Meeting Summary National Biodefense Science Board (NBSB) Public Meeting

December 16, 2021 Washington, DC (virtual) 1:00-4:15 p.m. ¹

Attendees

Non-Federal Members ²

Prabhavathi Fernandes, PhD, FISDA, NBSB
Chairperson
Carl R. Baum, MD, FAAP, FACMT
John Benitez, MD, MPH
Mark Cicero, MD
H. Dele Davies, MD, MSc, MHCM
David Gruber, MA
Craig Klugman, PhD
Beth Leffel, PhD, MPH
David Schonfeld, MD, FAAP
David Witt, MD, FIDSA
Mike Usman, MD, MMM (non-voting)

Ex Officio Members

Isaf Al-Nabulsi, PhD, Department of Energy
Joanne Andreadis, PhD, Centers for Disease
Control and Prevention
Brooke Courtney, JD, MPH, Food and Drug
Administration
Mamadou Diallo, PhD, MS, National Science
Foundation

M. Camille Hopkins, DVM, PhD, Department of the Interior, U.S. Geological Survey

Jim Levy, Department of State
RADM Paul Reed, MD, USPHS, HHS Office of the
Assistant Secretary for Health
CAPT Michael Schmoyer, PhD, USPHS, The White
House, Office of Administration
Marc Shepanek, PhD, National Aeronautics and
Space Administration
Ian Watson, Deputy Assistant Secretary,
Office of the Assistant Secretary for
Preparedness and Response (ASPR)

ASPR Staff

CAPT Christopher Perdue, MD, MPH, USPHS, NBSB Designated Federal Official, ASPR Policy Division

Dawn O'Connell, Assistant Secretary for Preparedness and Response

RADM Theresa Lawrence, PhD, ASPR Policy Division Director

Cicely Waters, ASPR Director of External Affairs LCDR Cliffon Smith, USPHS, NBSB Executive Secretary, ASPR Policy Division

Mr. Darrin Donato, ASPR Domestic Policy Branch Chief

Introduction

CAPT Perdue opened the meeting and LCDR Smith conducted roll call. As the designated federal official, CAPT Perdue explained the requirements and limitations established by the Federal Advisory Committee Act as well as the application of the Standards of Ethical Conduct for Employees of the Executive Branch to board members, who have been appointed by the Secretary of the Department of Health and Human Services (HHS) as Special Government Employees. None of the board members raised any conflicts of

¹ The public meeting on December 16, 2021 went over the planned time on the published agenda.

² A <u>full roster for the NBSB</u> is available on the ASPR website.

interest. The public can participate in the work of the NBSB by attending public meetings, sending comments via email to MBSB@hhs.gov, or by volunteering to provide verbal remarks when there are allotted time periods in public meetings. When appropriate and time is available, public remarks that are submitted through the Zoom Q&A feature will be considered by the Board. The current charter for the NBSB is available on the ASPR website.

Remarks by Prabha Fernandes, PhD, FIDSA, NBSB Chairperson. Dr. Fernandes welcomed the board members and explained that the primary purpose of this meeting was to finalize recommendations that were requested by staff in the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR). In October 2021, the NBSB was asked to examine the National Health Security Strategy (NHSS) and recommend priority issues for the next edition of the NHSS (2023-2026).

Remarks by Dawn O'Connell, the HHS Assistant Secretary for Preparedness and Response. HHS Assistant Secretary Dawn O'Connell thanked the board members for their expertise, continued work, and guidance on a range of issues, especially through a once in a lifetime pandemic. She explained that she and the agency have three main priorities:

- Respond. The Biomedical Advanced Research and Development Authority (BARDA) continues
 working with agency partners, including Department of Defense (DOD) colleagues as part of
 Countermeasures Acceleration Group (formerly Operation Warp Speed) to develop additional
 vaccines, therapeutics, and diagnostics. In addition to the work of federal scientific teams, the
 National Disaster Medical System (NDMS) continues to deploy medical personnel to hospitals
 that are overloaded with COVID patients.
- Restore. In addition to rebuilding and reimagining the Strategic National Stockpile (SNS), ASPR staff are leading HHS efforts to secure the national public health supply chain. This has become a mission of ASPR, to ensure improved domestic manufacturing and capabilities moving forward.
- 3. **Prepare**. Beyond COVID-19, ASPR continues to evolve and develop plans with partners to be ready for natural or human-made threats of any type.

Highlighting the importance of the SNS and supply chain challenges, Ms. O'Connell pointed out that it was not originally developed to function in the ways that have been needed during the COVID-19 pandemic. To better respond to future pandemics and other threats, she indicated that the NBSB could help to redefine and modernize ASPR's approach to supply chain and stockpiling to ensure that HHS has "the right things in the right time." How does ASPR prepare for an unknown or different sort of threat? What is the proper balance of items on hand and available through domestic manufacturing? Is the public health supply chain most secure where needed?

Dr. Fernandes asked about maintaining multiple supply chains, including supplies and alternatives from various countries. Ms. O'Connell confirmed that the current focus is to improve domestic manufacturing to ensure there are local suppliers, recognizing that some items will need to be manufactured outside of the United States. The overall public health supply chain strategy is working on many fronts simultaneously, though there remains the question about balancing domestic vs. international suppliers.

Dr. Klugman asked how ASPR will manage the SNS to ensure that is able to maintain adequate supplies. Ms. O'Connell noted that that is one of the key challenges, which (among other things) requires having multiple manufacturers who can provide essential products while also having measures for rotation of stock and limiting waste.

Dr. Diallo commented on the value of integrating expertise from sociologists and anthropologists in future public health response strategies, which Ms. O'Connell acknowledged would be a potentially useful way to strengthen response plans.

Mr. Gruber commented that the original structure of the SNS, which still exists today, was not designed to provide the kind of response needed during the pandemic. He asked how the SNS could move from "what it was" to what is needed. Ms. O'Connell agreed that the expectations for the SNS at the beginning of the COVID-19 pandemic were not practical; it seemed like different stakeholders had different expectations. The NBSB could support ASPR by helping to define (or redefine) the SNS.

Dr. Baum commented on problems related to counterfeit personal protective equipment (PPE) and asked about federal or private sector "surveillance" for fakes. Ms. O'Connell noted that she was aware that there have been counterfeits in the supply chain. Coordinating with the private sector to monitor for ineffective or unsafe material in the public health supply chain is something that could be discussed further with colleagues at FDA.

Dr. Benitez asked about plans to build back the public health workforce. Ms. O'Connell noted that staffing across all sectors is a challenge right now, and that funding for restoration and strengthening of the public health supply chain and workforce are included in President Biden's American Rescue Plan. She added that a long-term funding and training plan is going to be needed, with sustained funding and coordination beyond what has been provided in emergency appropriations. While ASPR will continue to provide short-term staffing solutions when there are emergencies, the solution to the workforce problem requires training and sustained hiring at local levels.

Ms. O'Connell thanks the board members again, saying farewell to Drs. Schonfeld, Cicero, and Heppner, who are retiring from the NBSB on December 31, 2021.

Special Presentations

National Strategy for a Resilient Public Health Supply Chain

Stuart Evenhaugen, Strategy Division Acting Director, Office of Strategy, Policy, Planning, and Requirements (SPPR), ASPR

Mr. Evenhaugen provided an overview of the <u>National Strategy for a Resilient Public Health Supply Chain</u> (or simply the Supply Chain Strategy), which the ASPR Strategy Division leads for HHS. Required by <u>Executive Order 14001</u>, the purpose of the interagency strategy is to protect the health and security of Americans by maintaining a public health supply chain that is consistent with our values and resilient against disruptions from pandemics and other threats. The public health supply chain includes the full range of medical countermeasures, including personal protective equipment, medical devices,

³ DFO postscript: a factsheet for the <u>American Rescue Plan</u> is available online.

diagnostics, therapeutics, biologics, vaccines, and other essential medicines. The strategy has three major goals:

- 1. Build a diverse, agile public health supply chain and sustain long-term U.S. manufacturing capability for future pandemics and other public health emergencies.
- 2. Transform the U.S. government's ability to monitor and manage the public health supply chain through stockpiles, visibility of manufacturing and distribution pipeline, and engagement with stakeholders and partners.
- 3. Establish standards, systems, and governance to manage the supply chain and ensure fair, equitable, and effective allocation of scarce resources when needed.

With implementation of those strategic goals, the future public health supply chain will be more flexible and reliable. Traditional stockpiling will be the approach for certain items, while innovations in manufacturing and logistics will occur in tandem with stronger and more comprehensive arrangements for vendor-managed inventory and virtual stockpiles. Concurrently, access to more diverse sources for raw materials is an essential component of domestic and global engagements. Platform technologies and other innovations in MCM development need to take a full life cycle perspective to include the fill finish network for finalized drug forms. The result of this coordination will be an expanded domestic, public health industrial base can then be activated or redirected when needed.

Overview of the Presidential COVID-19 Health Equity Task Force (HETF)

Tim Putnam, DHA, EMT, President of Rural Health Consulting, LLC, and former Presidential Appointee to the HETF

The HETF, inaugurated on February 26, 2021 and coordinated through the HHS Office of the Secretary, completed their assigned task in December 2021, <u>publishing a report with 55 priority recommendations</u> and <u>over 200 related recommendations</u>. Dr. Putnam reviewed the recommendations briefly, noting that the primary principle is that equitable healthcare will make the country stronger overall. The recommendations address the need to better manage and control chronic diseases, increase access to equitable healthcare that is not strictly tied to employment status, emphasize behavioral health, build better systems to communicate with communities that includes a feedback loop for multidirectional and highly trusted dialogue, and improve the process for distributing resources during an emergency in a way that is independent of political considerations. Other HETF priority recommendations include standardizing and simplifying health equity data collection, improving the diversity of the healthcare workforce, incentivizing underrepresented populations to enter careers in medicine, and focusing on maintaining rural healthcare infrastructure and preventing closure of critical access hospitals.

Overview of the HHS Office of Climate Change and Health Equity overview

Joe McCannon, Senior Advisory to the Director, HHS Agency for Healthcare Research and Quality Received

Postponed due to time constraints.

The Need for More Forensic Pathologist in the United States

Dr. Andrew Falzon, MD, Chief Medical Examiner, New Jersey Department of Health

Dr. Falzon asked to speak with the NBSB to explain the challenges facing medical examiners (MEs) in the United States. MEs conduct required death investigations, serving as coroners in some states, but the profession faces critical shortages of forensic pathologists who can provide the necessary clinical functions. Though significant variation exists by state, a critical overarching problem across ME offices is a lack of funding for mass fatality preparedness. As a result, MEs are under-resourced when there are events like COVID-19. Forensic data systems also require additional resources to support mass casualty reporting, including updated data infrastructure, appropriate modelling tools, and information specialists.

Review of the NBSB Recommendations

The board members present during the public meeting reviewed and evaluated each recommendation and the supporting paragraphs in the draft report. The recommendations were drafted by the Readiness & Resilience Working Group, which Dr. Davies and Dr. Witt co-chair, and published online for public review on December 10, 2021. During the meeting, the board members discussed numerous issues and made specific edits, which incorporated directly into the document. After all the changes were made and reviewed again by the board members, a quorum of the NBSB voting members present at the time (Drs. Benitez, Cicero, Fernandes, Klugman, Leffel, Schonfeld, Witt, Mr. Gruber) voted unanimously to approve the report.⁴

The meeting adjourned at approximately 4:15 p.m. Eastern time.

⁴ DFO postscript: Following the meeting, Drs. Fernandes, Davies, and Witt confirmed that CAPT Perdue had accurately recorded all the changes; the report was formatted by ASPR Office of External Affairs for online publishing. The final report, <u>Recommendations for the 2023-2026 National Health Security Strategy</u>, is available on the ASPR website.