) five other members as determined appropriate by the Secretary and/or ASPR, one of whom must be a practicing health care professional and one of

whom must be from an organization representing health care consumers. Additional members for category (d), above, will be selected from among State and local governments and public health agencies, emergency medical responders and organizations representing other appropriate stakeholders.

A member of the Board described in (b), (c), and (d) in the above paragraph shall serve for a term of 3 years, except that the Secretary and/or ASPR may adjust the terms of the initial Board appointees in order to provide for a staggered term of appointment of all members. Members who are not full-time or permanent part-time Federal employees shall be appointed by the Secretary as Special Government Employees.

A quorum for the Board and each of its working groups shall consist of a majority of the appointed members eligible to vote. Of the voting members, any who are disqualified from participating in an action on a particular issue shall not count toward the quorum.

Subcommittees

Subcommittees composed of members and nonmembers of the parent committee may be established with the approval of the Secretary and/or ASPR or his/her designee. The subcommittees must report back to the parent committee and do not provide advice or work products directly to the agency. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

Recordkeeping

The records of the Committee, established subcommittees, or other subgroups of the Committee, shall be managed in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

Filing Date

July 3, 2012

APPROVED:

JUL - 3 2012 /s/ Kathleen Sebelius

Date Kathleen Sebelius

National Biodefense Science Board (NBSB)
Voting and *Ex Officio* Member Roster

Voting Members

Chair, John S. Parker, M.D., Major General (Retired)
Senior Vice President
Scientific Applications International Corporation
Virginia Beach, VA

Georges C. Benjamin, M.D., FACP, FACEP(E), FNAPA, Hon FRSPH
Executive Director
American Public Health Association
Washington, DC

John S. Bradley, M.D., FAAP, FIDSA
Director
Division of Infectious Diseases
Rady Children's Hospital
San Diego, CA

Nelson J. Chao, M.D., M.B.A.
Chief
Division of Hematological Malignancies and Cellular Therapy
Duke University
Durham, NC

Jane Delgado, Ph.D., M.S.
President and Chief Executive Officer
National Alliance for Hispanic Health
Washington, DC

David J. Ecker, Ph.D.
Divisional Vice President and General Manager
Ibis Biosciences, Inc.
Carlsbad, CA

Emilio A. Emini, Ph.D.
Chief Scientific Officer
Vaccine Research
Pfizer, Inc.
Collegeville, PA

Daniel B. Fagbuyi, M.D., FAAP, Major
Medical Director
Disaster Preparedness and Emergency Management
Children's National Medical Center
Washington, DC

Manohar R. Furtado, Ph.D.
Founder and President
Biology for Global Good LLC
San Ramon, CA

Kevin A. Jarrell, Ph.D.
Chief Executive Officer
Modular Genetics, Inc.
Woburn, MA

Steven E. Krug, M.D.
Director
Division of Emergency Medicine
Ann and Robert H. Lurie Children's Hospital of Chicago
Chicago, IL

Sarah Y. Park, M.D., FAAP
State Epidemiologist and Chief
Disease Outbreak Control Division
Hawaii Department of Health
Honolulu, HI

Betty J. Pfefferbaum, M.D., J.D.
Chair
Department of Psychiatry and Behavioral Sciences
University of Oklahoma College of Medicine
Oklahoma City, OK

***Ex Officio* Members**

Executive Office of the President

Franca R. Jones, Ph.D.
Assistant Director
Chemical and Biological Countermeasures
Office of Science & Technology Policy
Executive Office of the President
Washington, DC

Intelligence Community

VACANT

National Aeronautics and Space Administration

Richard S. Williams, M.D.
Chief Health and Medical Officer
Office of the Chief Health and Medical Officer
National Aeronautics and Space Administration
Washington, DC

National Science Foundation

Amber L. Story, Ph.D.
Deputy Division Director
Division of Behavioral and Cognitive Sciences
National Science Foundation
Arlington, VA

U.S. Department of Agriculture

Randall L. Levings, D.V.M.
Scientific Advisor
National Center for Animal Health
U.S. Department of Agriculture
Ames, IA

U.S. Department of Commerce

Dianne L. Poster, Ph.D.
Special Assistant
Associate Director for Laboratory Programs
Director's Office
National Institute of Standards and Technology
U.S. Department of Commerce
Gaithersburg, MD

U.S. Department of Defense

Bernard L. DeKoning, M.D., FAAFP
COL, Medical Corps
Commander
U.S. Army Medical Research Institute of Infectious Diseases
U.S. Department of Defense
Fort Detrick, MD

U.S. Department of Energy

Patricia R. Worthington, Ph.D.
Director, Office of Health Safety and Security
U.S. Department of Energy
Washington, DC

U.S. Department of Health and Human Services

Centers for Disease Control and Prevention
Ali S. Khan, M.D., M.P.H.
RADM, U.S. Public Health Service
Assistant Surgeon General
Director, Office of Public Health Preparedness & Response
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
Atlanta, GA

National Institutes of Health
Hugh Auchincloss, M.D.
Principal Deputy Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
U.S. Department of Health and Human Services
Bethesda, MD

Office of the Assistant Secretary for Preparedness and Response
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Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
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Carol D. Linden, Ph.D.
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Office of the Assistant Secretary for Health
Bruce Gellin, M.D., M.P.H.
Director
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Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
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Food and Drug Administration
Luciana Borio, M.D.
Acting Director
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Department of Health and Human Services
Silver Spring, MD

U.S. Department of Homeland Security

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Department of Homeland Security
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U.S. Department of the Interior

Lori Caramanian
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U.S. Department of Justice
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Kerri-Ann Jones, Ph.D.
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U.S. Environmental Protection Agency

Peter Jutro, Ph.D.
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U.S. Environmental Protection Agency
Washington, DC

U.S. Nuclear Regulatory Commission

Patricia A. Milligan, R.Ph., C.H.P.
Senior Advisor for Emergency Preparedness
U.S. Nuclear Regulatory Commission
Rockville, MD

NBSB Staff

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Ayah Wali, M.S.
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U.S. Department of Health and Human Services
Washington, DC

APPENDIX B
Task Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for
Preparedness & Response
Washington, D.C. 20201

JUN - 7 2012

John S. Parker, MD, Major General (Retired)
Chair, National Biodefense Science Board
Senior Vice President
Scientific Applications International Corporation
656 Lynn Shores Drive
Virginia Beach, VA 23452

Dear Dr. Parker and Members of the National Biodefense Science Board (NBSB):

The Department of Health and Human Services has begun activities to develop a Public Health and Healthcare Situational Awareness (SA) Strategy and Implementation Plan (SIP). The Public Health and Healthcare SA SIP aims to strengthen our overall national health security by serving as a comprehensive and national strategy and implementation plan, as called for in the current legislation to reauthorize the Pandemic and All Hazards Preparedness Act (PAHPA). The Public Health and Healthcare SA SIP will provide a common approach to building SA capabilities, to ensure the early detection of incidents with potential adverse health impacts, as well as effective decision making and resource allocation during a response.

I would like the NBSB to review and evaluate the Public Health and Healthcare SA SIP during its development to offer guidance, including recommendations, on the measurable steps to take to enhance our current public health and healthcare situational awareness capabilities. Biosurveillance is one of the major components of situational awareness, therefore, I would also like the NBSB to assess current biosurveillance activities, identify efficiencies, and make recommendations, in coordination with the applicable existing Centers for Disease Control and Prevention (CDC) advisory committees. The Office of the Assistant Secretary for Preparedness and Response (ASPR) and the CDC will lead the SA SIP development process.

Given the NBSB's demonstrated ability, experience, and expertise, your contributions towards the development of this strategy and implementation plan are yet another critical step taken towards ensuring the public health and healthcare preparedness of our nation.

In performing your deliberations, however, I encourage the NBSB to obtain stakeholder views on this topic using whatever means is deemed most appropriate. I look forward to discussing your initial thoughts on this topic at the June 26, 2012, NBSB public meeting. The timeline for completion will be consistent with the timeline established in the final reauthorization of the PAHPA.

Thank you for your continued diligence in serving to strengthen our nation's resilience.

Sincerely,

/s/ Nicole Lurie

Nicole Lurie, MD, MSPH
Assistant Secretary for Preparedness and Response

APPENDIX C
NBSB SA SIP WG Roster

National Biodefense Science Board (NBSB)
Situational Awareness (SA) Strategy and Implementation Plan (SIP) Working Group (WG)

Voting Members

Chair, Sarah Y. Park, M.D., FAAP
State Epidemiologist and Chief
Disease Outbreak Control Division
Hawaii Department of Health
Honolulu, HI

Co-Chair, Manohar R. Furtado, Ph.D.
Founder and President
Biology for Global Good LLC
San Ramon, CA

Georges C. Benjamin, M.D., FACP, FACEP(E), FNAPA, Hon FRSPH
Executive Director
American Public Health Association
Washington, DC

Nelson J. Chao, M.D., M.B.A.
Chief
Division of Hematological Malignancies and Cellular Therapy
Duke University
Durham, NC

David J. Ecker, Ph.D.
Divisional Vice President and General Manager
Ibis Biosciences, Inc.
Carlsbad, CA

Emilio A. Emini, Ph.D.
Chief Scientific Officer
Vaccine Research
Pfizer, Inc.
Collegeville, PA

John S. Parker, M.D., Major General (Retired)
Senior Vice President
Scientific Applications International Corporation
Virginia Beach, VA

***Ex Officio* Members**

U.S. Department of Agriculture

Randall L. Levings, D.V.M.
Scientific Advisor
National Center for Animal Health
U.S. Department of Agriculture
Ames, IA

U.S. Department of Veterans Affairs

Victoria J. Davey, Ph.D., M.P.H.
Chief
Office of Public Health and Environmental Hazards
U.S. Department of Veterans Affairs
Washington, DC

Executive Office of the President

Franca R. Jones, Ph.D.
Assistant Director
Chemical and Biological Countermeasures
Office of Science and Technology Policy
Executive Office of the President
Washington, DC

Invited Federal Representative

Matthew Hepburn, M.D.
Director
Medical Preparedness
White House National Security Staff
Executive Office of the President
Washington, DC

Other Invited Representatives

Cheryl Austein Casnoff, M.P.H.
Senior Fellow, National Opinion Research Center
University of Chicago
Bethesda, MD

Mary Keating, R.N., M.A.
HPP Coordinator
State ESAR-VHP/MRC Coordinator
Public Health Preparedness and Response Branch
Connecticut Department of Public Health
Hartford, CT

Janet J. Hamilton, M.P.H.
Manager, Communicable Disease Surveillance and Reporting Section
Disease Control and Health Protection
Bureau of Epidemiology
Florida Department of Health
Tallahassee, FL

Paul L. Hewett, Jr.
Deputy Director
Center for Integrated Emergency Preparedness
Decision and Information Sciences Division
Argonne National Laboratory
Lemont, IL

Alonzo L. Plough Ph.D., M.P.H.
Director, Emergency Preparedness and Response
County of Los Angeles Department of Public Health
Clinical Professor, Health Services
University of Washington School of Public Health
Los Angeles, CA

Mark S. Smolinski, M.D., M.P.H.
Director, Global Health Threats
Skoll Global Threats Fund
San Francisco, CA

Cheryl Stroud, D.V.M., Ph.D.
Chair, North Carolina One Health Collaborative
AVMA Representative, One Health Commission
Chair, One Health Intellectual Exchange Group Discussion Series
Relief Veterinary Clinician
Raleigh, NC

John Wandelt
Chief, Information Exchange and Architecture Division
Executive Director, National Information Exchange Federation
Georgia Tech Research Institute
Atlanta, GA

Executive Secretariat

Jomana Musmar, M.S.
Biotechnology Policy Analyst
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
Washington, DC

APPENDIX D
Reference List

List of federal planning documents relevant to public health and healthcare situational awareness:

- US Department of Health and Human Services National Health Security Strategy of the United States of America (December 2009). (NHSS)
    - http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf
- Implementation Plan for the National Health Security Strategy of the United States of America (May 2012). (NHSS IP)
    - http://www.phe.gov/Preparedness/planning/authority/nhss/ip/Documents/nhss-ip.pdf
- National Strategy for Biosurveillance (July 2012). (NSB)
    - http://www.fda.gov/downloads/EmergencyPreparedness/MedicalCountermeasures/UCM314532.pdf
- US Government Accountability Office Public Health Information Technology Report: "Additional Strategic Planning Needed to Guide HHS's Efforts to Establish Electronic Situational Awareness Capabilities." (December 2010). (GAO PHIT)
    - http://www.gao.gov/new.items/d1199.pdf
- Improving the Nation's Ability to Detect and Respond to 21st Century Urgent Health Threats: First Report of the National Biosurveillance Advisory Subcommittee (April 2009). (NBAS 1)
    - http://www.cdc.gov/osels/pdf/NBAS%20Report%20-%20Oct%202009.pdf
- Improving the Nation's Ability to Detect and Respond to 21st Century Urgent Health Threats: Second Report of the National Biosurveillance Advisory Subcommittee (April 2011). (NBAS 2)
    - http://www.cdc.gov/about/advisory/pdf/NBASFinalReport_April2011.pdf
- US Department of Health and Human Services National Biosurveillance Strategy for Human Health (February 2010). (NBSHH)
    - http://www.cdc.gov/osels/pdf/NBSHH_v2.pdf
- National Strategic Plan for Public Health Preparedness and Response (September 2011). (NSPPHPR)
    - http://www.cdc.gov/phpr/publications/2011/A_Natl_Strategic_Plan_for_Preparedness_20110901A.pdf
- Office of the National Coordinator for Health Information Technology (ONC) -Coordinated Federal Health Information Technology Strategic Plan: 2008-2012 (June 2008). (ONC HIT 2008)
    - http://dhhs.nv.gov/HOLD/HIT/docs/ONC2008-2012HITStrategicPlanSummary.pdf
- Office of the National Coordinator for Health Information Technology (ONC) Federal Health Information Technology Strategic Plan: 2011-2015 (September 2011). (ONC HIT 2011)
    - http://www.healthit.gov/sites/default/files/utility/final-federal-health-it-strategic-plan-0911.pdf