DRAFT Anticipated Responsibilities of the Strategic National Stockpile (SNS) In the Year 2020

An Examination with Recommendations

A Joint Report from the National Biodefense Science Board
And
The Office of Public Health Preparedness and Response
Board of Scientific Counselors

In 1998, Congress appropriated funding to establish the National Pharmaceutical Stockpile, the precursor to the Strategic National Stockpile (SNS). Following the terrorist attacks of 2001, legislation to create the SNS was enacted.[1] Since its inception, the SNS has successfully and effectively closed the gap between emergency requirements and extant public health response capabilities. Today, the SNS is regarded as an essential part of a national public health response system; it is recognized for its ability to efficiently acquire, store, and manage medical materiel, and to then distribute those resources to disaster-affected areas.

Originally conceived as a means to meet health needs stemming from a chemical, biological, radiological, nuclear, or explosive (CBRNE) attack on the United States, the SNS has become a repository for specific, critical medical countermeasures (MCMs). Inasmuch as most of the medicines and therapeutic agents needed to treat victims of CBRNE incidents are not generally regarded as "everyday commodities," they must be specially procured. Some are for a specific single use and are stored to meet anticipated surge needs during emergencies of national significance. State, local, tribal, and territorial (SLTT) partners have come to rely on the SNS for

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[1] Congress charged HHS and the CDC with establishing the National Pharmaceutical Stockpile (NPS) under the fiscal year 1999 Omnibus Appropriations Act (Public Law 105-277). The mission of the NPS was to supply states and communities with large quantities of essential medical materiel during an emergency (within twelve hours of a federal decision to deploy). When signed into law in June 2002, the Public Health Security and Bioterrorism Response Act (Public Law 107-188) changed the name of the NPS to the Strategic National Stockpile (SNS) and expanded its mission to "…provide for the emergency health security of the United States."

both its inventory and its distribution capabilities. The SNS has been integrated into SLTT public health emergency response plans and into their emergency response systems.

The United States Government (USG) currently faces serious fiscal challenges and it is likely that funding for the SNS will be reduced or – at best, perhaps – sustained without growth. Decreased or static funding, however, is incompatible with SNS maintenance and replenishment of materiel, let alone the expansion of this vital national resource. Given the challenges facing the SNS, the Assistant Secretary for Preparedness and Response (ASPR) together with the Director, Office of Public Health Preparedness and Response (OPHPR), Centers for Disease Control and Prevention (CDC), jointly sent a letter dated June 1, 2012, to the Chairs of two U.S. Department of Health and Human Services (HHS) federal advisory committees (FACs), the National Biodefense Science Board (NBSB) and the OPHPR Board of Scientific Counselors (BSC)[2], charging them with three specific tasks:[3]

1. To identify anticipated responsibilities of the SNS in the year 2020;
2. To recommend approaches for meeting those responsibilities as efficiently as possible; and
3. To propose metrics for reporting program capability and informing improvement.

The Chairs of the NBSB and the OPHPR BSC met and determined to form a joint working group (WG), co-chaired by NBSB Chair Dr. John Parker and OPHPR BSC member Dr. Donald Burke; two additional members from each of the participating advisory committees were also asked to serve on the WG. This core group was augmented by three additional subject matter experts.[4]

Over the course of the subsequent eight months, the WG convened multiple teleconferences and two in-person meetings.[5] The joint WG received detailed briefings on the following topics: the legislative background and legal underpinnings of the SNS; function, management and logistics of the SNS; the relative merits and challenges posed by various inventory management

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[2] See Appendix A for NBSB and OPHPR BSC rosters and charters.

[3] See Appendix B for task letter from ASPR and Director of OPHPR.

[4] See Appendix C for joint NBSB/OPHPR BSC working group roster.

[5] See Appendix D for a list of WG activities, including: meeting agendas, participant lists, and a draft working group synthesis of key issues.

methods (vendor managed, user managed, and stockpile managed systems); review processes; leadership; acquisition authority and execution; threat assessment; advancements in science and innovation; requirement generation and risk evaluation; SLTT needs; and function of the SNS at the federal/state interface.[6]

The WG presented their responses to the three tasks in the June 2012 letter, together with a list of recommendations, to both parent FACs (NBSB and OPHPR BSC) for deliberation and vote at a joint April 3, 2013, public meeting, held in Atlanta, GA. Subsequently, the NBSB and OPHPR BSC voted on and unanimously approved the recommendations from the joint WG.

RESPONSE to TASKS

The NBSB and the OPHPR BSC present the following responses to the three tasks requested from the ASPR and OPHPR Director:

TASK 1: Identify anticipated responsibilities of the SNS in year 2020

The anticipated responsibilities of the SNS in the year 2020 will remain largely unchanged: to secure the public health of the United States and to augment our country's national security. This will be achieved by maintaining a cache of medical countermeasures and materiel necessary to support a robust response to the widest possible spectrum of public health emergencies, whether intentionally-caused, naturally-occurring or inadvertent.

From our review of the mission and functions of the SNS, the NBSB and the OPHPR BSC both affirm that the SNS has demonstrated a continual growth in capability and functionality since its inception. Some of this growth has extended the role of the SNS beyond its original legislative mandate. The focus has gradually but steadily shifted away from CBRNE response, exclusively, to that of a stockpile capable of responding to "all hazards." And as evinced by its history of incident response, the SNS has played a critical role in helping secure the public health of the US. By enhancing this country's capacity to respond to terrorist threats, the SNS also augments our national security.

[6] For more information on CDC's Strategic National Stockpile, see: http://www.cdc.gov/phpr/stockpile/stockpile.htm.

A mutual and critical dependence has developed between the SNS and SLTT public health agencies. Given this, the SNS should not be diminished but increasingly enhanced to meet its public health responsibilities.

This interdependency between the SNS and SLTT public health agencies has increased by the inclusion of additional SNS-stockpiled commodities and expected functions over time. The SNS has grown from being strictly CBRNE-oriented to being tasked with the responsibility of assuming an all hazards response posture. Yet, as responsibilities have expanded to cover an ever wider array of potential public health emergencies, the SNS is nevertheless being increasingly confronted with "unfunded" requirements. These requirements (in particular, the replacement of expiring inventories) are being driven by unbudgeted life cycle costs, some of which will occur in the near future even as funding for the SNS becomes more constrained.

If the current trajectory is left unchanged, we anticipate a widening gap between the explicit and implicit responsibilities of the SNS and the resources available to fulfill those responsibilities. An underfunded SNS will be challenged in its ability to: rotate stock and manage the expiration of current inventory; expand the scope of incidents to which its resources are deployed; add new formulations or dosing units for existing MCMs for use in children and other vulnerable populations; add new therapeutic drugs and vaccines to the inventory as threats evolve and/or improved options are identified.

The NBSB and the OPHPR BSC do not foresee a reduction in the critical national responsibilities of the SNS, nor do we see a reduction in the costs in fulfilling these responsibilities, especially as newer therapeutic drugs and vaccines are added to the inventory.

To effectively mitigate this predicted gap between the current mission and resources, senior leadership within HHS will need to re-examine the overall scope of the SNS, and carefully re-evaluate the risks that this nation is willing to accept, should the scope be diminished. The SNS itself will need to find ways to improve efficiencies through applied research and sound science. Given that 2020 is only seven years into the future, we recommend that decisions about scope be made, and that risk versus threat evaluations, requirement adjustments, and absolute priority setting all be addressed. And as part of this proposed foresight review, the following should be included: a critical assessment of the appropriateness of an all hazards responsibility versus a

strict CBRNE focus, and careful consideration as to how best to use basic and applied science to impact currently accepted therapeutic approaches and policies.

TASK 2: Recommend approaches for meeting those responsibilities as efficiently as possible

The NBSB and OPHPR BSC recommend an increased reliance on state-of-the-art risk management and applied science for the SNS to meet its responsibilities in the year 2020 as efficiently as possible.

To meet its responsibilities as efficiently as possible, the SNS must first address and manage its budget constraints. In the short term, innovations in business and supply chain processes, storage, and distribution will not contribute to cost reduction efforts in a meaningful way; rather, the most significant cost reductions are likely to come from inventory reductions.

Inventory reduction should not, however, detract from the SNS mission. The threat landscape – for example, the probability of various large-scale CBRNE events – is continually changing. At the same time, the inventory of so-called potential weapons of mass destruction is increasing. For these reasons, therefore, careful evaluation of the relative likelihood and consequences of potential incidents should be used to inform decisions about the levels of MCM, and other medical materiel needed, to mount appropriate responses to a wide variety of public health emergency scenarios. Similar assessments can identify the risks associated with maintaining ranges of inventory levels (if sufficient inventory is not available to fully respond to an incident). Where calculated risks can be moderated against scenarios of proper sizing, the logistical burden on the SNS can be reduced. If, on the other hand, cost savings become paramount and appropriate tradeoffs and acceptable balances between an increase in risk and a reduction in inventory cannot be achieved, then the SNS will have little option but to reduce its overall scope, revise its vision and mission, and constrict its capabilities to those of the original intent, specifically CBRNE, including other emerging infectious diseases.

The NBSB and the OPHPR BSC believe that as computational modeling and simulation become more sophisticated and increasing amounts of data are made available, these tools can be used to improve the decision-making process, providing senior leadership with the information necessary to make more rational and better-informed decisions. Both FACs are very supportive of the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE)

review process[7], and wish to emphasize the importance of making decisions on the basis of good science and consistent cost-benefit analyses. In addition, the development of innovative solutions for the SNS should be supported by the appropriate USG funding agencies. Newer therapeutic regimens could improve the ability of the SNS to respond to relevant incidents while maintaining a reduced and more efficient inventory. Funding for these development activities should be part of the strategic funding plans for the Biomedical Advanced Research and Development Authority (BARDA) as well as the National Institutes of Health (NIH).

TASK 3: Propose metrics for reporting program capability and informing improvement

The NBSB and OPHPR BSC believe that program capability metrics should be based on and derived from actual performance data (where such information exists), results of exercises, and computational modeling and simulations. Program capability assessment metrics should identify not only gaps and strengths in distribution of MCMs, but also in their delivery to the public.

Performance metrics for logistical systems in industry are typically embedded as part of daily on-going operations. When demand forecasting, order management, storage, distribution, and transport are executed on a regular basis, ongoing performance metrics may be used to quickly identify efficiencies as well as areas that need to be changed, improved or eliminated. By contrast, the real-life incident operational experience of the SNS has thus far been limited (and fortunately so). But this paucity of response activity has restricted the use and application of performance metrics.

The NBSB and the OPHPR BSC recommend that the SNS, as part of an integrated national response system, carry out rigorous exercises of their current capabilities to include SLTT partners.

This approach was emphasized in the recent Institute of Medicine (IOM) recommendations on prepositioning medical countermeasures.[8] So-called "no notice" exercises can lead to changes in practice and in behavior that can improve the effectiveness and readiness of both the SNS

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[7] For more information on the PHEMCE, see: http://www.phe.gov/preparedness/mcm/phemce/Pages/default.aspx.

[8] See IOM report *Prepositioning Antibiotics for Anthrax* (September 30, 2011) available at: http://iom.edu/Reports/2011/Prepositioning-Antibiotics-for-Anthrax.aspx.

and end-users, over time. Audits and the application of metrics across the SNS system contribute to improved readiness. The use of modern modeling and simulation specifically around procurement, storage, distribution and delivery is therefore suggested.

Computational modeling and simulation can also be deployed to teach, train, and test the SNS system. Building such a modeling and simulation system will improve both the testing and operational performance of the SNS. Metrics can be developed “ad hoc” and/or by running the models, focusing on the constraints within the system, and measuring against the results during a full-scale exercise. These tests should be fully coordinated with SLTT partners so they and the USG can benefit from seeing an operation performed in the manner expected during a real life disaster or public health emergency.

The SNS functions as one essential component of the nation’s public health and disaster preparedness system. In addition to using metrics unique to the operational performance of the SNS, there also exists a need for critical assessment of SLTT partner capacities and capabilities to dispense SNS-distributed assets to end users, because delivery of SNS supplies to states and territories will only benefit the American public if these measures can be received, processed, and delivered.

The NBSB and OPHPR BSC recommend expanding performance assessments to include the desired outcome: delivery of critical countermeasures to the public.

SNS simulation exercises and drills would provide an opportunity to better understand existing variations in SLTT partner performance as well as mismatches between SNS and SLTT partner capabilities. If SNS operational performance is inconsistent with SLTT partner capacities, SNS resources may then be modulated appropriately to better align with end-user capabilities.

RECOMMENDATIONS

1. Clearly articulate a vision for the SNS in 2020.

The following language is suggested: The Strategic National Stockpile (SNS) is a national resource that supports medical materiel and logistics requirements needed for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations. In particular, the SNS provides an emergency surge capacity to save lives in the early hours of emergency incidents.

2. Carefully tailor the SNS surge capacity.

The surge capacity referenced in the vision statement should be restricted to include only materiel that cannot be appropriately provided through existing commercial inventories and distribution networks. The top priority of the SNS should be the large-scale delivery of essential MCMs and other urgently required materiel in quantities sufficient to contain incidents and/or save lives in response to CBRNE incidents. The SNS may also provide support in an appropriate manner to other public health emergency situations.

3. Use science as a key strategic and tactical management tool.

The broad capabilities of the USG and academia in the areas of basic and applied science should be used as a key strategic management tool for the SNS. The NIH, National Science Foundation, the National Laboratories, and other relevant government institutions should actively collaborate with the PHEMCE in making procurement decisions based on sound science.

SNS inventory composition and volume should reflect the results of vigorous and ongoing evaluation of: new MCMs and therapeutics and their usage protocols; unique MCM needs for children and other vulnerable populations; new requirements based on updated threat analysis and probabilities of occurrence; best business practices; procurement reform; novel distribution methods and innovative disposal methods; and systems to improve communication.

4. Enhance critical review processes such as risk-benefit analysis and the requirement generation process.

The already valuable and critical PHEMCE review process should be enhanced by moving toward faster review cycles, and by improving cost versus risk-benefit analyses. The latter should include continual adjustments of SNS-stockpiled assets and materiel. The total number and location of warehouses, pre-positioned items, and Federal Medical Stations should be included as part of this assessment process. In addition, ongoing assessments of various features of public health emergencies are needed, including potential size, probabilities of occurrence, and number. Such evaluations can be used strategically to adjust and better align acceptable risk and SNS requirements.

The rapid and timely delivery of CBRNE MCMs should remain as the core mission and focus of the SNS. Consideration should also be given to expanding or enhancing the PHEMCE review process to include the all hazards arena. This involves reviewing the option of continuing to ask the SNS to meet surge demands for all hazards incidents versus tasking other agencies – or even industry – with the responsibility for responding to all hazards other than CBRNE.

5. Continue to move to a single appropriation model that would enhance fiscal management of the SNS.[9]

A single-funded budget line for the HHS-managed SNS enterprise, with a five-year budgeting program, should be the long-term goal. A five-year budgeting program would provide visibility into likely future SNS costs, including the cost of replacing existing therapeutics nearing shelf-life expiration and the cost of adding new products to the stockpile. A budgeting process that looks even five years into the future can help provide a framework for better acquisition, storage and distribution decisions. The advisory committees recognize and applaud the efforts that have been made in the direction of a multi-year planning and budget process to date and the alignment of HHS organizations that are important for the SNS effort. The implementation of this recommendation will assure proper recognition of life cycle costs for MCMs, provide a sound

[9] See NBSB report *Where are the Countermeasures? Protecting America's Health from CBRN Threats* (March 2010) available at: http://phe.gov/Preparedness/legal/boards/nbsb/meetings/Documents/nbsb-mcmreport.pdf.

fiscal picture into the future and add value in the areas of fiscal responsibility, preparedness and response.

6. Use sound cost versus benefit decisions, to include business principles and tools, as integral components of the management process.

The SNS currently employs Vendor Managed Inventory (VMI) in some of its warehousing, delivery, and distribution systems. Its decision to do so is based both on science (i.e., data to support its use) and a favorable cost-benefit profile. Sound cost versus benefit decisions based on requirements, source, quality, quantity, speed, reliability, and end user capabilities, will strengthen and invigorate the SNS.

Rational decision-making requires accurate and comprehensive information regarding past decisions and outcomes as well as the ability to plan and budget into the future. The SNS should obtain the historical financial data necessary to make and defend decisions concerning the use of stockpile managed inventory versus user-managed inventory (UMI) or VMI systems, and should judge UMI and VMI-based MCM storage and management plans on a case-by-case basis as well.

The SNS should also continue to engage industry by seeking bids that encourage potential industry partners to (re-) consider participating in VMI of the SNS and help develop innovative solutions that meet SNS needs.

7. Make greater use of computational modeling and simulation.

Modeling and simulation should be used to optimize effective and coordinated functioning throughout the entire SNS system. Modeling should be extended to include the distribution and use of appropriate countermeasures by at-risk individuals. Modeling and simulation can also be useful for training, conducting drills and exercises, planning and budgeting, and in some cases may assist in the decision-making process during actual incidents. Once modeling and simulation are in place and validated, such models can then be used to develop and execute meaningful metrics in conjunction with live exercises that highlight potential problem areas in the SNS system. The advisory committees recognize the key role that models can play. When

coupled with appropriate interpretation and an appreciation of their inherent strengths and weaknesses, models can serve as important adjuncts to the decision-making process.

8. Recognize the SNS and BARDA as the sole purchasers, and the SNS as the sole distributor, of certain CBRNE MCMs.

The SNS is an integral part of U.S. national security as well as the nation's public health and response system. Its critical role in maintaining effective national security should be fully and explicitly acknowledged among USG appropriators and authorizers, Office of Management and Budget, and agency budget officers. Such recognition will help facilitate a better understanding of the life cycle costs for sensitive assets and a well-planned stockpile.

The SNS and BARDA need to be recognized as the sole purchasers, with the SNS being the sole distributor for certain CBRNE MCMs. Free market forces are such that there is no commercial demand for (and therefore no incentive for private industry to supply) many of these MCMs in the private marketplace. As a result, if not for the SNS, critical CBRNE MCMs would be unavailable to meet surge requirements in public health emergencies.

9. Improve coordination among federal and SLTT public health partners.

SNS surge capacity and capabilities must be commensurate with the capabilities at the end-user level. To that end, HHS should encourage and facilitate better coordination between the National Association of County and City Health Officials (NACCHO), the Association of State and Territorial Health Officials (ASTHO), and the entities that comprise the Cities Readiness Initiative (CRI). Comprehensive due diligence must be carried out for all aspects of the MCM delivery and distribution system to achieve optimal success.

10. Apply laboratory science and animal models to reduce uncertainties and investigate unanswered important biomedical questions related to public health preparedness and SNS requirements.

For vulnerable populations, considerable uncertainty exists about the effectiveness, proper dosing, appropriate routes of administration, duration of protection, and overall safety of many of

the MCMs in the SNS. While laboratory science and animal models are imperfect surrogates for human response, the FACs note that even modest advances in narrowing these uncertainties may have substantial effects in lowering costs. The PHEMCE and the SNS should systematically review the range of uncertainties of MCMs, and initiate a focused research program to produce data to address these practical, applied problems.

APPENDIX A

NBSB and OPHPR BSC Information

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

Voting Members

Chair, John S. Parker, M.D., Major General (Retired)
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VACANT

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THE SECRETARY OF HEALTH AND HUMAN SERVICES
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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

Date

Kathleen Sebelius

Kathleen Sebelius

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Board of Scientific Counselors
Office of Public Health Preparedness and Response (OPHPR)

CHAIR

Thomas Inglesby, M.D.
Director and CEO
Center for Biosecurity of UPMC
Term: 3/7/2011 – 9/30/2013

DESIGNATED FEDERAL OFFICIAL

Samuel L. Groseclose, DVM, MPH
Associate Director for Science
Centers for Disease Control and Prevention
Atlanta, GA

MEMBERS

Ruth G. Bernheim, J.D., M.P.H.
Chair, Department of Public Health Services
and William Hobson Associate Professor of
Information Sciences
University of Virginia School of Medicine
Charlottesville, Virginia
Term: 11/20/2012 -09/30/2016

Margaret L. Brandeau, Ph.D.
Coleman F. Fung Professor, School of Engineering
Department of Management Science and Engineering
Stanford University
Stanford, CA
Term: 5/10/2012 - 9/30/2015

Donald Burke, M.D.
Dean, Graduate School of Public Health
University of Pittsburgh
Pittsburgh, PA
Term: 2/27/2011 – 9/30/2013

John Lumpkin, M.D., M.P.H.
Senior Vice President and Director, Health Care Group
Robert Woods Johnson Foundation
Princeton, NJ
Term: 3/7/2011 – 9/30/2014

Ellen J. Mackenzie, Ph.D.
Professor and Chair, Department of Health Policy
and Management, Johns Hopkins University
Baltimore, MD
Term: 5/5/2012 - 9/30/2015

Ian I. Mitroff, Ph.D.
Adjunct Professor, College of Environmental Design and
Research Associate, Center for Catastrophic Risk Management
Haas School of Business, University of California, Berkeley
Oakland, California
Term: 11/20/2012 -09/30/2016

Carol S. North, M.D., M.P.E.
Professor of Psychiatry and
Director, Division of Trauma and Disaster
The University of Texas Southwestern Medical Center
Dallas, Texas
Term: 11/20/2012 -09/30/2016

Herminia Palacio, M.D., M.P.H.
Executive Director
Harris County Public Health and Environmental Services
Houston, TX
Term: 2/25/2011 - 9/30/2014

Elaine Vaughan, Ph.D.
Research Professor
Department of Psychology and Social Behavior
University of California
Irvine, CA
Term: 3/23/2011 - 9/30/2014

EX OFFICIO MEMBERS

Alexander Garza, M.D., M.P.H
Assistant Secretary for Health Affairs and
Chief Medical Officer
U.S. Department of Homeland Security
Washington, DC

Nicole Lurie, M.D., M.S.P.H.
Assistant Secretary for Preparedness and Response
U.S. Department of Health & Human Services
Washington, DC

(Nomination Package Submitted)
United States Department of Defense

LIAISON REPRESENTATIVES

Christine Egan, PhD, CBSP
Association of Public Health Laboratories (APHL)
Chief, Biodefense Laboratory
Wadsworth Center
New York State Department of Health
Albany, NY

James Curran, M.D., M.P.H.
Association of Schools of Public Health (ASPH)
Dean, Rollins School of Public Health
Emory University
Atlanta, GA

Karen Smith, M.D., M.P.H.
National Association of County and City Health Officials (NACCHO)
Public Health Officer and Director of Public Health
Napa County Health and Human Services Agency, Public Health Division
Napa, CA

Jean O'Connor, JD, DrPH
Association of State and Territorial Health Officials (ASTHO)
Deputy Director, Public Health Division
Oregon Health Authority
Portland, OR

Patricia Quinlisk, M.D., M.P.H.
Council of State and Territorial Epidemiologists (CSTE)
Medical Director and State Epidemiologist
Iowa Department of Public Health
Des Moines, IA

Stacy Bohlen, M.A.
National Indian Health Board (NIHB)
Executive Director
Washington, DC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

CHARTER
of the
BOARD OF SCIENTIFIC COUNSELORS
OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RESPONSE

Authority

42 U.S.C §217a [Section 222 of the Public Health Service Act, as amended]. The Board is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees.

Objective and Scope of Activities

Section 301 of the Public Health Service Act, [42 U.S.C. §241], as amended, provides that the Secretary shall render assistance to public authorities in the diagnosis, treatment, control and prevention of physical and mental diseases and impairments of persons. In doing so, the Secretary is authorized to make available information as to the practical application of research and is authorized to obtain the assistance and advice of experts and consultants. Section 311 of the Public Health Service Act, as amended (41 U.S.C. §243) authorizes the Secretary to assist and advise State and local authorities in matters relating to the preservation and improvement of the public health.

Description of Duties

The Board of Scientific Counselors, Office of Public Health Preparedness and Response (OPHPR), shall provide advice and guidance to the Secretary, Department of Health and Human Services (HHS), the Assistant Secretary for Health (ASH); the Director, Centers for Disease Control and Prevention (CDC); and to the Director, OPHPR, concerning strategies and goals for preparedness and response activities pertaining to programs and research within the divisions; will administer and oversee peer-review of OPHPR scientific programs; and monitor the overall strategic direction and focus of the divisions and offices. The Board, after administering and overseeing the peer reviews, shall submit an annual summary of the results of the reviews and recommendations to the Associate Director for Science and the Director, CDC. The Board may perform second-level peer review of applications for grants-in-aid for research and research training activities, cooperative agreements, and research contract proposals relating to the broad areas within the office.

Agency or Official to Whom the Committee Reports

The Board shall provide advice and guidance to the Secretary, HHS; the Assistant Secretary for Health; the Director, CDC; and to the Director, OPHPR.

Support

Management and support services shall be provided by the Office of the Director, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention.

Estimated Annual Operating Costs and Staff Years

Estimated annual cost for operating the Board, including compensation and travel expenses but excluding staff support is $138,377. The estimate of annual person-years of staff support required is 1.80 at an estimated annual cost of $211,652.

Designated Federal Officer

CDC will select a full-time or permanent part-time Federal employee to serve as the Designated Federal Officer (DFO) to attend each 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 Board reports. The DFO or his/her designee shall be present at all meetings of the full Board and subcommittees.

Estimated Number and Frequency of Meetings

Meetings shall be held approximately two times a year at the call of the Designated Federal Officer, in consultation with the Chair.

Meetings shall be open to the public except as determined otherwise by the Secretary, HHS, or other official to whom the authority has been delegated, in accordance with the Government in the Sunshine Act (5 U.S.C. §552b(c)) and Section 10(d) of the Federal Advisory Committee Act; notice of all meetings shall be given to the public.

Duration

Continuing

Termination

Unless renewed by appropriate action prior to its expiration, the Board of Scientific Counselors, Office of Public Health Preparedness and Response will terminate 2 years from the date this charter is filed.

Membership and Designation

The Board of Scientific Counselors, Office of Public Health Preparedness and Response shall consist of 10 members, including the Chair, and may include a Federal employee. Members and the Chair shall be selected by the Secretary, HHS, or designee, from authorities knowledgeable in the fields relevant to the issues addressed by the offices and divisions within the coordinating office, e.g., medicine, epidemiology, laboratory science, informatics, behavioral science, social science, engineering, business, and crisis leadership. Members other than Federal government employees shall be deemed Special Government Employees.

The Board shall also consist of three voting ex officio members from the HHS Office of the Secretary; Department of Homeland Security; and Department of Defense; and such others as the Secretary deems necessary to carry out the functions of the Board. In addition, the Board shall consist of nonvoting liaison representatives from the Association of Public Health Laboratories; Association of State and Territorial Health Officials; National Association of County and City Health Officials; Council of State and Territorial Epidemiologists; Association of Schools of Public Health; National Indian Health Board; and such others as the Secretary deems necessary to carry out the functions of the Board. Liaisons shall be deemed representatives.

Members shall be invited to serve for overlapping terms of up to four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. Terms of more than two years are contingent upon the renewal of the Board by appropriate action prior to its termination. A member may serve 180 days after the expiration of that member's term if a successor has not taken office.

Ad hoc consultants/reviewers, which may include Federal employees, may be utilized as deemed necessary for the Board to carry out its functions. Ad hoc consultants/reviewers provide subject matter expertise in the formulation of advice or recommendations; however, they do not count towards the quorum and may not vote.

Subcommittees

Subcommittees composed of members and nonmembers of the parent committee may be established with approval of the Secretary, HHS, 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 subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

Recordkeeping

The records of the Board and established subcommittees of the Board 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

November 5, 2011

Approved:

10/24/11
Date

Director
Management Analysis and Services Office

APPENDIX B

Task Letter from ASPR and Director of OPHPR to NBSB and OPHPR BSC

DEPARTMENT OF HEALTH & HUMAN SERVICES

June 1, 2012

Thomas V. Inglesby, MD
Chair, Board of Scientific Counselors
Director and CEO
Center for Biosecurity of UPMC
621 E. Pratt Street, Suite 210
Baltimore, MD 21202

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 Drs. Inglesby and Parker,

Planning, building, and managing the Strategic National Stockpile (SNS) has taken a little over a decade worth of effort. In that time, increases in the number and types of threats and in the products and technologies available to manage those threats have broadened the scope and mission of the SNS program. Reductions in the resources necessary to support the SNS have, however, begun to constrain the ability of the program to deliver on its continued promise of countermeasure delivery in public health emergencies.

Because the imperatives to optimize the return on federal investments in health have never been greater, HHS must plan now for how it will support the SNS of the future (SNS 2020). At the same time, CDC needs to have access to the tools, processes, and mechanisms that will enable the SNS to efficiently anticipate and effectively meet novel challenges as they arise. Ideally, then, defining the mission of SNS 2020 will result from a calculated consideration and integration of current and future fiscal realities; an awareness of evolving and potential public health threats; and knowledge of available innovations – technological and otherwise – that permit efficiencies of economy, scale, and delivery of medical countermeasures. An SNS capable of responding to public health emergencies without compromise will require a combination of long-term investments – some financial, some strategic.

The Assistant Secretary for Preparedness and Response (ASPR) and the Director of the Office of Public Health Preparedness and Response (OPHPR), therefore, jointly charge the Chair of the National Biodefense Science Board (NBSB) and the Chair of the Office of Public Health Preparedness and Response (OPHPR) Board of Scientific Counselors (BSC) to form a joint review working group to:

1. **Identify the anticipated responsibilities of the SNS in the year 2020;**
2. **Recommend approaches for meeting those responsibilities as efficiently as possible; and**
3. **Propose metrics for reporting program capability and informing improvement.**

1. **Identify the anticipated responsibilities of the SNS in the year 2020.** This charge is for both Federal Advisory Committees (FACs) – through the joint working group – to explore potential future responsibilities of the SNS by looking backward at past experience and forward to expected changes.

The evolving mission and response experiences of the SNS (and that of related programs such as those for vaccine storage and deployment) provide insight into the ways that decision-makers have viewed the role of the SNS over the past ten years. The SNS program has had to develop expertise in many capabilities, including: efficient procurement, transportation, and storage of products; quality control and management procedures to effect optimization of product lifespan; support for planning and exercising to optimally leverage every-day health systems while assuring back-up mechanisms to deliver and dispense products under crisis conditions to myriad diverse and vulnerable populations; and tracking the use, impact, and safety of deployed SNS products. Fluidity in the roles that the SNS program has been asked to play and in the responsibilities it has been required to assume is likely to continue. And while the capabilities of the SNS and its mission have expanded as it has been called upon to respond to an increasingly wider array of events and incidents, anticipation of roles and responsibilities has become ever more challenging. Input from senior government leaders needs to be elicited to identify the top anticipated responsibilities of the SNS.

Guidance concerning the responsibilities of SNS 2020 should also take into consideration the addition of other critical functions to its portfolio. Indeed, managing the emergency medical supply chain in a public health crisis – the sine qua non responsibility of the SNS – may only be one among several roles that the SNS could be asked to play 10 years into the future.

The impact that major developments in the Public Health and Emergency Medical Countermeasure Enterprise (PHEMCE) will have on what SNS will be asked to do (and how it will have to conduct its business) must also be considered. These developments may include – but are not

limited to – PHEMCE governance procedures, FDA regulatory changes, Biomedical Advanced Research and Development Authority (BARDA) Advanced Development and Manufacturing facilities and the Strategic Investor. An informed vision of SNS 2020 may also properly include knowledge of or a better than working familiarity with: advances in disease detection and diagnosis; faster and more flexible manufacturing technologies; innovations in countermeasure storage, distribution and dispensing practices; mandated requirements for safety and effectiveness monitoring; potential benefits from public-private partnerships and alliances; and available multi-use products.

2. **Recommend approaches for meeting those anticipated responsibilities as efficiently as possible.** The FACs are charged with evaluating the relative merits and deficiencies of the different approaches used to meet the anticipated responsibilities of the SNS of the future.

   Innovations in information systems, in manufacturing, and in supply chain management may change the options for SNS operations. The FACs are being asked here to evaluate and provide a relative hierarchy of the operational efficiencies of a stockpile managed inventory vs. a vendor managed inventory (VMI) vs. user managed inventory (UMI) or other approaches, to help the SNS program achieve maximal efficiency of the medical supply chain, both now and in the years ahead. Since it is expected that more than one approach may be needed to best manage the various responsibilities, products, and operating conditions of SNS 2020, we request that the FACs provide guidance and, where available, tools that can be used to identify different approaches, either singly or in combination, to create maximal efficiency. Given the critical mission of the SNS – to assure the American public's access to appropriate medical countermeasures for identified key threats at the time they are needed – what approaches perform best and under what conditions? Where do proposed approaches underperform? And finally, what combination of approaches, if any, may be used to create maximal efficiency?

3. **Propose metrics for reporting program capability and informing improvement.** Measurement is the currency of process improvement. While we have robust and well-tested measures of inventory management that have allowed the SNS to achieve remarkable performance capabilities, many other supply chain functions have no such reliable metrics as yet. Upon refining and prioritizing the critical capabilities for SNS 2020, the FACs are asked to provide guidance from the practice of science and industry for how we can measure performance to gauge program effectiveness, drive improvement,

and appropriately communicate the information with our partners in emergency preparedness and response.

Given the complexity of this task, the joint working group should consult with a wide range of experts within and outside the United States Government, to include the public health community, industry, subject matter experts in supply chain logistics and distribution, among other relevant stakeholders. The joint working group will present their findings to both FACS for their deliberation at a joint public meeting within a 7 – 10 month timeframe. It is vital that both Boards explore the broad range of options available for assuring the American Public's access to appropriate medical countermeasures for identified key threats, at the time they're needed.

The Department looks forward to the report with recommendations on behalf of both the BSC and the NBSB, and applaud the collaborative efforts of both FACs in taking a critical step towards improving and advancing our nation's resilience, preparedness, and response efforts.

Sincerely,

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

for

Ali S. Khan, MD, MPH
Director, Office of Public Health Preparedness and Response

APPENDIX C

Joint NBSB/OPHPR BSC Working Group

Roster

Joint Office of Public Health Preparedness and Health Response (OPHPR) Board of Scientific Counselors (BSC) and National Biodefense Science Board (NBSB) Working Group (WG)

Roster

SNS 2020 Joint OPHPR BSC/NBSB WG Members

Co-Chair Donald Burke, MD (BSC Member)
Dean
Graduate School of Public Health
University of Pittsburg
Pittsburgh, PA

Co-Chair John S. Parker, MD, Major General (Retired) (NBSB Chair)
Senior Vice President
Scientific Applications International Corporation
Virginia Beach, VA

Margaret Brandeau, PhD (BSC Member)
Professor
School of Engineering
Stanford University
Stanford, CA

Emilio A. Emini, PhD (NBSB Member)
Chief Scientific Officer
Vaccine Research
Pfizer, Inc.
Collegeville, PA

Perry L. Fri (Representative)
Senior Vice President
Industry Relations, Membership and Education
Healthcare Distribution Management Association
Arlington, VA

Steven Krug, MD (NBSB Member)
Director
Division of Emergency Medicine
Children's Hospital of Chicago
Chicago, IL

Herminia Palacio, MD, MPH (BSC Member)
Executive Director
Harris County Public Health and Environmental Services
Houston, TX

Brian Richard, RPh (Representative)
Senior Director
Health and Wellness Operations
Walmart
Rogers, AR

George Schember (Representative)
Vice President
Transportation and Logistics
Cargill
Minneapolis, MN

Designated Federal Officials

Sam Groseclose, DVM, MPH, DACVPM (BSC)
Associate Director for Science
Office of Science and Public Health Practice
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
Atlanta, GA

CAPT Charlotte Spires, DVM, MPH, DACVPM (NBSB)
Executive Director, NBSB
Office of Policy and Planning
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
Washington, DC

Executive Secretariats

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

CAPT Jeffrey B. Nemhauser, MD (BSC)
Deputy Associate Director for Science
Office of Science and Public Health Practice
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
Atlanta, GA

APPENDIX D

WG Activities

Agenda

Board of Scientific Counselors (BSC) / National Biodefense Science Board (NBSB)
Strategic National Stockpile (SNS) 2020 Foresight Review
Joint Working Group Meeting

Co-Chairs: Donald S. Burke, MD and John S. Parker, MD

October 9-10, 2012

Building 19, Room 117
Roybal Campus, Tom Harkin Global Communication Center
1600 Clifton Road, NE
Atlanta, GA

Tuesday, October 9 (Day 1)

- **Day 1, Session I**

09:00 — 09:15 (15 minutes)
Welcome and Call to Order / Introductions and Opening Remarks / Working Group Policies and Procedures
Review of the Working Group Charge and Key Questions for Discussion*
Donald S. Burke, MD (OPHPR BSC); Working Group Co-Chair
John S. Parker, MD (NBSB); Working Group Co-Chair

09:15 — 10:00 (45 minutes)
SNS 2012: How We Got from There to Here (Part A: The Early Years)
W. Greg Burel; Director, Division of Strategic National Stockpile, CDC

10:00 — 10:45 (45 minutes)
The Strategic National Stockpile: A Legislative History
Joseph A. Foster, JD; Office of the General Counsel, CDC

10:45 — 11:30 (45 minutes)
Material Threat Assessment
David H. Walker; Intelligence Officer – Georgia, Office of Intelligence and Analysis, US Department of Homeland Security, Georgia Information Sharing and Analysis Center

11:30 — 12:15 (45 minutes)
Questions and Answers Day 1, Session I

Tuesday, October 9 (Day 1)

- **Day 1, Session II**

Lunch (12:15 — 1:30) - Lunches available for purchase

1:30 — 2:15 (45 minutes)	**Medical Countermeasures and the Structured Governance Process** Lisa Kaplowitz, MD, MSHA; Deputy Assistant Secretary for Policy, Office of the Assistant Secretary for Preparedness and Response US Department of Health and Human Services
2:15 — 3:00 (45 minutes)	**FDA's Medical Countermeasures Initiative (MCMi)** CAPT Carmen Maher; Deputy Director, Office of Counterterrorism and Emerging Threats, Office of the Commissioner, US Food and Drug Administration Brooke Courtney, JD, MPH; Regulatory Counsel, Office of Counterterrorism and Emerging Threats, Office of the Commissioner, US Food and Drug Administration
3:00 — 3:45 (45 minutes)	**SNS 2012: How We Got from There to Here (Part B: Challenges)** W. Greg Burel; Director, Division of Strategic National Stockpile, CDC
3:45 — 4:00	**Break**

Tuesday, October 9 (Day 1)

- **Day 1, Session II (continued)**

4:00 — 5:30 (90 minutes)	**Questions and Answers Day 1, Session II / Day 1 Recap and Review**
5:30	**Adjourn Day 1**

*** KEY QUESTIONS FOR DISCUSSION:**

- What will/should the SNS look like in the year 2020?
- What aspects of the SNS mission are fixed by law or regulation (core)?
- What aspects of the SNS missions are assigned as directed by Secretary of HHS or other similar authority (situational)?
- How has the threat environment evolved since the inception of the SNS and where could it be headed?
- How do other unanticipated/novel emerging infectious diseases fit in the SNS model?
- What are current emergency preparedness legislation and funding mechanisms that govern the SNS?
- How will funding cuts and centralization affect what we need to do federally?

Wednesday, October 10 (Day 2)

- **Day 2, Session I**

08:00	**Welcome and Call to Order** Donald S. Burke, MD (OPHPR BSC); Working Group Co-Chair John S. Parker, MD (NBSB); Working Group Co-Chair
08:00 — 09:30 (90 minutes)	**Working Group Discussion/Day 1 Review**
09:30 — 09:45 (15 minutes)	**Break**
09:45 — 10:30 (45 minutes)	**SNS 2012: Logistics of Public Health Emergency Response** Shirley Mabry; Logistics Branch Chief, Division of Strategic National Stockpile, CDC W. Greg Burel; Director, Division of Strategic National Stockpile, CDC
10:30 — 12:00 (90 minutes)	**Logistics and Supply Chain Panel Discussion** Nitin Natarajan, MA, Coordinating Director, Office of Preparedness and Emergency Operations, Office of the Assistant Secretary for Preparedness and Response, US Department of Health and Human Services George Schember; Vice President, Corporate Transportation and Logistics, Cargill Incorporated Brian Richard, RPh; Senior Director, Health and Wellness Operations, Wal-Mart Stores, Incorporated Perry L. Fri; Senior Vice President, Industry Relations, Membership and Education, Healthcare Distribution Management Association

Lunch (12:00 — 1:00) - Lunches available for purchase

Wednesday, October 10 (Day 2)

- **Day 2, Session II**

1:00 — 2:15 (75 minutes)	**Questions and Answers / Working Group Discussion**
2:15 — 2:30 (15 minutes)	**Break**
2:30 — 3:30 (60 minutes)	**Working Group Discussion – Questions for Charge 2**
3:30 — 4:00 (30 minutes)	**Future Topics and Presenters / Calendaring**
4:00	**Adjourn Day 2**

Board of Scientific Counselors (BSC) / National Biodefense Science Board (NBSB)
Strategic National Stockpile (SNS) 2020 Foresight Review
Joint Working Group Teleconference

Co-Chairs: Donald S. Burke, MD and John S. Parker, MD

November 30, 2012

Agenda

Call to Order:
Samuel Groseclose, DVM, MPH, Designated Federal Official, Office of Public Health Preparedness and Response (OPHPR), Board of Scientific Counselors (BSC)

Attendance List:

Dr. John Parker
Dr. Donald Burke
Dr. Herminia Palacio
Dr. Margaret Brandeau
Dr. Emilio Emini
Dr. Steve Krug
Mr. Brian Richard
Mr. Perry Fri
Mr. George Schember
Dr. Charlotte Spires
Ms. Jomana Musmar
Dr. Jeffrey Nemhauser
Mr. Greg Burel

Opening Remarks and Overview:
Donald S. Burke, MD, Working Group Co-Chair, OPHPR BSC
John S. Parker, Working Group Co-Chair, National Biodefense Science Board (NBSB)

- Identify anticipated responsibilities of the Strategic National Stockpile (SNS) in 2020
- Recommend approaches for meeting those responsibilities efficiently
- Propose metrics for reporting program capability and informing improvement

SNS Response to Questions from Working Group Chairs
W. Greg Burel, Director, Division of Strategic National Stockpile, CDC

Question 1: Describe the process by which a decision to deploy SNS assets gets made
Question 2: How are SNS capabilities trained, tested, evaluated, and exercised?
Question 3: Re: Hurricane Sandy

- Who tasked the SNS to respond?
- What assets were requested?
- What assets were mobilized?
- How were SNS assets used relative to the core mission?

SNS 2020 Working Group Discussion Topics

- Key Issues Document Discussion
- What *Should* the SNS Look Like in 2020?

Rough Proposal of Recommendation - Discussion Re-Cap

SNS 2020 Working Group

Wrap-up and Adjourn

Donald S. Burke, MD, Working Group Co-Chair, OPHPR BSC
John S. Parker, Working Group Co-Chair, National Biodefense Science Board (NBSB)

NBSB NATIONAL BIODEFENSE SCIENCE BOARD

Joint BSC/NBSB SNS 2020 Working Group Agenda
Thursday, January 31, 2013
8:00 am – 5:00 pm
375 E St. SW Patriots Plaza II, Room 12-1401, Washington, DC 20024
1-877-953-0866 code 2550544

8:00 am – 8:05 am	**Welcome and Agenda Overview** Dr. Donald Burke and Dr. John Parker, Joint BSC/NBSB SNS 2020 WG Co-Chairs
8:05 am – 8:30 am	**Opening Remarks** Dr. Nicole Lurie, Assistant Secretary for Preparedness and Response, HHS
8:30 am – 10:00 am	**SNS Acquisitions and Logistics – 45 mins per session** **NOTE: Please limit your presentations to 20 mins** **The PHEMCE: Impacts and Influences for the Strategic National Stockpile** Dr. George Korch ASPR/HHS **BARDA Product Development and Procurement** Dr. Carol Linden BARDA/ASPR/HHS
BREAK (15 mins)	
10:15 am – 1:00 pm	**State Needs and Capabilities** Shannon Calluori, Director Bureau of Public Health Preparedness, Pennsylvania Department of Health **WG DISCUSSION** **Performance Measures and Metrics** Dr. Christopher Nelson Senior Political Scientist, RAND Corporation Professor, Pardee RAND Graduate School **WG DISCUSSION**
1:00 pm – 2:00 pm	**WORKING LUNCH (1 HOUR)**
2:00 pm – 4:00 pm	**Draft Writing Session – Working Group Only** o Develop outline based on Key Issues o Draft Initial Recommendations o Assign sections to WG members
4:00 pm – 5:00 pm	**Marketing and Education of SNS to All End Users** WG Discussion
5:00 pm	**Adjourn**

Charge Questions:

1. Identify the anticipated responsibilities of the SNS in the year 2020
2. Recommend approaches for meeting those responsibilities as efficiently as possible
3. Propose metrics for reporting program capability and informing improvement

Joint Board of Scientific Counselors (BSC) and National Biodefense Science Board (NBSB) Working Group (WG) SNS 2020 Meeting
375 E St SW, Room 12-1401, Washington, DC
January 31, 2013

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Board of Scientific Counselors (BSC) / National Biodefense Science Board (NBSB)
Strategic National Stockpile (SNS) 2020 Foresight Review
Co-Chairs: Donald S. Burke, MD and John S. Parker, MD

KEY ISSUES – DRAFT NOTES

HISTORY

Pre 9/11
National Pharmaceutical Stockpile (NPS) – *Omnibus Appropriations Act* (1999)

- Mission
  - Terrorist event response
  - Re-supply of essential medical materiel during emergencies of national significance
- Funding
  - "Straight" government appropriation: $51 M Public Health and Social Services Emergency Fund
  - *Public Health Security and Bioterrorism Response Act* (2002)
    - Specific authorization to create Strategic National Stockpile (SNS)
    - Legal authority to support SNS activities
- Legislative Status
  - *Public Health Security and Bioterrorism Response Act* (2002): changed name from NPS to SNS, in coordination with Veteran's Administration (VA)
  - *Homeland Security Act* (2002): moved SNS to Department of Homeland Security (DHS), in coordination with US Department of Health and Human Services (HHS) and Veteran's Administration (VA)
- Logistics
  - Limited managed inventory
  - Origins of the 12-Hour Push Package

Post 9/11
Strategic National Stockpile

- Mission
  - Scope expanded and capabilities increased to protect greater numbers of people based on emerging priority public health emergency threats
  - SNS doesn't just provide supplies; helps create a prepared public health system
- Funding
  - Q: Will funding always be a driving criterion for SNS size, shape, content, and mission?
  - Centers for Disease Control and Prevention (CDC) has annual appropriated funds to maintain SNS and procure medical countermeasures (MCM)
  - Supplemental appropriations to HHS Secretary authorize purchase of additional products for inclusion in SNS (e.g., H1N1 MCM)
  - *Simplified Acquisition Procedures*: used if HHS Secretary determines need for specific MCM
  - *Special Reserve Fund* ($6.5 B)
    - Authorized by BioShield Act

        - Expires at end of FY13
        - Used to purchase MCM for inclusion in SNS[1]
    - FY 2106 inventory maintenance cliff: procurement peak to replace expired stock

- Status
    - CHEMPACK program and Cities Readiness Initiative (CRI)
        - *BioShield Act* (2004)
            - In coordination with DHS, responsibility for SNS transferred back to HHS (VA not included)
            - DHS retained SNS asset deployment authority
        - *Pandemic and All Hazards Preparedness Act [PAHPA]* (2006)
            - Provides Assistant Secretary of Preparedness and Response (ASPR) with explicit authority to *coordinate* SNS
- Logistics
    - Inventory and formulary expanded
    - Protect against new emerging priority threats

LOGISTICS

Inventory Management

- 1999: VA National Acquisition Center partnership
    - 3rd party logistics for storage
    - Transportation providers for deployment
- >90% of funding allocated to inventory management
- Vendor Managed Inventory (VMI)
    - Used for a small portion of the SNS
    - *Pros*: Single product rotation
    - *Cons*: high costs; vendors hesitant to participate; limited number of deployment sites
- User Managed Inventory (UMI)
    - *Pros*: Single product rotation; lower management costs
    - *Cons*: Difficult to track assets difficult to deploy assets when needed
- SNS Managed Inventory
    - Used for majority of current SNS
    - *Pros*: Multiple deployment sites; deploy assets whenever needed; lowest management costs
    - *Cons*: Difficult to rotate products
- Cities Readiness Initiative (2004)
    - Developed to strengthen preparedness capacity in major Metropolitan Statistical Areas
    - Benchmark: provide mass prophylaxis to the population within 48 hours of symptom recognition

[1] Special Reserve Fund Procurements: DHS determines material threats, HHS determines necessary countermeasures (delegation for some activities to ASPR), DHS and HHS make recommendations to OMB, OMB approves, BARDA makes procurements, CDC maintains procured countermeasures in SNS

- CRI funding: CDC's Public Health Emergency Preparedness (PHEP) cooperative agreement
- Alternate dispensing models
  - Designed/intended to alleviate burden on public health system and decrease MCM delivery time to affected population in an emergency
  - Examples: postal service; drive through dispensing; employer –based dispensing; community strike teams; community-based organizations
  - Alternative (less desirable) approach: delivery via other Federal organizations (e.g., Federal Emergency Management Agency [FEMA])

Deployment Authority

- Processes created to ensure rapid deployment of assets
- Authority to release lies with Secretary of HHS and Secretary of DHS
- Authority from Secretary of HHS delegated to ASPR
- Memorandum of understanding (MOU) between ASPR and CDC
  - MOU allows CDC Director to deploy materiel not available anywhere outside of SNS, if CDC subject matter experts contacted for assistance
- In absence of a disaster declaration, states can request assets through HHS or CDC
- In active disaster response, HHS tasks SNS to deploy, with or without mission assignment from DHS

Deployment Trends

- Since 2001: SNS assets mainly deployed in support of natural disasters (floods and flu)
- Few requests for MCMs from local and state departments
- SNS does not store pharmaceuticals to treat chronic health conditions

Other logistics issues

- Matching SNS capability to deliver assets with State/local capability to utilize/distribute them
  - Capacity, timeframe, and functionality [of SNS] need to align with user capability
- Dependence on international (re-)sources
  - Raw materials to formulate MCMs in SNS come from overseas and many MCMS in SNS not even manufactured domestically
  - Bottlenecks or changes in trade regulations may result in shortages of critical MCM[2]

Additional thoughts regarding logistics

- Core functions of the SNS enterprise: acquisition, storage, maintenance, and distribution
- Better decision-making tools (computational modeling and simulation) may provide guidance for "what" and "how much" is stockpiled in the SNS
- SNS Management
  - SNS is a relatively static system facing unpredictable and sudden demands
  - More difficult to manage than traditional industry logistics (dynamic and more predictable)
- SNS is respected throughout the world.

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[2] See *Reliance on Foreign Sourcing in the healthcare and Public Health (HPH) Sector: Pharmaceuticals, Medical Devices and Surgical Equipment* (December 2011), US Department of Commerce.

MANAGEMENT AND ACQUISITIONS

Public Health Emergency Medical Countermeasure Enterprise (PHEMCE)

- Federal coordinating body, headed by ASPR
- Drives SNS formulary

Recent survey of 300 state and local organizations

- Greater than 90% would depend on SNS for MCMs

SNS sustainability requires

- Lifecycle analysis of MCM costs
- Multi-year budgeting to build foundational support
  - Coherent integration of MCM requirements ranging from development to acquisition
  - Budget coordination: account for distinct appropriations to various agencies involved in MCM enterprise
  - Integrated budget planning: permits better detail and justification of budget requests over multiple MCM lifecycles

New PHEMCE Strategy and Implementation Plan (2012)

- All-hazards philosophy: move away from threat-based focus toward broad-spectrum capabilities approach
- PHEMCE prioritization framework based on two core principles
  - Limiting adverse health impacts
  - Maintaining fiscal responsibility

Various stakeholder responsibilities

- CDC: thinking about new products coming down the line
- Biomedical Advanced Research Development Authority (BARDA)
  - Maintaining/investing in a “warm base” for products
- Department of Defense (DoD)
  - DoD does not directly fund any SNS acquisitions
  - DoD can purchase from SNS – pays for packaging and shipping as well as materials, but then SNS immediately replaces those items
- NIH/FDA
  - Provides clinical data and studies and oversight of Emergency Use Authorizations (EUAs)
- DHS
  - Provides Material Threat Assessments (MTAs)
  - Continuously models threats and responses
  - Provides infrastructure protection
- ASPR
  - Develops concepts of operations (CONOPs); integrates all capabilities in end-to-end fashion

SNS Annual Review

- Mandated by PAHPA
  - Measures and tracks performance year-to-year – evaluation of inventory, acquisitions, etc.
  - Reviewed and approved by the Enterprise Senior Council (ESC) of PHEMCE
  - PHEMCE expected to fill identified gaps
- How used?
  - Informs budget preparation and the development of multi-year budget planning
  - Provides guidance to program managers (formulary needs, gaps, strategies)
- Not publicly released – goes to OMB and Congressional committees
- Additional key measures
  - Inventory validity
  - Were exercise objectives met or exceeded
  - Personal evaluations of senior executives
- Bi-monthly portfolio reviews generate priority action items
- 10 Integrated Program Teams (IPTs) responsible for specific threat areas and threat response
- Actions that result from the annual review process
  - Inventory maintenance/replacement
  - Inventory reduction/elimination
  - Addition of new items
  - Identification of products moving toward SNS acquisition
- *General operating rule when considering changes to the SNS inventory: balance high level of preparedness with prudent levels of risk*

Medical Countermeasures Initiative (MCMi) of the US Food and Drug Administration (FDA)

- Balances public health needs, regulatory requirements, and science that underlies intended product use
- MCM development challenge: market for boutique drugs (especially those for emerging threats) does not exist

BARDA

- Mission
  - Provide MCMs for CBRN threats, pandemic flu, and emerging infectious diseases
  - Work with partners within an overall framework set by PHEMCE
- Conducts R and D and *initial* acquisition of MCMs in the SNS
  - Does not acquire additional MCMs to sustain and maintain SNS
  - Any new technologies currently in R and D will take >8 years to incorporate into SNS
- Focus: innovation/development of multi-use platform technologies
  - Smaller respirators (for less storage space and better mobility)
  - Products with longer shelf-lives

Material Threat Assessment (MTA)

- BioShield Act requires MTA for any BARDA expenditure
- Military and civilian responses are coordinated

- BARDA works with DHS and DoD to synergize responses – each partner knows the others' capabilities, stockpiled assets

MCM management

- BARDA: systematic approach to MCM enterprise
  - Theory behind CONOPs
    - Reduce time needed to release products to SNS
    - Build commercial markets, e.g. through Vendor Managed Inventory (VMI)
      - BARDA purchases non-expiring "bubble" of commercial product, providing permanent access to production stream
      - Represents a net cost but may be cheaper than maintaining stockpile
      - Multi-purpose products such as broad spectrum antimicrobials could reduce SNS inventory needs – IPT established specifically for broad spectrum antimicrobials
- BioShield Act Funding
  - $1B in Special Reserve Fund with $220M under continuing resolution
  - Due to expire FY13 unless Congress passes revised PAHPA

WG Discussion

- Control of SNS
  - Centralized responsibility and control for SNS vs. non-centralized approach without a single authority
  - CDC director responsible for defending SNS budget in relation to other CDC capabilities
  - PHEMCE: need exists for governance that cuts across several agencies
- Moving materiel
  - Q: Barriers to moving materiel in a crisis?
  - A: Money; availability of appropriate technology; regulatory constraints
    - Money: appropriators can quickly provide funds in a crisis
    - Technology: ongoing efforts to develop and innovate
    - Regulatory constraints: rapid public health assessment teams facilitate movement of regulatory dollars to where they are needed

THREAT CHARACTERIZATION

Federal roles

- DHS: determines material threat to US population
- HHS: determines potential health consequences
- DHS and HHS: make recommendations to OMB for purchases

Threat evolution

- Natural disaster have always existed as a threat
- Terrorism, including homegrown violent extremists
- Other than conventional weapons: ricin, botulinum toxin, *B. anthracis*

Additional thoughts regarding threat characterization

- Apparent move away from "nation threat" to an asymmetric terrorist threat; limited scenarios
- Will never reach zero risk

EVOLUTION OF SCIENCE

QUESTION: With regard to pharmacy and therapeutics (P and T), equipment, storage, logistics, demand, will technology and science significantly change the SNS by the year 2020? For example, would a dramatic change in the approach to post-exposure prophylaxis of anthrax spore exposure relieve a significant SNS burden?

See also: MANAGEMENT AND ACQUISITIONS/BARDA for discussion on how science informs SNS assets

WG Discussion

- Use most current technology/science available to determine what (and how much) to include in SNS
  - Balance between significant cost reductions and potential risk increase should be *informed by science*
- Science-based decisions and risk-to-value implications should drive SNS evolution

SNS SUBMISSIONS

WG Discussion

- Pharmaceutical supply chain gaps
  - Warm supply base – economically inefficient
    - Not cost effective for companies to maintain excess manufacturing capacity
    - Cost of government incentives to maintain warm supply base, very high
    - Surge capacity in the absence of a warm supply base not easily accomplished
    - In H1N1 – supply of MCM well exceeded demand, and companies took a loss with excess inventory
  - Surge capacity at industry level
    - Either unreliable or non-existent due to current business practices
    - However, most MCMs are needed within a short time-frame to be effective – cannot wait for supply to meet demand
  - Supply vs. demand mismatch
    - For regional/local events, supplies can be routed to affected areas
    - For national events, no good way to cover shortages due to the intersection of a tight supply chain along with an already high seasonal product demand
  - Partnering with international allies to alleviate pressure on the US alone to expand MCM market (and support expanded surge capacity) is beginning to happen
  - Technology Readiness Levels (TRLs)
    - BARDA using TRLs to assist in portfolio development with other Federal partners and international allies

        - Provide better picture of MCM development status across US Government
        - TRLs should be used to clarify what MCMs are now and what will be available
        - Licensure of products is a goal
- SNS Asset Categories
    - Orphan: have very specific and limited requirements for use
    - No commercial market: United States Government (USG) is only purchaser (e.g., AVA – most expensive product in SNS)
        - Some or most MCMs will never have a market in everyday medical practice
    - Short supply products: includes back up antibiotics (to treat multi-drug resistant strains) and respiratory protection (to support surge)
- Non MCMs
    - Ventilators
    - Federal Medical Stations (FMS)
- Future and emerging threats
    - Next generation in supply chain pipeline
    - Bridging the gap: moving from unknown to known, potential threats to real products
    - Desired goal: multi-functionality – where 80% of MCMs can be used for >1 purpose while keeping in mind considerations like antibiotic resistance

EVOLUTION OF RISK

WG Discussion

- Material Threat Assessments (MTA)
    - Includes agents of terrorism (these fall under the Federal domain)
    - Process
        - DHS determines material threat to US population
        - HHS determines potential health consequences of threat and PHEMCE covers formulary
        - DHS and HHS make recommendations to OMB for purchases
    - BioShield Act legislation requires MTA for any BARDA expenditure
    - Is there anything else than should be considered that can improve the ability of the SNS to better manage the assets needed to address a full range of public health threats (intentional threats to the broader range of natural threats)?
- Create less restrictive mission space for SNS
    - Provide essential medical pharmaceuticals and devices to support and meet a surge requirement to save life or contain any *all-hazards* type incidents
    - Is the strategy for implementing the SNS mission compatible with available resources?
    - Start with fundamental question (what do we want the SNS to do), then look at the resources and determine how to achieve that mission
- Communications issues
    - Consent
        - Obtaining consent from an adult is different than asking for parental consent for a child
        - Advanced risk communication is necessary
    - Fostering public trust

        - Careful use of language
        - Avoid the misunderstanding/miscommunication
    - Communicating what cannot be done is as important as communicating what can
        - *See also: STATE NEEDS AND CAPABILITIES/WG Discussion/Communication for further discussion surrounding communication and risk*

REQUIREMENTS GENERATION

WG Discussion:

- Consequence vs. probability
    - SNS built around high consequence rather than high probability. To use available funding efficiently and effectively, need to find the right balance between material threats and likelihood of occurrence
    - SNS tries to strike a balance between high probability *and* consequence
- Consequential effects
    - If SNS experiences pressures, trickle-down effects impact state and local public health
- Situational awareness (SA) modeling and simulation
    - Needed to provide insight on future issues
    - Will advance as the years continue to better help prepare for a response
    - SA capabilities will become more prevalent but are difficult to model and understand due to number of assumptions that need to be incorporated
    - Behavior is hard to predict in a model
    - Envision an entity uniquely positioned to do what nothing else can. Then use that vision to change the existing paradigm

STATE AND LOCAL CAPABILITIES AND NEEDS

WG Discussion (conversation based on presentation from Pennsylvania State Department of Health)

- Major Challenges/Concerns
    - Finding and retaining qualified staff to run a distribution and dispensing program
    - Annual CDC assessment process
        - Test of *planning*, not necessarily execution or operation
    - Dispensing
        - Distribution personnel don't typically think about what it takes to dispense
        - Task of dispensing falls to local public health
    - Gap in depth of leadership
        - Large distribution/dispensing operations are supposed to take place within 48 hours
        - Many "day-of" decisions must be made that are not in written plans
        - Personnel involved in distribution/dispensing operations lack seniority/experience to make such decisions
    - State caches
        - Federal guidance on what assets/MCMs should be in a state cache is missing/needed
        - Assistance with managing expiration and disposal of product held in state caches

        - Warehousing costs are significant
        - Material Threat Assessment: what MCMs should be stocked by USG and by states?
            - How many threats might impact the entire country at the same time?
    - Pre-planning vs. "day of" arrangements
        - Often easier to make "day-of" arrangements in a crisis
        - Calling local distributors ad hoc and asking for help more efficient and cost effective than making long-term plans
        - Not known in advance what will be needed, where, when, how much
    - Surveillance and epidemiology needs
        - State and local personnel need to know when to mount a response
        - Ideally built on day-to-day (epidemiology) operations
- Communication
    - CDC gives a lot of recognition and support to states
        - States receive attention during a crisis
        - Messaging less widespread in normal times
    - Perspective on public opinion
        - We have not explained to the American people what it takes to do what they expect
        - Scant public support for expenditures to prepare for rare events
        - Public nevertheless expects the system to be there for them in times of need
    - People don't understand how much they do can individually
- MCM Delivery
    - H1N1: significant variability in delivery experience from one state to another, created distrust
    - Expectation that SNS will deliver the goods creates expectation that states will play their necessary roles
    - Recommendation: Federal government should not take over entire process

Additional thoughts regarding state and local public health partnerships

- Expectations and mandates that USG is prepared to respond to public health emergencies
- State and local public health planners and responders benefit from a single surge provider
    - Reliable
    - Works with them to provide proper and timely distribution
    - "Part of the team"
    - Provides back-up for special acquisition needs
    - Offers command and control opportunities
    - Has pre-set transportation priorities
- System drives trust, and trust from the "customer" is needed to execute the mission

PERFORMANCE MEASURES AND METRICS

Capacity (planning) leads to capability which leads to outcomes
Technical Assistance Review (TAR)

- Paper-based assessment of various function areas

- Aggregation of results yields a single performance measure – standards define needed performance levels
- Metropolitan Statistical Areas (MSAs)
  - TAR applies to states and the 72 MSAs that are part of Cities Readiness Initiative (CRI)
  - MSAs in highly centralized states tend to be higher than in decentralized states
    - Centralized states: all health functions are at the state level
    - Decentralized states: some health functions delegated to local levels
  - States with higher TAR scores tend to have a greater number of MSAs
  - What jurisdictions are having more trouble, and why?
- Limitations
  - Focuses mainly on plans, not execution
- Flexibility in measurement
  - Suggests a modular approach
  - Allow states and localities flexibility in how they do the exercises
- Modeling
  - Makes it possible to ask "what if" questions (change steps, add more supervision, etc.)
- Experience gained during H1N1 response – to run an effective POD, you need leadership to adjust plans in light of unexpected occurrences
- Limited evidence that measurement can be used as a tool for improvement
  - Inter-rater consistency among assessors has not been validated
  - Data on whether improvements have resulted do not exist
- Who is really good at emergency response?
  - People who live in areas where such services are often needed
  - In areas that don't have such needs, emergency response is hard to practice, and it's hard to know whether people will do what they're slated to do

FUTURE PROSPECTS

Additional thoughts regarding the future of the SNS

- 2020 is only 7 years away – technology platforms are not going to drastically affect current medical practices or protocols
- This country needs a Strategic National Stockpile
- Newer additions to the MCM inventory seem to require cold chain management
- Functions within the SNS structure need to re-validated
- International responsibilities (i.e., US response to incidents outside our borders) need to be carefully validated, accounted for, and funding allocated
- Revamped mission: Provide essential medical pharmaceuticals and devices to support and meet a surge requirement to save life or contain any all-hazards type incidents
- Requirements against current threat and thus quantities of material within the stockpile need to be re-visited and (if needed) reduced
- Individual, local, and state responsibilities need to be validated, stabilized, and plans made accordingly to get the public health response into an equilibrium that offers a chance to have a firm vision that can be fulfilled over time.