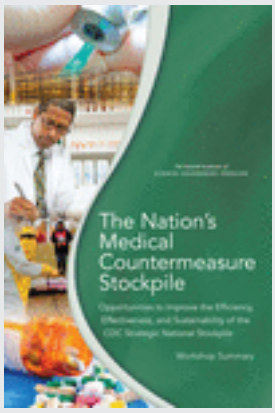

The Nation's Medical Countermeasure Stockpile: Opportunities to Improve the Efficiency, Effectiveness, and Sustainability of the CDC Strategic National Stockpile: Workshop Summary

DETAILS

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The Nation's Medical Countermeasure Stockpile

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Workshop Summary

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Board on Health Sciences Policy

Health and Medicine Division

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

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PLANNING COMMITTEE FOR THE NATION'S MEDICAL COUNTERMEASURE STOCKPILE: OPPORTUNITIES TO IMPROVE THE EFFICIENCY, EFFECTIVENESS, AND SUSTAINABILITY OF THE CDC STRATEGIC NATIONAL STOCKPILE—A WORKSHOP[1]

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[1] The National Academies of Sciences, Engineering, and Medicine's planning committees are solely responsible for organizing the workshop, identifying topics, and choosing speakers. The responsibility for the published workshop summary rests with the workshop rapporteurs and the institution.

Reviewers

This workshop summary has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published workshop summary as sound as possible and to ensure that the workshop summary meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process. We wish to thank the following individuals for their review of this workshop summary:

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MICHAEL LOEHR, Washington State Department of Health
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CHRISTOPHER G. SHIELDS, Chicago Department of Public Health

Although the reviewers listed above have provided many constructive comments and suggestions, they did not see the final draft of the workshop summary before its release. The review of this workshop summary was overseen by **LINDA DEGUTIS,** Henry M. Jackson Foundation for the Advancement of Military Medicine. She was responsible for making certain that an independent examination of this workshop summary was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this workshop summary rests entirely with the rapporteurs and the institution.

Contents

Acronyms and Abbreviations

AMMA	Army Medical Materiel Agreement
ASPR	Assistant Secretary for Preparedness and Response
ASTHO	Association of State and Territorial Health Officials
BARDA	Biomedical Advanced Research and Development Authority
CBRN	chemical, biological, radiological, and nuclear
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CERT	Community Emergency Response Teams
CGMP	Current Good Manufacturing Practice
CIADM	Center for Innovation in Advanced Development & Manufacturing
CONOPS	concept of operations
CRI	Cities Readiness Initiative
CTECS	Counter-Terrorism and Emergency Coordination Staff
DEA	Drug Enforcement Agency
DHS	Department of Homeland Security
DLA	Defense Logistics Agency
DoD	Department of Defense
DPHP	Directors of Public Health Preparedness
DSLR	Division of State and Local Readiness
DSNS	Division of Strategic National Stockpile

EDI	electronic data interchange
EID	emerging infectious disease
ESC	Enterprise Senior Council
EUA	Emergency Use Authorization
EVD	Ebola virus disease
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
HHS	Department of Health and Human Services
IDE	investigational device exemption
IND	investigational new drug
IPT	Integrated Program Team
ITRA	Integrated CBRN Terrorism Risk Assessment
LDS	local distribution site
MCM	medical countermeasure
MCMi	Medical Countermeasures Initiative
MOU	memorandum of understanding
NACCHO	National Association of County and City Health Officials
NBSB	National Biodefense Science Board
NIH	National Institutes of Health
OMB	Office of Management and Budget
OPHPR	Office of Public Health Preparedness and Response
ORR	Operational Readiness Review
PAHPRA	Pandemic and All-Hazards Preparedness Reauthorization Act
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PHEP	public health emergency preparedness
PHS	Public Health Service
PI	pandemic influenza
PIB	POD in a box
POD	point of dispensing
PPE	personal protective equipment
PREP Act	Public Readiness and Emergency Preparedness Act
PSMR	Pre-Scripted Mission Request
RAMPEx	Rapid Activation for Mass Prophylaxis Exercise
RFID	radio-frequency identification

ROI	return on investment
RSS	receipt, storage, and staging
SIP	Strategy and Implementation Plan
SLEP	Shelf Life Extension Program
SLTT	state, local, tribal, and territorial
SNS	Strategic National Stockpile
TOPOFF	top officials
VA	Department of Veterans Affairs
VHA	Veterans Health Administration

1

Introduction, Background, and Context[1]

Large catastrophic events, or rare acute events, may cause situations in which a local jurisdiction's medicines and medical supplies are not sufficient to provide care to the population it serves. In these cases of natural or engineered disasters, such as a terrorist attack, influenza pandemic, or earthquake, state or local authorities can request that the federal government provide assets from the Strategic National Stockpile to augment the state and local jurisdictions' resources.

The Centers for Disease Control and Prevention's (CDC's) Strategic National Stockpile (SNS) is the nation's repository of antibiotics, chemical antidotes, antitoxins, vaccines, antiviral drugs, and other medical materiel designed to supplement and resupply state and local public health agencies in the event of an emergency. The materiel is intended to support national health security and is managed by the Office of Public Health Preparedness and Response's (OPHPR's) Division of Strategic National Stockpile (DSNS). The stated mission of the SNS is to prepare and support partners and provide the right resources at the right time to secure the nation's health.[2]

The SNS includes a multi-billion-dollar inventory that is managed to ensure that these supplies can be rapidly deployed as needed to support

[1] The planning committee's role was limited to planning the workshop, and the workshop summary has been prepared by the workshop rapporteurs as a factual summary of what occurred at the workshop. Statements, recommendations, and opinions expressed are those of individual presenters and participants, and are not necessarily endorsed or verified by the National Academies of Sciences, Engineering, and Medicine, and they should not be construed as reflecting any group consensus.

[2] See http://www.cdc.gov/phpr/stockpile/stockpile.htm (accessed April 15, 2016).

the response to a public health emergency. States may request federal assistance from CDC to deploy SNS assets, and CDC works with federal, state, and local health officials to determine what assets are needed during an emergency.

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE),[3] established by the Department of Health and Human Services (HHS) and led by Office of the Assistant Secretary for Preparedness and Response (ASPR), was created to coordinate the efforts of the numerous federal agencies that have roles in optimizing public health emergency preparedness with respect to the creation, stockpiling, and use of medical countermeasures (MCMs). PHEMCE's primary responsibilities are threefold: defining and prioritizing requirements for public health emergency MCMs; focusing research, development, and procurement activities on the identified requirements; and establishing deployment and use strategies for the MCMs in the SNS. Key players among PHEMCE's interagency efforts include the ASPR (which leads PHEMCE), The Biomedical Advanced Research and Development Authority (BARDA, a component of ASPR), CDC (which houses the SNS), the National Institutes of Health, the Food and Drug Administration (FDA), the Department of Defense (DoD), and the Department of Homeland Security (DHS). The collaborative effort by these agencies provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies.

BARDA's specific mission[4] is to develop and procure MCMs that address the public health and medical consequences of chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks, pandemic influenza, and emerging infectious diseases. Through its programmatic initiatives, BARDA supports the SNS by leading the advanced development and procurement of drugs, vaccines, and other products considered to be priorities for national health security.

SNS STANDING COMMITTEE

The National Academies of Sciences, Engineering, and Medicine established a standing committee of experts to help inform decision making by CDC DSNS, including experts in state and local public health, MCM production, warehouse and product distribution, logistics management, emergency medical services, emergency medicine, risk communications, and FDA regulatory issues. The standing committee was established to provide a venue for the exchange of ideas among federal, state, and local

[3] See https://www.medicalcountermeasures.gov/phemce.aspx (accessed April 15, 2016).
[4] See https://www.medicalcountermeasures.gov/barda.aspx (accessed April 15, 2016).

governmental agencies, the private sector, and the academic community, as well as other relevant stakeholders involved in emergency preparedness and emergency response services.

Tara O'Toole, chair of the SNS Standing Committee, and Senior Fellow and Executive Vice President, In-Q-Tel, explained that the SNS Standing Committee was asked by Stephen Redd, Director of CDC's OPHPR, to investigate three areas of interest with respect to the complex enterprise of the SNS. The first area of focus concerned how to increase the efficiency of the SNS and ensure adequate distribution to the people in need during crises; this area is to be informed by lessons learned from past experiences and geared toward generating specific strategies for effective partnerships with the private sector and other federal agencies. The second request was to help CDC develop a risk-based approach to the inventory of the SNS, which currently holds approximately $7 billion[5] in products across more than 900 separate line items, which are distributed across 6 large facilities in different locations (undisclosed for security reasons) throughout the United States. The third request was to reevaluate the focus of the SNS; since its inception in 1999, the emphasis has been on MCMs designed for potential CBRN attacks on the United States.

To best explore those ideas in the context of the workshop, O'Toole introduced a set of key questions to guide the discussions during the workshop in addition to the stated workshop objectives listed in the workshop statement of task (see Box 1-1):

- Should the SNS be used to treat diseases that are emerging naturally, such as the Zika virus?
- Should SNS contents be deployed internationally upon request?
- Should the SNS be used to shore up routine drug shortages that occur in the course of medical practice?

Each of these questions gives rise to further complex issues, noted O'Toole. For example, the use of the SNS to address routine drug shortages could jeopardize the central purpose of the stockpile, which is to be stocked and ready to be activated immediately when needed. She commented that the stockpile itself gives rise to its own set of questions and management complexities. PHEMCE is host to complicated DHS and HHS processes regarding how to decide what to put in the stockpile inventory. The back end, often referred to as the "last mile," involves the actual dispensing of MCMs to the public after DSNS has delivered them to state- and local-level public health authorities, O'Toole noted. She commented that the declining federal budget is constraining front-end decisions about inventory, even

[5] According to Greg Burel, director of DSNS, CDC.

BOX 1-1
Workshop Statement of Task

An ad hoc committee will organize a 2-day public workshop that will explore opportunities to improve the efficiency, effectiveness, and sustainable methods used by the Centers for Disease Control and Prevention (CDC) Division of Strategic National Stockpile (SNS) to distribute medical countermeasures and other supplies during disasters and other public health emergencies, especially those which result in disruption of physical infrastructure such as the electrical grid, central roadways, bridges, and tunnels within the impacted community. Furthermore, the workshop will explore relevant distribution lessons learned from other federal agency stockpiles and the private sector as well as opportunities to develop public–private collaborations in the purchase, warehousing, management, and distribution of medical countermeasures.

The committee will develop the workshop agenda, select and invite speakers and discussants, and moderate the discussions. The workshop discussions will provide participants an opportunity to better explore the applicability of existing and new technology and practices to inform CDC's distribution of medical countermeasures and supplies within the SNS. Specifically, the workshop will feature invited presentations and discussions that will:

- Provide a broad overview of current efforts under way at CDC, the Department of Defense (DoD), and the Department of Veterans Affairs to distribute medical countermeasures and other supplies during a disaster or other public health emergency;
- Review novel practices used by private industry to distribute medical products and supplies on a day-to-day basis as well as during an emergency;
- Identify major gaps in currently available distribution methods in the public and private sectors;
- Identify opportunities for collaboration and coordination between CDC and among relevant federal as well as industry programs to support effective and efficient medical countermeasure distribution; and
- Examine opportunities to enhance the economic sustainability of the SNS in view of evolving mission expectations and new medical countermeasures research and development.

A summary of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.

as the threats are becoming very dynamic and impacting what should be included in the stockpile. Furthermore, O'Toole said budget constraints have had a devastating impact on state public health services, with CDC reporting that the number of state and local health officials has decreased by 50,000 since 2008.

SNS CHALLENGES

Greg Burel, director of DSNS, commented that the stockpile has continued to expand its inventory even in the face of shrinking federal budgets. He pointed to the key concerns about the disposal and replacement of expiring pharmaceuticals as well as a formulary that is constantly evolving to adapt to new threats and new requirements. He also emphasized the importance of strengthening the dispensing system in the last mile by providing support and guidance to state and local public health officials. Burel explained that the SNS operates in as commercial a manner as possible in the sense that during large-scale events, it essentially becomes a very large distributor of particular products for a limited period of time. SNS is the distributor for emergency MCMs because it is optimized for emergency events outside of daily supply-chain operations. He characterized the SNS as acting on a day-to-day basis like a specialty distributor of products that are not available anywhere else; for instance, in certain circumstances the SNS can deploy an MCM on a one-off basis to an individual in need.

Ali Khan, dean of the College of Public Health, University of Nebraska Medical Center and former director, OPHPR, CDC, explained that the creation of the National Pharmaceutical Stockpile (later renamed the Strategic National Stockpile) at CDC was one of the critical components of the Chemical, Biological, Radiological and Nuclear Defense Program established in 1999, when a convergence of many factors led to an emergency appropriation to create a program to protect the nation's health security. During his tenure as the director of OPHPR between 2010 and 2014, the value of the SNS inventory at that point increased by about 50 percent, from $4 billion to approximately $6 billion.

The key challenges Khan faced as director were insufficient resources to not only sustain the growth of the SNS, but also maintain the existing inventory. Resources were also needed to enable the necessary risk-informed decisions regarding the holdings and other management practices in order to ensure better CDC engagement, reinvigorate the PHEMCE process, and align the SNS efforts with the Public Health Emergency Preparedness Grant Program. CDC subject-matter experts were engaged with the PHEMCE process and managed by a medical officer; health care preparedness activities were moved to the SNS Division to better support health care and public health integration. An SNS 2020 Review was commissioned to institute a risk-based approach to make purchase decisions in conjunction with DHS in a way that integrated the best available intelligence information.

Khan offered three observations concerning the SNS based on his experiences. First, he emphasized that now is the time to revise the SNS mission and statute. The National Health Security Program (within which the SNS is situated) has evolved from a CBRN program to an all-hazards

program, meaning that natural disasters and pandemics are already part of its statute. He argued that the SNS needs to be more than a stockpiling program by focusing more on the last mile. That is, the SNS should not only deliver MCMs to local public health authorities, but also support local-level dispensation efforts, provide clinical guidance about the use of MCMs, and implement the appropriate systems to monitor treatment compliance during adverse events. He suggested that the SNS is ideally placed within CDC to perform these additional functions, which should be made explicit in authorizing language and should be budgeted separately by the SNS. He maintained that this authorization should also include a designation for international use of MCMs as well as the authority to sell or give away MCMs as appropriate for the program.

Khan's second observation was that the SNS needs to continue to innovate. The Cities Readiness Initiative, the shelf-life extension program, and the use of vendor-managed inventory are examples of past successes in this regard, but there is still ample opportunity to increase engagement with industry. Khan's final observation was that the current SNS model is not sustainable: the SNS cannot continue to buy MCMs for an ever-expanding list of material threats; it needs to integrate across these threats in conjunction with the PHEMCE and make critical decisions about what to buy and what not to buy given its resource constraints.

Daniel Sosin, deputy director and chief medical officer, OPHPR, CDC, reflected that as a capability designed for catastrophic events, the SNS has had no actual experience to draw upon over the past 17 years to inform how its future should look, yet the SNS has been engaged in everyday events over its entire history. CDC has successfully guided it through those missions and built a broader constituency of interest that has expanded the expectations of what the stockpile mission and role should be, but he noted that with a broader spectrum of partnerships come varied and increasing demands. The bottom line and key challenge he identified is that "the resources that American people are willing to commit to a Strategic National Stockpile are not sufficient to meet all of the expectations." Without better focus, he contended, the SNS will not be able to fulfill the greatest amount of life-saving potential.

Sosin noted that the mission of the SNS has expanded over time to include, for example, response to natural disasters and operation of federal medical stations for displaced populations. During the responses to Hurricane Katrina, the H1N1 pandemic flu, and Ebola, the DSNS helped to guide the existing medical supply chain in the provision of medications and equipment. He suggested that this role has the potential to help leverage existing supply-chain infrastructure to bring efficiencies to the work of the stockpile.

The "last mile" issue has come to prominence over the past 5 years, commented Sosin, as evidenced by the spotlight of attention on state- and local-level public health response capacity for mass dispensing of oral MCMs. Sosin also pointed to the SNS's critical role in sustaining upstream investment in research, development, and production of MCMs for non-routine conditions that thus lack enabling market forces: "That commitment to sustaining the investments in producing these medical countermeasures strains and constrains the ability of the Strategic National Stockpile to address the areas of greatest risk." Over the past 17 years, Sosin reported, fiscal and performance audits of the SNS have demonstrated good fiscal responsibility and stewardship of resources, but this is impeded by the constraints of insufficient resources and the expanding SNS mission.

Sosin called for the urgent need "to bring a scientific perspective, going beyond a performance audit and helping us match the resources that are realistic to expect for an SNS and put that against the potential to reduce the greatest amount of risk." Building a sustainable SNS to achieve these important roles will require prudent selection of targets, ensuring that the material and the capability built at the national level will be able to deliver effectively to the individual at the local level.

Sally Phillips, deputy assistant secretary for policy, ASPR, HHS, reflected on the sustainability of the SNS and how investments are being made, noting that sustainability requires taking into consideration not only the amount of resources that go into procuring a stockpile, but also the costs involved in developing, procuring, storing, and deploying the stockpile, which are only a small fraction of the network of the stockpile's contributions. Challenges layered on top of the stockpile's demands are ensuring that MCMs can be received by a sufficient number of trained providers ready to accept and dispense those MCMs at the point of dispensing (POD) level. She advised that tails on the stockpile—including clinical guidance, diagnostics, treatment modalities, and the health care system's response capacity—must feed into modeling and considerations of cost. Reaching the last mile is a critical concern: "the operational challenges of the stockpile are as intense as the early upfront investments in procuring."

2

The Strategic National Stockpile: Origin, Policy Foundations, and Federal Context

HISTORICAL AND CURRENT PERSPECTIVES

Burel provided historical context for the stockpile with reference to several landmark events in the history of the enterprise. In 2000, the first formulary was developed and it was configured as the initial "push-package," that is, repacked and configured materiel assembled for rapid deployment to resupply overwhelmed local medical supplies. This was built around the understanding that in most cases, public health professionals at the state or local level would be able to break down the packages and use them rapidly.[1] Push packages were loaded into specialized air cargo containers for rapid loading and air delivery, and were prepositioned in multiple secure facilities near major transportation hubs. The system was designed to be able to reach any point in the United States or its territories within 12 hours from a decision to deploy.

Burel explained that the first real deployments were during the events of September 11, 2001, and the Anthrax incident in 2001. Both deployments consisted of 12-hour push packages with appropriate equipment and medical countermeasures (MCMs); the Strategic National Stockpile (SNS) also provided support via technical assistance staff. After those events, the scope of the SNS began to widen and has continued to grow, according to Burel. The program was codified in the Public Health Service Act in 2002, which increased SNS funding to expand its capabilities. Push-package capability

[1] One of the subsequent evolutions at the state level is that professional logistics firms are contracted to receive materiel and further deploy it into the state.

BOX 2-1
Cities Readiness Initiative
Greg Burel, Director, DSNS, CDC

Burel described the Cities Readiness Initiative (CRI), which was developed in 2004 to test and strengthen preparedness capacity in an event requiring mass prophylaxis with MCMs (within 48 hours of a decision to deploy) to populations in major metropolitan statistical areas. Aerosolized anthrax was selected as the driving scenario. Burel commented that the initiative had a great effect on strengthening preparedness capacities as well as promoting alternative dispensing methods, such as the use of the U.S. Postal Service to deliver MCMs and drive-through dispensing sites. As a result, many states have now engaged in Memoranda of Understanding (MOUs) with retail outlets for the latter. Other innovations included contraflowing expressways for dispensing to people in cars and employer-based dispensing to take pressure off the local public health department. Community strike teams and community-based organizations (e.g., Meals on Wheels™) can now deliver MCMs in certain localities.

The initiative demonstrated that products actually need to reach people within less than 48 hours after a decision, especially given that exposure may not be known for several hours. The SNS continues to work to improve speeds within the auspices of its own program as well as at the state and local levels.

He commended New York City's (NYC's) public health capability in terms of its plan to quickly set up multiple points of dispensing (PODs) and rapid dispensing processes, and pointed out that in some situations the SNS itself could become the delaying factor when PODs are open but still waiting for supplies to arrive. "We are talking with them (NYC) about other alternatives and how we can preload them. They were the first people to show us capability that we can't match up with on that front end."

was expanded from 8 different types to 12 and the managed inventory of products expanded, currently sitting at more than $7 billion.[2] The Division of Strategic National Stockpile's (DSNS's) role in the development of federal medical stations and the Cities Readiness Initiative (see Box 2-1) began in 2004, and the SNS also provided supplemental funds to stockpile pandemic influenza MCMs and personal protective equipment (PPE).

Significant Events in SNS History

Burel explained that in 2009, the H1N1 influenza pandemic triggered the largest deployment in SNS history when 12.5 million antiviral regi-

[2] This includes materiel purchased by the SNS as well as materiel developed and acquired by the Biomedical Advanced Research and Development Authority (BARDA).

mens were deployed across the country (a further 300,000 were deployed internationally), as well as 19.6 million pieces of PPE, 85.1 million N95 respirators, and 2,129 regimens of Peramivir IV (the latter were deployed in conjunction with BARDA). Burel said the experience exposed the need to better integrate the operations of the SNS during an emergency with the functions of the day-to-day medical supply chain, which requires educating state and local partners about what the supply chain does and how it operates.

The 2014 outbreak of Ebola virus disease (EVD) was an emerging infectious disease (EID) event that did not fall within the original scope of the SNS, explained Burel. However, the experience revealed that the DSNS has a great reach into the commercial supply chain for many of the products required to deal with this type of threat. For instance, DSNS was asked to supply PPE for hospitals and agreed to do so, given that they would also be useful for other EIDs. They developed a tiered approach to evaluating and treating individuals for EVD, which helped hospitals to calculate needs based on the numbers of patients they would be able to treat. Even more important than acquiring materiel, Burel suggested, was the experience of supply chain and multiagency government partners working together to create a "whole government" response to a real-world incident.

Burel explained that shortages trigger what is called "allocation," the details of which are not publicly available, but one of the determinants of how items are allocated is based on whether there is a contract with the provider, how big the contractor is, and how big the buyer is. SNS worked with supply-chain partners to find a better way to allocate scarce products during a specific event without entirely depleting the stocks for cases of immediate short-term need. Burel reflected that the expanding scope of the SNS has had a positive effect in terms of being able to work with the commercial supply chain to help in these types of allocation situations, and to provide short-term assistance as needed before the regular commercial supply chain takes back over.

Observations on the Current State of the SNS

Based on his experiences, Burel observed that none of the historic SNS responses have yet matched pre-event planning or expectations, but planning has built in the flexibility to address the unexpected and has allowed for the most effective use of available resources, material, and commercial marketplace capabilities. Coordination with other federal buyers allows agencies to work together with a coordinated government approach to obtain items that are needed without disrupting the entire supply chain.

Furthermore, Burel noted that the SNS expansion into all-hazards response (e.g., hurricanes, earthquakes, EIDs) has drained some funds that

were built around a CBRN threat. As an example, he cited federal medical stations which are an important resource, but are expensive to maintain. However, he described the SNS as a good value, with costs of less than 2 cents on the dollar for all of the products they manage, inventory accuracy of almost 100 percent, and full confidence in the safety and efficacy of products in the stockpile.

Better integration with the commercial supply chain has been fostered by working with the commercial sector to better understand its needs, noted Burel. The DSNS continues to try to better leverage the strengths of the commercial market by, for example, using commercial and third-party logistics partners for management, storage, and transportation.

SNS POLICY FOUNDATIONS

Susan E. Sherman, senior attorney, Office of the General Counsel, Department of Health and Human Services (HHS) provided a brief legal history of the SNS's statutory foundations. The statutory origin of the SNS is in the Public Health Service Act, which authorized CDC and other components of the U.S. Public Health Service at HHS with broad authorities to assist states and localities to control communicable disease. Beginning in 1998, Congress began providing funding in annual appropriations to CDC for pharmaceutical stockpiling. Sherman explained that Congress can instruct agencies by means of enabling statutes to run a program or carry out a task, with the award of appropriations being tied to conditions. In the case of the SNS, she noted, money came before an enabling statute: CDC was running the program based on the annual appropriations that it is still receiving.

The first enabling statute for the SNS was the Public Health Security and Bioterrorism Preparedness Act of 2002.[3] It directs the Secretary of HHS to maintain a "Strategic National Stockpile," whose statutory mission is to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency. The SNS at that point was explicitly coordinated with the Department of Veterans Affairs (VA). The Act also specifically directs the SNS to procure smallpox vaccines and potassium iodide as part of the stockpile and includes provisions for stockpile management and security requirements; it also authorized annual appropriations. Sherman explained that the way the statute is written provides broad discretion to HHS and the Secretary; public health officials are the ones who decide what is needed, what constitutes a public health emergency, and how to protect the emergency health security of the

[3] Strategic National Stockpile, Public Health Service (PHS) Act § 319F-2(a), 42 U.S.C. § 247d-6b(a).

United States. The language is not particularly prescriptive, but does provide guidance and a standard. Shortly thereafter, the Homeland Security Act of 2002 transferred responsibility for the SNS from HHS to the Department of Homeland Security (DHS), to be carried out in coordination with the Secretaries of HHS and VA; other requirements remained the same.

Sherman continued that under the Project BioShield Act (2004),[4] responsibility for the SNS was transferred back to the Secretary of HHS to be maintained in coordination with the Secretary of DHS. The VA coordination provision was removed, and provisions for deployment authorities were added: as required by the Secretary of Homeland Security to respond to an actual or potential emergency; and at the discretion of the Secretary to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect the public health or safety. She pointed out a common misconception that the Secretary of HHS must declare a formal health emergency to deploy the stockpile; however, this is not actually required. The SNS can respond when it determines that circumstances meet the standards written in the statute. The Project BioShield Act also enacted programs related to the stockpile MCM initiative. It authorized procurement of security countermeasures against CBRN threats to be included in the SNS, and established a "Special Reserve Fund," of $5.6 billion (available between 2004 and 2013), which was initially housed at DHS but later transferred to HHS. She noted that a process in that statute is fairly prescriptive about what determinations need to be made by DHS and HHS in order to spend the Special Reserve Fund to buy these MCMs. She explained that exceptional authorities are also included because they are considered necessary for making it easier and faster to procure products for the stockpile. The Project BioShield Act is also when the Emergency Use Authorization (EUA) was enacted for civilian purposes. Furthermore, it expands the authority for the Food and Drug Administration (FDA) to authorize emergency use[5] of unapproved products or approved products for unapproved uses.

Sherman explained that the Public Readiness and Emergency Preparedness (PREP) Act of 2005[6] authorizes the HHS Secretary to issue a declaration to provide liability immunity (except for willful misconduct)[7]:

- to manufacturers, distributors, states, local governments, tribes, and others who supervise or administer countermeasures pro-

[4] PHS Act § 319F-2(c), 42 U.S.C. § 247d-6b(c).

[5] Emergency Use Authorization, other emergency authorities, Federal Food, Drug, and Cosmetic (FD&C) Act §§ 564 and 564A, 21 U.S.C. §§ 360bbb-3, 360bbb-3a.

[6] PREP Act, PHS Act §§ 319F-3, 319F-4, 42 U.S.C. §§ 247d-6d, 247d-6e.

[7] The declaration triggers emergency funds for injury compensation for serious physical injuries or deaths directly caused by administration or use of covered countermeasures.

grams and to licensed health professionals and others who prescribe, administer, or dispense countermeasures;
- for claims causally related to development, distribution, administration and use of FDA-approved, licensed, or authorized countermeasures against pandemic or epidemic disease, or CBRN agents as necessary to protect public health.

The PREP Act covers a very specific category of products, which are not limited to stockpile products. The PREP Act Declarations can cover any activity involving the distribution and dispensing of MCMs. Similarly, she noted that the EUA is not limited to MCMs.

Sherman next described the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) of 2006, which established that the stockpile should be maintained by the Secretary of HHS in collaboration with the CDC director and added the SNS annual review requirement. This was when BARDA was established to fill the gap in advanced research and development. This Act enhances BARDA's authority to procure CBRN countermeasures (e.g., milestone payments, warm-based surge capacity). The statute also authorizes the Assistant Secretary for Preparedness and Response (ASPR) to "exercise the responsibilities and authorities of the Secretary [of HHS] with respect to the coordination of" the stockpile and to oversee advanced research and development of MCMs carried out by BARDA. This, she noted, sets up the relationship between CDC, ASPR, and several of the other agencies from a statutory perspective.

The 2013 PAHPRA, Sherman explained, was the point at which the PHEMCE Strategy and Implementation Plan (SIP) was codified into law. It requires ASPR to submit this plan and the associated multiyear MCM budget to Congress. Another clause requires stockpile contents to be determined consistent with ASPR authority, with an explicit provision for an annual report to Congress, and another provision addressing the depletion and replacement of the current contents. It further enhances CBRN procurement and advanced research and development authorities, and reauthorizes the Special Reserve Fund. Sherman pointed to one of PAHPRA's biggest effects, the streamlining of the EUA process, which provides new expanded authorities to FDA to authorize emergency use of approved products in emergencies and products held for emergency use, allowing for easier deployment.

CONGRESS AND THE SNS

Frank Gottron, specialist in science and technology policy at the Congressional Research Service, examined the relationship between Congress and the SNS. It began in 1998 with the Consolidated Appropriations

Act,[8] which, in response to an emergency budget supplement request by President Clinton, provided $51 million for pharmaceutical and vaccine stockpiling activities at CDC. To provide more direction to the statute, in 2002 Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act[9] to emphasize consultation with a working group to coordinate stakeholders and establish the HHS Secretary's role in ensuring appropriate inventory, accounting, and security of the stockpile. It was further aimed at ensuring consultation with federal, state, and local official partners with respect to special events and special needs, as well as periodic review and revision of the contents of the stockpile.

Congress has been broadly supportive of the program, according to Gottron, roughly appropriating the amounts the Executive Branch has requested over the years and funding the SNS with between $500 million and $625 million per year since 2004 (see Figure 2-1).

Gottron explained how Congress's significant investment in the program has given rise to significant policy concerns since its inception. In a Senate Appropriations Report from 1999, they asked the department to articulate a clear and coherent biosecurity strategy to the public and to Congress that is rooted in both national security needs and scientific opportunities, as well as requesting a long-term strategic plan (including 5 years of funding requirements) for the National Pharmaceutical Stockpile based on the results of a documented national-level threat and risk assessment. This required estimating the cost and time needed to acquire and establish proposed MCMs and identifying the long-term costs and benefits of establishing and sustaining the production and inventory infrastructure for the stockpile and management of its inventory (including stock replacement and rotation).

The same questions raised by Congress in 1999 still persist, noted Gottron. Progress has been made to address them, but they are still ongoing concerns. Many of those issues were incorporated into the 2013 PAHPRA.

Transparency in the planning and operation of the SNS is a priority for Congress, according to Gottron. PAHPRA addressed certain transparency requirements relating to the annual revision of the stockpile. Additional reporting requirements written into the statute to improve transparency include integration with annual PHEMCE SIPs as well as the 5-year coordinated biodefense budget. More recently, Congress requested additional reports on certain supplies within the stockpile, and for future budgets to include additional information about planning for replacement and acquisition of new MCMs, for example. PAHPRA also includes additional in-statute requirements regarding coordination with other federal agencies

[8] Omnibus Consolidated and Emergency Appropriations Act, 1999 (P.L. No. 105-277).

[9] See https://www.gpo.gov/fdsys/pkg/BILLS-107hr3448enr/pdf/BILLS-107hr3448enr.pdf (accessed June 6, 2016).

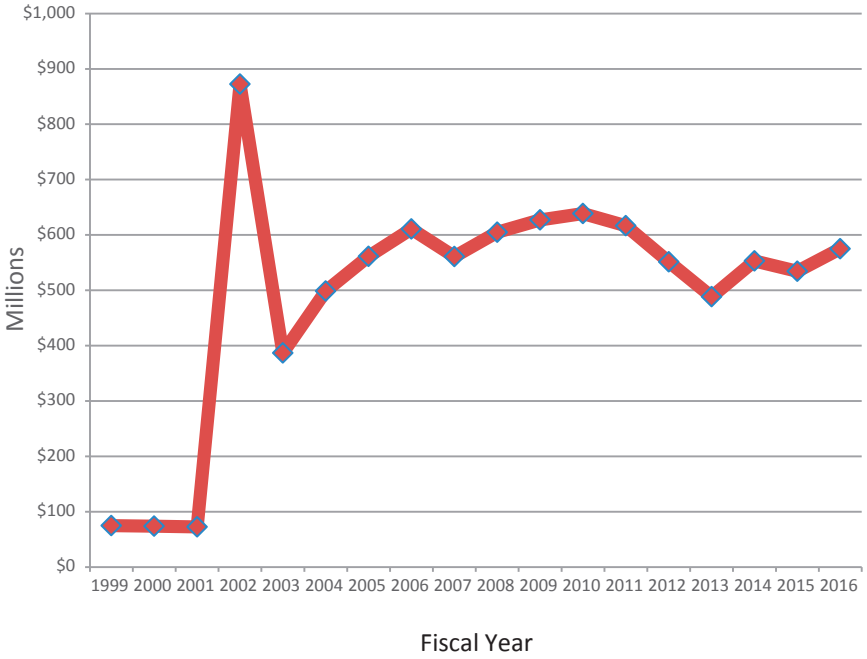

FIGURE 2-1 SNS Appropriations (millions of 2015 dollars, inflation adjusted).
SOURCE: Gottron presentation, February 4, 2016.

and nonfederal partners, although there are ongoing concerns about the process and whether the outreach has been sufficient. In 2015, Gottron reported that Congress called for CDC to update guidance to state and local public health officials regarding new acquisitions to the SNS and how they would be used.

Gottron noted that Congress, on certain occasions, has also been interested in the inclusion of specific items in the stockpile; for example, the originating legislation specifically calls out the inclusion of potassium iodide and the smallpox vaccine. In the intervening years there have been strong suggestions to consider including psychotropic medications, various antiviral medications, and specific medical equipment such as face masks. The protection of pediatric populations is also an ongoing concern being taking into consideration.

Also ongoing are concerns about item expiration and replacement costs; Gottron commented that Congress is particularly interested in the repurposing of soon-to-expire medications (e.g., efforts to allow DoD to use the expiring anthrax vaccine in their vaccination program; proposals to allow first-responders access to the anthrax vaccine on a voluntary basis).

SNS AND THE FEDERAL MEDICAL COUNTERMEASURES ENTERPRISE: FEDERAL PROGRAM AND AGENCY PARTNERSHIPS

Sherman explained that the HHS Secretary maintains the stockpile in collaboration with CDC, in coordination with DHS, and consistent with ASPR authorities. He or she deploys the stockpile to respond to an actual or potential public health emergency or other situations in which deployment is necessary to protect the public health or safety, and issues declarations needed for liability protections and emergency use of countermeasures. The ASPR exercises the authorities of the HHS Secretary to coordinate the stockpile, manages the PHEMCE and multiyear budget, and oversees Project BioShield procurements and BARDA advanced research and development. CDC manages and operates the stockpile and deploys products for specific individual conditions. It is also responsible for testing and evaluation of government programs, sharing with other federal agencies, prepositioning, and other preparedness activities. FDA conducts regulatory oversight of products and authorizes emergency use.

The Public Health Emergency Medical Countermeasures Enterprise

Phillips provided an overview of PHEMCE. Established in 2006 and led by the Office of the ASPR, it provides direction and jointly partners with the SNS. It is tasked with strategic planning surrounding MCM prioritization and support for developing, procuring, and planning for the effective use of MCMs against CBRN threats and EIDs, including influenza. This effort involves a wide range of partnerships (BARDA, CDC, FDA, National Institutes of Health [NIH], DoD, DHS, VA, and the Department of Agriculture; see Figure 2-2).

Phillips commented that these partnerships have been fruitful in establishing new capabilities[10] as well as delivering 12 new MCMs to the stockpile, building a more robust interagency governance structure, and conducting 10 major portfolio reviews of MCM development by threat. Two major studies by the Government Accountability Office have ensured the integrity of the process from beginning to end. She highlighted the SNS's integration as a core part of PHEMCE. ASPR and CDC have coordinated and integrated with respect to state and local grantees, as well as public

[10] FDA Regulatory Science Initiatives, the BARDA Centers for Innovation in Advanced Development & Manufacturing, National Institute of Allergy and Infectious Diseases' Concept Acceleration Program; the HHS Five Year Budget Overlook for the Medical Countermeasures Program; the annual review of the National Stockpile, and the National and International Portfolio Tracking Tool for CBRN and MCM products.

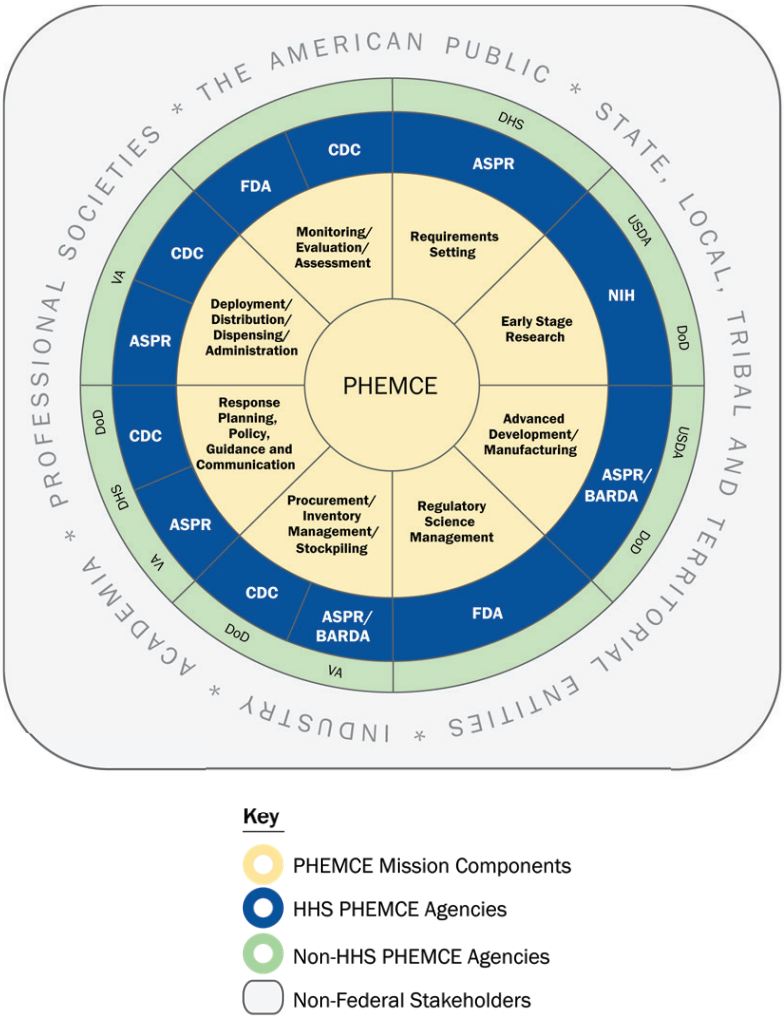

FIGURE 2-2 PHEMCE agencies, partnerships, and mission components.
NOTE: ASPR = Office of the Assistant Secretary for Preparedness and Response; BARDA = Biomedical Advanced Research and Development Authority; CDC = Centers for Disease Control and Prevention; DHS = Department of Homeland Security; DoD = Department of Defense; FDA = Food and Drug Administration; HHS = Department of Health and Human Services; NIH = National Institutes of Health; PHEMCE = Public Health Emergency Medical Countermeasures Enterprise; USDA = U.S. Department of Agriculture; VA = Department of Veterans Affairs.
SOURCE: Disbrow presentation, February 4, 2016.

health emergency preparedness programs and health care communities (through the grant programs).

Phillips explained that the 2012 PHEMCE SIP examined response planning as a strategic goal for PHEMCE. There are ongoing joint efforts to engage with state and local agencies (as well as other stakeholders) and to evaluate the risk posed by emerging threats to public health, with PHEMCE providing structure and institutional support through a working group co-led by DHS and CDC. For those EIDs determined to require MCM intervention, resources from across PHEMCE partner agencies are leveraged for requirement setting, research and development, procurement, and/or possible utilization levels. Partnerships are focusing on the SNS's role in developing enhanced diagnostics. The network of partnerships also allows interagency partners to come together on major emerging issues when convened for other purposes.

Philips outlined some of the challenges faced by PHEMCE, including dealing with competing demands as to what the SNS is and what it should be, as well as the constantly evolving issues that are intrinsic to the entire MCM enterprise (pandemics, new EIDs, CBRN threats, and its BioShield underpinnings). Addressing these challenges, she noted, requires a balancing act between the original intent of the stockpile and these new concerns. Doing so requires multiple levels of assessment and prioritizing to inform investments and critical decisions. She further maintained that the PHEMCE model provides an opportunity to broadcast a continuous, loud, and clear message about what is being done, the progress being made, and strategies being implemented moving forward. Box 2-2 explains the public expectations around the SNS.

BOX 2-2
PHEMCE and the Public Context for the SNS
Sally Phillips, Deputy Assistant Secretary for Policy, ASPR, HHS

Sally Phillips of ASPR emphasized that the public is aware of a broad spectrum of potential threats (e.g., bioevents, terrorist attacks, and natural disasters) and thus expects to have a "resilient, highly qualified, highly skilled health care system that provides the perfect pill, the perfect vaccine, or the high-tech care that their families need when threatened." The public expects that public officials are preparing for the provision of immediate response to any threat at any time, with MCMs available for any event; the SNS was established to ensure that the public had access to some of those assurances. However, she commented that the continuity of the program has been hampered by the waning and ebbing of financing, public awareness, and congressional interest in the stockpile.

PHEMCE and the Strategic National Stockpile Annual Review

An overview of PHEMCE's role in the SNS annual review, and how the review process fits into the requirements process and informs preparedness, was provided by Richard Jaffe, director, Division of Medical Countermeasures Strategy and Requirements, Office of Policy and Planning, ASPR, HHS. The SNS annual review is mandated by the Public Health Services Act (as amended by the PAHPRA in 2013)[11] and the Homeland Security Presidential Directive 21.[12] This is important from an interagency perspective for enabling agreed-upon formulary policy recommendations and a defensible budget, with responsibility spread over multiple agencies.

Jaffe noted that the review also provides for both top-down and bottom-up analyses of the makeup of threat areas, and allows for the use of integrated program teams composed of subject-matter experts to set requirements and analyze threats (with senior-level review) to make recommendations on increasing preparedness across the SNS formulary.

Jaffe explained that the review is developed via partnership between the ASPR and CDC to ensure that policies are not disconnected from the available assets at present. The ASPR leads and coordinates departmental policy development and implementation on SNS-related policy, ensures documentation of plans and procedures that include SNS assets, and oversees the Enterprise Senior Council (ESC), with participation of the CDC director, to advise the HHS Secretary regarding strategic priorities for the SNS. He clarified that the ASPR generally leaves policy planning to the oversight of the ESC (the senior level of the PHEMCE), where they make major policy decisions and recommendations for the SNS assets. CDC participates in ASPR-led policy and planning activities, coordinates the end-to-end management of the SNS,[13] and coordinates with state, local, tribal, and territorial (SLTT) public health officials on plans and exercises for SNS-provided assets.

Jaffe described how the ASPR and CDC co-lead the SNS annual review process, which involves five phases[14] to prioritize formulary gaps for the SNS

[11] "Secretary shall conduct an annual review (taking into account at-risk individuals) of the contents of the stockpile, including nonpharmaceutical supplies, and make necessary additions or modifications to the contents based on such review and shall submit such review annually to the appropriate congressional committees of jurisdiction to the extent that disclosure of such information does not compromise national security."

[12] The SNS annual review is to be delivered to the director of the Office of Management and Budget (OMB) and assistant to the President for Homeland Security and Counterterrorism at the time of HHS's budget submission.

[13] Budget proposals, procurements as directed by the ESC and the HHS Secretary, management of SNS facilities, and disposal of expired products.

[14] Phase I: DSNS Review of SNS Contents; Phase II: IPT Gap Analysis and Threat Specific Recommendations; Phase III: Enterprise Executive Committee (EEC) Cross-Threat Prioritization; Phase IV: ESC Deliberation and Finalization; Phase V: Report Development and Approval.

and to ensure that the best portfolio of stockpiled products are included, given budget constraints, to optimize the HHS's capability. The process relies heavily on input from threat-specific subject-matter experts and senior leaders to inform program prioritization and budget formulation. This is coordinated with a PHEMCE multiyear budget that is aligned with the SIP. In the first phase, the SNS performs a content review and a business process review to find ways to improve the process. The second phase is a deep dive into the threat-specific areas to see if there are any "game changers" in threats or technologies. The third phase is cross-threat prioritization, looking within and across the Integrated Program Teams (IPTs)[15] to see how MCMs could be leveraged (i.e., if there are different ways MCMs can be used for one threat versus another) to obviate the need for threat-specific countermeasures. The fourth phase incorporates senior-level input; Jaffe noted that this requires clear communication in explaining these complex issues to senior leadership outside of the domain. The final phase is writing the report to Congress, obtaining executive clearance, and delivering the report to the Office of Management and Budget (OMB) and Congress.

Jaffe explained that the goal of the assessments themselves is to continue to improve estimates of what is needed in the stockpile and what can be effectively used, driving toward achieving a process that effectively balances the current status and the preparedness goals. To that end, he outlined five parameters for inclusion of MCMs in the SNS as a high-level overview for workshop participants:

- Can we develop it (research and development)?
- Can we make it (manufacturing)?
- Can we stockpile it and procure it (purchasing)?
- Can we plan on how we are going to use it (response planning) and how we use the operational capacity?
- Can we use everything that we say we are going to use?

Turning to the requirements process, Jaffe explained that there is a three-tiered process to identify what the threat is, how to mitigate that threat, and how much it needs to be mitigated. He clarified that the aims are not to stock more MCMs than are needed to mitigate threats and determining what the product looks like in a stockpiling goal. At that point,

[15] "The IPTs provide an end-to-end vision of MCMs against a particular threat type (e.g., anthrax, smallpox) or capability (e.g., diagnostics) that ranges from requirements setting (i.e., stockpiling targets and product characteristics) through to stockpiling, delivery and dispensing, and monitoring and evaluating MCM effectiveness. The IPTs develop strategies for addressing key cross-cutting issues, in consideration of available programmatic resources at the federal and SLTT levels. IPTs serve as subject-matter expert communities of practice for interagency vetting and input on issues within their purview. They report to the EEC" (http://www.phe.gov/Preparedness/mcm/phemce/Pages/governance.aspx [accessed April 15, 2016]).

PHEMCE members work together with the partners at BARDA to develop acquisition strategies and other downstream components.

Jaffe commented that the preparedness goals to "develop, make, stockpile, plan, and use" track very well with how much is needed, how much is being used, and what the product would look like in a stockpiling goal for requirements. All of these goals are informed by the SNS, tracked, and aligned to create the best stockpile with the best product to mitigate threats.

The Biomedical Advanced Research and Development Authority

Gary Disbrow, director, CBRN Division, ASPR/BARDA, explained that the mission of BARDA is to support advanced development and availability of countermeasures for CBRN threats, pandemic influenza, and EIDs through product development, innovation, acquisition, stockpiling, building manufacturing infrastructure, and core service assistance.

Disbrow explained that BARDA's role within PHEMCE is, in essence, to act as a virtual pharmaceutical company. In addition to providing contractual support for the development of MCMs, BARDA also is responsible for the initial acquisition and purchasing of products, stockpiling them, and working in collaboration with the DSNS to place them in the SNS or other venues. BARDA also builds manufacturing infrastructure and provides core service assistance to certain companies.

Disbrow highlighted two methods for procurement and stockpiling. The first method is for the DSNS to use its fund to purchase licensed products that were not developed by PHEMCE partners. The second is for BARDA to support[16] successful products (those that meet scientific milestones for safety, efficacy, and control of manufacturing) through late-stage development, procurement, and maintenance when products are under potential EUA. Products are also supported through approval/licensure under Project BioShield (which is a different funding stream). Once a product is approved or licensed, BARDA works with them to fulfill postmarketing commitments and requirements.[17]

In addition to contractual support, BARDA has established a National Countermeasure Response Infrastructure, which was presented by Disbrow (see Figure 2-3).

[16] BARDA's advanced research and development contracts do not permit them to actually buy products, only to support them.

[17] Products supported by Project BioShield have included Anthrax Immune Globulin (AIG), Anthrax Vaccine Adsorbed general use prophylaxis (AVA GUP), heptavalent Botulinum Antitoxin Therapeutic (hBAT), Neulasta, Neupogen, and Raxibacumab. Approved/licensed products supported under PI (pandemic influenza) funding include Peramivir, 5N1 (one) and H1N1 (six) vaccine candidates, cell-based vaccine and recombinant vaccine, and diagnostics (five).

FIGURE 2-3 BARDA's National Countermeasure Response Infrastructure.
NOTE: ADS = Analytical Decision Support; BARDA = Biomedical Advanced Research and Development Authority; CIADM = Center for Innovation in Advanced Development & Manufacturing; Mfg. = Manufacturing.
SOURCE: Disbrow presentation, February 4, 2016.

Disbrow explained that there are three Centers for Innovation in Advanced Development & Manufacturing (CIADMs) in the United States that can help developers to manufacture their products and provide other core services. The Fill-Finish Manufacturing Network has four centers located throughout the United States that can assist companies that have manufacturing capacity but not fill-finish capacity. The Nonclinical Development Network can develop animal models that can stand up to regulatory rigor; most of these products are licensed or approved under the

Animal Rule.[18] This network can also evaluate products on the commercial market for suitability for another purpose in treating threats that should be addressed. The Clinical Studies Network (four sites located throughout the United States) can perform clinical studies for products. This infrastructure also includes a modeling hub as well as regulatory and quality affairs.

Disbrow explained that these infrastructure capabilities were actually activated during the EVD response. For the EVD therapeutic, a regulatory and quality affairs group helped the company write some sections of their investigational new drug (IND) application so they could submit it more quickly. The Fill-Finish and Manufacturing Network actually took over and was eventually responsible for shipping the finished product to West Africa. The Nonclinical Development Network was used to evaluate other EVD therapeutics; the CIADMs were actually leveraged to manufacture monoclonal antibodies that could address the EVD outbreak through a partnership with Genentech Inc.

Disbrow noted that as the value of the SNS formulary has increased over the past several years, the range of products supported under Project BioShield that have been (or will soon be) added to the SNS include products for smallpox, botulism, anthrax,[19] chemical injury, and radiation and burn injury from nuclear detonation. During the discussion, Skip Skivington, vice president of operations, Kaiser Permanente Finance Operations, asked Burel about the cause of the rapid increase in inventory cost from $6 billion to more than $7 billion. Burel attributed the valuation increase to the inclusion of additional products in the SNS, due in large part to BARDA's advanced development efforts. But he commented that while the products delivered by BARDA are of high quality, many have very high costs associated with them. Thus, acquiring even a few of those products drives the valuation very high. He noted also that those products will have to be continually procured and replaced by the DSNS or BARDA's great work and great investment will have been squandered. Burel commended BARDA for its role in developing new products and expanding capabilities for the SNS, but warned that plans will need to be in place to maintain that level of contribution going forward.

According to Disbrow, BARDA provides a range of stockpiling options for the SNS. They can deliver CBRN countermeasures and pandemic influenza products to the SNS if there is not a commercial market. Vendor-managed inventory can be used when there is a commercial indication and

[18] See http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm399217.pdf (accessed June 3, 2016).

[19] The anthrax vaccine has completely transitioned to the SNS. Disbrow commented that he is aware that costs are being transferred to the SNS (personnel, inventory storage, etc.) even without purchasing or production costs.

market that can be leveraged to decrease life-cycle management costs.[20] In such cases the product is stored at the vendor in a cage that is owned by the U.S. government. As it nears expiration, it rotates into the commercial market and then new product comes into that cage. This means that the product is available to the U.S. government at any time; however, this method for managing and storing pharmaceuticals is not possible for all MCMs.

BARDA also manages pre-pandemic stockpiles of bulk vaccine, adjuvant, plasma, or bulk intermediates for CBRN threats, according to Disbrow. Although bulk intermediates have a longer shelf life, a several-month-long lead time may be necessary to actually take that bulk and manufacture it into final drug product. Furthermore, if the product is fill-finished but does not meet release specifications, then the product is unusable. BARDA also makes investments in next-generation products to potentially decrease life-cycle management costs, for example, products in lyophilized forms to extend the shelf life from 3 to 10 years. Disbrow explained that such investments always require a return on investment (ROI) analysis: there is very clear justification to invest going from 3 to 10 years, but less so from 5 to 6 years, or going from an IV administration to a pill. He estimated that such investments might require several hundred million dollars over a much longer period of time. During the discussion, Sheldon Jacobson, professor and director, Simulation and Optimization Laboratory, Department of Computer Science, University of Illinois at Urbana-Champaign, asked for clarification about how ROI is measured for MCMs that are never actually used. Disbrow explained that this is determined by how quickly the investment will be recouped to develop the second-generation MCM (life-cycle cost includes the development and then the out-year cost for replenishment); such investments require savings over time.

Disbrow outlined numerous ways that BARDA interacts with CDC and DSNS, arguing that they are not in fact siloed (as Skivington had suggested). For instance, Flu Risk Management Meetings involve high-level PHEMCE partners. BARDA must brief both the Enterprise Executive Committee and the Enterprise Senior Council before making acquisitions for Project BioShield, meaning that all PHEMCE partners are informed. Integrated program teams are PHEMCE-wide teams of subject-matter experts that make decisions on requirements for different types of products. DSNS and CDC personnel participate in BARDA-established technical evaluation panels for proposals and in-process reviews, where decisions are made about moving forward with a contractor on the basis of scientific merit. Project coordination teams manage the day-to-day oversight of individual

[20] Neupogen and Leukine are products that were previously approved to treat cancer patients undergoing myelosuppressive therapy. Neupogen has now been approved for the acute radiation syndrome indication. These products are out in the commercial market.

contracts. The multiyear budget allows NIH to inform BARDA about potential product transfers and transitions over a 5-year period; BARDA also informs DSNS about potential product transfers to the stockpile over the same period, according to Disbrow. The SNS annual review informs the review committee about when potential products will be ready for procurement and stockpiling, and BARDA and the SNS work together to support submission of pre-EUA packages, among numerous other venues of collaboration.

Finally, Disbrow explained that as products become approved and licensed, the DSNS will be responsible for their replenishment and maintenance. BARDA/PHEMCE partners have achieved approval for 19 products, with additional approvals expected in the coming fiscal years. However, Disbrow cautioned that the SNS budget will need to increase as the role of maintenance transitions to the SNS.

The Food and Drug Administration and the Federal Medical Countermeasures Enterprise

The role of FDA in the federal MCM enterprise was described by Brad Leissa, deputy director and emergency coordinator, Counter-Terrorism and Emergency Coordination Staff, Center for Drug Evaluation and Research. He explained that FDA's overarching MCM objective is to facilitate the development of and access to safe and effective MCMs (i.e., drugs, biologics, and devices, including diagnostics and PPE to counter high-priority CBRN and EID threats).

Leissa explained that FDA has numerous MCM roles throughout products' life cycles.[21] FDA engages with product sponsors throughout the MCM development process and collaborates with government partners (e.g., PHEMCE, state and/or local governments) as needed. It is involved in approving, licensing, clearing, and regulating MCMs with the Animal Rule as the authority for when safety still needs to be assessed in both animals and humans.[22] FDA has legal mechanisms to prepare for and facilitate the emergency use of MCMs (e.g., EUA, IND application or investigational device exemption [IDE], and other emergency-use authorities) and associated import/export laws and liability protections (PREP Act). FDA supports MCM product development via scientific research. The Medical Countermeasures Initiatives (MCMi) can support anticipating, monitoring for, and managing potential MCM shortages.

[21] MCMi Annual Report: http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCounterm easures/AboutMCMi/ucm270744.htm (accessed April 15, 2016).

[22] The principal efficacy determination is made through animals with the extrapolation of pharmacokinetics and pharmacodynamic endpoints to humans.

FDA works closely with the DSNS regarding potential MCM shortages, according to Leissa. The DSNS will occasionally contact FDA to seek advice about whether the size and magnitude of a procurement being considered will affect general use of the product in the community. If supported by science, FDA has the ability to extend drug expiration dates through the shelf-life extension program. FDA monitors MCM use for adverse events (e.g., through MedWatch and the Vaccine Adverse Event Reporting System) and ensures consumer protection against fraudulent claims, enforcing against misbranded and adulterated products.[23] FDA addresses evolving challenges with respect to emerging threats during an event through intraevent MCM surveillance that evaluates both the safety and the operational effectiveness of the product.

Leissa explained that use of investigational new drugs is relatively straightforward for approved products, unless they have an indication for which they are not approved. When a product is in the SNS it can be used under IND application.

Emergency Use Authorization and Legal Mechanisms

EUA opened the door for mass preparedness planning, noted Leissa. Pre-EUA is a mechanism by which FDA communicates with drug developers or with other agencies in the government about a product that is not yet at the stage of EUA and comes to an agreement about what is needed. An example of an EUA from 2009 is Peramivir IV; CDC then was on the operational side of distributing Peramivir to requesting physicians who agreed to the conditions of the EUA. A summary of EUAs issued between 2005 and 2015 is listed in Table 2-1.

Emergency-use legal mechanisms allow expanded access to investigational drugs and devices; Leissa explained that in certain circumstances, clinical trials under an IND/IDE may be the most ethical and fairest means to provide access, given limited supplies and need to assess products.[24] EUA[25] was established by the Project BioShield Act (2004) and amended by PAHPRA in 2013.[26]

Leissa described how under EUA authority,[27] FDA can authorize for use in CBRN emergencies the unapproved MCMs (despite lacking the amount of data necessary for approval) and the unapproved use of approved MCMs

[23] Six Warning Letters were issued in response to Ebola claims, including three in September 2014. See http://www.cnn.com/2014/09/26/health/ebola-fake-drugs (accessed June 6, 2016).

[24] IND application (21 CFR §§ 312.300-312.320), IDE (21 CFR Part 812).

[25] FD&C Act § 564.

[26] Other emergency-use authorities include FD&C Act §§ 564A, 505-1, and 564B; established by PAHPRA in 2013.

[27] FD&C Act § 564.

TABLE 2-1 Summary of EUAs Issued (2005-2015)

EUAs Issued by FDA			
Year	**MCM**	**Requester**	**Status**
Anthrax (*Bacillus anthracis*)			
2005	Anthrax Vaccine Adsorbed (AVA)	DoD	Terminated
2008 (reissued in 2009, 2010, and 2011)	Doxycycline hyclate 100 mg oral tablets (in National Postal Model home/workplace kits)	HHS (ASPR/ BARDA)	Current (2011 version)
2011	All oral formulations of doxycycline (mass dispensing)	HHS (CDC)	Current
2009 H1N1 Influenza Pandemic			
2009-2010	Antivirals (3)	HHS (CDC)	Terminated (all H1N1 EUAs)
	IVDs (18)	Various	
	Disposable N95 respirators	HHS (CDC)	
Novel Influenza A (H7N9) Virus			
2013	CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Infleunza A/H7 (Eurasian Lineage) Assay	HHS (CDC)	Current
2014	Lyra Influenza A Subtype H7N9 Assay	Quidel Corporation	Current
2014	A/H7N9 Influenza Rapid Test	Arbor Vita Corporation	Current
Middle East Respiratory Syndrome Coronavirus (MERS-CoV)			
2013 (reissued in 2014)	CDC Novel Coronavirus 2012 Real-time RT-PCR Assay	HHS (CDC)	Current
2015	RealStar MERS-CoV RT-PCR Kit U.S.	Altona Diagnostics GmbH	Current
Enterovirus D68 (EV-D68)			
2015	CDC EV-D68 2014 rRT-PCR Assay	HHS (CDC)	Current
Ebola EUAs Issued by FDA			
Year	**MCM**	**Requester**	**Status**
2014 (reissued in 2014)	DoD EZ1 Real-time RT-PCR Assay	DoD	Current
2014 (reissued in 2015)	CDC Ebola VP40 rRT-PCR Assay	HHS (CDC)	Current
2014 (reissued in 2015)	CDC Ebola NP rRT-PCR Assay	HHS (CDC)	Current

TABLE 2-1 Continued

Ebola EUAs Issued by FDA			
Year	**MCM**	**Requester**	**Status**
2014 (reissued in 2015)	FilmArray NGDS BT-E Assay	BioFire Defense, LLC	Current
2014	FilmArray Biothreat-E test	BioFire Defense, LLC	Current
2014 (reissued in 2014)	RealStar Ebolavuris RT-PCR Kit 1.0	Altona Diagnostics, GmbH	Current
2014	LightMix Ebola Zaire rRT-PCR Test	Roche Molecular Systems, Inc.	Current
2015 (reissued in 2015)	ReEBOV Antigen Rapid Test	Corgenix, Inc.	Current
2015	Xpert Ebola Assay	Cepheid	Current
2015	OraQuick Ebola Rapid Antigen Test	OraSure Technologies, Inc.	Current

NOTE: ASPR = Office of the Assistant Secretary of Preparedness and Response; BARDA = Biomedical Advanced Research and Development Authority; CDC = Centers for Disease Control and Preparedness; DoD = Department of Defense; EUA = Emergency Use Authorization; HHS = Department of Health and Human Services; IVD = in vitro diagnostics; PCR = polymerase chain reaction; rRT-PCR = real-time reverse transcription polymerase chain reaction; RT-PCR = reverse transcription polymerase chain reaction.
SOURCE: Leissa presentation, February 4, 2016.

(e.g., for a new indication). When scientific evidence is available to support MCM use in a CBRN emergency, issuing an EUA enables response stakeholders to use, or prepare to use, an MCM without violating the FD&C Act of 1938, as amended. The DHS, DoD, or HHS Secretary makes a specific type of determination regarding requirements for EUA issuance. The HHS Secretary issues a declaration that circumstances exist to justify EUA issuance based on one of the four determinations, and FDA ensures that EUA criteria for issuance are met (e.g., based on totality of scientific evidence, the known/potential benefits outweigh known/potential risks; no adequate, approved, available alternative). Conditions of authorization are put in place as safeguards for use of the product under EUA.[28]

Leissa explained that there are also other emergency-use authorities available in certain circumstances. PAHPRA established emergency-use

[28] For example, information on emergency use, fact sheets for recipients and health care professionals, dispensing/screening procedures, monitoring of adverse events, clarification of roles.

authorities for eligible FDA-approved MCMs intended for use in CBRN emergencies to facilitate stakeholder preparedness and response without an EUA.[29] Emergency dispensing orders (FDA authority) allow mass dispensing at PODs without an individual prescription or all required labeling. Emergency-use instructions (CDC authority) are streamlined fact sheets on MCM use for recipients and health care providers. Expiration dating extensions are allowed when FDA determines, through either the Shelf Life Extension Program (SLEP) or other announcements it makes about extensions, that these are legally covered as well under these emergency-use authorities.

Current Good Manufacturing Practice (CGMP) waivers (FDA authority) are used when there may be a limited period of time during an emergency in which a product might need to be transported or stored outside of its labeled storage conditions. Risk Evaluation and Mitigation Strategy waivers (FDA authority) are also in place for certain products. Prepositioning of approved or unapproved MCMs[30] facilitates rapid deployment during an actual emergency; it allows prepositioning of MCMs by or on behalf of government entities (federal, state, or local) in anticipation of FDA approval, clearance, or licensure or EUA issuance. These authorities preserve otherwise applicable liability protections (e.g., PREP Act) for MCM planning, preparedness, and response stakeholders.

During the discussion, Boris Lushniak, professor and chair, Department of Preventive Medicine and Biostatistics, F. Edward Hébert School of Medicine, Uniformed Services University, asked whether there have been legislative or regulatory approaches that have been discussed at FDA or other agencies to improve the process, given existing constraints. Leissa replied that on the emergency preparedness side with respect to state and local capabilities, there are preexisting authorities that can be used. Emergency-use guidance for these authorities will be issued soon, so that local-level officials will know that they exist and to resolve any misunderstanding about when EUAs are required or not in various circumstances. In terms of MCM development, he explained that FDA is somewhat limited in its authorities for improving the process (e.g., the Animal Rule does require animal data, not in vitro data, in quality animal models). Various avenues are being explored to assist in the development of MCMs, according to Leissa, such as an established qualified animal model that could be used by multiple developers, not just the government.

[29] FD&C Act § 564A.
[30] FD&C Act § 564B.

3

Studies and Reports Related to the Strategic National Stockpile

ANTICIPATED RESPONSIBILITIES OF THE SNS IN THE YEAR 2020

John Parker, former chair, National Biodefense Science Board (NBSB)[1] and report co-chair for *Anticipated Responsibilities of the SNS in the Year 2020: An Examination with Recommendations, A Joint Report of the National Biodefense Science Board and the Office of Public Health Preparedness and Response Board of Scientific Counselors*,[2] outlined the three tasks that the NBSB and Office of Public Health Preparedness and Response Board of Scientific Counselors (OPHPR BSC) were charged with by the Office of the Assistant Secretary of Preparedness and Response (ASPR) and the Centers for Disease Control and Prevention (CDC) director of the OPHPR:

1. To identify anticipated responsibilities of the Strategic National Stockpile (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.

[1] The National Biodefense Science Board was renamed in April 2014 to the National Preparedness and Response Science Board.

[2] See http://www.phe.gov/Preparedness/legal/boards/nprsb/recommendations/Documents/nbsb-bsc-sns-2020-final.pdf (accessed June 3, 2016).

The Joint SNS 2020 Working Group comprised members of the NBSB, the OPHPR BSC, and industry representatives.

Responses to Task 1, Parker reported, included the need to secure the public health of the United States and to augment the U.S. security posture. He commented that if "we don't have a good secure public health policy, we can't have any other type of security posture." The next response is to maintain a cache of medical countermeasures (MCMs) and materiel necessary to support a robust response to the widest possible spectrum of public health emergencies. Next, because of the mutual and critical dependence existing between the SNS and state and local public health agencies, the SNS should be increasingly enhanced to meet public health responsibilities. The NBSB and the OPHPR BSC agreed that they did not foresee either a reduction in SNS responsibilities or a reduction in the cost of fulfilling these responsibilities because of continuing needs.

Parker explained that the response to the second task, recommending approaches for meeting responsibilities as efficiently as possible, called for an increased reliance on state-of-the-art risk management and applied science. Metrics proposed for reporting program capability and informing improvement in response to Task 3 include deriving program capability metrics from actual performance data (where such information exists), results of exercises, and computational modeling and simulations. The latter component was emphasized due to the expense of full-blown exercises. The program capability assessment metrics should identify not only gaps and strengths in distribution of MCMs, but also delivery to the public. The report stated that the SNS should carry out rigorous exercises of their current capabilities as part of a wholly integrated national response system (despite the expense, these are still necessary, particularly when dealing with staff on retainers). Finally, Parker noted that the report said performance assessments should be expanded to include the desired outcome: rapid delivery of critical countermeasures to the public. The report's recommendations are listed in Box 3-1.

A NATIONAL BLUEPRINT FOR BIODEFENSE: LEADERSHIP AND MAJOR REFORM NEEDED TO OPTIMIZE EFFORTS

Ellen Carlin, co-director, Blue Ribbon Study Panel on Biodefense, and principal, Carlin Communications, presented on the report *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*.[3] She explained that the self-prescribed mandate was broad, covering the four pillars of biodefense as outlined in Homeland Security

[3] See http://www.biodefensestudy.org/SiteAssets/1425-2139_BRSP_Report_100815b[1][6].pdf (accessed June 3, 2016).

BOX 3-1
10 Recommendations from
Anticipated Responsibilities of the SNS in the Year 2020

Parker explained that the report also issued 10 recommendations, which he provided with commentary:

1. *Articulate a vision for SNS 2020*: The 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.
2. *Tailor SNS surge capacity*: surge capacity should be restricted to include only materiel that cannot be appropriately provided through existing commercial inventories and distribution networks (the Public Health Emergency Medical Countermeasures Enterprise [PHEMCE] should play an important role). The top priority of the SNS should be the large-scale delivery of essential medical countermeasures and other urgently required materiel in quantities sufficient to contain incidents and/or save lives in response to CBRN incidents, but it may also provide support in an appropriate manner to other public health emergencies.
3. *Use science as a key strategic and tactical management tool*: The broad capabilities of the U.S. government and academia in the areas of basic and applied science should be used as a key strategic management tool for the SNS. The National Institutes of Health, National Science Foundation, national laboratories, and other relevant government institutions should actively collaborate with PHEMCE in making procurement decisions based on present and future science. The SNS inventory composition and volume should reflect the results of vigorous and ongoing evaluation of the new medical countermeasures and therapeutics and their usage protocols, unique MCM needs for children and other vulnerable populations, new requirements based on updated threat analyses 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*: Include risk-benefit analysis and the requirements generation process.
5. *Continue to move to a single appropriations model*: This would enhance the fiscal management of the SNS.
6. *Use sound cost versus benefit decisions as integral components of the management process.*
7. *Make greater use of computational modeling and simulation*: Include business principles and tools as integral components of the management process.
8. *Recognize the SNS and BARDA as sole purchasers—and the SNS as sole distributor—of certain MCMs.*
9. *Improve coordination among federal, state, and local public health partners.*
10. *Apply laboratory science and animal models to inform SNS stockpile requirements*: This should be applied to reduce some uncertainties and investigate unanswered important biomedical questions related to public health preparedness.

SOURCE: Parker presentation, February 5, 2016.

Presidential Directive 10, and the panel found that the federal government is carrying out many important activities in a siloed and uncoordinated manner in the absence of a single point of responsible leadership for biodefense or a national strategy that coheres all of the activities of its different departments and agencies.

Carlin described how the report is structured into three thematic areas of deficiency: interagency coordination, collaboration with stakeholders and innovation (particularly in areas of biodetection and biosurveillance), and MCM development. It contains 33 recommendations, of which she focused on the two primarily related to management of the SNS.

Carlin explained that Chapter 2 of the report focused on the need to elevate collaboration with the many SNS stakeholders across the country, with Section IV devoted to advancing planning for MCM distribution and dispensing. Carlin noted that while preparedness for distribution and dispensing has improved greatly over the past 10 years, there are still populations that will not be reached within the 48-hour window within the current system. She said that further challenges that persist within the MCM response architecture include lack of clear centralized leadership; lack of clear and consistent directives for coordination of state, local, territorial, and tribal plans; lack of clear goals and objectives for response; and insufficient funding for health departments.

The panel analyzed various modalities of distribution, such as the postal approach; Carlin contended that an optimal national mass prophylaxis capability would have to reach far beyond what the U.S. Postal Service could provide and into private delivery companies, pharmaceutical chains, and volunteer health care worker coalitions. Similarly, she suggested that dependence on the static open-point of dispensing (POD) model will not meet the need in a mass event. The panel ultimately concluded that national mass prophylaxis must depend on nonfederal input planning and implementation, with a national stakeholder-driven MCM response framework providing structure and guidance for local planning efforts.

Carlin commented that these deliberations led to Recommendation 22 (see Box 3-2), which calls for the development and implementation of an MCM response framework, coordinated by CDC, the ASPR, and the Federal Emergency Management Agency (FEMA) alongside nonfederal partners from states, localities, industries, and nongovernmental organizations.

Carlin highlighted the conclusion that national mass prophylaxis must depend on nonfederal input, planning, and implementation, with the recommended framework addressing parameters for federal commitments such as expectations at the state and local levels, the important issue of clinical utilization guidance (she noted that there are MCMs that were in the stockpile for years before they had clinical guidance published), and essential information sharing with nonfederal partners. Carlin also

BOX 3-2
Recommendation 22 from
A National Blueprint for Biodefense:
Leadership and Major Reform Needed to Optimize Efforts

Develop and implement a Medical Countermeasure Response Framework. A stakeholder-driven framework for solving continued challenges in operational MCM response will provide greater assurance that distribution and dispensing can be achieved quickly, efficiently, and safely.

ACTION ITEM:

a. *Produce a comprehensive framework to guide medical countermeasure distribution and dispensing planning*. Together with non-federal partners, the ASPR, the Director of the CDC, and the Administrator of FEMA should identify requirements and capacities needed to achieve successful distribution and dispensing of MCM from the SNS as well as from local caches. The framework they develop must address unresolved issues. It should be a progressive and innovative approach that pushes the envelope beyond what a given agency might devise and beyond the bureaucratic impediments associated with a federal-only distribution system. If implementation would exceed funding available through current grant allocations, additional funding must be requested.

SOURCE: Carlin Presentation, February 5, 2016.

emphasized the importance of Recommendation 23 (see Box 3-3), which calls for select forward deployment of SNS assets to localities that have a demonstrated ability to handle them appropriately.

PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE REVIEW: A STRATEGIC REPORT

Robert L. Burhans, senior executive, Tetra Tech, Emergency Management and Community Resilience, served as a special project advisor to the Association of State and Territorial Health Officials (ASTHO) report *Public Health Emergency Medical Countermeasures Enterprise Review: A Strategic Report*,[4] completed in November 2013. The report was commissioned by ASTHO to better inform its membership about issues surrounding the country's medical countermeasures enterprise. Burhans described three areas of focus that informed the review. The first focus area centered on actions to better integrate and involve the public health enterprise in the

[4] A summary of the report's findings are available at http://www.astho.org/Preparedness/DPHP-Materials-2013/PHEMCE (accessed June 3, 2016).

BOX 3-3
Recommendation 23 from
A National Blueprint for Biodefense:
Leadership and Major Reform Needed to Optimize Efforts

Allow for forward deployment of Strategic National Stockpile assets. Pre-deployment of SNS caches to those jurisdictions that have demonstrated the capability to appropriately handle SNS contents will vastly improve preparedness.

ACTION ITEMS:

a. *Determine logistics and funding needs*. The Director of the CDC should determine the necessary assessment, logistical, and funding requirements to forward deploy SNS assets.
b. *Implement forward deployments*. Once the requirements are established, the President should request funding in the next budget cycle to support forward deployments to cities that have demonstrated readiness. Deployments of reasonable quantities should go toward to high-threat, high-density urban areas that have demonstrated an ability to stand up PODs faster than SNS medications can be delivered to these jurisdictions and subsequently distributed to PODs. The Director of CDC should actively encourage leaders of other major urban areas to plan for and demonstrate ability to stand up PODs faster than SNS medications can currently be delivered.

SOURCE: Carlin Presentation, February 5, 2016.

Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and specifically to engage in priority activities identified in the 2012 HHS PHEMCE Implementation Plan. The second centered on actions to further the implementation of Executive Order 13527, "Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack." The third focus was on actions to enhance the effectiveness of MCM and Public Health Preparedness Program activities within ASTHO.

The review methodology included the identification, cataloging, and review of relevant documents and websites; individual interviews with federal officials, state and city directors of public health preparedness, ASTHO Preparedness Policy Committee members, and other key informants; review of source documents describing ASTHO's current MCM portfolio; and the participation in meetings and conference calls conducted by ASTHO's Directors of Public Health Preparedness Executive Committee and Emergency Medical Countermeasures Steering Committee.

Employing the methodology, according to Burhans, generated sig-

nificant evidence that the PHEMCE Strategy and Implementation Plan, particularly the federal inter- and intraagency organizational structure, had been successful in increasing collaboration and alignment among the federal agencies engaged in PHEMCE. Examples he cited included the Medical Countermeasures Initiative (MCMi), FDA's initiative to organize around MCM development, approval, and use. This initiative demonstrates multilayered collaboration with internal FDA partners, external PHEMCE partners, and drug manufacturers to advance FDA's PHEMCE activities. CDC and ASPR/Biomedical Advanced Research and Development Authority (BARDA) aligned their efforts to accomplish a stockpile of new botulinum and anthrax antitoxins identified by the implementation plan as top priorities.

Burhans summarized the review's recommendations concerning PHEMCE's organizational structure, noting that the report was directed to ASTHO, not to the PHEMCE agencies, and focused on what ASTHO should do to become more fully engaged in the PHEMCE organizational structure. The first recommendation was to work with ASPR to identify a point person to manage the public health emergency preparedness (PHEP) relationship with PHEMCE. To date, he noted, the strongest relationship that the public health enterprise has is with CDC because of relationships established over the years, grant activities through PHEP, and the fact that the public health enterprise relies on the SNS to provide its MCMs. Further recommendations were to discuss the optimal structure to engage the public health enterprise with the PHEMCE Enterprise Executive Committee at a strategic level, identify PHEMCE priority activities that require public health enterprise input, and meet with ASPR and the Department of Homeland Security (DHS) to address issues with the PHEMCE requirement-setting process.

Burhans emphasized that the public health enterprise (see Box 3-4), which has the responsibility for dispensing MCMs, needs to be engaged in the requirement-setting process because decisions on the formulary and the attributes of the MCMs absolutely dictate dispensing strategies. If the public health enterprise is not fully engaged in the requirement-setting process, then there is the potential for decisions to be made that may not fully reflect the concerns of those doing the dispensing.

The next set of recommendations from the ASTHO report relates to strategic issues identified in Executive Order 13527, which Burhans described as high-level objectives. The first recommendation is to work to communicate the U.S. Postal Service dispensing model to the public health enterprise and find ways to support law enforcement participation in the execution of that model, because having sufficient law enforcement capacity was determined to be a limiting factor in the actual use of that plan by many local and state health departments. The second, understanding and

BOX 3-4
Follow-Up:
National Health Security Strategy Implementation Plan

Objective 6—Promote an Effective Countermeasure Enterprise

Burhans outlined selected activities to implement the National Health Security Strategy Implementation Plan's Objective 6:

- 6.1.2—Relevant departments and agencies will coordinate the determination of MCM requirements based on risk assessment. (Potential partners: Other federal agencies.)
- 6.4.1—HHS will encourage continued collaboration regarding federal. state, local regional, and private MCM stockpiles and put in place systems that facilitate sharing and augment equitable and efficient MCM use. (Potential partners: State and local governments, regional entities, and private sector.)
- 6.4.2—CDC will work with partners to align strategies and ensure adequately stocked and positioned repositories of MCM, and/or laboratory testing equipment and supplies, and devices. (Potential partners: FDA and other federal agencies; local, state, territorial, and tribal governments; private sector.)
- 6.4.3—CDC will continue to work with each state and its respective local health departments to develop plans to receive and distribute SNS medical products and medical supplies to local communities as quickly as possible, and to explore diverse distribution and dispensing strategies to best meet the needs of their populations. (Potential partners: Local, state, territorial, and tribal health departments and other agencies.)

SOURCE: Burhans presentation, February 5, 2016.

communicating the federal rapid response plan to the public health enterprise, he described as essentially developing a concept of operations about how federal resources would be brought to bear to enhance local dispensing efforts. This also includes a federal continuity-of-operations plan, whereby essential personnel in federal agencies would be identified and provided with MCMs. The third is to identify and advance lessons learned from the first round of "big city" reviews, and the fourth is to engage FEMA in the routine assessment of state SNS planning.

Burhans outlined a final set of recommendations that were provided for ASTHO regarding how they could better organize their internal structures to be more effective:

- Identify an ASTHO staff member to be the primary PHEMCE liaison.

- Develop clear protocols for gaining the Directors of Public Health Preparedness (DPHP) endorsement of federal guidance.
- Assign the DPHP Executive Committee to vet emergency medical countermeasures (eMCMs) projects.
- Assign DPHP Executive Committee members as liaisons to the eMCM Planning Group.
- Include a National Association of County and City Health Officials (NACCHO) representative on the Preparedness Policy Committee.
- Increase collaboration between ASTHO and NACCHO on PHEMCE issues.

In helping wrap up the discussions, Burel reflected that during his 8-year tenure as director of the CDC Division of Strategic National Stockpile, the division has been the recipient of more than 120 reviews and audits that have benefited the program in numerous ways. It has developed increasingly stronger partnerships with other federal and nonfederal agencies that have been parlayed into better ability to respond to events such as Ebola. Burel has been invited to be part of the DoD Medical Logistics Senior Steering Council, for example, which he referred to as a forum for sharing topics of discussion that the SNS has with PHEMCE, as well as how the agencies can mutually support each other in health emergencies.

4

Potential Opportunities for Restructuring Strategic National Stockpile Scope, Governance, and Decision Making

POTENTIAL OPPORTUNITY TO REEXAMINE THE MISSION AND SCOPE OF SNS

Tom Inglesby, chief executive officer and director, University of Pittsburgh Medical Center (UPMC) Center for Health Security, maintained that the Strategic National Stockpile (SNS) is improving, commending its financial accountability mechanisms, inventory control, security systems, low administrative costs, business practices, number of products developed through the Biomedical Advanced Research and Development Authority (BARDA), its decision and review processes, and its regulatory interactions. Key challenges to be addressed going forward, according to Inglesby, concern the SNS mission and scope. Even if it is limited to chemical, biological, radiological, and nuclear (CBRN) threats alone, it is still almost beyond sustainability in terms of current cost environment and the development of the stockpile to meet requirements; this is compounded with all hazards, emerging infectious diseases (EIDs), and drug shortages: "Ultimately, even though we talk about that scope and mission like it is a science or a programmatic decision, I think it is absolutely a political decision and in fact a national security governance decision."

Inglesby advised that the SNS should focus on events that the country cannot deal with without the SNS: CBRN; influenza; EIDs; and events that have the potential to lead to massive loss of life, crisis, and instability. He commented that whatever decision is made should be political, with assets and structure that are aligned. Carlin commented that the SNS mission and scope must be limited largely because of funding. She also advised that its

remit should be CBRN, flu, and EIDs. However, because EIDs are more common, she suggested that perhaps they should be moved to another non-stockpile mechanism altogether because sustainability makes SNS capacity for EID stockpiling likely to be infeasible. Carlin cautioned about a near-term funding issue as products transition from Project BioShield to the SNS, noting that Congress has been informed but will likely still be surprised with the cost of the SNS moving forward. However, because the standing committee mandate came from Congress, it provides a platform to speak to Congress directly and make realistic budget requests.

As to whether the SNS should have a role in responding to day-to-day (non-CBRN) events and routine supply-chain shortages, Burel explained that although the original intent was for the SNS to be able to address CBRN threats, that scope has continued to expand to cover all types of hazardous events, natural disasters, pandemic influenza, and EIDs. Although day-to-day drug shortages do not currently fall under the auspices of the SNS, in the role as a specialty distributor of pharmaceuticals, the SNS can respond to a need on a one-off basis for life-saving purposes within the health care system if the SNS holds a product that is available nowhere else (see Box 4-1).

Sosin commented that a national resource such as the SNS, which has tremendous potential in terms of skilled personnel, materiel, and relationships in the medical and pharmaceutical distribution network, should be available in crisis situations: "Those who appropriate funds and expect stewardship and good response, and those who are responsible for those responses, appreciate the ability to utilize those resources. I think there is a natural expectation that an insurance product like a stockpile will not just sit on the shelf and be forgotten."

Jacobson raised the issue of who should be responsible for the management of the SNS in a crisis situation to maximize a response (see Box 4-2) that requires coordinating many different components of items, people, places, and logistics. Jason Frederick, vice president of operations, FedEx Custom Critical, and Mitch Mattingly, president, Metro Logistics, Inc., both replied that they receive instructions directly from the Centers for Disease Control and Prevention (CDC).[1] Burel noted that once the decision is made to deploy, SNS does everything necessary to deploy it all the way to the state level with support from their third-party logistics providers. Then the states and localities take responsibility for dispensing to the public. Performance is monitored by the DSNS, which intervenes if things go wrong.

[1] Frederick commented that CDC is their number one priority customer when there is an event, but that they also hear from other government agencies trying to circumvent the system to lock down capacity.

BOX 4-1
Perspectives on the Role of the SNS in Addressing Day-to-Day Supply Shortages

Concerning the role of the SNS in shortages, David Starr, director of the Countermeasures Response Unit, New York City Department of Health and Mental Hygiene, echoed the concern of several other participants that it has the potential to dilute the primary message of the SNS and divert resources from the SNS's public health emergency preparedness focus. Furthermore, there is the potential for unintended consequences to the pharmaceutical supply chain. Given that most shortages result from decisions made at the supplier and marketing levels, SNS involvement could actually extend the length of the shortage, when prices are suppressed by the additional supplies and the financial incentives for resolving the shortages in the field are removed.

Michael Poole, SNS coordinator, Texas Department of State Health Services, noted that CDC is almost already doing this, for example, with CHEMPAK and the nursing home shortages of Tamiflu. But he noted two potentially negative consequences of this role. First, it would build dependency: "They can just press the CDC button and here comes their product." The second problem is the potential lack of information sharing at the state and local levels. However, he suggested that the SNS program could interact with the supply chain most efficiently and effectively if it serves an "assist" role that does not build dependency, and if information is shared with all necessary agencies so that they are aware that there is a shortage and can coordinate appropriately.

Khan concurred that shortages are usually due to manufacturing deficiencies, and thus purchases by the SNS to smooth out a purported deficiency in the supply chain would actually exacerbate a shortage. Therefore, he advised that these shortages need other regulatory and legislative solutions, including the use of the new BARDA manufacturing capacity to make these medications (many of which are off patent).

Margaret Brandeau, Coleman F. Fung Professor of Engineering, Stanford University, commented that the SNS is part of a much broader system, within which it has much responsibility but not much authority (PHEMCE places items in the stockpile with the expectation that the stockpile must respond quickly to all hazard-type crises within 48 hours, etc.). She suggested an actionable response: quantifying the mission expansion and connecting it to funding. That is, as part of the political process of determining the role of and the funding for the SNS, push back by laying out the core mission and explaining that the expansion of the core mission must lead to increased funding. Brandeau observed there are financial trade-offs that should be considered in the context of widening of the mission of the SNS, saying "If we do not have enough money to replace these expiring things then it will be at the cost of not covering this. If we do not prepare for this

BOX 4-2
Medical Ethics and the Scope of the SNS

Carlin highlighted the issue of medical ethics with regard to the scope of the stockpile: medical countermeasures (MCMs) simply will not reach everyone in need within a 48-hour time frame, so she questioned whether there is a level of failure that we are willing to accept. She noted that the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) probably considers this privately in the context of consequence modeling and dosages, distribution, and dispensing. She commented that there are interesting medical ethics discussions to be had related to expanding or decreasing the scope of the SNS, but that such discussions should factor in how many people the program is realistically trying to reach. For instance, even if there is a vaccine for smallpox for every American in the stockpile, dispensing it in time may not be realistic. Perry Fri, executive vice president, industry relations, Healthcare Distribution Management Association, noted similarly that the focus of the stockpile should take into account the understanding that we cannot save everyone.

particular hazardous scenario that we now have found, it will cost or save this much money."

Skivington observed that the increased demands on the SNS as it has evolved have changed the value proposition of the stockpile. He suggested that there may be substantial value in a review of the SNS's governance, given its administrative complexity, to analyze where components of the process of maintaining and operating a stockpile are working well, where things can be improved, and how the benefits provided by having an SNS can be optimized.

O'Toole advocated for keeping SNS in the national security space, because the latter has different salience, priorities, and budget lines that garner the attention of Congress and the Executive Branch in a way that public health can never do: "We are in a moment of great jeopardy. I do not remember a time when America has had as many potential adversaries, let alone an adversary as brutal as ISIL [Islamic State of Iraq and the Levant] seems to be. They have avowed that they are interested in bioweapons." Thus, she argued that it is important for the standing committee to proceed carefully in making recommendations, in order to help the Department of Health and Human Services (HHS) restructure the SNS without seeming to have failed.

Umair Shah, executive director, Harris County Public Health & Environmental Services, Harris County, Texas, pointed to turnover of expertise and experience as a critical issue, for people involved with the SNS at the

state and local levels in particular. He suggested finding systemic strategies to allow new personnel to be smoothly incorporated and educated about institutional knowledge using strategies proven to have worked elsewhere.

Burhans suggested an integrated, unified budgeting process among all agencies participating in PHEMCE, the SNS itself, and those responsible for the last mile so that there are discrete appropriations for each activity that does not compete or conflict with each other, causing difficult decisions for directors about budgeting (e.g., lab equipment versus SNS drill). A discrete budgeting process would provide transparency as to which resources are being directed to which aspect of the countermeasures enterprise and allow adjustments to be made to resources as needed to respond to gaps.

Carlin remarked that the idea of unifying budgets around this issue is starting to become a common refrain that is echoed in the Blue Ribbon Panel Recommendation 4, which calls for a unified budget for biodefense (not only the SNS). She cautioned that unifying the budget for the SNS would require unification of all aspects of biodefense and preparedness.

Burhans suggested breaking down the budget not only at the state and local levels, but across the spectrum. BARDA provides outputs; those outputs are often inputs into the SNS. Therefore, he suggested, it would make sense to align those budgets and products so that the output of one part of the process becomes part of another, which enables predicting what those costs are. O'Toole clarified that this is different from the integrated biodefense budget concept proposed by the Blue Ribbon Commission, which is to look across the entire government.

POTENTIAL OPPORTUNITY FOR PROMOTING VISIBILITY OF THE PUBLIC HEALTH ENTERPRISE

It is evident that public health enterprise is important, held Parker, who suggested implementing a strategy to bring it to greater public prominence. He further suggested another standing committee on public health in the United States: "that committee could work really hard to tie public health into national security, which is needed desperately. . . . I would recommend strongly that we do something to bring attention to the entity called public health in America," which Parker elaborated is suffering a lack of funding and attention that is perhaps a consequence of its own reliability. Starr agreed: "The first year that we got 100 on our technical assistance review, there was a great deal of rejoicing within the city. Then the next year, [same score,] a little less [rejoicing]. By the third year, no one cared anymore. It is true. You are a victim of your own success." Paul Petersen, past SNS coordinator and current director of the Emergency Preparedness Program, Tennessee Department of Health, suggested the use of storytelling and videos (similar to examples at PHE.gov or PublicHealthEmergency.gov)

to demonstrate the impact of the SNS and show how the job gets done; it also allows government to let people know what is being done with funds to protect them.

Parker suggested that if public health structuring was given more priority, some SNS issues would fall into place. For instance, some models (e.g., Federal Aviation Administration, Selective Service) are run by counties or states, but can be federalized at the flip of a switch, which is needed in the event of an EID disaster or terrorist incident.

POTENTIAL OPPORTUNITY FOR IMPLEMENTING A SCIENTIFIC PERSPECTIVE FOR RISK ANALYSIS, INVENTORY, AND DECISION MAKING

Risk Analysis and Risk-Based Decision Making

Skivington pointed to the need to reexamine and restructure SNS governance and oversight, echoing Khan's observation that here we are 17 years into the SNS and there has been no substantial change in this regard. He likened the current structure to a coordinated silo, but a silo nonetheless: he highlighted the need for a risk-based approach to ensure that every decision made is inclusive of the state and local officials, as well as being assessed post hoc for the purposes of improvement. Sosin countered that in his view, the government has in fact evolved. Rather, the issue is that risk is very difficult to quantify and contextualize, and the PHEMCE itself cannot make those determinations. The greatest challenge, he noted, is to identify the "risks we accept that we cannot prepare for," that is, acknowledging and accepting that there is risk that will not be covered. Early targets set for CBRN events were too large and thus unsustainable, yet it has been difficult to walk those triggers back to a more sustainable level. This is a political decision, and "it isn't . . . governance necessarily unless you include . . . governance within [the] political process."

Jacobson construed the issue of risk-based management as a multicriteria problem to which the traditional use of cost–benefit analysis does not apply because averages are meaningless. "We are dealing with rare events, which have great cost, but may never occur." He questioned what specifically is being done in the SNS context to evaluate quantitative and/or qualitative risk. Sosin responded that public health consequences are risk as defined in the intelligence community context, imperfect though that may be. Qualitative input from the intelligence community contributes to understanding and modeling the intentions and plans of groups intending to do harm and how those agents might be disseminated in populations.

Risk Assessment and Scientific Approaches for the SNS Inventory

Starr suggested reexamining the threat assessment to limit the scope of the stockpile even further if possible, with those decisions justified on the basis of sound science. To reduce pressure on public health in rural settings, requirements should be adjusted on the basis of scientifically sound threat profiles.

Parker noted that therapies can change over time, and we are at a scientific standpoint where we should review our therapeutics and regimens using new technologies and techniques (i.e., animal models) to see if we still have the same requirements. For example, one of the most expensive commodities in the stockpile is anthrax vaccine, which is there for both preventive and therapeutic reasons. Therefore, he questioned whether the recommended 60 days of antibiotics and anthrax vaccine is really warranted.[2] Applying innovation and science could change not only the cost structure of the SNS, but also the cold chain distribution, which is expensive.

Khan suggested that the SNS should also redefine its antibiotic holdings based on a portfolio that covers more microbes with fewer broad-spectrum drugs. He suggested that there are also things around margins that can help to deal with resource constraints; for instance, an effective solution to the problem of unsustainability could be for BARDA to assume a more powerful role, for example, by developing pathogen- or agent-independent therapeutics that target sepsis independent of bacterial or viral etiology. To deal with the problem of expiration dates, BARDA could also focus on new formulation strategies that make MCMs inert and thus infinitely stable until they are activated for use: "buy one and be done" to improve sustainability. Furthermore, developing a universal influenza vaccine would also reduce pressure on the SNS.

O'Toole reiterated that it is time to rethink and reexamine the sparsely substantiated assumptions about the critical premises of the SNS. There are revolutionary advances going on in bioscience and biotechnology, but they are stove piped in universities, and an entirely new strategy for research and development around bioscience is urgently needed, she said, not just for biodefense, but for the economy as well. According to the offensive weapons program data, we will not rescue anyone in the initial plume; it is better to discuss this now rather than after a bioterror attack.

Eva Lee, professor and director, Center for Operations Research in Medicine and Healthcare, H. Milton Stewart School of Industrial and Systems Engineering, Georgia Institute of Technology, emphasized the need for

[2] Based on one study of primates where one primate had spores in the mediastinum at 60 days.

innovation in vaccine design and MCM development, citing the difficulty in maintaining compliance with current regimens. Prophylactic MCMs are important, as are innovations in design and rapid testing to improve security, save lives, and protect the economy.

Informing Resource Decision Making for the SNS

Rocco Casagrande, managing director at Gryphon Scientific, presented the results of a Department of Homeland Security (DHS)–CDC partnered risk mitigation study for informing resource decision making for the SNS. Its purpose was to leverage information in the DHS Integrated CBRN Terrorism Risk Assessment (ITRA; see Box 4-3) to provide quantitative information that is useful when making decisions about procurements for the SNS. Essentially, the study aim was to provide a risk-based analysis for informing discussion on how and why the SNS is stocked, specifically, to determine what products, if included in the SNS, would reduce the risk associated with CBRN incidents and how much of these products would be needed to best reduce risk.

Casagrande explained that CBRN incidents can be small (hurting a handful of people) or they can be enormous, so the question at hand is how much of an MCM is needed to address the threat. Some MCMs are specific to a particular agent, and so investment decisions between MCMs should be prioritized: "How do you make an investment in a countermeasure that

BOX 4-3
What Is the DHS Integrated CBRN Terrorism Risk Assessment?
Rocco Casagrande, Managing Director, Gryphon Scientific

Casagrande explained that the DHS Integrated CBRN Terrorism Risk Assessment (ITRA) is a probabilistic risk assessment that incorporates intelligence data from the broader intelligence community on terrorists' preferences for targets and roots of acquisitions for various agents. It also incorporates terrorist capabilities for production of CBRN agents and weapons: Are they likely to get what type of resources, and how much time are they likely to have? What kind of technical savvy are they likely to acquire or otherwise purloin so that they could produce or otherwise acquire CBRN agents and then make weapons out of them?

This information is coupled with the modeling suite that determines the likelihood that various weapons could be produced and acquired by the terrorists, given their resources and preferences, and then the consequences of these attacks on various targets. The ITRA actually represents the capstone of a suite of tools, one of which looks at a particular set of CBRN agents.

only addresses agent X versus agent Y?" The effectiveness of some MCMs is dependent on the dose received by a victim, giving rise to decisions about which MCMs are likely to have real utility in a response. For example, if a victim gets an overwhelming dose of many chemical or radiological agents, the countermeasure will not change the medical outcome. Furthermore, the length of a prophylactic window is a function of dose for some agents (which itself depends on weapon payload and target). According to Casagrande, this requires determining the likelihood or risk that these victims are going to get an overwhelming dose of the agent versus a dose that is treatable.

Casagrande explained that the study methodology first employed the ITRA to generate several hundred biological and radiological attack scenarios that represent the risk of terrorism with these agents. The second phase also looked at chemical and nuclear attack scenarios, before looking at the CBRN space in total. Exposure information in these scenarios was used in models that can predict the ability of the public health response system to mitigate the consequences given the dispensing of MCMs in the SNS. Then other, equal-cost, SNS formularies were generated to determine how the dispensing of MCMs from these notional formularies mitigates consequences (risk is defined actuarially as probability × consequences). Then, to make recommendations, the performance of the current and alternative SNS formularies was compared against the suite of scenarios when considered together.

Casagrande noted that PHEMCE was heavily involved to determine what metrics are used to evaluate the performance of the SNS, as well as the predicted deployment and use of MCM from a federal level. From the local and state levels, several stakeholders were involved to help understand how MCMs are used in the last mile: what trigger decisions are, what their dispensing options are, etc.

According to Casagrande, the ITRA is a rich resource that contains millions of scenarios, each of which differs in terms of probability, consequences, agent, and target. To represent the risk space best, the investigators chose the riskiest scenarios that cover a variety of consequences, agents, and targets. The aim was to select scenarios where the combination of consequence and probability are actually going to drive risk (only the thousand out of a million or so scenarios). They selected a variety of scenarios that differ in terms of the probability and consequences (some were lower probability but higher consequence, and others that were higher probability and lower consequence) but also capture a variety of agents and many targets to represent the risk space (see Figure 4-1).

When sampling the risk assessments, the investigators ranked the ITRA simulations by their total risk and took samples through them: 100 scenarios from the median sample; 100 scenarios from each type of agent and CBRN;

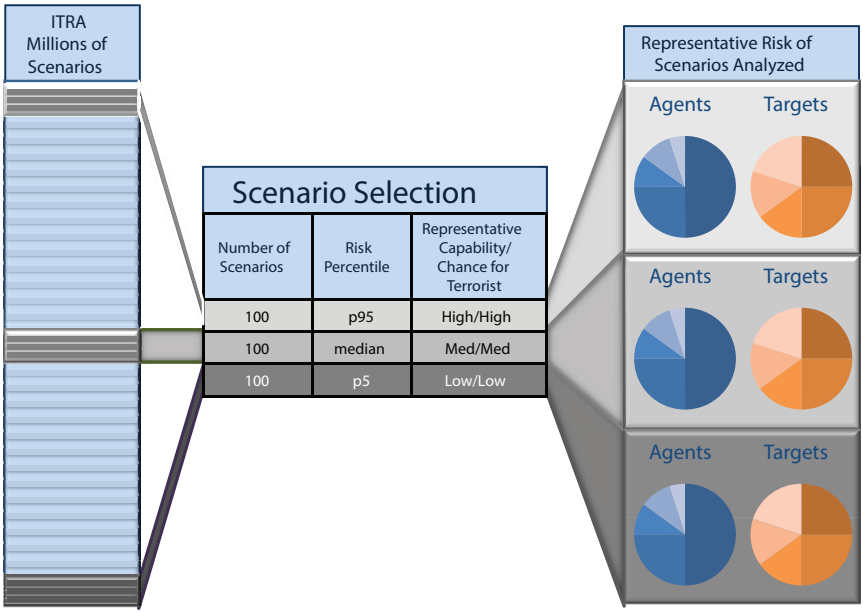

FIGURE 4-1 Sampling the risk assessments.
NOTE: ITRA = Integrated CBRN Terrorism Risk Assessment.
SOURCE: Casagrande presentation, February 4, 2016.

100 samples from the low end, the P5, such that 95 percent have a greater total risk; 100 scenarios from the top end, the P95 such that 95 percent of the scenarios have a lower total risk. He construed the samples as bracketing the possibilities in terms of the threat, with the high end being considered the best possible day for the terrorists, which Casagrande explained as

> They happened to be well resourced. They happened to be technically savvy. They happened to know about the sophisticated agents that the general public doesn't know about. The targets that they chose were packed with people. The agents were particularly hot. The wind was blowing in the right direction, etc. Everything was working well for them.

On the low end, the P5, everything was going against them, so they got a lower total risk. The investigators made sure to capture that variety of uncertainty in what the terrorists might do or how luck or fortune might play in their favor or against them. Uncertainty in public health response was accounted for using three response capabilities: optimistic, average, and pessimistic (see Figure 4-2).

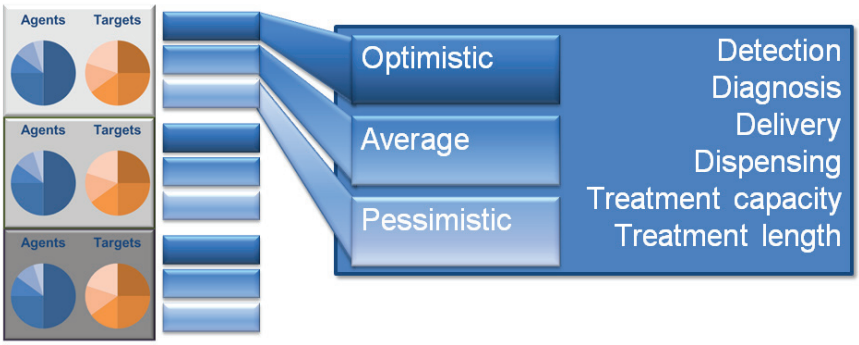

FIGURE 4-2 Sampling public health response capabilities.
SOURCE: Casagrande presentation, February 4, 2016.

Casagrande explained that there are a range of ways that MCMs might actually be used, how quickly they might be dispensed, or what the trigger point for calling SNS would be. Treatment length, for example, can vary significantly according to how many doses of MCM a victim receives. As with the risk assessment sampling, the investigators took the most optimistic case and the most pessimistic case to bracket the uncertainty in the public health response. This approach provided an understanding of the upper and lower bounds of current, possible response capabilities, demonstrated which responses had the most impact, and the best possible reduction of risk with MCMs. Conclusions would only be robust if they held across all nine of those uncertainty combinations, the most and least sophisticated terrorists, and the high and low response capabilities. Furthermore, if some of the conclusions are only valid under certain circumstances they might possibly be leveraged.

To bound the analysis, the investigators tried to create an SNS opportunity space to determine what risk looks like (e.g., how many people die across how many different scenarios; see Figure 4-3), given the complete absence of the SNS. Nonexistence of SNS and MCM availability only in the local medical system could be used. The number of deaths from that scenario was then compared to the number with an SNS with unlimited resources. The area between these curves is the "opportunity space" that the SNS can occupy, with all of the alternative formularies between the two curves.

Referring to the investigators' formula for risk, Lee questioned how it is possible to differentiate between events with high risk but low consequence and events with huge consequences in which the risk will be identical, because it is represented by a number. She commented that this is

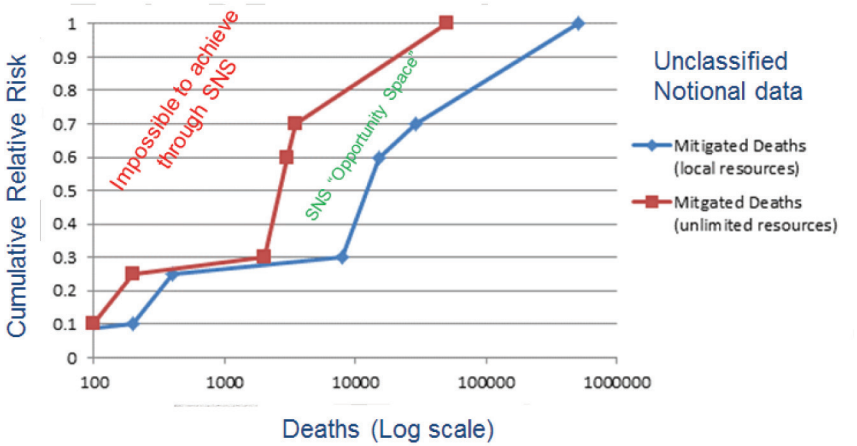

FIGURE 4-3 Opportunity space to determine what risk looks like, given the complete absence of the SNS.
SOURCE: Casagrande presentation, February 4, 2016.

critical in terms of looking at an investment portfolio: the key part is using that information to determine how you make investments downstream. Casagrande replied that they intentionally chose risk as the metric (as opposed to consequence or probability) to capture a spectrum of scenarios, some of which are less likely, but of much higher consequence than others that are lower consequence but much more likely. Investment decisions ideally would cover events that are extremely common but lower consequence as well as those that are really rare and extremely high consequence, but understanding the diversity of events (e.g., a thousand scenarios) will help to guide investment decisions and assess where the gaps are at present. Producing these scenarios on a risk basis enabled them to identify the types of scenarios that are not well prepared for and to analyze the similarities among those scenarios.

Jacobson contended that the investigators' risk analysis has a fundamental flaw in that terrorists can choose the most optimistic setting for an attack, thus rendering the balance invalid. Casagrande explained that although terrorists would indeed like to have unlimited resources, in reality they do not have that choice. The optimistic/pessimistic sampling is to understand the best judgment of the intelligence community on their capabilities. There is also some built-in uncertainty: atmospheric conditions might not be ideal for issuing the attack; the chosen venue may not have many people in it. Many factors beyond terrorists' control determine their final capabilities in terms of the weapons they are able to produce,

the target they are able to hit, and the consequences of the strike. There is extensive game theory on behalf of what the adversary is predicted to do; for example, they are not allowed to execute stupid attacks or ones that they know are going to fail (they are not allowed to try to attack a city by releasing something downwind as opposed to upwind, for instance).

Jaffe raised the topic of requirement setting; he commended the investigators' work insofar as bounding the question and deciding how to determine consensus scenarios (which are the on-ramp of how to define the threat). But he cautioned against having this "wide-open aperture," because we should be able to determine the best possible scenario for the terrorists and the worst possible for us, and vice versa. This information generates the exposure data for each of the different scenarios that are chosen for each of the different threats. From that point, modelers working in BARDA's Analytical Decision Support area can assess the unmitigated to the mitigated benefit, forming the basis for the public health consequence assessments that are used for requirements setting—which, although not directly related to the formulary study, is part of the overall process. Requirement setting is necessary for determining quantities—how much will be used and what the product will look like in a stockpiling goal.

Casagrande clarified that the ITRA was intended to be a small piece of the overall decision-making process. Sosin explained that when looking across this spectrum of risk, it is possible to buy down 50 to 75 percent of the risk by aiming at 10 percent of the scale; he cautioned against stockpiling to very rare but catastrophic scenarios. He commented that a piece of this exercise was to better understand that spectrum of risk to make better decisions about what those targets might be. ITRA, by design, is about nonstate terrorist risk and thus is relatively limited with respect to the spectrum of what the SNS might be. He highlighted as the most valuable part of the exercise the process of carefully considering each scenario and how it might play out in an actual event and response, as well as challenging assumptions and striving toward improvements in the concept of operations and best possible use of resources for MCMs.

5

Reaching the Last Mile: Potential Opportunities to Improve Coordination and Communication Among Local, State, and Federal Agencies

PERSPECTIVES OF PUBLIC HEALTH DEPARTMENTS AT THE STATE AND LOCAL LEVELS

Michigan MCM Planning

Jennifer Lixey Terrill, health care and public health emergency management and policy specialist, Michigan Department of Health and Human Services, provided an overview of the state of Michigan's emergency preparedness strategy, which comprises 83 counties and 45 local health departments divided into 8 regions with 100 emergency management programs.[1] She provided a schematic of the state's distribution strategy (see Figure 5-1).

Lixey Terrill explained that one warehouse serves as the receipt, storage, and staging (RSS) site for the state and is set to receive countermeasures, which are then shipped by ground or air to 45 local distribution nodes and to hospitals, with roughly 225 to 245 different shipment locations. Dispensing is a local function, with local health departments responsible for transporting the assets to dispensing locations (hospitals run alternate care facilities with support from emergency management and the health departments). She emphasized that local health departments have autonomy as to their dispensing operations (e.g., the use of open or closed points of dispensing [PODs]), with the state providing guidance and support.

[1] Serviced by more than 190 hospitals, 435 long-term-care facilities, 800 life-support agencies, and 300 federally qualified health centers, migrant health centers, and rural health centers.

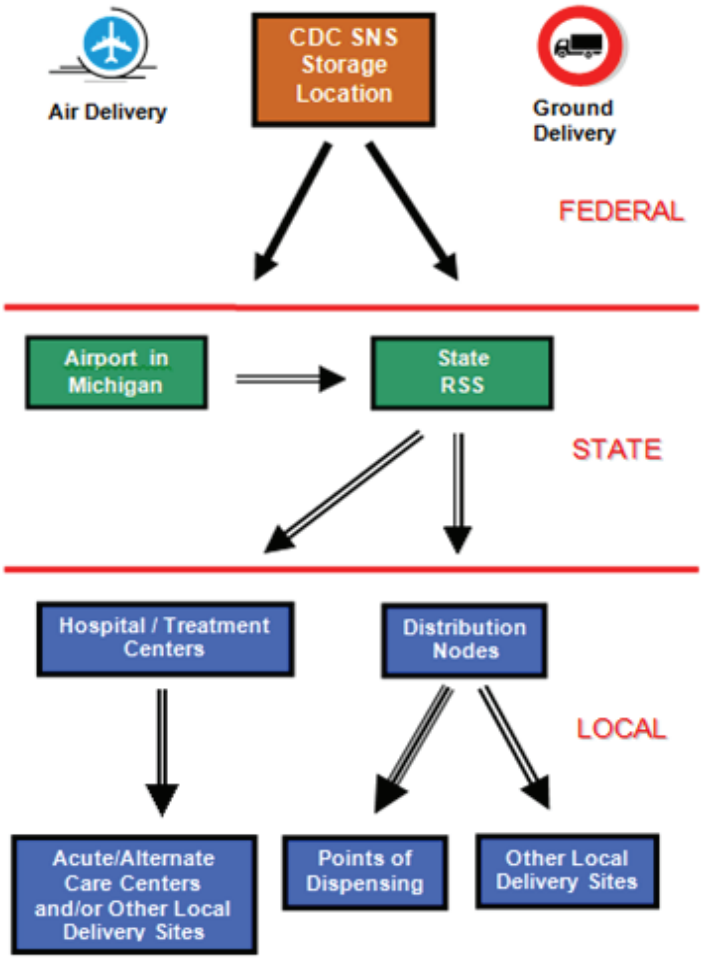

FIGURE 5-1 Michigan state emergency preparedness distribution strategy.
NOTE: CDC = Centers for Disease Control and Prevention; RSS = receipt, storage, and staging; SNS = Strategic National Stockpile.
SOURCE: Lixey Terrill presentation, February 5, 2016.

Lixey Terrill described some of the challenges in medical countermeasures (MCMs) distribution and dispensing faced by Michigan, including lack of resources as well as challenges with respect to its geography and climate. It can take 9 to 10 hours to ship countermeasures from state-identified warehouses to the most northwestern portions of the upper peninsula, even with favorable weather conditions.

Another set of major challenges in Michigan pertains to the feasibility and acceptability of POD operations, Lixey Terrill explained. She elaborated that feasibility issues surround establishing and staffing the dispensing sites to the extent that the necessary throughput can be achieved. Acceptability relates to the public's willingness to bring their entire families to a government-staffed site to deal with large crowds, parking, traffic, security, and so forth: "We know that trust of government in general is going to be tough in an emergency." Further concerns are that a predicted small percentage of people will actually come to the POD, then only a percentage of those who will actually take the medication, and a further diminishing percentage of those who will take a full 60-day course of antibiotics when they do not feel sick and do not even know that they have been exposed. Adding a three-dose vaccine with an annual booster to the regimen makes it an even harder sell to the public, according to Lixey Terrill.

Importance of Partnerships in Dealing with MCM Distribution and Dispensing Challenges

Lixey Terrill explained that partnerships have been crucial to the way that the state of Michigan deals with challenges of MCM distribution and dispensing. The Civil Air Patrol plays a critical role in addressing the state's unique geographical challenges with respect to distribution. It is a national organization with the largest fleet of single-engine aircraft in the world, staffed by around 60,000 volunteer members nationwide and 1,400 members in the Michigan division[2] whose services can be requested through the National Operations Center. The organization is emergency driven; its members are security and incident-command trained. During the H1N1 event, the Civil Air Patrol was deployed and was able to deliver six separate shipments of antivirals from Lansing (centrally located in the lower peninsula) to the upper peninsula in less than 8 hours. The Civil Air Patrol can also be mission-assigned through the Air Force, at which point it becomes a federal resource and thus paid (alleviating the need for the state to pay) and able to tap into a network of resources, including aircraft, from all over the country.

[2] She noted that only 200 of those are actually pilots and the others are ground crews who could augment local operations in other contexts.

Fostering acceptability of POD operations, Lixey Terrill commented, also requires working with trusted public- and private-sector partners in the community to work within and leverage existing infrastructure and routine distribution systems, ideally supported by professionals who perform distribution and dispensing functions on a day-to-day basis. In Michigan, pharmacies and pharmacists are serving effectively in this role because they are already trusted community resources. More than 95 percent of Americans live within 5 miles of a pharmacy; everyone knows where their local pharmacies are located. She noted, however, that pharmacies can tend to be small and congestion may become an issue. Independent pharmacies do not have the huge storage capacity that large pharmacy chains have, with their own warehouses facilities and the ability to ship to local stores.

Michigan also has a vital and robust system of eight regional health care coalitions, each of which is supported by a medical director and health care coalition coordinators, which have monthly regional meetings and perform regular trainings and exercises. Partners include local public health agencies, private-sector partners, emergency management agencies, long-term-care facilities, dialysis centers, and hospitals. Many community-based organizations are involved; for example, Dearborn, Michigan, which is home to more Arab Americans than anywhere else outside the Middle East, has a group called Access, sponsored by the Henry Ford Health System. As part of the health care coalition, the organization is one of the largest closed POD partners that has unique access to that community. Muskegon, Michigan, has a mass dispensing plan that includes using all the physician offices in the county as closed PODs that works well for its jurisdiction, but is not a "one-stop shop"—they also have other open PODs in federally qualified health centers that participate in the health care coalitions. During an emergency response, the state's Medical Coordination Center works with partners up to the state level.

Texas MCM Planning

Poole offered the state's perspective on MCMs. The size of Texas poses a challenge in and of itself, with 254 counties divided into 8 health service regions, 45 local health departments, and 20 additional Cities Readiness Initiative jurisdictions coordinated with county emergency managers. The state of Texas has a multiple-point delivery system for MCMs (see Figure 5-2). The Centers for Disease Control and Prevention (CDC) ships to 18 RSS warehouse sites across the state (operated in partnership with 18 private vendors), at which point the state is responsible for distributing to closed PODs, open PODs, and local jurisdictions. This number of RSS sites is necessary due to the size of the state and the time sensitivity of many Strategic National Stockpile (SNS) products.

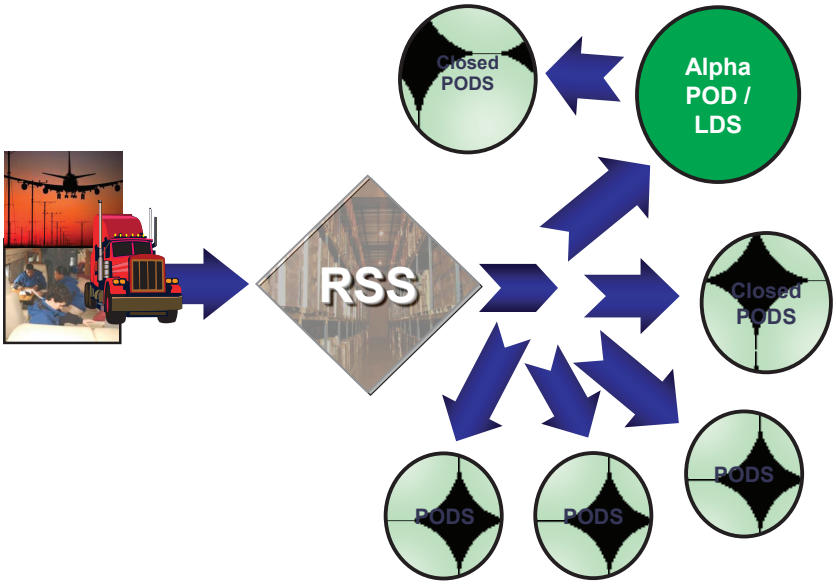

FIGURE 5-2 Multiple-point delivery system in Texas.
NOTE: LDS = local distribution site; POD = point of dispensing; RSS = receipt, storage, and staging.
SOURCE: Poole presentation, February 5, 2016.

Poole explained that the state's strategy for distribution comprises around 75 percent open PODs, 20 percent closed PODs, and 5 percent mobile PODs (e.g., school buses, Meals on Wheels™). The "alpha POD" is the point at which responsibility is transferred to the local level for distribution to smaller closed PODs. However, there are direct delivery drops whereby assets are shipped directly from the RSS to each of the open PODs as well as larger closed PODs (including hospitals) in certain regions. Some of the smaller closed PODs, such as nursing homes, depend on local health departments to set up an alpha POD to facilitate distribution (usually by pick up). But Poole noted that Texas considers distribution a state responsibility, so the system tries to avoid placing too much of the responsibility for distribution on the local level to allow its primary focus to be on dispensing. Transportation is variable depending on the specific setting, but the first stage is typically making the resources available for transport at the RSS site, followed by contractors with the Department of State Health Services, and then the state operations center or emergency management (which has many contracts, but is subject to more delays).

Engagement with private partners has been one of the state's biggest successes, according to Poole, who noted that H1N1 exposed the fact that public health cannot provide dispensing operations on its own and must depend on private partners who perform these types of operations on a daily basis: "we need to be flexible and our system needs to be able to pick and choose what will work best given whatever the scenario we are facing." For instance, Texas has statewide closed PODs with large grocery store chains that cover 200,000 people across the state.

Poole highlighted the success of RE-PLAN, based out of the University of North Texas Center for Computational Epidemiology and Response Analysis, which is aimed at improving the balance between distribution and dispensing (resources that take on distribution take away resources from dispensing). RE-PLAN is a modeling software that can be used for dispensing operations, identifying POD locations, and helping RSS sites to increase their number of direct deliveries. The program can automatically select POD sites using heads of households, and provides visual information regarding location, transportation routing, and traffic information (see Figure 5-3).

Poole noted that one of the benefits of RE-PLAN is helping new SNS program coordinators to visualize their jurisdictions' challenges and vulnerabilities, allowing them to optimize POD locations and incorporate public

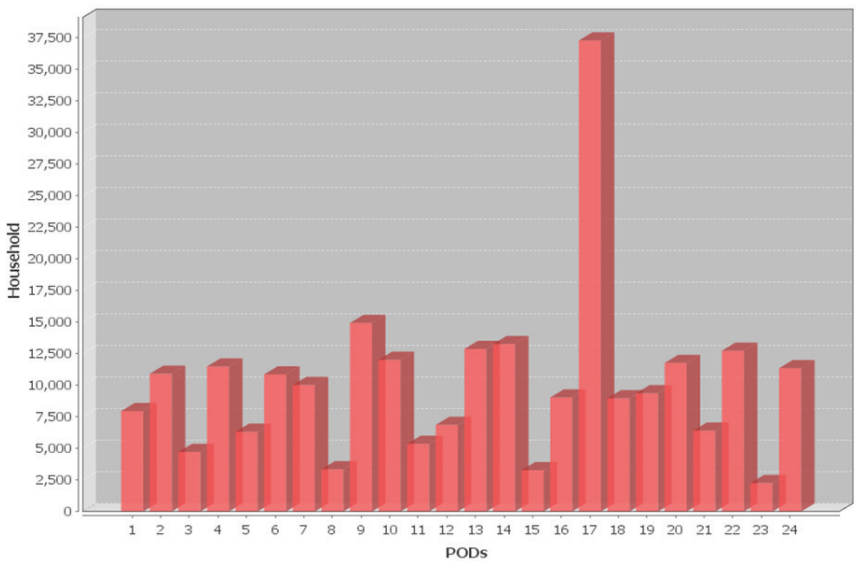

FIGURE 5-3 Household distribution across points of dispensing (PODs).
SOURCE: Poole presentation, February 5, 2016.

transport options into planning. So far, the program has been used in the Dallas-Fort Worth region, and since 2010, the number of direct delivery sites in Texas has decreased from more than 3,000 to fewer than 2,000, improving the distribution network and freeing available resources for other purposes. See Box 5-1 for a description of the differences between rural and urban MCM planning in Texas after distribution is completed at the state level.

New York City MCM Planning

David Starr is the director of the Countermeasures Response Unit, which is situated within the Office of Emergency Preparedness at the New York City Department of Health and Mental Hygiene. The unit is responsible for all mass prophylaxis and MCM planning in New York City. See Box 5-2 for a description of New York City's 2014 mass prophylaxis exercise.

Starr explained that one of the key goals of the exercise was to test the ability to mobilize staff, truck assets, and warehouse, and then set up PODs as fast as possible. But another aim was to beat the delivery time lines set by the CDC Division for Strategic National Stockpile (DSNS), and the exercise demonstrated that those time lines could leave PODs waiting for hours to receive their medications after setup was complete: in this context CDC was in fact a rate limiter. When provided with data proving that this was the case, CDC responded appropriately, and Starr's unit and CDC have been working together to mitigate the effects of this delay by forward-deploying assets into the unit's warehouse in order to dispense to large numbers of the public without delays at the PODs. Starr cited this as an example of collaboration that is a model for the interaction between the local, state, and federal levels.

The postexercise participant survey had an extremely high response rate (89 percent; 763 of 860 field staff), and confirmed that 91 percent of participants were not aware of the date of the exercise. The unit has an extensive training program for POD leadership staff in the field (a full day of operations training every other year), the value of which was confirmed when 80 percent of participants stated that training helped them perform. The survey responses further confirmed ability to respond (86 percent were able to report to the POD on time) and willingness to respond (92 percent stated that they would have responded in their role if it had been an actual event).

Last-Mile Successes and Challenges Demonstrated by RAMPEx

One of the last-mile successes demonstrated by RAMPEx (Rapid Activation for Mass Prophylaxis Exercise) was the preassignment of

BOX 5-1
Rural Versus Urban MCM Planning in Texas
Emily Gore, Public Health Manager,
Public Health Preparedness Division,
Dallas County Health and Human Services

Emily Gore, public health manager, Public Health Preparedness Division, Dallas County Health and Human Services, described her experiences in SNS planning in two distinctly different types of settings in Texas: Brown County and Dallas County. Brown County, with a population of 40,000 spread over a large geographic area, has a public health response program with just two employees not specifically dedicated to the SNS but to all aspects of public health in the county. The program uses a head-of-household model with five sites designated as potential POD sites, staffed by city employees and Community Emergency Response Team (CERT) volunteers. It has a medical model with the potential to transition to a nonmedical model because there are not enough trained medical/pharmaceutical professionals to dispense in a worst-case scenario. They also rely on alternative dispensing modalities such as an alpha POD that can dispense to closed PODs (mainly nursing homes and long-term-care facilities) and push teams.

Dallas County, in contrast, has a population of 2.5 million and a response program with a full-time, dedicated staff of 19. It also uses a head-of-household model and has 35 primary POD sites (schools/colleges, stadiums, and public facilities). POD staffing varies by jurisdiction and may include Medical Reserve Corps volunteers, county/city/school district employees, other volunteer groups, and pharmacy/nursing school students, for example. It is an exclusively medical model with alternate dispensing modalities, including closed PODs, door-to-door,[a] and drive-thru alpha PODs.

She pointed to the local request and activation/mobilization process as successful in both settings, in terms of the transition from an impacted municipality through the county and state levels. This is practiced and used even in non-MCM events. The same holds for volunteer recruitment, retention, and coordination; the system is so well operated that they are also called on to play a role organizing volunteers for non-MCM events such as tornadoes.

Effective public- and private-sector partnerships have played an important role in POD staffing. During the Federal Emergency Management Agency's (FEMA's) MCM initiative, multiple federal agencies came on board as closed PODs. POD training, drills, and full-scale exercises are another strength arising out of effective core management and primary management teams that run regular drills as well as yearly full-scale MCM exercises. The capacity of the system was demonstrated during the response to H1N1. The program was ready before the vaccine deployed from the SNS had even arrived.

[a] She uses this terminology because she considers "postal model" to be a misnomer.

BOX 5-2
New York City's Rapid Activation for Mass Prophylaxis Exercise
David Starr, Director, Countermeasures Response Unit, New York City Department of Health and Mental Hygiene

Starr provided a detailed overview of the Rapid Activation for Mass Prophylaxis Exercise (RAMPEx) that took place in New York City on August 1, 2014. The Countermeasures Response Unit relies primarily on a network of public PODs and has built a robust capacity to support them; the overarching objective of the exercise was to verify the ability to mobilize for citywide dispensing operations consisting of the immediate mobilization of 30 POD sites citywide.

It was a no-notice exercise for all involved parties (field staff, warehouse, transportation vendors,[a] etc.). Staff were given a 2-week window and the exercise took place in the middle of that window. To collect data, 100 evaluators were deployed across the 33 exercise sites, including the Joint Traffic Management Center where all the law enforcement escorts were organized and the routing was handled, as well as at the POD operations center. The exercise began at 5:15 a.m.; by 6:10 a.m. the predefined plan to notify staff had been completed and by 7:30 a.m. the field staff were at their sites. By 7:42 a.m. the first trucks left the warehouse, and at 8:50 a.m. the first POD received its POD in the box (PIB), the administrative supply kit that the POD teams use to set up and operate their PODs. By 9:40 a.m., 776 of 860 participating staff were at the sites. This was the last point in time that participants had been told to sign up or to report to work. Participants were notified in waves based on the estimated delivery sequence, so that they would not arrive at their designated PODs and have to wait for supplies for hours. Actually by 11:15 a.m., the first POD was ready to open, but had no medications to dispense. At 12:08 p.m., the last POD received its PIB and by 2:17 p.m., the last POD was ready to open (28 of the PODs received their supplies before 11:30 a.m., much closer to the delivery estimates).

In approximately 7 hours, 30 PODs were opened effectively.[b] Multiple scenarios are also in place for incremental numbers of PODs up to 165. He noted that their ability to execute any of these predefined scenarios is a way to give leadership a choice about the scope of the response.

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[a] Starr highlighted two key components concerning the delivery sequence. First, the transportation vendor has agreed to prioritize SNS requests over all other deliveries during an actual event, but could not do so during this exercise. He predicted that delivery timelines during an event would be better than those recorded during the exercise, but the vendor still responded within reasonable timeframes. Secondly, the trucks followed all traffic rules. Even though they were escorted by law enforcement through heavy traffic, the police cars did not use their lights and sirens and did not run red lights or clear lanes, as they would in an actual response.

[b] The extra hour for that last POD was due to their failure to call in properly—they were ready to open much earlier.

leadership staff to POD sites. Starr noted that a primary reason that New York City is so vulnerable to bioterrorist attack is due in large part because of its density, so they tried to use the fact that the vast majority of participating staff live in the city to their advantage. Leadership staff (in particular) are preassigned to the 165 POD sites around the city, which are distributed according to models of population density. People are assigned according to distances on the street network (as opposed to "as the bird flies" distance lines), with a significant number of the people assigned to staff POD sites very close to their homes. Although the system tries to equalize assignments, some people may have to travel farther to fulfill specific positions in certain PODs. For instance, all leadership staff are assigned to PODs in the city regardless of where they live (see Figure 5-4).

Around 47 percent of the leadership team are assigned to POD sites 1 mile or less from their homes, with around 70 percent within 2 miles or less. This type of preassignment allows leadership staff to be provided with detailed site manuals (including, for instance, floorplans specific to their assigned site), as well as a detailed POD Procedure Guide giving step-by-step directions for setting up and operating a POD.

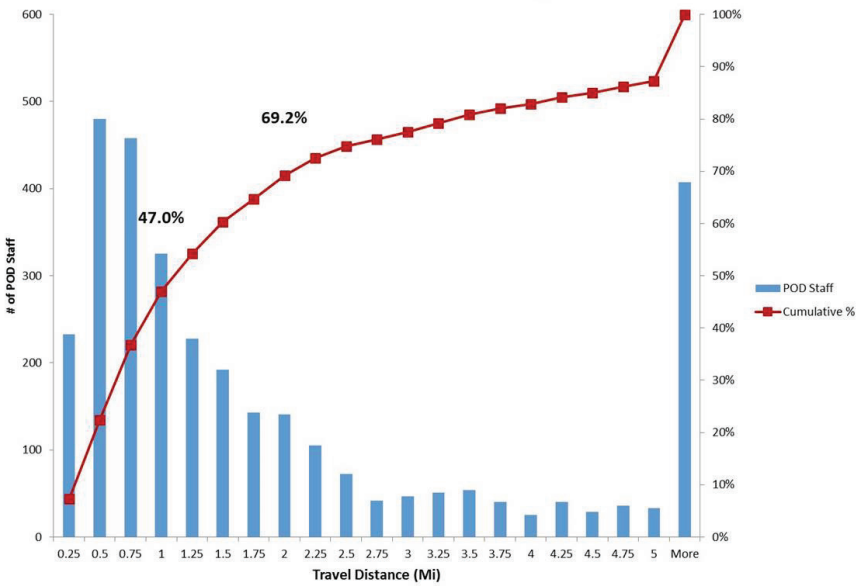

FIGURE 5-4 Point of dispensing (POD) leadership staffing: Distance analysis of leadership team assignment data.
SOURCE: Starr presentation, February 5, 2016.

Around half of the general staff in the city are also assigned to PODs, with the aim of no staff having to leave their borough (except Brooklyn and Queens) or cross a bridge (see Figure 5-5).

Starr explained that this strategy resolves multiple issues because "You have a neighborhood serving a neighborhood. You have a community serving a community. Your chances of staffing your site with people who come from the neighborhoods, speak the languages, and understand the culture of that neighborhood are extremely high."

Starr emphasized that this type of data and analysis are particularly useful when dealing with city governments, for example, having health department staff mandatorily assigned to PODs. This was difficult, even though the city incident management system mandates this as a core competency for the unit to be able to execute these operations. Assignment of staff had not become a focal issue until shelter understaffing proved a problem during Hurricanes Irene and Sandy, and the commissioner ordered health department staff to respond to that (not their core mission), but not to POD assignment, which is in fact their core mission. When pointed out, this contradiction facilitated mandatory assignment and, more recently, mandatory training of staff.

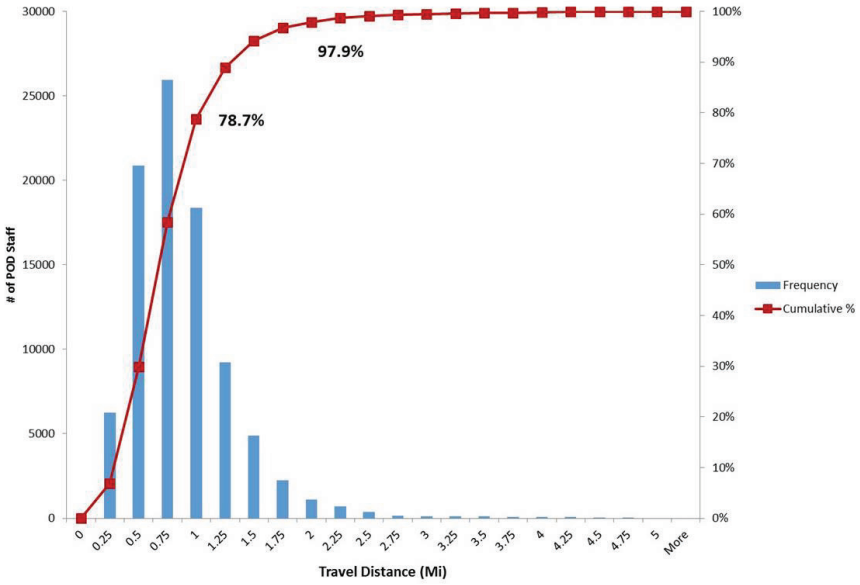

FIGURE 5-5 Distance analysis of latest point of dispensing (POD) general staff site assignment.
SOURCE: Starr presentation, February 5, 2016.

A challenge that Starr identified is the need for more quality leadership staff to be assigned as close to their homes as general staff are. Nominally, there are three leadership staff assigned to every position in about 32 of the 165 PODs. But there is a battle between quantity and quality, in terms of having people assigned appropriately in terms of skill levels and geography to enable easy response.

Starr highlighted a key point of contention in Executive Order 13527. Research from the Bureau of Labor indicates that there are roughly 30,000 federal workers working in New York City, though about 9,000 live in New Jersey; that still leaves 21,000 federal workers living in New York City and New York State. In several venues, New York City made the request for access to federal staff living in the local area who want to participate in the POD Responder Program and support PODs in their neighborhoods, most recently as a key element in the Federal Emergency Management Agency (FEMA) Region II federal MCM plan as well as to various federal executive boards, but to no avail, despite advocacy from DSNS. Starr characterized this as an appalling gap, and the FEMA New York City MCM plan remains in "draft" status because of the inability to fulfill the principal request in the document.

Starr outlined further last-mile successes with regard to emergency medical logistics planning on the dispensing side.[3] The Countermeasures Response Unit recently finalized pre-scripted mission requests (PSMRs) that detail the various elements of the SNS request,[4] which are now on file at the City Office of Emergency Management Watch Command so that when leadership chooses a Phase I response, the appropriate request on file can be pulled immediately. It defines the exact quantities of each type of antibiotic (doxycycline and ciprofloxacin) that matches the screening algorithm in the field and what public messaging guidelines should be used. The ratios of antibiotics that go to each warehouse differ depending on the scenario, because they will be serving different numbers of PODs in the second wave after the Phase 1 response is complete.

Another success factor has been the development of predefined turn-by-turn routing in the form of a routing book developed by New York City Department of Transportation staff that will be provided to the drivers and the law enforcement escort officers. It covers a multitude of potential routes (with 13-foot clearance height) in great detail, including the exact entrance to the POD. The POD site manual shows the primary receiving area and the

[3] The unit is responsible for receiving supplies from SNS distribution as well as dispensing them, unlike many jurisdictions in which the state is responsible for the first part and the locality for the other.

[4] These PSMRs have been reviewed by City and State Offices of Emergency Management, New York State Department of Health, FEMA, the Department of Health and Human Services (HHS), and CDC.

path into the POD and the pharmacy room. Starr noted that professional transportation vendors do a great job of routing on a day-to-day basis on routes that they know, but they could not be depended on to develop routing to match every response scenario.

Starr reported that after a 2-year process, a Memorandum of Understanding has been signed with HHS to work with the General Services Administration in New York City to dispense MCMs to federal emergency response officials. This is not a traditional federal closed POD; it is only for mission-essential federal personnel, because other employees could come to the public POD network.

Greg Burel commended New York City's efforts and ability to demonstrate, through its RAMPEx exercise, that it is a suitable candidate for predeployment of materials, sharing that the risk-based approach has been beneficial; a new effort is being made to identify specific at-risk areas and work with them on more in-depth planning regarding dispensation of MCMs.

However, he noted that in many cases SNS materials arrive long before localities are prepared to dispense them, which is a big concern. He suggested that hard-line logistics consulting and discussions with those localities would be a way to address this.

He also noted that many of the issues at hand, particularly upstream components such as the development of MCMs, are not directly under the SNS's control, although they do have some degree of engagement. Regarding the last mile, Burel noted that the SNS does not want to hand materials off to local jurisdictions without support or guidance, but commented: "We also recognize that we don't have command and control from the time we turn it over to the state. Each one has to handle things differently in the way that makes sense in their particular area for their particular population and needs."

CDC STRATEGIES FOR ENSURING READINESS AT THE LAST MILE

Christine Kosmos, director, CDC Division of State and Local Readiness (DSLR), focused on CDC strategies for ensuring preparedness at the "last mile"; specifically, she explored what CDC is doing to ensure operational readiness at the state and local levels to improve capabilities within state and local public health departments (see Box 5-3).

Public Health Emergency Preparedness Program

Kosmos explained that CDC embarked on a very deliberate process to describe the contributions of the Public Health Emergency Prepared-

BOX 5-3
CDC's Role in Public Health Emergencies

CDC prepares local and state public health departments by providing funding and technical assistance to strengthen their abilities to respond to all types of emergencies and build more resilient communities.

When local and state resources become overwhelmed, CDC responds and supports national, state, and local partners to save lives and reduce suffering. This includes providing scientific and logistic expertise and deploying personnel and critical medical assets to the site of an emergency.

CDC also helps these partners recover and restore public health functions after the initial response.

CDC's Office of Public Health Preparedness and Response leads the agency's preparedness and response activities by providing strategic direction, support, and coordination for activities across CDC as well as with local, state, tribal, territorial, national, and international public health partners.

SOURCE: http://www.cdc.gov/phpr/whatcdcisdoing.htm (accessed April 15, 2016).

ness (PHEP) Program to state and local public health, with the intent to frame the program to better understand both its original intent and ways to move forward. The process generated a set of key messages for understanding the conversation about medical countermeasure readiness. First, since 9/11, the PHEP Program has created the new domain of "public health emergency management" experts, which differs from traditional emergency management in that it views emergency management through a public health lens. The second key message is to support the public health capabilities that are necessary for state and local public health by framing those into a doctrine of 15 public health preparedness capabilities published in 2012 (see Box 5-4).

The CDC PHEP Program is also intended to ensure response readiness within the nation's public health system for public health emergencies and disasters, with the broader aim of ensuring the health security of our nation and our communities. Together with the SNS, the program further seeks to ensure a nationwide system capable of rapidly distributing and dispensing lifesaving medications and emergency medical supplies to the public during emergency responses.

After developing the PHEP Program capabilities, Kosmos explained that CDC gauged the progress made since 9/11, which she characterized as an "eye opener" for state and local public health that helped to expose gaps in terms of emergency preparedness. For example, prior to 9/11, the

BOX 5-4
CDC Division of State and Local Readiness
Public Health Preparedness Capabilities

To support key public health capabilities necessary for emergency planning and response, the DSLR created a set of Public Health Preparedness Capabilities[a] aimed at establishing mature, organized, and capable public health emergency management and response programs within state, local, and territorial public health agencies:

1. Community preparedness,
2. Community recovery,
3. Emergency operations coordination,
4. Emergency public information and warning,
5. Fatality management,
6. Information sharing,
7. Mass care,
8. Medical countermeasure dispensing,
9. Medical materiel management and distribution,
10. Medical surge,
11. Nonpharmaceutical interventions,
12. Public health laboratory testing,
13. Public health surveillance and epidemiological investigation,
14. Responder safety and health, and
15. Volunteer management.

[a] See http://www.cdc.gov/phpr/capabilities/DSLR_capabilities_July.pdf (accessed April 15, 2016).

capabilities for storage, delivery, dispensation, and distribution were practically nonexistent, but reflecting on a review of capabilities in 2012, Kosmos observed "post-9/11, 2012 across the board yes, yes, yes, and yes. Yes, we have warehousing capability. Yes, we have plans. Yes, we have people. Those people are trained. They are prepared and they can do it."

Development of the CDC Medical Countermeasures Readiness Review Process and Tool

Kosmos explained that DSLR has worked closely and productively with DSNS from the beginning in efforts to build capabilities for state and local readiness for MCM planning; today, the DSLR continues to work with the DSNS to advance the work of state and local public health. Moving forward will require the flexibility to adapt to the changes of the ever-evolving

discipline of emergency preparedness and response, so they looked to a wide range of stakeholders, including state and local experts, for input. She quoted a former SNS director as suggesting a focus on doing what they say they can do: "Can we really execute the plans that are on our shelves?"

To continue improving the process, DSLR developed a new evidence-based tool, called the Medical Countermeasure Operational Readiness Review (ORR), in consultation with subject-matter experts for evaluating operational readiness at the state and local levels. It was designed with extensive input from state and local partners in order to determine the specific capabilities to focus on, to understand the targets, and to establish where state and local public health needs to be going forward. It evaluates evidence of a jurisdiction's operational ability to execute components of preparedness (e.g., staff, mobilization ability, associated throughputs, gathering data and meeting objectives with data, and ability to evaluate the capacity to execute), rather than merely asking jurisdictions for a plan.

Kosmos explained that the tool has now been piloted, tested, and rigorously evaluated. At the current stage in the process, staff are evaluating every state, every directly funded city,[5] every U.S. territory, and selected local municipalities in each state to evaluate their levels of operational readiness. By the end of 2016, they will have evaluated more than 400 states, directly funded cities, and local jurisdictions, providing a useful snapshot of the levels of capability within state and local public health. To date, more than $300 million has been invested in MCM planning since the beginning of the project. "We have to be able to answer the question of what the level of readiness in state and local public health is; we have to be able to answer that question in a very scientific evidence-based way. . . . It has got to be a deliberative process."

Kosmos described how the tool itself contains 90 planning and operational elements across 8 public health preparedness capabilities, with level of readiness status (1 = early, 2 = intermediate, 3 = established, and 4 = advanced) assessed within each of those 8 domains, based on criteria outlined in CDC's preparedness capability standards. The planning section is used for analyzing the content of the plans and evaluating the completeness of those plans. A companion section focuses on evidence of their ability to execute. The PHEP Program goal is that by 2022, all 62 PHEP jurisdictions will achieve a status of "established" for planning and operational elements.

Baseline data reveal that on the planning side, many state and local partners are assessed at 3/4 (a score at which the metric is considered complete or achieved) on the planning side and 2/4 or 3/4 on the execution side. Kosmos explained that this provides very granular specific information

[5] Directly funded cities include Chicago, Los Angeles, New York City, and Washington, DC.

about where we need to drill down, exposing the gaps and vulnerabilities in state and local public health in a way that facilitates the design of appropriate technical assistance strategies.

State and local partners completed an anonymous survey about the process; 89 percent of the responses were overwhelmingly supportive of how it will move the nation forward in MCM readiness. Kosmos construed this as very positive, because the process is aimed not only at improving the level of readiness in state and local public health, but also at ensuring that the program is accountable for the dollars that they have invested in state and local public health.

Petersen noted that his state has carried out more than 60 evaluations for the preparedness programs and operational activities. Though it is not a CDC requirement, Tennessee requires each jurisdiction to carry out exercises, including large-scale exercises every 5 years per grant requirement. They evaluate how often they can use their redundant communication systems, how often they can activate their emergency operations centers effectively, and so forth; those exercises are documented appropriately with after-action reports and improvement plans developed to enhance the system going forward. Multiple metrics are captured, including accuracy. Furthermore, there has been activity with the CDC ORR tool that he attributed to raising the bar and setting higher goals for state and local agencies. He commented that state and local public health departments are not funded to the degree that they can carry out preparedness functions without support (they have many responsibilities other than just dispensing and distribution), so they must work with private-sector partners, the health care community, and others to be able to have force multipliers to ensure preparedness.

MCM CHALLENGES FROM THE STATE AND LOCAL PERSPECTIVES

Poole explained some of the challenges that Texas faces. Acquiring and maintaining local and state caches is problematic due to rotation issues that drain resources. Time and space are also barriers, due to the size of the state and the amount of storage needed.

Poole noted that local SNS program staff turnover continues to be a challenge; there is a 10-35 percent turnover rate for SNS coordinators in Texas' 45 local health jurisdictions (due to promotion or transfers out), so it can be difficult to train new coordinators and bring them up to speed as quickly as possible. New and improved training manuals and informational materials incorporating the wealth of available information from other states and agencies are being developed to address this.

Exercising with the private partners (closed PODs and RSS sites) in Texas has been a challenge, according to Poole, due to the volume of agree-

ments and number of partners that need to be coordinated, but efforts are under way to truly test the state's SNS system. To enable a tighter delivery time frame at each RSS, Poole suggested that it would be very beneficial to have site-specific estimates regarding shipment volumes and timing for each of the eight regions, which can be used to help private vendors to be better prepared.

Gore, from Dallas, maintained that key challenges derive from the lack of clarity with regard to the time frame of the formal request process for the SNS, coupled with distribution uncertainty. From the local perspective, once a threat or trigger is identified and the request for SNS assets is activated, it is unclear what concrete steps and formal processes are required before the trucks are on the road. In terms of long-term planning, her concern is not how quickly she can set up the POD, but the subsequent delay in when the medicines will actually arrive.

Noting that all programs, regardless of size, are subject to the same program requirements, documentation, and level of response, Gore suggested that realistic versus worst-case planning should be factored into those requirements. She emphasized that the expectations and priorities of rural versus urban jurisdictions are very different: "When I was in Brown County, it was very much the understanding that we were on our own and that even if distribution was happening, it was going to the big jurisdictions first. And if I wanted the drugs, I was going to have to drive to go get them regardless of what on paper was the plan."

Another issue for Gore is the modularization of the SNS; a push pack can cover about 500,000 people, which is sufficient for smaller jurisdictions, but in Dallas County, it will only cover first responders. Furthermore, push packs contain a range of items, and she suggested that it would be much better to be able to automatically activate vendor inventory of the specific item needed. Citing the example of the H1N1 vaccine that was not available when demand was high and they were ready to dispense, she reiterated that dispensing is not where the problem will be, it will be how fast the MCMs come out.

Starr highlighted a barrier that pertains to the process of requesting supplies from the SNS due to confusion surrounding the process. He suggested the possibility of integrating the request exercises with SNS's ongoing annual exercises to help address this. A related issue raised by Starr is the discovery that SNS would not be able to fulfill exact requests being made, due to a decision made years ago by the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) regarding the ratio of antibiotics held in the SNS stockpile. Starr criticized this decision as being made without local-level input, despite its significant impact on local-level operations and planning. The SNS would be able to provide the overall quantity of requested antibiotics, but could not fulfill the specific ratio requested (i.e.,

85 percent doxycycline and 15 percent ciprofloxacin).[6] The quantity would only be available in the ratios held in the SNS, which is 50:50. Starr contended that receiving a 50:50 ratio regardless of the request,

> we are going to be encountering bottlenecks and difficulties from the very beginning, from the time it hits the warehouse when we are not prepared to receive it. We cannot build the orders that we prebuilt and that we prewaived into our warehouse management system. And then we have to start making allocation decisions based on no guidance whatsoever. . . . This is an upstream decision that has deep and critical downstream consequences.

For instance, people will assume that they are being mistreated when different people are receiving different antibiotics (this was borne out in the 2001 anthrax response). Equitability of response is a primary concern for Starr, who noted that it cannot be alleviated with risk messaging; it must be evident in the response itself.[7] Gore concurred that supply uncertainty is an issue because most jurisdictions have a doxycycline-dominated algorithm that is not compatible with the PHEMCE-mandated 50:50 ratio of doxycycline to ciprofloxacin.[8]

Lack of funding is an ongoing problem, as is lack of visibility on the supply chain inbound to warehouses from the SNS. This is particularly problematic when multiple requests are going to multiple warehouses for multiple jurisdictions in a congested region: what is being shipped, where the trucks are, what is on each truck, etc. Starr suggested that some kind of electronic portal with the ability to pull data could be operationalized in the field.

POTENTIAL OPPORTUNITY FOR ALTERNATIVE DISTRIBUTION AND DISPENSING MODELS

Sosin remarked that identifying unique approaches to distribution and dispensing models that leverage existing resources is important, but reminded the group that the work involved is more than just, for example, a suggestion to do user-managed inventory. Strains of the volume of material that can be held in the stockpile should be taken into account. He commented:

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[6] Like most jurisdictions, New York City has a doxycycline-dominant screening algorithm.

[7] He cited surveys of pandemic response demonstrating that the people in the neighborhoods of lower socioeconomic levels believe that they are going to be treated last if they get treated at all.

[8] A related concern is the availability of amoxicillin for people who are counterindicated for both ciprofloxacin and doxycycline. Currently, the plan is to send people to pharmacies, but the mechanism for funding that is unclear.

> To the point that we need to have more options, we need to understand what our options are and the scenarios within which they work. We must consider that every unique and creative solution to distribution and stockpiling will have constraints, and we need to effectively work to assure we understand them.

Engaging the Private Sector in Distribution

Michael Loehr, chief of emergency preparedness and response, Washington State Department of Health, drew on his experiences in working with issues associated with the response to and recovery from biological disasters to suggest a set of distribution strategies that could be applied to the MCM enterprise. Not only are the issues highly complex, but their cascading effects are linked to both the hazards and the decisions made surrounding a response. This exposes the limitations of the current planning and thinking around the development of MCM distribution capability and dispensing. He cast into doubt the current ability to achieve the core objectives of a large-scale MCM response: making medications available to all who need them in any part of the jurisdiction, with sufficient speed and accuracy to minimize mortality and morbidity, and in a manner that retains the public's trust and confidence. "The public is an unwritten responder in our plans. We assume they are going to do certain things but in reality, we don't know." Loehr called for three areas of focus to improve the chances of being able to achieve those objectives in the future.

The first is rethinking how the SNS distribution process works, Loehr said, from storage to dissemination to the public during an incident—to remove all inefficiencies from the system and add value by improving the safety and accuracy of products at each step in the process. The vast supply of MCMs must pass through the extraordinarily tight bottleneck of a government-run, government-designed, and single-purpose distribution process. During a large-scale, rapidly moving biological disaster, Loehr contended, a government-centric approach to distribution and dispensing was destined to fail. So the State of Washington partnered with pharmacies, which medicate 60 percent of the population on a daily basis, to use their existing capacity; all 700 pharmacies in the State of Washington have been incorporated into the statewide MCM-dispensing plan as PODs. See Box 5-5 for another example of collaboration between pharmacies and state health officials.

With state health departments still hampered by recession and reduced capacity, Loehr suggested turning to large private-sector health care systems[9]

[9] One of these systems touches 10 percent of the entire state population, 700,000 people, between members and employees.

BOX 5-5
Michigan's State Pharmacy Dispensing Project
Jennifer Lixey Terrill, Healthcare and Public Health Emergency Management and Policy Specialist, Michigan Department of Health and Human Services

Lixey Terrill provided an overview of the state's pharmacy dispensing project, which was initiated after the H1N1 event and arose out of stakeholder workgroups with CDC, the Association of State and Territorial Health Officials, and the National Association of County and City Health Officials (NACCHO) that led to meetings with pharmacy partners and the Michigan Pharmacists Association to gauge commitment, interest, and level of engagement regarding potential support operations fitting into the system of distribution and dispensing. The level of interest was very high; some chains (e.g., Walgreens) already have emergency trailers suitable for on-site dispensing, and different mechanisms for communicating with their constituents. This was followed by the launch of the Michigan Pharmacy Dispensing Toolkit, which provides a formal commitment letter for interested pharmacies, information, and list of resources about volunteering in Michigan with the Emergency System for Advance Registration of Volunteer Health Professionals Medical Reserve Corps. Pharmacies that have committed to being a partner in preparedness are listed on the website to apply a degree of "peer pressure," which she noted can be useful when working with the private sector. Commitment does not necessarily mean that they will sign a Memorandum of Understanding (MOU): Michigan does not require that MOUs be signed with pharmacies, closed PODs, or any other dispensing partner facility; some form of a written agreement suffices (e.g., letter of support or commitment letter). Within the first 5 months, the project obtained statewide MOUs with Kroger, Walgreens, Meijer, and more than 100 independent pharmacies. More than 600 pharmacies are committed to being partners in preparedness. She commended pharmacies for proving to be excellent, engaged, enthusiastic partners.

with large-scale capacity for distribution and dispensing. They approached the private-sector health care systems and pharmacies to build dispensing capacity; they stressed the need to learn from the problems of H1N1 and to inculcate central decision making, organization, and a coordinated approach to priorities to protect the people. Loehr said the approach would thus focus on sustaining the private sector's critical infrastructure for dispensing as well as maintaining the public's trust. Incorporating private-sector expertise has led to a dramatic increase in capacity over the past several years. He acknowledged that there is certainly a role for state and local governments in distribution, particularly among rural populations without pharmacy capacity in the area, but that the government's role should be closely measured to ensure that it is only adding value.

The second area of focus Loehr highlighted is the need for "quick-strike" capabilities such that medicines are being consumed by people within hours of the decision being made to make them available. Loehr endorsed the idea of forward deployment to cities who have proven ability to rapidly open public PODs quicker than the SNS medications can arrive, but argued that the same should also be granted to jurisdictions that have any capability that is sufficient to meet the needs of a significant portion of the public. He cited two reasons for this. First, public PODs in some states and local jurisdictions do not provide sufficient capacity and are a strategy geared toward specific populations who cannot get medications in any other way; Loehr predicted that many states will recognize the need to involve the private sector in this part of dispensing.

Second, a bioevent in an urban area is not going to be restricted to the city; quick-strike capabilities must be activated across city and county boundaries. Furthermore, he argued that RSS sites are redundant for jurisdictions that rely on pharmacies and health care systems as the backbone of distribution and dispensing capabilities. Thus, Loehr suggested forward-deploying medications directly into the supply chain to improve efficiency, bypassing the RSS except for a small portion for quickly deploying to a few public PODs. A commitment to establishing quick-strike capability requires the willingness to cede control to private-sector partners when they say "just give us the drugs and get out of the way."

The third area of focus Loehr mentioned is to invest in decision making, which represents a critical gap across the country. There are many different types of dispensing modalities, but there is limited knowledge of their relative efficiencies and whether they are complementary or conflicting.[10] Loehr said planning needs to be refined despite the many unanswered questions going forward, but he suggested the development, modeling, and testing of decision tools at the national level to give leadership "decision space" with justification for various options and a better understanding of how to make controversial decisions during rare but high-consequence events. According to Loehr,

> We should rethink the entire SNS distribution model from the standpoint of logistical efficiency. . . . There is a lot of talk about that last mile and for me, it's really that last 10 feet. It's going to be the private sector that makes a difference. It's not government. We don't have an effect on the

[10] Loehr queried: "Should the size of incident affect which dispensing and distribution strategy we mobilize? If so, how? When should we widely distribute our medications across a wide range of modalities but when should we concentrate them on just a select few? Are some modalities applicable in only certain scenarios, like closed pods? Very controversial in certain scenarios. Are some modalities conflicting with others? Did they slow us down during certain events?"

last mile other than the decisions we make. And I think the decisions at the federal level regarding how distribution happens dramatically impacts whether we can succeed in that last mile.

Noting that pharmacies are often overwhelmed during regular operations, O'Toole questioned their ability to deliver as a POD during a biological event in which MCMs need to be delivered very quickly to very large numbers of people.

Loehr countered that there are no real-world examples demonstrating the success of either a government-managed or private-sector-managed approaches, but there are reasons for optimism about pharmacies' capacities to deliver. The public POD strategy is a government model that relies on either government or volunteer staffing (which is limited). So many PODs would have to be set up in order to instill public confidence that the lines will be short enough to move people through in a rapid amount of time; with parking capacity as a critical limiting factor. Pharmacies are everywhere, often in large shopping centers, and they are already medicating a large proportion of the population every day. They have demonstrated expertise and skills in inventory management, distribution, and dispensation. He stressed that the key is recognizing the full available capacity by partnering with everyone, including private-sector organizations, to contribute their capacities to protect the community.

Engaging Large Employers in Dispensation of MCMs at the Local Level

Meg Nash, vice president, Consulting Services, Bio-Defense Network, emphasized the challenge of engaging large national-level employers to participate under the Public Readiness and Emergency Preparedness (PREP) Act to alleviate the burden on public health; it is difficult to get a large employer to engage and commit to participate. She explained that a primary barrier is the burden (from the employers' perspectives) of entering into an agreement at jurisdictional level in all of their locations. If those employers are resistant to these types of jurisdiction-by-jurisdiction-level agreements, she questioned whether there is a way to quantify their participation in the distribution of MCMs under the PREP Act. For example, she suggested the possibility of providing a more generic agreement than jurisdiction-level MOUs that would still allow employers to be covered under the PREP Act for their liability.

Sherman replied that the declaration so far has covered two different scenarios: situations that involve any type of federal agreement and situations involving emergency response mass dispensing. The language was purposefully broad to cover a range of situations whereby the jurisdiction has the authority to respond in any declared emergency; there is not a specific arrangement required. The statutes can only point to conditions thought to

be helpful to people and suggest why they should be covered. For example, if a person sues a retailer who claims protection under the PREP Act, ultimately it is up to the presiding judge to make that decision. That said, Sherman sympathized with why these employers are looking for specific documentation and highlighted this as an issue to address going forward.

Burel commented that it would be difficult for a big-box retailer, for example, to successfully assist in a dispensing operation in the absence of a state- or local-level agreement: "I don't think you would want Best Buy acting independently to try to distribute countermeasures without some agreement with you about how you were going to do that with them." Sherman noted that any federal arrangement could be pointed to as the basis for coverage regardless of the relationship to the authority having jurisdiction to respond.

Gore elaborated that from the employers' perspective, the primary issue does not seem to be liability, but rather the desire for a national-level paper document agreement; retailers, communications companies, banks, and corporations generally refuse to cooperate with individual jurisdiction-specific agreements. Sherman commented that this gives rise to a tension because every state and locality has its own requirements, prescriptions, authorities, and actors. Thus, it became very difficult to create a national-level agreement that is generic enough to be effective while balancing those competing needs.

Nash reiterated that a national-level agreement, whereby the employer agrees to participate and gives its locations the authority to participate, would simplify things significantly at the local level. For instance, her department has a national-level agreement with a very large grocery store chain, but they still have to negotiate MOUs individually in each jurisdiction (a huge burden for the employer).

O'Toole concluded the exchange by commenting: "I think [this] is a very important issue that is quite familiar to many people in the room in different versions and guises. It illustrates the complexity of actually administering a big federal program across all of the different public health jurisdictions in the country. It is another illustration of the brilliance and the complexity of the federal–state arrangement that is the United States of America when it comes to health authorities."

POTENTIAL OPPORTUNITY FOR IMPROVING TRANSPARENCY AND COORDINATION AMONG LOCAL, STATE, AND FEDERAL AGENCIES

From the local perspective, Gore suggested several ways to move forward with the SNS. The first is exercising the whole SNS process from beginning to end: from identification of a bioterrorism threat that triggers

the request, to the activation and mobilization of the asset, to the distribution and then the dispensing. Gore cautioned that expanding the scope and mission of the SNS should be done with an awareness of local impact. That is, a fast response to emerging threats concerns not just the countermeasure itself, but the local capacity to identify said threat (testing and confirmation rule out or require lab capabilities, for example).

Transparency Around SNS Inventory and Planning Assumptions

Gore emphasized that better information sharing with the local level is crucial: better clarity regarding how much of each individual item is needed and in what form, and being aware of what else is in the stockpile beyond ciprofloxacin and doxycycline in pill form. Much of what she knows about other stockpile contents she learned from her own research, not directly from DSNS. Access to these kinds of information is crucial for informing local-level operations and planning. Fri similarly contended that DSNS leadership needs to make its structure more visible to people working in public health and the commercial supply chain.

Gore raised the issue of whether planning assumptions regarding delivery are standardized across the board for the products in the SNS (e.g., why a certain product is a one-off, versus coming through traditional routes of distribution). She suggested better informing local agencies about these types of assumptions would allow for more effective planning and clinical guidance, noting that the concept of operations (CONOPS) framework idea would be ideal, especially if it were tied into a mechanism among local jurisdictions as well as between the local, state, and federal levels.

Starr also called for increasing visibility into the SNS at the local level:

> Smoothing that interface when it comes so that not only do we know what is in it, but they know what we want and we know what is on its way. We know when it is going to get there. We can upload. We have all the data that we need to receive it and move it on properly so it smooths that seam. I think you can reduce some of the seams, those tiers, but you cannot get rid of all of them, particularly in all scenarios.

Carlin asked whether the challenge of understanding what is in the stockpile beyond planning and preparation for anthrax (oral medications) drives planning at the local level to the exclusion of preparedness for other types of threats. Gore explained that because of the program requirements and the way they are structured, the amount of time spent focusing on MCM specifics prevents the opportunity to adequately prepare and plan for other types of non-CBRN threats (e.g., sheltering or water crisis). Even within the CBRN space, the focus is on CHEMPAK, on pills and people.

Involvement of State and Local Stakeholders in Requirement Setting (PHEMCE)

Starr maintained that it is important that decisions on requirement setting and quantities purchased take into account the ground-level operational impacts of the decisions that are made. Burhans emphasized the importance of including state and local stakeholders in the requirement-setting process for PHEMCE, because decisions on CONOPS and on the formulary have profound impacts on the last mile. Specifically, he advised that as CONOPS are developed, they should be shared with state and local health departments to make sure they understand the assumptions from PHEMCE's side. Jaffe commented that operationally, the state and local levels are CDC's responsibility, but in the requirement-setting process the scenarios are based on material threat assessments. The threat assessments that are used to identify which scenarios are requirement setting will soon be shared with state and local authorities in nonclassified form.

The scenarios upon which requirements are set are the same ones that can be used for exercising and planning. The PHEMCE operational capacity workgroup is also an important venue for state- and local-level engagement and involvement, Jaffe noted. Burhans suggested a formal process identified by the executive committee of PHEMCE to integrate local health department input into requirement setting for the stockpile. Furthermore, Burhans suggested the development of scenario-specific CONOPS tailored for the most likely scenarios that would require deployment of the SNS, in order to better align the federal, state, and local agencies.

Sosin commented that: "Information system problems just are inevitable, especially in public health, but they seem like low-hanging fruit. Just articulating the specific things that you need, I need this bill of lading to come electronically. We can take many of those off the table pretty quickly and we should."

Best-Practice Sharing Among Local Entities

Petersen suggested reviving best-practice sharing among local entities in regional planning meetings to learn from other's experiences (see Box 5-6).

Lee also called for improved integration between state and federal governments. For example, complex macro- and micro-level models at different levels of granularities could be used to analyze risk assessment and trade-off, and how it propagates upstream as well as downstream. This is important, because decision making at any level is going to influence many parts of the system. Decision makers and policy makers are facing a challenging problem with many variables and stakeholders with differing objectives. Best practice across different jurisdictions should be shared, but a mecha-

BOX 5-6
Local Health Authority Meetings and Consensus Building

State and local public health officials discussed the benefit of meeting to share plans and best practices. Gore commented that the NACCHO Public Health Preparedness Annual Summit is an excellent opportunity to do so, but it is not affordable because of administrative and bureaucratic barriers for many local officials. Furthermore, many local jurisdictions are not members of NACCHO or do not even know what NACCHO is. Lixey Terrill agreed about the value of the NACCHO Preparedness Summit, but commented that it has expanded to so many different topics in both public health and health care preparedness, with such a wide variety of partners, that some of the benefits of the smaller, regional meetings have been lost. Petersen noted that the SNS coordinators of southeastern states do meet annually, and that such regional settings allow for particularly fruitful discussions. Starr pointed to the lack of venues and opportunities for local officials to meet with each other on their own terms and work toward consensus. Meetings organized by larger, national groups have agendas set that often are not organically generated at the state level, which means that feedback provided to the national level may be contradictory and fail to generate action, noting that: "It is incumbent on us to really start generating this consensus building."

nism for doing so is needed. She suggested that communication—including horizontally among state and local agencies—also needs to be improved.

POTENTIAL OPPORTUNITY FOR IMPROVING CAPACITY TO REACH THE LAST MILE

Fri noted that starting at the dispensing level, response is primarily local and location specific. Thus, the SNS should transfer the medicines to the local and state authorities in the most efficient and effective way possible (improved electronic data interchange [EDI], standardization,[11] logistics, etc.) and "get out of the way." Petersen advocated for a "Swiss cheese" approach to fill gaps in capacity through layering at the state and local levels: incorporating private-sector partners (see Box 5-7), including pharmacies and multiple forms of PODs (closed PODs; public PODs, drive thru). Petersen construed the last mile as when someone actually consumes the MCM, noting that controlling compliance with those medications is part of a bigger issue. Innovative ways to ensure public compliance is needed

[11] She noted that standards already exist in the health care industry for barcoding, EDI, recalls, reverse logistics, etc.

BOX 5-7
Third-Party Logistics Provider Capacity for the Last Mile

Frederick suggested bringing third-party logistics providers such as FedEx to the table to discuss their potential involvement in the last mile; at present they deliver very effectively to the state level, and they have the capacity to deliver all the way to the local level. Brandeau advised thinking about the last mile as part of the entire supply chain, considering all the people in it, what their incentives are, and how to coordinate; there are benefits from working with third-party logistics providers in really sensible ways, but she suggested that there is more that needs to be done.

(e.g., he suggested transdermal patches for ease of use for both children and adults).

Inglesby reiterated that the last mile is a huge area of concern, and that no system can work in every location in the country. Working collaboratively will be important to make this complicated process work; everyone is working hard, but the transitions, handoffs, and bridges are difficult and require renewed focus and energy. He suggested that the public health enterprise and PHEMCE should work together to address logistical requirements for a variety of programs, and he suggested the benefit of comparing plans from disparate jurisdictions along common metrics.

Reevaluate Stockpiling in Local-Level MCM Caches

Petersen noted that as funding decreases, it not always sustainable for locals to continue to put funding in local caches. For years, they have had to dispose of medications when there is a national repository of the needed drugs, but it is contingent on timing, and how critical it is to get the product to where it needs to be. He noted that while there are myriad existing innovations that could be applied, not everyone has had access to innovation about how to have industry rotate products, for example.

Gore suggested that utilizing federal buying power for local responses could benefit local jurisdictions that have purchased their own caches for first responders because they could not dispense to them fast enough with SNS assets. In terms of rotation and recycling, having access to the Shelf-Life Extension Program—or even just knowing what the standards for qualifying are—would be very helpful.

Adapting to Variations in Capabilities and Standards Among State and Local Health Authorities

Shah commented that there is wide variation in capabilities at the local public health level. Starr called into question the need to resolve perceived gaps in the last mile in the same way across all municipalities: whether they need to be held to the same standard of necessary preparedness, or if basic capacity related to the risk analysis is sufficient (e.g., being able to provide prophylaxis to the entire state in 48 hours).

Gore sought clarification about what triggers that 48-hour window,[12] because it means different things to different people.[13] Holding people to a standard requires clearly establishing what that standard is. Lixey Terrill applied this concern to the time frame for dispensing, noting that it could take up to 12 hours for the state to receive the product, plus additional time to move it from the state to the local levels (which still have to dispense to first responders before the general public). She maintained that because state and local caches are often unaffordable, to dispense to staff and first responders and then open to the public narrows that window down to 24 hours. Carlin suggested that two options for "low-hanging fruit" with respect to specific challenges from the state and local perspectives that can be addressed by the standing committee: What does 48 hours really mean? What is in the stockpile, and how can that information be relayed to state and local jurisdictions? These answers, she predicted, would help smooth the handoff or transition and bridge the existing gap.

Improving the "Handoff" Transition

Khan suggested moving away from framing the transition of products from the federal to the state and local levels as a "handoff," but rather a seamless transition from warehouse to POD to mouths without breakpoints. Poole commented that this could be improved by factors such as exercising and standardized barcoding. Petersen noted that whenever a product is placed into a distribution chain that works every day, then it will be more effective: "If we can push the product out to some of these multimodal partners that we have, it is going to help us be more efficient and make the handoff be more integrative." Starr commented that the capacities and skill sets that are there to rapidly adapt and be flexible to different things are built as part of a system in New York City that has been used in practice for a variety of responses.

[12] Khan noted that events such as influenza outbreak do not need to be addressed within that same 48-hour window that an anthrax attack requires.

[13] Is it being exposed versus the confirmation testing? Is it from when the request is made? Is it from when the drugs go out the door, or is it when the drugs get to my doorstep?

6

Potential Supply-Chain Opportunities and Lessons from the Commercial Sector and Government Partners

STRENGTHENING THE PUBLIC HEALTH RESPONSE SUPPLY CHAIN

Brandeau co-authored a paper (Brandeau et al., 2007) with her research group that focused on how to improve the public health response supply chain with lessons from optimized commercial supply chains relevant to the public health supply chain. The paper also looked at lessons from responses to events such as natural disasters, naturally occurring outbreaks, and the 2001 anthrax attacks. She commented:

> We view the public health response supply chain really as an effort that involves not only procurement and distribution of medical and pharmaceutical supplies but more broadly, we think it is about the personnel involved in response and information. We think of it more holistically . . . it's not just material; it's people and information.

Brandeau explained that a public health emergency necessitates rapid procurement and distribution of medical and pharmaceutical supplies, trained personnel, and information. However, publications (Bravata et al., 2004) and preparedness drills (e.g., top officials [TOPOFF] exercises) have demonstrated that gaps in preparedness exist that underscore the need to better understand the best ways to design and maintain the public health response supply chain. She noted that previous research has focused on limited aspects of the public health response supply chain, such as models for planning the facility design and personnel requirements for large-scale dispensing clinics (Hupert et al., 2002; Lee et al., 2006).

Brandeau's group examined models (Bravata et al., 2006; Zaric et al., 2008) for evaluating local stockpiling and dispensing strategies by modeling the supply chain of materials for an anthrax attack, from the Strategic National Stockpile (SNS) to state and local stockpiles to dispensing. The limited model demonstrated that the bottleneck is likely to be dispensing capacity, not inventory.

The Public Health Response Supply Chain Versus the Commercial Supply Chain

Brandeau provided a schematic of the public health response supply chain (see Figure 6-1). She emphasized that the system is more than people (suppliers, manufacturers, purchasers, assemblers, first responders, public health officials, clinicians, and the affected population), material, equipment, and sites but the flow of materials, information, and people through the system.

Brandeau pointed to a set of critical differences between the commercial and public health supply chains. The commercial supply chain operates continually; demands are known with some certainty and the speed of response is important. The public health supply chain operates infrequently; demands are highly uncertain and the speed of response is essential. The latter also has more players—beyond the suppliers, manufacturers, assemblers, and retailers that constitute the former, there are agencies (national, regional, and local), local public health officials, first responders, and many others. Whereas commercial supply chains center on cost efficiency, the public health supply chain's success metrics include costs but also health outcomes and, also importantly, social outcomes: "it's not just that lives were saved by our response, but it was done in a way that there was minimum social disruption."

Her group's study suggested five strategies for public health supply-chain improvement:

1. Effective supply-chain network design,
2. Effective inventory management,
3. Postponement of product customization and modularization of component parts,
4. Coordination of supply-chain stakeholders and appropriate use of incentives, and
5. Effective information management.

Commercial supply chains are very efficient in managing inventories and inventory flows, explained Brandeau. However, she advised that the public health response supply chain may well need a more robust network

FIGURE 6-1 Public health response supply chain.
SOURCE: Brandeau presentation, February 4, 2016.

design than commercial supply chains because of the unknowns: where the event will occur, what magnitude it will be, and so forth. This means that planning models and exercises are essential in thinking about what the public health response supply chain looks like and not just planning models but exercises, taking into account that there are planners at all levels of response to be organized with an overarching strategy.

The next strategy concerns effective inventory management, a management effort that strikes the right balance at the federal, regional, and local levels in the coordination of inventory management. As an example, Brandeau cited a report on the issue of prepositioning and forward deployment (IOM, 2012) and the associated trade-off between pushing inventories all the way down the supply chain versus holding them centrally, which is more cost-effective but less flexible. Inventory pooling is more cost-effective, but local inventories allow for more rapid response. A related issue is that the very lean level of inventory favored by commercial supply chains may not be as desirable in public health supply chains (which also very often have items needed for response that may need to be quickly manufactured—another key aspect of planning).

Appropriate postponement of product customization and modularization of component parts was pinpointed by Brandeau as an important point to consider. For example, a TOPOFF exercise in 2000 found that modularization, like prepackaging items for response, was extremely efficient but much less flexible. The research group maintains that a model of the public health response supply chain, including dispensing, could be used to evaluate options for modularization versus postponement of inventory customization.

Brandeau stressed that the coordination of supply-chain stakeholders and appropriate use of incentives is important because the affected public, and its expectations, are part of the supply chain that should be aligned along with all other groups involved: different branches and levels of government, private industry, and all levels of responders. Beyond the financial and cost-based incentives in the commercial supply chain, the public health supply chain also has legal and jurisdictional incentives and constraints as well as personal incentives (e.g., volunteers who are dispensing at points of dispensing [PODs] who are personally or altruistically rather than financially or legally motivated).

Finally, the research group suggested that effective management of timely and accurate information is also critical: what information the affected population needs and what the available resources for response are at all levels. Technology can play a key role here (e.g., radio-frequency identification [RFID] device tags, two-dimensional barcodes on inventory, Web-based portals for inputting and obtaining real-time information), but because of the unknown nature of events, the group recommends

building redundancies into systems for obtaining and managing response information.

Brandeau summarized the study's conclusions: a well-designed and managed public health response supply chain can minimize costs while maximizing health outcomes and, ideally, minimizing social disruption. The public health response supply chain likely needs to be more robust than any single commercial supply chain (see Box 6-1), and it is important to coordinate and appropriately incentivize the activities of the many stakeholders. Brandeau maintained that even though the public health response supply chain is rarely activated, "we can and must learn from experience."

BOX 6-1
Supply-Chain Surge Capacity

Monique Mansoura, head, Medical Countermeasures and Government Affairs, Americas, Novartis Influenza Vaccines, raised the issue of surge capacity for systems that are designed for efficiencies under very different circumstances. If commercial supply chains are designed for efficiencies and yet there is surge of 2×, 10×, 100×, 1,000×, or even 1,000,000×, Mansoura asked at what point the Strategic National Stockpile (SNS) would communicate that the expectations surrounding that type of surge are incompatible with the systems upon which they are designed to respond. For instance, she noted that some of the medical countermeasures (MCMs) within the purview of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) are stored in bulk, particularly the prepandemic stockpile. She further asked what additional complexities are associated with products that are manufactured in real time, and thus may be produced and ready to ship at a relatively unpredictable rate, and how that might contribute to the up-front added uncertainty of the response time. Burel acknowledged that products held in bulk, which have to be fill-finished before they are distributed for use, will indeed create a delay. Therefore, in preparing many of the SNS products, this has necessitated special packaging, devised for specific quantities of drugs to be handed directly to people for oral prophylaxis or for other purposes.

Mansoura followed up by asking about the bulk antigen stockpile specifically—an already finished product stored in a bulk container. Burel replied that the same holds true: a fill-finished product in the warehouse is straightforward; if it is not a filled-finished product, then the SNS is reliant on the fill-finish process before the product can be distributed (he noted that this is actually the Biomedical Advanced Research and Development Authority's [BARDA's] arena). That signal to a supply chain is optimized, for most drug products, around a 30-day window of supply, all the way from a point of delivery. However, the market does not have enough products in it to meet the expected need for certain scenarios, and so SNS stockpiles against the market's non-optimization.

UNDERSTANDING AND LEVERAGING PRACTICES OF THE COMMERCIAL SUPPLY CHAIN: LESSONS FROM PRIVATE-SECTOR THIRD-PARTY LOGISTICS PROVIDERS

Third-Party Logistics—Supporting the SNS

Thomas Mattingly, president of Metro Logics, Inc., and Frederick of FedEx Custom Critical (see Box 6-2) each spoke about their company's working relationship with the SNS. Metro Logics, Inc., is a third-party logistics (3PL) service provider specializing in temperature-controlled distribution that has worked with the SNS for 16 years. He explained that the job of a 3PL service provider is to manage the storage and movement of inventory, in compliance with all applicable regulatory authorities and requirements. Specifically, Metro Logic's key commitments are to ensure that its customer's products are safe, accurately counted, continuously stored at predefined storage conditions, and ready for rapid shipment if needed.

Mattingly noted that today, the SNS actively pursues new technology opportunities to increase both speed and accuracy, whereas in the early years of the program, every function was a manual process with little or no electronic data interchange (EDI) capability. He attributed significant improvement in multiple areas of the program to the application of various types of technological advances. For instance, transactions are communicated electronically to the SNS using flat files passed through the Public Health Information Network Messaging System to ensure a secure, encrypted transfer.

Perpetual inventory files are electronically transmitted on a weekly basis to identify and report any inventory discrepancies, which are then investigated and reconciled. Internal warehouse product movement files are electronically transmitted on a daily basis to ensure the integrity of product location within the facility. Outbound orders and receipt, storage, and staging (RSS) files are processed electronically to decrease potential typing input errors and significantly reduce the amount of time necessary to process orders. Physical inventory count times have been reduced by over 80 percent by using radio-frequency technology.[1] Physical inventory accuracy has also increased significantly, with the last one taken yielding a 100 percent financial accuracy rating and a 99.99 percent overall accuracy rating.

Services Provided by Third-Party Logistics

Mattingly provided an overview of the types of services provided by 3PL providers such as Metro Logics. They maintain an ongoing accounting

[1] What previously took up to 42 8-hour shifts to complete now takes 5 to 7.

BOX 6-2
Planning for an SNS Event:
How FedEx Custom Critical Works with the SNS
Jason Frederick, Vice President of Operations,
FedEx Custom Critical

Frederick explained how this specialized division within the FedEx organization has worked with CDC over the past 15 years. As one of the largest time-specific expediters in North America, FedEx Custom Critical provides customized surface and air solutions for its customers' critical shipping needs, including a suite of temperature-controlled services appropriate for pharmaceuticals. Its fleet of equipment on the ground side ranges from cargo vans to 53-foot trailers (with truckload solutions available); on the air side they can leverage the support of partners such as Envirotainer and CSafe, using containers to ship within the express network.

Frederick described how a dedicated team of employees at Custom Critical is responsible for working with CDC. Shipments are moved for CDC as required, but the team's primary focus is carrying out regularly scheduled drills (monthly, with a major drill yearly) to test plans for operating during a potential event. He emphasized that maintaining frequent, open lines of communication with CDC during quarterly meetings allows plans to be updated and refined on an ongoing basis. For example, Custom Critical maintains contingency plans to deal with a scenario in which something happens to their primary facility; they have a backup facility roughly 30 miles away that can be staffed and operational within 40 minutes (alternatively, agents can work from home). Custom Critical also has a closed POD location, enabling them to treat the dedicated Custom Critical CDC team first to enable uninterrupted support operations.

Custom Critical is able to ensure the capacity to move products in the face of a large-scale SNS deployment event by "locking" the entire fleet for CDC,[a] with priority over any other customers, to be used on an as-needed basis. Frederick explained that Custom Critical also has the ability to leverage the entire FedEx network, comprising a further 30,000 pieces of equipment that include more than 700 aircraft—a capacity that cannot currently be matched by any other carrier, according to Frederick.

[a] Consisting of more than 1,200 vehicles (with owner operators) and approximately 2,500 contractors.

for all products as they are received, stored, and withdrawn, with inventory of stored projects performed to ensure that 100 percent of product is accounted for annually. All products are stored and maintained according to specified temperature requirements, and in compliance with all applicable regulations including those of the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), and the Drug

Enforcement Agency (DEA) and other such federal, state, or local laws that may apply. Metro Logics labels, tags, and otherwise prepares product for shipment as directed by the customer and ensures that the lot, dating, and quantity of product that appear on each shipment manifest reconcile with what is on the customer order identified on the pack list. To enable rapid shipment capability, facilities are designed and laid out to ensure that 100 percent of the product is available 100 percent of the time with minimum effort. They also monitor warehouse product locations to ensure that a given item is stored throughout the warehouse rather that in a concentrated area.[2] Surge support is also critical; Metro Logics maintains a supplemental workforce that is utilized during an emergency. These employees receive a monthly on-call stipend and are required to work and train a minimum of 4 hours per month. This monthly training requirement also serves to help determine an employee's level of commitment to the program.

In addition to managing the storage and movement of inventory, Mattingly explained that Metro Logics is also committed to maintaining the highest standards of quality and regulatory compliance, which is demonstrated by their highly qualified and experienced quality staff. All processes are managed through controlled procedures (e.g., document control is maintained using a validated electronic document management system). Regulatory conformance remains compliant with 21 CFR Parts 11, 210, 211, and 820 and other customer-specific requirements. Validation and calibration processes are used to ensure that all equipment and storage areas are qualified, with performance qualifications implemented annually on all validated storage areas (software systems are validated according to 21 CFR Part 11).

Government Partner Supply Chain and Stockpile Strategies

Veterans Health Administration All-Hazards Emergency Cache Program

Lewis Radonovich, director, National Center for Occupational Health and Infection Control, Department of Veterans Affairs (VA), reported on the Veterans Health Administration (VHA) All-Hazards Emergency Cache Program. The VHA is the largest integrated health care system in the country, comprising 167 medical centers and 1,026 outpatient clinics.[3] He outlined several ways that the VA stockpile differs from the SNS. It is primarily intended to ensure easy accessibility and rapid access to large quantities of commonly used medical supplies and countermeasures as determined by hazards vulnerability assessments at the national, regional, and local levels;

[2] This practice eliminates the "hourglass effect" that occurs when too many employees are attempting to pull product from the same aisle.

[3] Approximately 823 community-based, 144 hospital-based, and 59 mobile units.

the SNS is more focused on providing access to medications and supplies that may not be commonly available. The VA system is widely geographically distributed across a national network of hospitals and clinics and is complementary in the sense that it is intended to dovetail with medical supplies and countermeasures held in local VA pharmacies and supply inventories. It is integrated and can be replenished quickly through routine supply chains, as necessary, and is scalable to meet small surge needs for routine care at the local level or larger-scale crises at the regional or national level.

Radonovich explained that the VA stockpile is designed for response to CBRN events and, as such, its content categories include antibiotics, antivirals, emergency medications, chemical countermeasures, intravenous (IV) fluids, wound care, and personal protective equipment. Full contents are available in local caches in VA medical centers with larger supplies of selected items stored in a central location. Its contents are primarily intended for the 8 million veterans and 300,000 VA staff members for the short-term preservation of VA operations in a crisis and to bridge the gap between what is available in local pharmacies and what other resources such as the SNS would provide, as well as supporting the VA facility's involvement in the local community disaster plan. Cache operations are managed by the VA Emergency Pharmacy Service, which provides logistics support and manages product acquisition and life-cycle management, as well as VA participation in the Shelf Life Extension Program. Several executive committees oversee operations, which are reviewed on a regular basis.

Radonovich characterized the VA as both a community asset and a federal asset, which therefore deals with some competing objectives. However, he emphasized that first and foremost, it is a community medical center that is engaged in the local emergency response and at times may be called on to serve as a national resource in the event of a national or large regional emergency. One of the aims of the VA is to build the community-level understanding of its dual role as a federally governed asset and local community health care provider.

Radonovich explained the VA cache's scalability and interoperability in Figure 6-2. He noted that routine operations use the inventory that is available in VA pharmacies, but during a national crisis, supplies that are normally available from vendors and local inventory would likely be exhausted and necessitate reaching out to the cache locally. If the local cache is insufficient, the next step is the central warehouse where additional supplies are stored. If that is exhausted, the next option is to reach out to the local and state levels (essentially, the SNS).

The VA used the Federal Emergency Management Agency National Planning Scenario to study what might happen in a large city such as Chicago in the event of an aerosolized anthrax attack. An estimated 300,000 people would be exposed to anthrax, including 20,000 veterans.

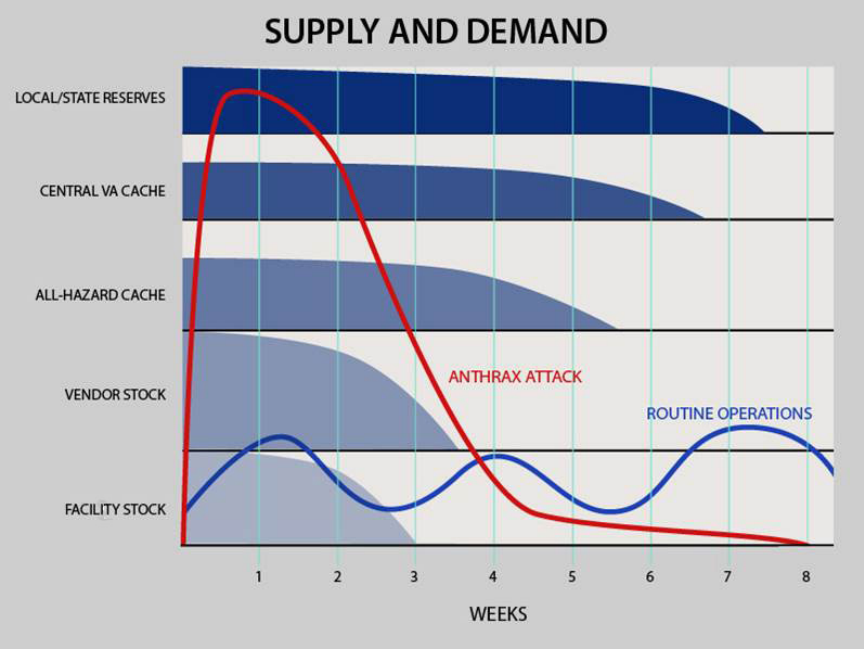

FIGURE 6-2 The Department of Veterans Affairs (VA) cache scalability and interoperability.
SOURCE: Radonovich presentation, February 4, 2016.

Radonovich reported that in that scenario, they have estimated that they could provide prophylactic antibiotics to all veterans and VA staff on the campus, as well as a 60-day prophylactic course after they were relocated.

Although the VA stockpile was not necessarily intended to be used for pharmaceuticals shortages, Radonovich explained that it is in fact tapped into somewhat regularly for that purpose. Each week they might receive five pages' worth of pharmaceutical shortages, some of which trigger usage of the supplies in the cache. Noting that the VA stockpile is used regularly to relieve drug shortages, Carlin asked about the decision-making process and how the potential negative consequences are balanced with the benefits. Radonovich explained that it is needs based, not a formula. If they run out of supply that cannot be immediately acquired from the vendor, then the most logical option is the stockpile.

Radonovich described how future efforts are aimed at being able to dispense MCMs to large numbers of people efficiently (e.g., through host demonstrations optimizing VHA dispensing capabilities) as well as refining the contents of the VHA emergency cache based on vulnerability assess-

ments and clarifying its role during pharmaceutical shortages. Finally, they seek to optimize federal and local community partnerships by enhancing the integration of each VA medical facility within each local community and working closely with the Centers for Disease Control and Prevention (CDC), the Department of Defense (DoD), and PHEMCE.

DoD Support to Contingency Operations

Colonel Alex Zotomayor, director of the Medical Supply Chain for the Defense Logistics Agency (DLA), DoD, described DLA's role as the logistics provider for DoD and U.S. military forces. The medical supply chain is situated within DLA Troop Support, which manages a range of supply chains, contracts, and programs. The DLA medical support strategy has a dual focus: both institutional and operational. Its everyday focus is the former, which requires speed, reliability, responsiveness, and affordability for military treatment facilities worldwide. During a crisis, the focus shifts to operational and being ready to respond immediately to surge requirements to support contingency operations spanning the range of natural disasters up to wars on multiple fronts.

Zotomayor explained that prior to the 1990s, medical troop support was a stockpile-heavy organization, but during Operations Desert Shield and Desert Storm, the support provided was not optimal due to both the lack of responsiveness to time lines and the fact that the items being pushed out were not actually needed or used by deployed forces. That forced DLA to reorganize, realizing the warehousing and depot strategy was not optimal. They pared down the inventory of depot stock (from tens of thousands of lines to 1,100 current lines of stock) and adopted a commercial-type "just-in-time" model, drawing on e-commerce solutions such as Prime Vendor and Electronic Catalog. These two programs meet 91 percent of their customers' requirements, with a delivery time frame of 1 day within the United States and 5 to 7 days for overseas customers. Materiel not covered by the e-commerce programs is purchased through direct vendor delivery (e.g., for seasonal flu vaccines). The DLA distribution depot does maintain a small stockpile for military unique materiel and MCM supplies.

Forward Presence Inventory: Delivery Agents

Zotomayor described the Army Medical Materiel Agreement (AMMA), a formalized partnership between DLA and the Army Medical Command which grants designated army activities access to and the use of DLA's working capital fund. This provides the Army with a reliable source of funds for ordering and maintaining supplies for particular activities, including the support of surge requirements. There are currently four Army hos-

pitals designated as AMMA sites, including three overseas; the agreement is that the Army manages the stock for DLA, but it remains DLA property until sold by the Army. The advantage for DLA is that they have these AMMA sites as mini distribution depots.

The majority of distribution is handled by commercial vendors, according to Zotomayor, who deliver directly to customers using their own robust distribution networks, with DLA providing movement via Transportation Command's commercial carrier contracts for the transport of hazardous material, controlled substances, and cold-chain management. As a DoD entity, DLA also has access to military assets and distribution hubs that are set up during contingency operations.

Surge Requirements and Readiness Contracts

During a surge requirement, Zotomayor explained that the military forces maintain a limited amount of stock in their own units and are supported with AMMA sites. Beyond that, DLA relies primarily on readiness contracts with the health care industry through which they purchase guaranteed access to materiel or production capability with time-phased deliveries that minimize DLA's requirement to stockpile and maintain material at our distribution depots (see Figure 6-3). Currently, DLA has invested approximately $27 million per year in readiness contracts providing access to approximately $780 million of material in stock (a $28.10 return on investment). Zotomayor outlined the four types of readiness contracts. Corporate exigency contracts are long-term partnerships with manufacturers providing guaranteed product availability, in order to provide sustainment material to meet the surge requirements. The benefit from this type of contract is large quantities due to access to manufacturers and to their production capabilities. Vendor-managed inventory contracts focus on long-term partnerships with distributors to provide guaranteed product availability, with the benefit of timely response within a 24-hour delivery period (currently the only vendor-managed inventory contracts that they have are for pharmaceutical items). Prime vendor war readiness contracts are adjunct to prime vendor contracts that allow prenegotiated access to stocks in support of surge requirements. Industrial base maintenance contracts are long-term partnerships with select manufacturers to maintain a warm production base for particular items of military significance; these are items with production time lines and capabilities such that DLA needs to ensure that the industry maintains a consistent flow of production. DLA Troop Support uses "Warstopper" funds to pay fees associated with its various readiness programs.

DLA has strategic relationships that are formalized in the Defense Medical Logistics Enterprise; Zotomayor emphasized that DLA cannot be

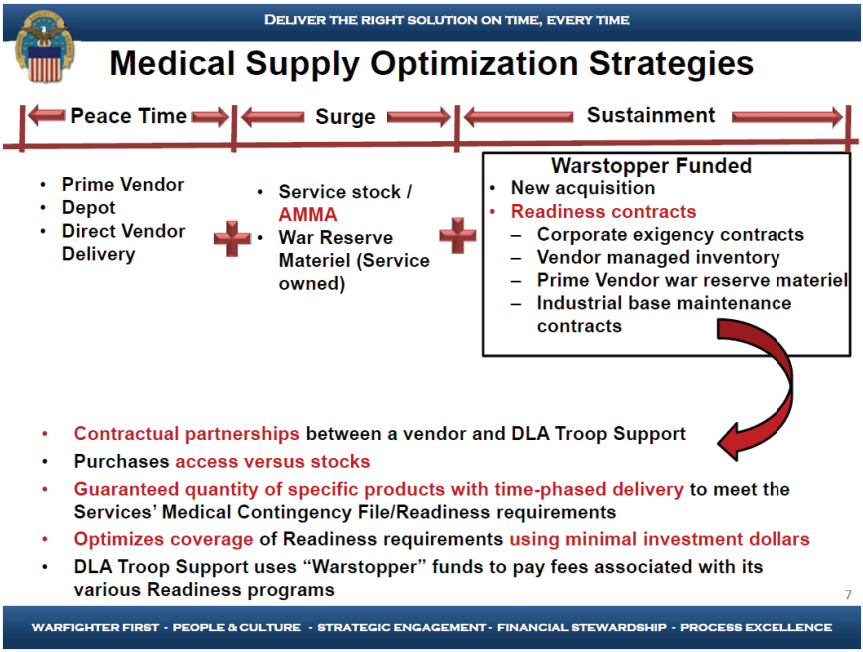

FIGURE 6-3 Medical supply optimization strategies.
NOTE: AMMA = Army Medical Material Agreement; DLA = Defense Logistics Agency.
SOURCE: Zotomayor presentation, February 4, 2016.

stove piped and look at things only from a DoD perspective. Looking at things from a broader government perspective and incorporating other government partners regarding procurement of medical supplies is important because of competition in sources of supply. DLA is currently conducting industrial preparedness planning assessments, a collaborative effort among DLA Medical Troop Support, the Armed Services, and the health care industry to assess industrial capabilities of manufacturers and distributors to provide materiel to meet the time-phased mobilization and sustainment requirements of the Services. Once the assessment is completed, decisions will be made about purchasing and maintaining stock, negotiating a contingency contract, and/or accepting risks regarding the ability of future production time lines to meet requirements in light of current inventory.

In the context of the large number of products in the SNS inventory and the associated tensions of sustainability, Inglesby asked how DoD and the VA determine the boundaries for their stockpiles and whether their stockpiles are subject to the same types of tensions as the SNS. Decision making

is simple and streamlined for DoD, according to Zotomayor, because they are told what the requirements are by Health Affairs, Defense Health Agency, and the Services. Radonovich explained that the VA uses two parallel processes. At the national stockpile level, they back into numbers by estimating the number of veterans in a community and the number of expected exposures in that group, then extrapolating that to estimate the number of MCMs needed for the entire country. At the local level, they use standard hazard vulnerability assessment levels.

Sosin asked about DoD's use of multiple intermediary holders of material, as one of the challenges for CDC is ensuring that the quality of the management and control of that material by intermediaries. Zotomayor explained that there is a standard across DoD that military medical logistics forces have to maintain in the management of items, which is clearly laid out in formalized agreements. They also perform follow-up inspections, follow-up inventories, and so forth to ensure that there are good management practices and established quality control.

POTENTIAL OPPORTUNITY FOR BETTER ENGAGEMENT WITH THE COMMERCIAL AND PHARMACEUTICAL INDUSTRIES

Fri pointed out the "gray area" of overlap between products in the stockpile and those in the commercial supply chain (e.g., antivirals). He suggested finding ways to collaborate in overlap spots in the supply chains to ensure that medicines are reaching the right people in the right place at the right time. He elaborated that unique medicines in the stockpile are governed by very specific contracts, but many products in the commercial supply chain are made in China, Europe, India, and Israel. Much of that responsibility is external to the United States, even though the United States still is by far the largest pharmaceutical marketplace in the world. Furthermore, at least two of the large U.S. distributors are now international entities negotiating contracts on a global basis.

Mansoura suggested that relationships with industry need more attention, as the notion of developing products with an indefinite shelf life, for example, would likely be detrimental from the perspective of the manufacturer: "things that are upside and cost-efficient on the government side are potentially the opposite on the other side of the partnership." She noted that vaccines, for example, are a particularly fragile system; expanding production will require looking at some of the broader, strategic, and system-level issues in the vaccine industry.

Khan suggested the use of reverse inventory contracts such that SNS materials can be returned to industry partners if requested for distribution through their routine supply chains in order to address nationwide need, and then replenished with new materials. But he cautioned that the SNS has

previously assessed scenarios where this actually would not be helpful, and products in the SNS have never been used to support select shortages in the commercial supply chain. Either the supply chain has recovered quickly so that the federal assistance has not been needed, he explained, or products to support the commercial inventory gaps did not exist in sufficient amounts in the SNS to make a substantial difference.

SNS Role in Fiscally Sustaining the MCM Industry

Referring to economic tension between the Division of Strategic National Stockpile's (DSNS's) desire for lower-cost countermeasures and the limited market viability of some of the products it stockpiles, Sosin maintained that the SNS's role in fiscally sustaining the MCM production is a legitimate one, but pointed to the question of whether that optimizes the use of resources for the spectrum of risk: "Does it buy down the most risk? Can we effectively do both or do we have to choose?" He contended that Khan's suggestion of moving toward the development of products with indefinite shelf lives would not alleviate the problem, because manufacturing those product lines would not make financial sense from the industry's perspective. Khan clarified that these products were not necessarily purchased with SNS funds and that SNS dollars are relatively stable if adjusted for inflation—a process is needed then to buy down the biggest risk given the resources that are available.

Price Negotiation

Lewis Grossman, professor of law, American University Washington College of Law, noted that the pharmaceutical market is an unusual one (e.g., regulatory barriers to entry) and that the products stocked by the SNS are also particularly atypical from a market perspective. From a procurement and price negotiation perspective, he questioned whether the SNS faces any challenges and whether its statutory underpinnings provide any special provisions regarding procurement. Sherman explained that the Project BioShield Act put forth the authority to procure security countermeasures, with quite a few special contracting authorities for exceptional circumstances that have been adjusted over time. In terms of price negotiation and conditions, Burel reported that historically, the SNS has been very effective in obtaining the best possible prices for products given the circumstances, but he conceded that for commercial products, they are far off the retail prices. For sole-provider products, there are enough benchmark products to make reasonable estimates (e.g., vaccines can be compared to other vaccines). Khan noted that while the SNS is already working on the ability to bargain for materials that come into the SNS based on actual cost, the reality is that most of these products

have no other commercial market, and so the SNS should be doing more. Burel explained that MCMs have benchmarks for the early and advanced development stages that BARDA can use to suggest the financial model that is appropriate to achieve a fair and reasonable price for that product. Those data, coupled with other procurement-sensitive data, are used to further negotiate new pricing on products as they come for purchase.

Commercialization of the SNS Supply Chain

Larry Glasscock, senior vice president, Global Accounts, MNX Global Logistics, contended that moving to the commercial arena as much as possible is important for the SNS, because a very high percentage of material and ingredients that go into the more sophisticated and complex countermeasures are imported. He questioned how the SNS can address this additional layer of complexity (e.g., shortages in the commercial supply chain and changes in the marketplace) in the move toward commercialization. Burel responded that the SNS distribution process tries to act like the commercial market to the extent possible because it is known to work, but that they will have to plug into systems that are designed to dispense in a different way than they normally operate. Challenges further upstream in the supply chain, back to the raw material for particular holdings, becomes even more complex. Burel noted that although nothing prevents the SNS or BARDA (or a joint effort) from buying and stocking raw materials from a procurement perspective, it adds a layer of procurement responsibility—and a layer of cost—for which resources are not currently available. Pharmaceutical supply-chain security will pose an issue going forward, but again, he noted that the SNS does not have the financial capability to move into that space except for specifically targeted concerns that must be addressed.

POTENTIAL OPPORTUNITY FOR IMPROVED ELECTRONIC DATA INTERCHANGE

Mattingly highlighted areas for improvement with respect to EDI issues. In the early stages, the SNS was not able to preload the RSSs, requiring extensive time spent manually keying in RSS files. This problem was rectified by creating a program to match files submitted by the SNS (flat file to flat file), but there is room for improvement. His organization would benefit from being able to communicate with vendors and manufacturers directly by importing their information and scanning their native labels, which allows more capacity to be devoted to logistical operations. He also suggested using available technology for advanced shipping notices to allow visibility of trucks at all times.

Fri noted that there are specific standards in the pharmaceutical supply chain for transmitting information electronically and for labeling case- and pallet-level barcodes; thus any company in the commercial supply chain that works with large wholesalers must be doing EDI and be compliant with these barcode guidelines. Given that the SNS labels differently, she asked about the potential to use some of those industry standards. Burel explained that the SNS can accept any type of commercial barcode and has not specified a different standard, because it already exists. However, the SNS's own inventory system does have compliance issues around barcoding.

Mattingly clarified that the flat-file-to-flat-file system is effective, but not in the standard EDI format used widely; it would be beneficial to move toward the point of being able to communicate in real time:

> I'll move a pallet in my warehouse. I'm scanning. It updates now. Their files don't update until the end of the day. It's an automatic. We send it automatically to PHINMS [Public Health Information Network Messaging System], they pick it up, and they execute it. But there are still a couple hours our locations could be off, but we're working on that. We're not the standard format that's recognized in the industry, but we are trading information.

Burel continued that the use of flat files is related to specific security issues around how data can be exchanged between CDC's firewall systems and external firewall systems—at this point, exchanging that flat file is the best option that does not involve prohibitive cost, and the delay is not an issue for the SNS.

Poole described a common problem from the state perspective: they receive the product from CDC and the bill of lading, but they or their private vendors cannot import that into the RSS. Burel explained that because they are in a unique position of interfacing with every state, and possibly every locality, further facilitating EDI would require dealing with a wide range of different systems. However, for localities that have contracted with private-sector vendors who are accustomed to receiving electronic data, it would be relatively easy for DSNS to provide them with EDI information in addition to the bill of lading.

Petersen related that during H1N1, his department received the product from CDC but did not get the expected electronic files; instead they received many pages of physical bills of lading that they had to input manually into the inventory management system. This was time intensive, especially during the initial phase when the severity of the pandemic and how or whether the product would be distributed were unknowns. He commented that improving that EDI side for managed inventory needs further progress. Burel agreed, noting that the SNS does not mandate an inventory system

to be used in every state and every locality; that said, having 62 separate Public Health Emergency Preparedness Cooperative Agreement holders gives rise to the potential for 62 different formats. However, he stated that the SNS would continue to work to address this issue.

Judith Robinson, supervisory public health analyst, District of Columbia (DC) Department of Health, asked if in addition to the bill of lading, it would be possible to also send a flat file that could be imported into the inventory management system. Burel replied that there is the potential to provide files for import into inventory management systems easily if the locality is using the system that the SNS offers. Otherwise, the file would need to be formatted in such a way that it would match up with the location-specific inventory management system. Every project area could potentially use a different file format, which might change over time and have to be continually updated.

7

Wrap-Up

In bringing the workshop to a close, O'Toole invited all of the panelists to take seats at the table and spend several minutes highlighting areas that in their opinions needed additional exploration based on the workshop discussions. Several speakers raised the question of validating or confirming the scope and mission of the Strategic National Stockpile (SNS) in the current environment, with Inglesby commenting that an SNS focused only on chemical, biological, radiological, and nuclear (CBRN) threats pushes the bounds of sustainability, and that all hazards and emerging infectious diseases (EIDs) being included in the paradigm increases the pressure even further. Carlin expanded on the pressure caused by EIDs, adding "we need to think about what a stockpile for EID actually means though. It seems like we're getting one a year at this stage, and how sustainable would having a stockpile for EID be?" Addressing the topic of scope and mission pressures from a different perspective, Parker provided that participants, therapies, and preventative measures can change over time as the science underpinning them evolves. Parker suggested that a "deep breath" was needed, that assumptions be reassessed and validated as part of any reviews of SNS products. Skivington took the revalidation idea in a parallel direction, suggesting that a similar administrative and governance "deep breath" might be of value in such a complex structure.

Other speakers raised the question of trade-offs in decision making as an enduring topic. Brandeau offered that it may be valuable to decision makers to frame the possible expansion of the SNS mission in terms of both financial and operational cost-benefit trade-offs, while Carlin suggested

that there may be ethical questions to be considered with some of those trade-offs as well.

O'Toole closed out the workshop by reminding participants that the threats and hazards that prompted the creation of the SNS remain as extant and challenging currently as they have ever been and suggested that continued enhancement of the SNS be considered from a national security perspective in addition to a public health perspective.

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Appendix A

Workshop Agenda

February 4-5, 2016
Keck Center, Room 100
500 Fifth Street, NW
Washington, DC

Workshop Objectives:

- Provide a broad overview of current efforts under way at the Centers for Disease Control and Prevention (CDC), the Department of Defense (DoD), and the Department of Veterans Affairs (VA) to distribute medical countermeasures and other supplies during a disaster or other public health emergency including during times of major infrastructure failure;
- Review novel practices used by private industry to distribute medical products and supplies on a day-to-day basis as well as during an emergency;
- Identify major gaps in currently available distribution methods in the public and private sectors;
- Identify opportunities for collaboration and coordination between CDC and among relevant federal as well as industry programs to support effective and efficient medical countermeasures distribution; and
- Examine opportunities to enhance the economic sustainability of the Strategic National Stockpile (SNS) in view of evolving mission expectations and new medical countermeasure (MCM) research and development.

DAY 1: FEBRUARY 4, 2016—OPEN SESSION

8:30 a.m. **Welcome and Introductory Remarks**
Tara O'Toole, *Chair, SNS Standing Committee*
Greg Burel, *Director, Division of Strategic National Stockpile, Office of Public Health Preparedness and Response (OPHPR), CDC*

Session I:
The SNS: A National Asset for Lifesaving MCMs

Session Objectives:

- Provide a past and present perspective on the SNS as a national asset.
- Provide a broad overview of the SNS, its history, policy foundations, operations, relationships with other CDC divisions and programs, and other federal stakeholders.
- Provide insight on the future direction of the SNS.

8:45 a.m. **Panel I**
Moderator: Tara O'Toole, *Chair, SNS Standing Committee*

Panelists:

- Ali Khan, *Dean, College of Public Health, University of Nebraska Medical Center, and Former Director, OPHPR, CDC*
- Frank Gottron, *Specialist in Science and Technology Policy, Congressional Research Service*
- Sally Phillips, *Deputy Assistant Secretary for Policy, Office of the Assistant Secretary of Preparedness and Response (ASPR)*
- Dan Sosin, *Deputy Director and Chief Medical Officer, OPHPR, CDC*

Q/A

9:30 a.m. **Panel II**
Moderator: Tara O'Toole, *Chair, SNS Standing Committee*

Panelists:

- Greg Burel, *Director, Division of Strategic National Stockpile, OPHPR, CDC*
- Susan Sherman, *Senior Attorney, Office of General Counsel, Department of Health and Human Services (HHS)*
- Christine Kosmos, *Director, Division of State and Local Readiness, OPHPR, CDC*

Q/A

11:00 a.m. **Break**

11:15 a.m. **Panel III: The Federal Medical Countermeasures Enterprise**
Moderator: Tom Inglesby, *Director, University of Pittsburgh Medical Center (UPMC) Center for Health Security*

Panelists:

- Richard Jaffe, *Director, Medical Countermeasures Strategy and Requirements, ASPR*
- Gary Disbrow, *Director, Chemical, Biological, Radiological, and Nuclear (CBRN) Division, Biomedical Advanced Research and Development Authority (BARDA), ASPR*
- Brad Leissa, *Deputy Director, Counter Terrorism and Emergency Coordination Staff, Food and Drug Administration (FDA)*
- Rocco Casagrande, *Managing Director, Gryphon Scientific*

Q/A

12:30 p.m. **Lunch**

Session II:
The SNS Supply Chain and Partnerships

Session Objectives:

- Provide an overview of the MCM supply chain and stockpile strategies of DoD and VA, and explore opportunities to leverage lessons learned.
- Develop an understanding of the commercial supply chain, its interface with the SNS and how the resources of the private sector can be best leveraged.

1:30 p.m. **Panel IV: MCM Distribution Lessons from Other Government Partners**
Moderator: Ellen Carlin, *Principal, Carlin Communications*

Panelists:
- Lewis Radonovich, *Director, National Center for Occupational Health and Infection Control, VA*
- COL Alex Zotomayor, *Director, Medical Supply Chain, Defense Logistics Agency, DoD*
- Michael Loehr, *Chief of Emergency Preparedness and Response, Washington State Department of Health*

Q/A

2:45 p.m. **Break**

3:00 p.m. **Panel V: Understanding and Leveraging Practices of the Commercial Supply Chain**
Moderator: Perry Fri, *Executive Vice President, Industry Relations, Healthcare Distribution Management Association*

Panelists:
- Margaret Brandeau, *Coleman F. Fung Professor of Engineering, Stanford University*
- Jason Frederick, *Vice President of Operations, FedEx Custom Critical*
- Mitch Mattingly, *President, Metro Logics, Inc.*

Q/A

4:15 p.m. **Break**

4:30 p.m. **Review of the Day's Discussions and Looking Ahead**
Tara O'Toole, *Chair, SNS Standing Committee*

5:00 p.m. **Adjourn**

DAY 2: FEBRUARY 5, 2016—OPEN SESSION

8:30 a.m. **Welcome**
Tara O'Toole, *Chair, SNS Standing Committee*

Session III: Studies and Reports Related to the SNS

Session Objective:

- Provide an overview of studies and reports conducted in the past several years that have addressed the challenges and opportunities of the SNS.

8:40 a.m. **Panel VI: Reports on SNS**
Moderator: Eva Lee, *Director, Center for Operations Research in Medicine and Healthcare, Georgia Institute of Technology*

Panelists:

- *Anticipated Responsibilities of the SNS in the Year 2020: An Examination with Recommendations: A Joint Report of the National Biodefense Science Board and the Office of Public Health Preparedness and Response Board of Scientific Counselors*, John Parker, *Former Chair, National Biodefense Science Board and Report Co-Chair*
- *A National Blueprint for Biodefense: Leadership and Major Reforms Needed to Optimize Efforts*, Ellen Carlin, *Co-Director, Blue Ribbon Study Panel on Biodefense*
- *Association of State and Territorial Health Officials (ASTHO) Public Health Emergency Medical Countermeasures Enterprise Review: A Strategic Report*, Robert L. Burhans, *Senior Executive, Health Emergency Management, Tetra Tech, Emergency Management and Community Resilience (EMCR)*
- Greg Burel, *Director, Division of Strategic National Stockpile, OPHPR, CDC*

Q/A

10:25 a.m. **Break**

Session IV: SNS Collaboration with State and Local Partners

Session Objectives:

- Provide an overview of state and local partnerships with the SNS.
- Explore best practices and opportunities for SNS collaboration between different levels of government.

10:40 a.m. **Panel VII: State and Local Perspectives**
Moderator: Paul Petersen, *Director, Emergency Preparedness Program, Tennessee Department of Health*

Panelists:

- Jennifer Lixey Terrill, *Healthcare and Public Health Emergency Management and Policy Specialist, Michigan Department of Health and Human Services*
- Michael Poole, *SNS Coordinator, Texas Department of State Health Services*
- David Starr, *Director, Countermeasures Response, New York City Department of Health and Mental Hygiene*
- Emily Gore, *Public Health Manager, Public Health Preparedness Division, Dallas County Health and Human Services*

Q/A

12:25 p.m. **Lunch**

Session V: The Road Ahead

Session Objective:

- Review previous days' discussions and explore key themes and ideas relevant to the future success of the SNS.

1:25 p.m. **Panel VIII: Implications and Opportunities for the Future**
Moderator: Tara O'Toole, *Chair, SNS Standing Committee*

Panelists:

- Tom Inglesby, *Director, UPMC Center for Health Security*
- Eva Lee, *Director, Center for Operations Research in Medicine and Healthcare, Georgia Institute of Technology*

- Ellen Carlin, *Principal, Carlin Communications*
- Perry Fri, *Executive Vice President, Industry Relations, Healthcare Distribution Management Association*
- Paul Petersen, *Director, Emergency Preparedness Program, Tennessee Department of Health*

Q/A

3:00 p.m. **Adjourn**

Appendix B

Workshop Speaker Biographies

Margaret Brandeau, Ph.D., M.S., is the Coleman F. Fung Professor in the School of Engineering and a professor of medicine (by courtesy). She holds a B.S. in mathematics and an M.S. in operations research from the Massachusetts Institute of Technology, and a Ph.D. in engineering-economic systems from Stanford. She is an operations researcher and policy analyst with extensive background in the development of applied mathematical and economic models, and a distinguished investigator in HIV. Among other awards, she has received the President's Award from the Institute for Operations Research and Management Science (INFORMS) for contributions to the welfare of society, the Pierskalla Prize from INFORMS for research excellence in health care management science, the Award for Excellence in Application of Pharmacoeconomics and Health Outcomes Research from the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), a Presidential Young Investigator Award from the National Science Foundation, the Department of Management Science and Engineering Graduate Teaching Award, and the Eugene L. Grant Faculty Teaching Award. She is a Fellow of INFORMS. Professor Brandeau has published numerous articles in areas of applied operations research and policy analysis, has co-edited the books *Modeling the AIDS Epidemic: Planning, Policy, and Prediction* and *Operations Research in Health: A Handbook of Methods and Applications,* and has served as principal investigator on a broad range of funded research projects. She has served on the board of several journals, including *Operations Research, Management Science,* and *Health Care Management Science*. Her HIV research focuses on using mathematical and economic models to assess the value of different HIV and

drug abuse interventions, both in the United States and abroad. Recently she has studied policies for control of hepatitis B both in the United States and abroad, and preparedness planning for potential bioterror attacks.

Greg Burel currently serves as the Centers for Disease Control and Prevention's (CDC's) director of the Division of Strategic National Stockpile (DSNS) in the Office of Public Health Preparedness and Response. Prior to his leadership at DSNS, Mr. Burel developed an extensive background in federal government service that began in 1982. In addition to CDC, his service includes management roles with increasing responsibility with the Internal Revenue Service, General Services Administration, and the Federal Emergency Management Agency (FEMA). Mr. Burel was selected as a member of the Senior Executive Service and joined CDC in April 2005. He was initially assigned as management officer for the newly created National Center for Public Health Informatics (NCPHI). In March 2007, he assumed his current position. In this role, Mr. Burel directs the nation's premier medical material preparedness and response organization charged with delivering critical medical assets to the site of a national emergency. Mr. Burel holds a Bachelor of Business Administration degree from Georgia State University. He is a graduate of the Federal Executive Institute's Leadership for a Democratic Society, Harvard University Kennedy School of Government National Preparedness Leadership Initiative and has completed numerous courses in process improvement, contracting, finance, and incident command.

Robert L. Burhans is currently a consultant in health emergency preparedness, management, and response. He is senior executive, Health Emergency Management, for Tetra Tech Emergency Management and Community Resilience. He served as the first director of health emergency preparedness for the New York State Department of Health (NYSDOH). With 33 years of public health experience at both the state and local levels, Mr. Burhans led the state's Office of Health Emergency Preparedness, which coordinated NYSDOH's comprehensive all-hazards preparedness and response activities, including integrating local health departments and the state's health care system in readiness and response activities. He was a member of the Department's executive staff, and NYSDOH's primary preparedness liaison with federal, state, and local agencies and key community partners. He served on the state's Homeland Security Executive Committee and was NYSDOH's representative to the state's Disaster Preparedness Commission. Prior to that, he served in progressively responsible positions in environmental health. He was a founding member and chair of the Association of State and Territorial Health Officials' (ASTHO's) Directors of Public Health Preparedness Executive Committee and a member of the ASTHO

Preparedness Policy Committee. He was a member of the Institute of Medicine's Committee on Prepositioned Medical Countermeasures for the Public, and was a member of the organizing committee for the National Alliance for Radiation Readiness. He is a member of the National Advisory Committee and Model Design workgroup for the National Health Security Preparedness Index—a project of the Robert Wood Johnson Foundation and a thought leader for the National Public Health Information Coalition. Mr. Burhans earned a B.A. in biological science from the State University of New York, New Paltz, and has completed graduate-level coursework at the Nelson A. Rockefeller School of Public Administration and the State University of New York at Albany School of Public Health. He is a graduate of the Albany School of Public Health's Northeast Public Health Leadership Institute and has completed the National Preparedness Leadership Initiative at Harvard University's John F. Kennedy School of Government and School of Public Health.

Rocco Casagrande, Ph.D., is the managing director of Gryphon Scientific, LLC. His projects at Gryphon Scientific focus on bringing rigorous scientific analysis to problems of homeland defense. For the past 12 years, Dr. Casagrande has led more than 50 projects to evaluate and improve U.S. preparedness efforts for a CBRN attack or emerging infectious disease event and to support a better understanding of the threat. Dr. Casagrande also served as the principal investigator of several projects supporting the U.S. government's stance on emerging biotechnologies, including the guidance to the synthetic DNA industry and its moratorium on funding research involving engineered influenza viruses. From December 2002 to March 2003, Dr. Casagrande served as an United Nations Monitoring, Verification and Inspection Commission (UNMOVIC) biological weapons inspector in Iraq where he acted as the chief of the UN biological analysis laboratory. Prior to working for UNMOVIC, Dr. Casagrande worked in private industry as an inventor in a nano/biotechnology company. Dr. Casagrande holds a B.A. in chemistry and biology from Cornell University, where he graduated magna cum laude, and a Ph.D. in biology from the Massachusetts Institute of Technology (MIT).

Gary Disbrow, Ph.D., joined the Biomedical Advanced Research and Development Authority (BARDA) in January 2007 and began working on the smallpox vaccine program. Dr. Disbrow played a key role in awarding a contract for the modified vaccinia Ankara (MVA) vaccine. MVA is a smallpox vaccine developed for immunocompromised individuals who are contraindicated for the currently available live vaccine, Acam2000. Dr. Disbrow accepted the position of deputy director, chemical, biological, radiological, and nuclear (CBRN) Division of Countermeasures in October

2008 and has been overseeing the budget for both advanced research and development and Project BioShield efforts. BARDA's advanced research and development efforts have grown significantly since 2007. In October 2013, Dr. Disbrow was named the acting director of the CBRN Division after the departure of Dr. Gerald Kovacs. The CBRN Division has successfully licensed/approved two novel products under FDA's Animal Rule, delivered 11 new products to the Strategic National Stockpile (SNS), and built a robust pipeline of candidate products under advanced research and development. Prior to joining BARDA, Dr. Disbrow was an assistant professor of oncology and pathology at Georgetown Medical Center, where he worked on the development of the human papillomavirus vaccine (HPV), which is currently licensed and available in the United States. In addition to the virus-like particle (VLP) technology, Dr. Disbrow and his colleagues developed a next-generation vaccine based on GST-L1 fusion technology funded by the Bill & Melinda Gates Foundation. In addition, he worked on discovery of therapeutic agents for the treatment of cervical intraepithelial neoplasia (CIN) grades I and II. This work led to the discovery of a lead compound that is extracted from a Chinese herb. Dr. Disbrow attended the University of Rochester and Georgetown University for his undergraduate degree and Ph.D., respectively.

Jason Frederick is vice president of operations at FedEx Custom Critical, a leading North American expedited freight carrier located in Green, Ohio. He oversees the company's Surface Expedite, Air Expedite, and White Glove Services operations, as well as the Safety and Recruiting departments. Mr. Frederick is responsible for strategic planning, employee development, and process improvements to ensure the highest quality and most efficient service to customers. Mr. Frederick has more than 20 years of experience in operations and sales. He joined FedEx Custom Critical in 2007 after serving in various management roles for the operations team at FedEx Freight. Mr. Frederick has been recognized for his accomplishments by receiving the FedEx Five Star Award in 2013, Corporate Account Manager of the Year Award in 2005, and the Extra Mile Award 2 years later. Mr. Frederick also received the Human Resources Manager of the Year Award in 2000 and 2002 for his leadership efforts. Mr. Frederick has a bachelor's degree in business administration from Walsh University.

Frank Gottron, Ph.D., is a specialist in science and technology policy, Congressional Research Service (CRS). Dr. Gottron earned his B.S. in biological sciences from the University of Maryland, Baltimore County, and his Ph.D. in neuroscience from Washington University in St. Louis. He joined the Congressional Research Service in 2001. Housed in the Library of Congress, CRS provides members of Congress, congressional committees, and

their staff with timely, objective, and nonpartisan policy analysis. At CRS, Dr. Gottron focuses on science and technology issues related to homeland security, biomedical research, and the role of the federal government in supporting and regulating scientific research.

Richard Jaffe, Ph.D., M.S., brings almost 30 years of technical and operational experience in government, academia, military, and industry. He utilizes this insight and expertise to provide program analysis and evaluation to improve the process and management of the Division of Medical Countermeasures Strategy and Requirements within the Office for Policy and Planning, Office of the Assistant Secretary of Preparedness and Response (ASPR), Department of Health and Human Services (HHS), for which he currently serves as director. He is an internationally recognized subject-matter expert in CBRN defense issues and public policy, public health, biosurveillance, emerging infectious diseases, and scientific issues in general. This is accomplished by his work as a facilitator and liaison between the client and the external scientific community in this rapidly changing arena. This is performed with the application of business improvement processes, assessing operational studies and reports, and investigating specific research topics to improve the government's ability to respond to quick-reaction, high-level tasks and actions in a responsive manner. Dr. Jaffe's division leads the efforts to develop policy initiatives, planning and analysis, activities for storage, dispensing, administration, and so on, and requirements for medical countermeasures that help protect the U.S. civilian population during public health emergencies. This requires working in close collaboration with the HHS Enterprise (Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Institutes of Health) to coordinate interagency collaboration, to include the Department of Homeland Security, the Department of Defense, and the Department of Veterans Affairs, on a broad range of policy options and strategic planning initiatives to support domestic and international public health preparedness and response activities. Dr. Jaffe received a Ph.D. in microbiology and immunology from Medical College of Virginia, an M.S. in human genetics from George Washington University, and a B.S. in microbiology from the University of Maryland. Dr. Jaffe is a board-certified medical technologist and served honorably in the U.S. Air Force before separating at the rank of Major. He is a recent graduate of the National Preparedness Leadership Initiative's Executive Education Program at the Harvard Kennedy School of Government.

Ali S. Khan, M.D., M.P.H., is a former assistant surgeon general and current dean of the College of Public Health at the University of Nebraska Medical Center (UNMC). His career has focused on health security, global

health, and emerging infectious diseases. He completed a 23-year career as a senior director at CDC, where he led and responded to numerous high-profile domestic and international public health emergencies including Hantavirus, Ebola, monkeypox, avian influenza, Rift Valley fever, severe acute respiratory syndrome, the Asian tsunami, and Hurricane Katrina. He was one of the main architects of CDC's public health bioterrorism preparedness program. In 2015, he responded to the West Africa Ebola outbreak in Sierra Leone as a World Health Organization consultant, and he enrolled UNMC as a member of the Global Outbreak Alert and Response Network (GOARN). Dean Khan's vision is for the UNMC College of Public Health to play an integral role in making Nebraska the healthiest state in the Union as a national and global model for wellness.

Christine Kosmos, M.S., is director of the Division of State and Local Readiness in OPHPR, CDC. Ms. Kosmos has served in this role since 2009 and has directed a number of important initiatives designed to improve state and local readiness to respond to emergencies, including (1) developing a set of core public health capabilities every state and local public health agency needs to be capable of performing and (2) redesigning the medical countermeasures operational readiness assessment process for state and local public health that guides agencies on how to prepare for large-scale responses that require the use of medical countermeasures. Before joining CDC, Ms. Kosmos worked for more than 20 years in state and local public health agencies and served as the deputy commissioner for the City of Chicago. In that role, she managed both public health and health care system preparedness and response for Chicago. Recently, as a senior executive at CDC, Ms. Kosmos was awarded the Presidential Rank Award—the highest award for federal senior executives—for her outstanding contributions to preparing the nation for any public health emergency. Ms. Kosmos is a registered nurse and began her career as a staff nurse. She later served as the senior manager of one of the busiest trauma centers in Chicago before joining the City of Chicago Department of Public Health as a senior deputy.

Brad Leissa, M.D., received his medical degree from Ohio State University. He received postgraduate training in internal medicine and pediatrics at the Ohio State University Hospitals. He went on to receive subspecialty training in pediatric infectious diseases from George Washington University and the Children's National Medical Center in Washington, DC. He began his career at the Food and Drug Administration in 1989 as a medical officer with a focus on anti-infective drug development in the Center for Drug Evaluation and Research (CDER). During the October 2001 anthrax attacks, Dr. Leissa was assigned as the FDA liaison to the Secretary's Bioterrorism Command Center at HHS. Since then he has continued to work

on medical countermeasures development and emergency response planning and works closely with SNS staff on regulatory issues. He currently holds the position of deputy director of CDER's Counter-Terrorism and Emergency Coordination Staff (CTECS).

Jennifer Lixey Terrill, M.A., has been at the Michigan Bureau of Emergency Medical Services (EMS), Trauma, & Preparedness (BETP) since May 2008. She served as the state SNS Coordinator and Cities Readiness Initiative coordinator until 2015, when she was promoted to her current position. Ms. Lixey Terrill served on the ASTHO Emergency Medical Countermeasure Steering Committee from 2010 to 2015, and was chair of that committee from 2012 to 2014. Prior to working at BETP, Ms. Lixey Terrill served as the administrative director of the nongovernmental organization Crossing Borders, founded by fellow University of Michigan undergraduate students. In addition to being the director, Ms. Lixey Terrill lived in a rural commune in northern Vietnam where she conducted research linking nutrition knowledge systems, feeding practices, and food production systems to the increasingly high rates of child malnutrition. Upon her return from Vietnam, Ms. Lixey Terrill led a team of student researchers in their preparation for a trip to the Dominican Republic to complete a study on the mitigation of HIV/AIDS in children and young adults. Ms. Lixey Terrill graduated from the University of Michigan, Ann Arbor, with a pre-allied health degree in biomechanics, physiology, and neuro-motor control from the Movement Science Program within the School of Kinesiology. During her time at the University of Michigan, Ms. Lixey Terrill worked in the Internal Medicine and Infectious Disease Division at the University of Michigan Hospital where she studied antibiotic-resistant, infectious bacterial diseases in the Surgical Intensive Care Unit. In 2011, Ms. Lixey Terrill graduated with honors from the American Military University where she earned a Master of Arts in Homeland Security. Ms. Lixey Terrill has actively participated in the Community Health Emergency Coordination Center (CHECC) activations, to include the 2009 novel H1N1 public health emergency and the recent Ebola response.

Michael Loehr, M.R.P., has served as the chief of emergency preparedness and response for the Washington Department of Health since February 2014. His responsibilities with the Department of Health include establishing and maintaining partnerships with health care facilities, tribes, local health jurisdictions, community based organizations, businesses, state agencies, neighboring states, and Canadian provinces; developing all hazards operational readiness within the Department of Health; and implementing strategic initiatives that increase and sustain statewide disaster response capability. Mr. Loehr is an affiliate professor in the University

of Washington School of Public Health, and serves on the World Health Organization's Interdisciplinary Advisory Group on Mass Gatherings. Prior to joining the Washington Department of Health, Mr. Loehr served for 11 years as the preparedness director with Public Health–Seattle & King County, and 2 years as the operations chief for the King County Office of Emergency Management. Before coming to Washington, he served for 6 years as an operations and response leader with the Florida Division of Emergency Management. Mr. Loehr has more than 20 years of disaster preparedness and response experience. He has managed local and state emergency operations centers and has provided training and technical assistance on disaster response at the national and international levels. He is a graduate of the University of North Carolina with a master's degree in regional planning.

Thomas Mattingly graduated from the University of Mississippi in 1982 with a degree in business. Having started as a part-time warehouseman at Metro Logics in 1980, Mr. Mattingly progressed through various positions and became president in 2007. With more than 35 years of experience in the temperature-controlled distribution industry, and 16 years of experience providing those services to the SNS, Mr. Mattingly is well versed in all facets of being an effective commercial third-party logistics provider.

John S. Parker, M.D., is a physician and is the past chairman of the National Biodefense Science Board—now known as the National Preparedness and response Science Board. He is a cardiothoracic surgeon and a retired Major General from the Army. His 39 years in the Army saw him practice surgery, teach, and manage very large health care institutions. He is an associate professor of surgery at the Uniformed Services School of Medicine. He served as the assistant surgeon general of the Army. He has broad experience in managing or being significantly involved in disasters such as Chernobyl, the Beirut bombing, the *USS Stark* incident, Amerithrax (Senate office building exposure to Anthrax), and the Berlin disco bombing. His last assignment in the Army was as Commanding General of the U.S. Army Medical Research and Materiel Command and Fort Detrick. Following retirement, Dr. Parker worked for the Science Applications International Corporation (now Leidos) supporting work for defense against weapons of mass destruction and significant work in the biological threat reduction area.

Sally Phillips, R.N., Ph.D., was selected to serve as the deputy assistant secretary for policy in ASPR, HHS, in October 2015. In this position, Dr. Phillips is responsible for leading preparedness and response policy development and analysis; strategic planning and evaluation; and ensuring the coordination and collaboration of domestic and international partners in

order to reduce the adverse health effects of public health emergencies and disasters. In August 2010, Dr. Phillips joined the Department of Homeland Security (DHS) Office of Health Affairs (OHA) as the deputy assistant secretary and director for the Health Threats and Resilience Division. Later in her tenure, Dr. Phillips served as the acting principal deputy assistant secretary within DHS OHA. In fall 2001, Dr. Phillips joined the Agency for Healthcare Research and Quality (AHRQ) in Rockville, Maryland, as a senior nurse scholar, where she managed a portfolio ranging from bioterrorism preparedness to multidisciplinary safety education and related health care workforce initiatives. Dr. Phillips was appointed director of the Bioterrorism Preparedness Research Program (later the Public Health Emergency Preparedness Research Program) in 2002 and served in that capacity until July 2010. In July 2009, at the request of the ASPR, Dr. Phillips was detailed to ASPR as a senior advisor. In this capacity Dr. Phillips was an active member of the H1N1 Task Force where she demonstrated leadership in addressing medical surge capacity and other policy issues related to the health care system's preparedness and response to H1N1. Prior to joining the staff at AHRQ, Dr. Phillips was a Robert Wood Johnson Foundation Health Policy Fellow and Health Policy Analyst for Senator Tom Harkin for 2 years. She has also had a distinguished academic career in the Schools of Nursing and Medicine at the University of Colorado, Health Science Center. Dr. Phillips received a bachelor's degree from Ohio State University, a master's degree from the University of Colorado, and a doctorate from Case Western Reserve University. Her primary area of clinical practice is the care of women, infants, and children, with a specialty in the care of high-risk neonates.

Michael Poole, M.S.P.H., graduated in 2007 from the University of Alabama at Birmingham (UAB) with an M.S.P.H. in epidemiology. Upon graduation, Mr. Poole began work at the South Central Center for Public Health Preparedness, organizing and conducting training for first responders, receivers, and public health professionals. He holds a Master Exercise Practitioner certification from FEMA and is certified in public health by the National Board of Public Health Examiners. Mr. Poole has served as the state SNS coordinator for Texas since March 2010. He coordinates state initiatives through 8 health service regions, consisting of approximately 50 local health departments, and 3 Cities Readiness Initiatives Metropolitan Statistical Areas. Mr. Poole is currently serving as chair for the ASTHO Emergency Medical Countermeasures Steering Committee.

Lewis Radonovich, M.D., is director of the national Center for Occupational Health and Infection Control (COHIC) in the Department of Veterans Affairs (VA), Public Health. As director, Dr. Radonovich leads the

performance of health policy analysis, demonstration projects, and highly applied operational research aimed at answering important questions about public health practice and health care delivery in the nation's VA medical centers. Projects typically involve the disciplines of infection control, occupational health, industrial hygiene, and/or biosafety. Key projects over the past 2 years have included Project BREATHE (Better Respiratory Equipment using Advanced Technologies for Healthcare Employees), an interagency effort of the U.S. government, chaired by the VA, that has sought to shepherd one or more new respirators for health care workers to the U.S. marketplace; several energy-saving and infection control projects that have sought to improve methods of ventilation and infection control while meeting current energy reduction guidelines for VA medical centers; and the Respiratory Protection Effectiveness Clinical Trial (ResPECT), a multisite study comparing the amount of protection provided to health care workers by N95 respirators and surgical masks against influenza and other respiratory illnesses. Dr. Radonovich is board certified in internal medicine and holds appointments in the Colleges of Public Health and Medicine at the University of Florida. He has practiced internal and occupational medicine since 1997 and continues to see patients on a part-time basis. He was formerly a senior associate at the Center for Biosecurity at the University of Pittsburgh Medical Center and a senior fellow at the Johns Hopkins Center for Biodefense Strategies. He has authored numerous peer-reviewed articles and government reports in the field of biosecurity and related disciplines.

Susan E. Sherman, J.D., M.S., is a senior attorney with the Office of the General Counsel, HHS. She provides legal advice to the ASPR, advising on a wide variety of legal issues related to federal public health emergency preparedness and response. Earlier in her career at HHS, she advised the National Institutes of Health on legal issues related to biomedical research grants administration, human subjects protection, and laboratory animal welfare. Prior to working at HHS, she worked at the Institute of Medicine on studies leading to publications, including *The Future of Public Health and Quality of Care in Nursing Homes*. She holds a law degree from the George Washington University National Law Center and a master's degree in health science from the Johns Hopkins Bloomberg School of Public Health.

Daniel M. Sosin, M.D., M.P.H., is the acting director of the Division of Select Agents and Toxins, CDC, and serves as the deputy director and chief medical officer of OPHPR, CDC. In this role, he is the lead science advisor and provides scientific representation for preparedness on behalf of the OPHPR director and CDC. He serves as a liaison to CDC programs and external partners and ensures strategy and program coordination for OPHPR in medical and public health preparedness and response. Dr. Sosin

began his CDC career in 1986 as an Epidemic Intelligence Service (EIS) officer assigned to Kentucky. He served as associate director for science at the National Center for Injury Prevention and Control, coordinating national injury surveillance and extramural research activities. He also served as director of CDC's former Division of Public Health Surveillance and Informatics, where he managed notifiable disease surveillance systems and tools and introduced CDC to biosurveillance concepts. Dr. Sosin joined OPHPR in 2004 as the senior advisor for science and public health practice. In 2008, Dr. Sosin initiated the Biosurveillance Coordination Unit at the request of CDC and OPHPR directors. In this role he was the federal lead for the development and integration of the nationwide biosurveillance capability for human health. Dr. Sosin served as acting OPHPR director from January 2009 through July 2010. Dr. Sosin is board certified in preventive medicine and internal medicine and is a fellow of the American College of Physicians. He received his bachelor's degree in biology from the University of Michigan; his medical degree from Yale University School of Medicine; and his master's degree in epidemiology from the University of Washington School of Public Health.

David Starr, M.A., is director of the Countermeasures Response Unit in the Office of Emergency Preparedness and Response at the New York City (NYC) Department of Health and Mental Hygiene (DOHMH). Since 2006, he has overseen NYC's medical countermeasures planning, including SNS receipt and distribution, and citywide mass dispensing planning. During his tenure at DOHMH, he and his team have built unique, flexible, and dynamic operational plans that have been tested in real life, and numerous full-scale exercises, including the Rapid Activation for Mass Prophylaxis Exercise (RAMPEx) in 2014, the largest no-notice full-scale exercise ever conducted in NYC with 30 PODs set up citywide by more than 800 staff, supported by 22 trucks escorted by more than 30 law enforcement units from 3 jurisdictions, all in less than 8 hours. In fall 2014, he served as the Quarantine and Monitoring Branch director for much of NYC's response to Ebola, and in April 2015, he deployed to West Africa for 5 weeks to support CDC's response to Ebola in Guinea. He has testified before the House Subcommittee on Emergency Preparedness, Response and Communications as well as to past Institute of Medicine committees on medical countermeasures issues. He received his master of international affairs and international security policy from Columbia University where he also received an international economics teaching fellowship and interned with the United Nations and the U.S. Army Corps of Engineers. Prior to joining DOHMH, he spent 3 years managing a reconstruction project at an agricultural training center in Burkina Faso and responded to various NYC emergencies as a volunteer emergency medical technician.

COL Alex Zotomayor, M.S., was born in the Philippines in 1966 but grew up in Chicago. He graduated from Northwestern University with a bachelor of arts in biology. He has a master of science in health sciences–health care management from Trudent University International. In 1988, he was commissioned as a Second Lieutenant in the Medical Service Corps from the Reserve Officers Training Corps, Loyola University of Chicago, graduating as a Distinguished Military Graduate. After attending the Army Medical Department Officer Basic Course, COL Zotomayor began his military career in a variety of positions throughout the 194th Separate Armored Brigade at Fort Knox, Kentucky, to include Platoon Leader and Assistant S-4, 42nd Field Hospital; Brigade Medical Supply Officer, 75th Forward Support Battalion; and Platoon Leader, 1-10th Cavalry Combined Arms Task Force. He deployed to Honduras to serve as the Company Commander for the Medical Element, Joint Task Force Bravo. Upon redeployment, he attended the Army Medical Department Officer Advance Course and was then assigned to the 131st Field Hospital, Fort Bliss, Texas, serving as the Battalion S-4 and, subsequently, as Company Commander. Following command, COL Zotomayor was assigned to Fort Sam Houston, Texas, as the Medical Logistics Officer, Directorate of Combat and Doctrine Development, Army Medical Department Center and School. He transitioned to Fort Irwin, California, serving as the chief, Logistics Division, Weed Army Community Hospital. He moved on to Fort Hood, Texas, and was assigned as the Support Operations Officer, 1st Medical Group, and as the Medical Logistics Officer, III Corps Surgeon's Office. He returned to Fort Sam Houston as the chief of the Battle Lab Support Element, Army Medical Department Center and School. COL Zotomayor's next assignment was as the Deputy G4, 3d Medical Command, Fort Gillem, Georgia. In 2004, he deployed to Camp Arifjan, Kuwait, to serve as the Medical Logistics Officer for the Coalition Forces Land Component Command Surgeon's Office. In 2006-2007, he deployed as the G4 with the Task Force 3rd Medical Command at Camp Victory, Iraq. COL Zotomayor's next duty assignment was as the division chief for the Operational Customer Facing Division and for the Medical Materiel Executive Agent Office, Medical Directorate, Defense Logistics Agency (DLA) Troop Support, Philadelphia. In 2010, he deployed as Detachment Commander, DLA Support Team, Kandahar Airfield, Afghanistan. From 2011 to 2014, he moved to Hawaii where he was assigned as the Pacific Region Medical Command G4 and the Tripler Army Medical Center Chief of Logistics. In July 2014, COL Zotomayor returned to the DLA Troop Support where he currently serves as the director, Medical Supply Chain. COL Zotomayor's military education includes the Army Medical Department Officer Basic Course and Officer Advance Course, Medical Logistics Management Course, Combined Arms and Services Staff School, and Command and General Staff College. His awards and decora-

tions include the Bronze Star Medal, Defense Meritorious Service Medal, Meritorious Service Medal (eight awards), Joint Service Commendation Medal, Army Commendation Medal (three awards), Joint Service Achievement Medal (two awards), Army Achievement Medal, National Defense Service Medal (two stars), Afghanistan Campaign Medal, Iraq Campaign Medal (two stars), Global War on Terrorism Service Medal, Army Service Ribbon, Overseas Service Ribbon, and North Atlantic Treaty Organization Medal. He has earned the Expert Field Medical Badge and the Parachutist Badge, and is a member of the Order of Military Medical Merit.