

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE STRATEGIC NATIONAL STOCKPILE
WAS NOT POSITIONED TO RESPOND
EFFECTIVELY TO THE COVID-19
PANDEMIC**

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The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: October 2023

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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Audit

HHS is the U.S. Government's principal agency for protecting the health of all Americans. Included in its role of protecting the health of Americans is the responsibility to respond to pandemics. The Strategic National Stockpile is part of HHS's Federal medical response infrastructure. Before COVID-19, the most recent pandemic occurred in 2009 and was caused by the H1N1 influenza virus. When COVID-19 first reached the United States in January 2020, some public health officials criticized Stockpile management for failing to act with urgency when responding to State requests for personal protective equipment (PPE).

Our objective was to determine whether the Stockpile, under the direction of the Administration for Strategic Preparedness and Response (ASPR), was effective in responding to the COVID-19 pandemic.

How OIG Did This Audit

We interviewed officials from ASPR, the Centers for Disease Control and Prevention, the Stockpile, the Biomedical Advanced Research and Development Authority, and the U.S. Marshals Service and assessed available documentation during our audit period, which covered January through June 2020.

The Strategic National Stockpile Was Not Positioned To Respond Effectively to the COVID-19 Pandemic

What OIG Found

The Stockpile was operationally effective in distributing its limited inventory in response to the COVID-19 pandemic, based on established policies and procedures and consistent with its statutory obligations. However, the Stockpile's strategic effectiveness and its ability to meet COVID-19 demands were impacted by external and internal factors outside of its control.

Despite the challenges it faced, the Stockpile used established processes to distribute its limited supply of PPE and other items during the first 3 months of 2020. However, because of external and internal factors beyond its control, the Stockpile could not meet demand and was not equipped to handle the COVID-19 pandemic.

What OIG Recommends and ASPR Comments

We made several recommendations, including that ASPR: (1) mitigate the risk presented by relying on foreign supply chains and just-in-time inventory strategies when determining annual Stockpile purchases; (2) develop a strategic plan for the Stockpile that clearly defines the goals and objectives of the Stockpile and the Stockpile's roles and responsibilities for responding to emergency events, including pandemics; and (3) work to increase the Stockpile's annual funding to keep pace with the Stockpile's increased responsibilities. The full recommendations are in the report.

In response to our draft report, ASPR concurred with our first and third recommendation. ASPR neither concurred nor non-concurred with our second, fourth, fifth, and sixth recommendation. For these recommendations ASPR instead discussed actions it has taken or plans to take to implement our recommendations. ASPR stated that it established the Office of the Industrial Base Management and Supply Chain to address the risk of relying on foreign supply chains and just-in-time inventory strategies. ASPR also stated that the Stockpile continues efforts to clarify capabilities for State, local, territorial, and Tribal partners and develop and share resources with them. ASPR continues efforts to fully integrate the Stockpile into ASPR, while relaunching the Public Health Emergency Medical Countermeasures Enterprise and continuing to work with Congress to advocate for additional funding. We commend ASPR on the actions it has taken or is taking to address our recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

The Department of Health and Human Services (HHS) is the U.S. Government’s principal agency for protecting the health of all Americans. Included in its role of protecting the health of Americans is the responsibility for responding to pandemics. The Strategic National Stockpile (Stockpile) is part of HHS’s Federal medical response infrastructure. The Stockpile is a repository of vaccines, antibiotics, antidotes, antitoxins, medical devices, supplies, and medications meant to supplement and resupply State and local public health agencies in the event of a national emergency in the United States or its Territories.

From 1999 to 2018, the Stockpile was managed by the Centers for Disease Control and Prevention (CDC). During that time, we conducted several audits that identified systemic issues that could place Stockpile inventory at risk.¹ Effective October 1, 2018, HHS transferred responsibility for the Stockpile from CDC to the Administration for Strategic Preparedness and Response (ASPR).² A change in responsibility for a program or activity can create new risks that often require effective mitigating controls and strategies.

Before COVID-19, the most recent pandemic occurred in 2009 and was caused by the H1N1 influenza virus. In response to that virus, the Stockpile released antiviral medications, vaccines, diagnostics, and personal protective equipment (PPE). When COVID-19 first reached the United States in January 2020, some public health officials criticized Stockpile management for failing to act with urgency when responding to State requests for PPE. Multiple members of Congress requested that the Office of Inspector General (OIG) review various aspects of Stockpile operations during the COVID-19 pandemic.

COVID-19 has created extraordinary challenges for the delivery of health care and human services to the American people. As the oversight agency for HHS, OIG oversees HHS’s COVID-19 response and recovery efforts. This audit aligns with OIG’s COVID-19 oversight priorities as outlined in our COVID-19 response strategic plan.³

¹ *Public Summary Report: Readiness of CDC’s Strategic National Stockpile Could Be at Risk in Case of a Public Health Emergency* ([A-04-16-03554](#)), issued June 2017.

² During our audit, ASPR was the Office of the Assistant Secretary for Preparedness and Response. In July 2022, after our audit period, ASPR was elevated from a staff division to an operating division and was renamed the Administration for Strategic Preparedness and Response. In this report, we refer to ASPR as the Administration for Strategic Preparedness and Response, and “the ASPR” as the head of that office.

³ OIG’s COVID-19 response strategic plan and information on OIG’s oversight activities can be accessed at <https://oig.hhs.gov/coronavirus/index.asp>.

OBJECTIVE

Our objective was to determine whether the Stockpile, within ASPR, was effective in responding to the COVID-19 pandemic.

BACKGROUND

Strategic National Stockpile

The Stockpile was established in 1998 with the passage of the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, which provided funding for the stockpiling of pharmaceuticals and vaccines.⁴ In the wake of the terrorist attacks on September 11, 2001, and subsequent anthrax attacks, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which directed the HHS Secretary to maintain a “Strategic National Stockpile” with an official mission 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.”⁵ To meet this mission, the Stockpile maintains a national repository of antibiotics, chemical antidotes, vaccines, antitoxins, life-support medications, medical devices, intravenous administration supplies, and other supplies,⁶ and delivers those materials to supplement and resupply State, local, territorial, and Tribal (SLTT) inventories. In addition to stockpiling certain materials, the Stockpile uses its purchasing power to acquire needed materials that can be distributed during a public health emergency.

Since its mission was established in 2002, a series of laws and events have transformed the Stockpile’s focus from bioterrorism preparedness (the ability to respond to chemical, biological, radiological, and nuclear (CBRN) incidents) to an all-hazards level of preparedness (the ability to respond to a host of public health emergencies, including emerging infectious diseases and natural disasters). Multiple laws, regulations, and agencies place requirements on or provide input into the role and function of the Stockpile. In particular, the ASPR-led Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and its internal HHS agency and interagency partners have input into the role and function of the Stockpile.

The Stockpile has various options at its disposal for responding to a public health emergency. It may use 12-hour push packages, managed inventory, or its purchasing power when tasked to

⁴ The Stockpile, in its original form as the National Pharmaceutical Stockpile (NPS), was created in 1998. Congress began annually funding CDC for pharmaceutical and vaccine stockpiling activities under the NPS (P.L. No. 105-277 (October 21, 1998)).

⁵ P.L. No. 107-188 (June 12, 2002).

⁶ 42 U.S.C. § 247d-6b(a).

provide materials not in its inventory.⁷ The Stockpile has an influenza pandemic plan that includes large-scale deployment of its inventory using a population-based distribution plan that pushes items to jurisdictions in three phases over the course of 28 days. The Stockpile has deployment teams to assist jurisdictions with a public health emergency; an inventory tracking system to account for its inventory balances and distributions; pre-established facility locations for receiving shipments; strategic, tactical, and support communication channels; and training programs for jurisdictions.

Administration for Strategic Preparedness and Response

Established in 2006, ASPR was created to address gaps in emergency management and response.⁸ Subject to the authority of the Secretary, ASPR leads the Nation’s medical and public health preparedness for, response to, and recovery from disasters and public health emergencies.⁹ ASPR collaborates with hospitals; health care coalitions; biotech firms; community members; SLTTs; and other partners across the country to improve readiness and response capabilities.

When a public health emergency arises, ASPR coordinates the Federal Government’s response efforts from the Secretary’s Operations Center (SOC), which is the emergency operations center for HHS. Within the SOC, the SOC Director works closely with the Director of Emergency Management and Medical Operations to oversee the coordination, notification, activation, mobilization, deployment, and demobilization of ASPR resources.

Public Health Emergency Medical Countermeasures Enterprise

Established by HHS in 2006, PHEMCE’s mission is to: (1) define and prioritize requirements for public health emergency medical countermeasures (MCMs); (2) coordinate research, all stages of product development, and procurement activities addressing the requirements; and (3) set

⁷ The 12-hour push packages are transport-ready containers (strategically located across the country) that can supply a community with a broad range of pharmaceuticals and medical supplies in the event of a large-scale public health incident related to an unknown agent, or to help initiate response activities while more targeted countermeasures from the “managed inventory” are being mobilized.

⁸ Pandemic and All-Hazards Preparedness Act, P.L. No. 109-417 (Dec. 19, 2006).

⁹ 42 U.S.C. § 300hh-10.

deployment and use strategies for MCMs held in the Stockpile.^{10, 11} Led by the ASPR, PHEMCE coordinates the efforts of numerous Federal agencies that have roles in optimizing public health emergency preparedness with respect to the creation, storage, and use of MCMs. PHEMCE's internal HHS agency and interagency partners consist of: ASPR, CDC, the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Department of Defense (DoD), Department of Homeland Security, Department of Veterans Affairs, Office of the Director of National Intelligence, and the Department of Agriculture. PHEMCE coordinates these Federal agencies' efforts to enhance the Nation's ability to respond to CBRN threats and prepare for emerging infectious diseases from an MCM perspective.

PHEMCE recommends which products and the quantities the Stockpile should include in its inventory. PHEMCE's role is to assist the Secretary with making recommendations regarding research, development, procurement, stockpiling, deployment, distribution, and prioritization of MCMs. Additionally, PHEMCE assists the Secretary in developing strategies that may be applicable to the Stockpile.¹² In consultation with PHEMCE, the Secretary is required to conduct an annual threat-based review to include a review of the contents of the Stockpile.¹³ PHEMCE also assists the ASPR in developing the PHEMCE Strategy and Implementation Plan (PHEMCE SIP), which is a coordinated strategy and plan for MCMs to address chemical, biological, radiological, and nuclear threats. The PHEMCE SIP provides the blueprint it will use to enhance national health security through the procurement and effective use of MCMs. Using this PHEMCE SIP, the ASPR develops and updates annually a coordinated 5-year budget plan for MCM development.¹⁴ This multiyear budget highlights spending plans for development and procurement of MCMs with budget estimates for Stockpile, the Biomedical Advanced Research and Development Authority (BARDA), NIH, and FDA and provides Congress with information on funds that have been invested in specific threat areas and future plans for investments in specific threat areas, based on availability of funds. PHEMCE faces the challenge of making recommendations that address a plethora of low-probability, high-consequence

¹⁰ 71 Fed. Reg. 38403, 38404 (July 6, 2006). In 2019, PHEMCE was enacted into law, and its functions are fully summarized in 42 U.S.C. § 300hh-10a.

¹¹ MCMs include both pharmaceutical interventions (e.g., vaccines, antimicrobials, antidotes, and antitoxins) and nonpharmaceutical interventions (e.g., ventilators, diagnostics, personal protective equipment, and patient decontamination) that are used to prevent, mitigate, or treat the adverse health effects of a deliberate, unintentional, or naturally occurring public health emergency. They include qualified countermeasures (42 U.S.C. § 247d-6a(a)(2)), qualified pandemic or epidemic products (42 U.S.C. § 247d-6d(i)(7)), and security countermeasures (42 U.S.C. § 247d-6b(c)(1)(B)).

¹² 42 U.S.C. § 300hh-10a(c)(1).

¹³ 42 U.S.C. § 247d-6b(a)(2) and (3). When referring to the process of conducting this review, we refer to the "annual threat-based review" or the "annual review." When referring to the report required by 42 U.S.C. § 247d-6b(a)(2)(A), we refer to the "annual review report."

¹⁴ 42 U.S.C. § 300hh-10(d) and (b)(7). The PHEMCE SIP is required to be submitted annually to Congress. Beginning in June 2019, the PHEMCE SIP is required to be submitted beginning on March 15, 2020, and then biennially. We also refer to the PHEMCE SIP as the "MCM strategic plan."

threats while also maintaining the capacity to rapidly respond to novel threats like emerging or reemerging infectious diseases.

HOW WE CONDUCTED THIS AUDIT

To conduct this audit, we assessed the effectiveness of the Stockpile's internal controls related to the strategies and operations for distributing available inventory during early COVID-19 response efforts. Specifically, we reviewed Stockpile operations during the first 6 months of 2020 and assessed related strategies, operations, and various factors that ultimately affected the Stockpile's ability to effectively respond to the pandemic. In addition, we used available testimony and documentary evidence to determine what impact other organizations' strategic decisions (related to Stockpile inventory) had on the Stockpile's pandemic response. We interviewed officials from ASPR, CDC, the Stockpile, BARDA, and the U.S. Marshals Service and assessed available documentation during our audit period, which covered January through June 2020.

We used the Government Accountability Office's *Standards for Internal Control in the Federal Government; September 2014*, GAO-14-704G (Green Book) and the Government Performance and Results Modernization Act of 2010 (GPRA), P.L. No. 111-352 (Jan. 4, 2011), as the basis of our review of operational and strategic internal controls. The Green Book states that effective operations produce the intended results of an organization through operational processes (Green Book Overview 2.19). In evaluating operating effectiveness, management determines whether controls were applied at relevant times during the period under evaluation, the consistency with which those controls were applied, and by whom or by what means the controls were applied (Green Book Overview 3.06).

We reviewed Stockpile operations by reviewing all five components of Green Book internal controls:

1. Control Environment – The control environment provides the foundation of an internal control system. It provides the structure that management and the oversight body use to achieve its objectives.
2. Risk Assessment – Management assesses the risks from both external and internal sources facing an entity. This assessment provides the basis for developing appropriate responses to those identified risks.
3. Control Activities – Control activities are the actions management establishes through policies and procedures to achieve objectives and respond to risks.
4. Information and Communication – This component pertains to the quality information that management and personnel communicate and use to support the internal control system. Access to relevant and reliable communication related to internal as well as external events is vital for an entity to be effective.

5. Monitoring – This component pertains to activities that management establishes and operates to assess the quality of performance over time. The internal control system must be monitored to keep it aligned with changing objectives, environment, laws, resources, and risks.

We used GPRA to assess the strategic effectiveness of decisions made on behalf of the Stockpile on what should be included in its inventory. GPRA requires Federal agencies to have strategic goals and objectives that contain:

- a comprehensive mission statement covering the major functions and operations of the agency,
- a description of how the goals and objectives are to be achieved including the operational process, and
- key factors beyond the agency’s control that could significantly affect the achievement of the general goal and objectives.

During the course of our audit, we determined that numerous internal and external factors affected the Stockpile’s ability to respond effectively during the COVID-19 pandemic and were outside of the Stockpile’s control. We did not review the decision-making process used by the ASPR, nor did we review ASPR’s response protocols during the pandemic.¹⁵

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains more details of our audit scope and methodology.

FINDINGS

We identified certain factors that affected the Stockpile’s effectiveness in responding to the COVID-19 pandemic. Operationally, the Stockpile distributed its limited inventory in response to the COVID-19 pandemic by effectively following its established policies and procedures. However, the Stockpile’s strategic effectiveness and its ability to meet COVID-19

¹⁵ We have ongoing work to determine whether ASPR has implemented controls and mitigating strategies to address identified risks associated with coordinating the Government’s response to emergency events. [Audit of ASPR’s Actions to Address Previously Identified Deficiencies in HHS’s Ability to Coordinate the Federal Government’s Response to Emergency Events.](#)

demands were impacted by external and internal factors outside of its control. External factors included the following:

- Supply chains relied on foreign manufacturers and could not meet demand during COVID-19.
- Inventory management strategies at hospitals and SLTTs contributed to PPE shortages.
- Stockpile strategies and Government preparedness training generally focused readiness on CBRN response efforts as well as influenza mitigation.

Internal factors included the following:

- The Stockpile's role and operational activities had expanded since its inception, and funding levels have not kept pace with that expansion.
- The Stockpile annual review and PHEMCE Strategy and Implementation Plan were not completed leading up to the pandemic.
- The Stockpile's transfer from CDC to ASPR had not been completed as of the beginning of the pandemic.
- Communication with SLTTs was disrupted when management of the Federal Government's COVID-19 response was transferred from HHS to the Federal Emergency Management Agency (FEMA).

Despite the challenges it faced, the Stockpile used established processes to distribute its limited supply of PPE and other supplies during the first 3 months of 2020. However, because of external and internal factors beyond its control, the Stockpile could not meet demand and was not equipped to handle the COVID-19 pandemic. After exhausting its inventory, the Stockpile worked with FEMA to procure and distribute PPE and other supplies to areas where they were needed.

THE STOCKPILE EFFECTIVELY FOLLOWED ESTABLISHED PROCEDURES IN DISTRIBUTING LIMITED INVENTORY

GPRA requires Federal agencies to have a strategic plan that provides a description of how goals and objectives are to be achieved, including operations. The overview of the Green Book defines effective operations as those that produce the intended results. One key area of focus within the internal control component, control activities, pertains to implementing policies and procedures to achieve objectives.

The Stockpile effectively deployed its inventory by delivering approximately 90 percent of its inventory that was applicable to the nationwide COVID-19 response effort. When confronted

with the COVID-19 pandemic, the Stockpile relied on established policies and procedures and worked with SLTTs and Federal officials to determine the approach for distributing its inventory. Examples of policies and procedures included tracking locations and types of inventory located across the country, identifying and distributing inventory from Stockpile sites, transporting inventory, and handling of donated and returned inventory.

The Stockpile's operational objective for responding to a public emergency is to supplement and resupply State and local inventories of medicines and supplies during emergencies severe enough to exhaust local supplies.¹⁶ During the early weeks of the COVID-19 pandemic (January and February 2020), the Stockpile mainly deployed its assets across the United States in response to approved requests. These approved requests were task orders from the SOC directing what inventory to deploy. Decisions on deployment of Stockpile assets were made by ASPR, funneled through the SOC, and subsequently relayed to the Stockpile to fulfill. Beginning in early March, due to the volume of requests for Stockpile inventory, the Stockpile utilized ASPR's approved inventory distribution plan that was based on the Influenza inventory distribution plan to deploy its on-hand PPE and medical supplies that could be used to respond to the COVID-19 pandemic. This plan allowed the Stockpile to deploy 90 percent of its pandemic-related inventory in three shipments between March 11, 2020, and March 24, 2020, to all jurisdictions.^{17, 18}

After exhausting its inventory, the Stockpile worked with FEMA and other Government partners to obtain and distribute necessary PPE to hospitals and SLTTs amid supply chain shortages. Later in its pandemic response, the Stockpile used supplemental COVID-19 funds provided by Congress to rent new warehouses to specifically house PPE. Finally, ASPR worked with manufacturers to expand domestic PPE production and storage.

To ensure that the Stockpile is better prepared to respond to future emergencies, HHS developed and has continued to ramp up its initiative, to impact the future scope of the mission of the Stockpile. The goal of this initiative is to restock and revamp the Stockpile based on vulnerabilities in the global medical supply chain identified during the pandemic and to improve inventory management and distribution. This initiative seeks to bolster the U.S. industrial base to produce critical pharmaceuticals and medical supplies and reduce America's reliance on

¹⁶ *Strategic National Stockpile (SNS) What is the SNS?* Available online at <https://chemm.hhs.gov/sns.htm>. Accessed on May 23, 2022.

¹⁷ The Stockpile retained some items to supply Federal medical staff. Distributed inventory items included approximately: 12 million N95 face masks, 30 million other face masks, 6 million face shields, 5 million surgical gowns, 22 thousand coveralls, and 16 million pairs of gloves.

¹⁸ The third distribution of Stockpile inventory occurred after FEMA became the Lead Federal Agency for the COVID-19 response.

foreign suppliers and manufacturers.¹⁹ Stockpile personnel participated with a group of representatives from other Federal agencies and the White House to develop strategies to modernize the Stockpile to better protect the health and safety of the Nation by acquiring and storing critical items needed in the event of a resurgence of COVID-19 or any other pandemic.

EXTERNAL FACTORS IMPACTED THE STOCKPILE’S ABILITY TO MEET COVID-19 DEMAND FOR SUPPLIES

Risk assessments, one of the Green Book internal control components, pertain to assessing both external and internal sources of risk and developing appropriate responses to these risks so that objectives can be achieved. Examples of external risk factors may include new or amended laws or regulations, economic instability, or potential natural disasters.

Several external factors impacted the Stockpile’s ability to meet demand for supplies during the early months of the COVID-19 pandemic. These external factors were: (1) the supply chain’s reliance on foreign manufacturers, (2) SLTT and hospital inventory management strategies, and (3) Government strategies that primarily focused on responding to CRBN events and pandemic influenza. These three identified external factors highlighted that Government response strategies did not take into consideration all risks, which ultimately contributed to the Stockpile’s inability to meet the unprecedented demand when the pandemic began.

Supply Chains Relied on Foreign Manufacturers

Strategic decisions for what the Stockpile should purchase primarily focused on items not available in the commercial market resulting in the Stockpile having limited inventory of items, such as PPE and other supplies, and having to rely on foreign supply chains for these items.

In the years leading up to the COVID-19 pandemic, the Federal Government identified that reliance on foreign manufacturers could cause supply chain and inventory failures during a pandemic-type event. Specifically, after action reports from two previous public health emergencies emphasized the need to maintain a domestic PPE and medical supply manufacturing base capable of meeting future demands.²⁰ In addition, in late 2019, Crimson Contagion, a whole-of-government pandemic exercise in which the Stockpile and HHS participated, identified that:

- the MCM supply chain would not meet global demands during an influenza pandemic;

¹⁹ *Expanding and Enhancing SNS Capabilities*. Available online at <https://www.phe.gov/about/sns/COVID/Pages/expanding-sns-capabilities.aspx>. Accessed on June 16, 2022.

²⁰ The Federal Government’s response and lessons learned from the 2009 H1N1 influenza pandemic and the 2014 Ebola virus epidemic published in agency after action reports emphasized the importance of maintaining a domestic PPE and medical supply manufacturing base capable of meeting demand for future responses.

- global manufacturing capacities for PPE and other supplies would be unable to meet domestic demands, and countries would keep their supplies for their own citizens; and
- a lack of domestic manufacturing capacity could cause a limited supply of PPE that would be difficult to restock because of U.S. reliance on foreign manufacturers.²¹

Inventory Strategies Contributed to Limited Supplies

The inventory management strategies of both hospitals and SLTTs, contributed to a short supply of PPE and other supplies.

Specifically, SLTTs and hospitals entering the commercial market increased competition for these limited goods, which placed more demand on the Stockpile for PPE and medical supplies. As a result of manufacturing inventory strategies, PPE and other medical supplies needed by SLTTs and hospitals to help the Federal Government reduce COVID-19's spread, protect medical staff, and care for people was difficult to obtain.

Generally, hospitals in the United States rely on a just-in-time (JIT) medical delivery inventory strategy. Manufacturers also use JIT inventory, and the States did not maintain their own stockpiles and did not have the medical supplies on hand when the pandemic broke. The goal of JIT inventory is to have the minimum amount of inventory or raw materials on hand to meet demand. Such a strategy reduces the cost of carrying these materials. For manufacturers, this strategy requires working closely with suppliers so that raw materials arrive as production is scheduled to begin.

During the COVID-19 pandemic, the JIT inventory systems for PPE and medical supplies were unable to provide the necessary specialized PPE and medical supplies to hospitals and other medical facilities. Most notably, surgical gloves and N95 masks were in short supply.

A related OIG report noted that this reliance on JIT inventory systems during the pandemic, combined with supply chain shortages, forced hospitals to purchase PPE from nontraditional suppliers such as home supply stores, paint stores, auto body supply shops, and beauty salons.²² The sharp increase in demand also increased competition for these items, and the effects of this increased competition were felt nationwide. For example:

- In March 2020, the U.S. Conference of Mayors surveyed 213 mayors and found that most cities did not have and could not obtain adequate equipment and supplies such as COVID-19 test kits, face masks, and ventilators.

²¹ In August 2019, multiple Federal agencies, States, and other stakeholders participated in a 4-day training exercise called "Crimson Contagion." In January 2020, ASPR issued a report to its stakeholders with various recommendations to bolster supply chain development and enhance manufacturing capacity.

²² *Hospitals Reported That the COVID-19 Pandemic Has Significantly Strained Health Care Delivery (OEI-09-21-00140)*, issued Mar. 2021.

- In April 2020, the National Governors Association, whose membership comprises State Governors and the leaders of territories and commonwealths, noted in a memorandum to Governors' offices that the need for PPE, ventilators, and other supplies was causing competition between States and the Federal Government.

Response Strategies Focused on CBRN and Influenza

At the Stockpile's inception, the Federal Government designed it to be a critical component used to respond to CBRN threats. Over time, this focus has taken an all-hazards approach to include responding to natural disasters and infectious diseases, such as influenza. PHEMCE faces the challenge of addressing the competing and increasing demands of the Stockpile, which requires a balancing act between the original intent of the Stockpile and the prioritization of these new concerns, including emerging infectious diseases.

HHS's MCM strategic plan (PHEMCE SIP) and associated 5-year budget includes products that should be purchased and stockpiled for responding to high-priority threats. PHEMCE makes recommendations for MCM requirements so that MCMs can be available during a public health emergency.

The last PHEMCE SIP that was prepared and submitted to Congress before the COVID-19 pandemic was for 2017 and 2018, and the last 5-year budget was for fiscal years 2017 through 2021. These documents primarily focused Government MCM response strategies on CBRN events and influenza. According to the 2017-2018 PHEMCE SIP, the procurement and replenishment contracts for the Stockpile included spending for the following threats: anthrax, Burkholderia, chemical threats, influenza, radiological and nuclear threats, and smallpox. Other contracts included Federal medical stations, medical supplies, and ancillary items.²³ The list of contracts did not specifically include PPE procurements.

Before the pandemic, the last Stockpile Annual Review Report was conducted in 2016. This gap analysis included recommendations for the Stockpile to purchase MCMs focused on anthrax, Burkholderia, Botulism, nerve agents and other products for a chemical attack, pandemic influenza, plague, radiation and nuclear treatments, and smallpox vaccines.

In the years before the pandemic, the Stockpile used all three of these reports that primarily focused on CBRN events and influenza mitigation, to determine which items to purchase for the Stockpile. The Stockpile prioritizes products that are unavailable in the commercial market, and PHEMCE considers the commercial availability of certain products when developing its strategy. If certain products are normally available in the commercial market, the Stockpile would tend to buy less of those products. As a result, supplies and equipment needed to respond to a novel coronavirus were severely lacking at the start of the COVID-19 pandemic.

²³ Medical supplies and ancillary items only included sutures, catheters, gloves, syringes, gel packs, temperature monitoring devices, and shipping containers.

Since 1900, the majority of disease outbreaks within the United States have been related to influenza and for almost the past two decades most of the Federal Government's training exercises focused on influenza not any other type of diseases that could cause a pandemic. Specifically, there was no planning or requirement for diagnostic testing scenarios since the focus was on a symptom based pandemic influenza in which tests and testing equipment would not be necessary to evaluate whether individuals were infected. However, because of the ability of this coronavirus to spread from asymptomatic and pre-symptomatic people, these diagnostic tests and testing equipment would have been vital in controlling its spread. As a result, testing supplies and equipment in the stockpile was severely lacking during the start of the coronavirus pandemic.

In August 2019, HHS conducted the Crimson Contagion Exercise, a multi-State, whole-of-government exercise. This 4-day exercise tested the Nation's ability to respond to a large-scale outbreak of a novel avian influenza virus. The exercise focused on workforce viability, critical infrastructure protection, economic impact, social distancing, scarce resource allocation, prioritization of vaccines and other countermeasures, and medical surge operations. In January 2020, the same month the first cases of COVID-19 were being reported in the United States, ASPR issued an internal report on this exercise highlighting deficiencies to State, local, regional, Federal, non-governmental, and private sector partners. Findings and recommendations related to this exercise pertaining to the Stockpile focused on participants' lack of clarity on federal interagency partners' roles and responsibilities tasked with responding to a pandemic, and on Stockpile inventory and asset requests and distributions during a response.

External Factors Related to the Supply Chain, Inventory Management, and Response Strategies Impacted the Stockpile's Response to the COVID-19 Pandemic

The Stockpile was not able to meet the demand for PPE and medical supplies during the pandemic. By the middle of March 2020, the Stockpile had received requests for millions of items, but it did not have the items available to respond to those requests and was limited in its resources to meet this demand. Supply chain and inventory issues during the pandemic highlighted that Federal government response strategies had not considered all risks facing the United States. Additionally, an unrealistic view of the Stockpile's capabilities highlighted the lack of strategic planning built into the Stockpile's changing focus.

The reduction in supply and increase in demand that started in China in February 2020 exposed vulnerabilities in organizational inventory strategies and supply chains. Specifically, shortages of pharmaceuticals, critical medical supplies, and other items highlighted the risks of relying on global supply chains (instead of domestic production) and JIT inventory practices. In addition, the COVID-19 pandemic highlighted that the strategy for the Stockpile to prioritize its purchases of noncommercial items, mainly CBRN and pandemic influenza MCMs, and not focus on purchasing items available on the commercial market, created gaps in U.S. preparedness for a global novel coronavirus pandemic.

In 2019, the United States had taken proactive steps to prepare for a pandemic. Specifically, ASPR conducted a government-wide exercise called the Crimson Contagion and made recommendations to address issues it identified. For example, recommendations addressed funding for response activities and supplies, investing in domestic manufacturing capacity, and developing a prioritization strategy for the distribution and allocation of scarce response resources. However, Federal agencies did not have enough time to take corrective action because the report was issued just as the COVID-19 pandemic was emerging. Although the U.S. Government had some overarching objectives that may have improved MCM strategies and preparedness, those objectives had not been fully developed.²⁴

The United States has faced and continues to face a range of threats to its health security from CBRN agents and infectious diseases. Failure to anticipate these risks or threats—or a lack of capacity to respond effectively to them—could result in substantial illness and death among the U.S. population. Specifically, the Federal government’s strategy did not include assessing all risks facing the Stockpile. The external factors we identified stretched available inventory and supply chains beyond their capacities and created shortages of pandemic supplies. Failure to plan beyond a CBRN and influenza focus and identify inventory and supply chain issues that would affect the Stockpile during a broader public health emergency, resulted in the Stockpile not having the products that were needed to meet the unprecedented demands of the COVID-19 pandemic.

INTERNAL FACTORS IMPACTED STRATEGIC DECISIONS REGARDING STOCKPILE INVENTORY

The Green Book states that there is a direct relationship between an entity’s objectives, the five components of internal control, and the organizational structure of that entity. The objectives are what an entity wants to achieve. The five components of internal control provide the framework to achieve those objectives. The organizational structure encompasses the operations and management structures used to achieve these objectives. Of the five components of internal control, the control environment provides the foundation by defining the structure and objectives of an entity. This structure should periodically be evaluated and adapted to new entity objectives such as a new law or regulation. Information and communication is another component of internal control and is vital for an entity to achieve its objectives. Quality information should be relevant, reliable, and timely. Quality information should be communicated to both internal and external sources.

For more than 20 years, the Stockpile has existed to supplement the need for emergency health care supplies and equipment when State and local supplies are depleted during a public health

²⁴ These objectives included ensuring a robust and sustainable product pipeline that includes consideration of viable commercial markets, promoting innovative approaches to inventory management to create a sustainable preparedness infrastructure, and developing logistical and operation plans that promote timely and efficient approaches to distribution, dispensing, and administration of MCMs.

emergency. However, the following internal factors regarding strategic decision-making impacted the Stockpile’s effectiveness in responding to the COVID-19 pandemic:

- Stockpile funding had not kept pace with the Stockpile’s expanded roles and responsibilities,
- Stockpile and PHEMCE reviews had not been conducted timely,
- the Stockpile was not fully integrated into ASPR, and
- communication with SLTTs and other stakeholders had been disrupted.

The Stockpile’s Funding Has Not Kept Pace With Its Expanding Role

The Stockpile’s mission, as established by Congress in 2002, has never changed. However, the role of the Stockpile has expanded, as more responsibilities were placed on it. Compounding matters, Stockpile funding has not been adequate to meet these expanding responsibilities.

The Stockpile’s Expanding Role

From 1998 until 2001, the Stockpile was a national repository of medicines and medical supplies that could be deployed in response to a biological or chemical event, and its funding remained relatively flat at \$51 million annually.²⁵ In response to the events of September 11, 2001, and subsequent anthrax attacks, the Stockpile’s mission was expanded 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.²⁶ As a result, the Stockpile began to maintain anthrax medications, nerve agent antidotes, and smallpox vaccines.

Subsequent congressional actions and public health events since 2002 have incrementally expanded the Stockpile’s initial role from a CBRN focus to an all-hazards approach. For example:

- In 2003, as a result of the Homeland Security Act of 2002, the Stockpile added approximately 400,000 doses of antiviral drugs for pandemic influenza. This was a major step in expanding the Stockpile’s focus beyond CBRN events.

²⁵ “Annual funding” or “annual appropriations” are made for a specific fiscal year and are available for obligation only during that specified fiscal year. All appropriations are presumed to be annual unless the appropriation act provides otherwise and any remaining funds at the end of the fiscal year are considered expired and unavailable for future obligation. The Federal government’s fiscal year runs from October 1 through September 30 of the following year. For example, fiscal year 2022 began on October 1, 2021, and ended on September 30, 2022.

²⁶ Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. No. 107-188.

- In 2004, after the passage of Project BioShield, the Stockpile added Federal Medical Stations (250-bed modular units) to its inventory and contracted for other antitoxins, next generation vaccines, and radiological and nuclear agents.²⁷
- In 2005, the Stockpile was called upon to assist with the response efforts for Hurricanes Katrina and Rita. To assist with these natural disaster response efforts, Stockpile management purchased supplies that it did not have in its inventory, and the Stockpile was required to store and maintain these supplies.
- In 2006, the Pandemic and All-Hazards Preparedness Act created BARDA within ASPR. BARDA is responsible for entering into contracts to procure CBRN MCMs that are then stored in and distributed by the Stockpile. Although BARDA makes the initial contracts and MCM purchases, the Stockpile is responsible for storing items acquired by BARDA and replacing them when they expire.
- In 2009, the Stockpile responded to the H1N1 pandemic. This was its first pandemic response effort. It initially deployed millions of doses of antiviral drugs that were already part of its inventory. In June 2009, as the pandemic continued, Congress provided one-time supplemental funding to prepare for and respond to the pandemic. This funding also came with the requirement that the Stockpile purchase influenza vaccines, antivirals, medical supplies, diagnostics, and other surveillance tools.²⁸
- In 2014, in response to the Ebola outbreak in West Africa, Congress provided funding for the Stockpile to assist hospitals in their response efforts by purchasing items necessary to combat the virus, such as PPE. PPE, seen as a market commodity, had not previously been held in large quantities within the Stockpile.

Insufficient Annual Funding

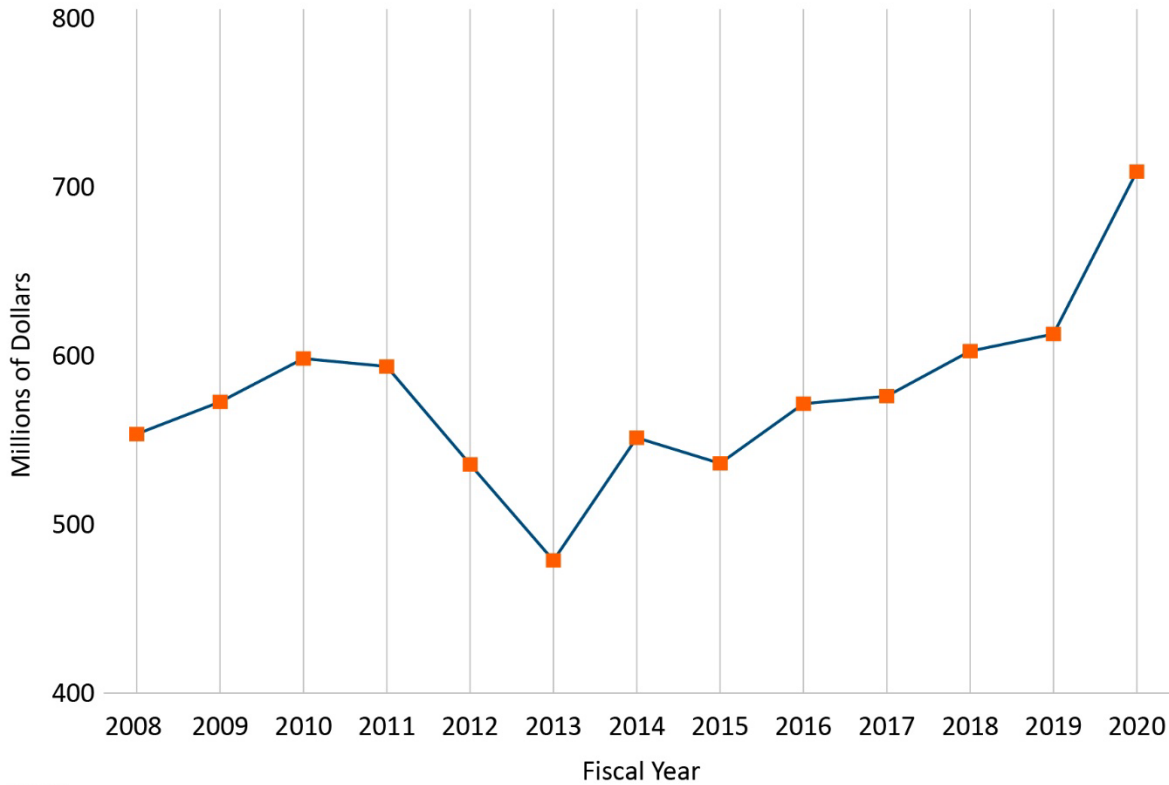
The Stockpile's annual budget authority has not kept pace with the cost of maintaining increasing inventory requirements and procuring items recommended by PHEMCE in anticipation of identified threats. While the Stockpile's budget authority has remained relatively flat since 2002, it increased slightly from 2008 to 2010 and declined overall from 2010 to 2017. Figure 1 on the next page charts Stockpile's final budget authority.²⁹

²⁷ Project BioShield Act of 2004, P.L. No. 108-276 (July 21, 2004).

²⁸ Supplemental Appropriations Act, 2009, P.L. No. 111-32, (June 24, 2009).

²⁹ Final budget authority amounts can, and often do, include funding received outside of the annual appropriations process, including secretarial transfers and supplemental funding, for example.

Figure 1: Stockpile FY2008-FY2020 Budget Authority



NOTE:

The source for data points on the figure, are as follows:

- FY2008 – FY2017 - Department of Health and Human Services, Centers for Disease Control and Prevention, Justification of Estimates for Appropriation Committees—“Final” budget figures
- FY2018 – FY2020 - Department of Health and Human Services, Public Health and Social Services Emergency Fund, Justification of Estimates for Appropriation Committees—“Final” budget figures

Under CDC, the Stockpile’s budget authority fluctuated slightly between 2008 and 2017. These fluctuations were often a decrease in the Stockpile’s budget authority. Stockpile officials indicated that this was because it could not request additional Stockpile funding in CDC’s budget without reducing funding for or dissolving other CDC programs. When the Stockpile was transferred to ASPR in October 2018, budget authority levels began to increase slightly. In fiscal year 2019, the first year the Stockpile was transferred to ASPR, the *Public Health and Social Services Emergency Fund’s* justification of budget estimates stated that ASPR requested an increase that would allow it to replace expiring Stockpile inventory but could not purchase new products required to close all identified and prioritized gaps.

Stockpile Budget Process

The Stockpile is responsible for the management of all products contained within it. This management includes the maintenance costs of products; acquisition of pharmaceuticals, devices, and ancillary supplies needed to meet PHEMCE recommendations; as well as replacements for MCMs initially procured by BARDA through Project BioShield. Each product

developed and acquired under Project BioShield increases the resource needs for maintaining these capabilities over time. Beyond the cost of the product itself, the Stockpile assumes financial responsibility for storage, security, and overhead for all of the products it stores.

Before the Stockpile makes any purchases, it sets aside funds to cover fixed costs (such as utilities, staffing, and security). The remaining balance is used to purchase items required by law, recommended by PHEMCE, or contracted by BARDA, as well as maintain items already in its inventory. According to the previous Stockpile Director, the Stockpile has had to make difficult decisions about what items to purchase or replace when funding was not sufficient to cover the costs. The previous Stockpile Director stated that without additional Stockpile funding, PHEMCE has made recommendations not to purchase products such as PPE that can be acquired generally in the commercial market, and instead focus the Stockpile's efforts and resources on items that could not be secured quickly from the market during an emergency response.³⁰

Congressional testimonies given in May and June 2020 highlighted this dilemma of what the Stockpile should purchase, considering its increasing responsibilities and relatively flat budget. In May 2020, the previous CDC Director, Tom Frieden, testified before Congress that the Stockpile's baseline budget needed to increase to sustain and prepare the Stockpile to be responsive. He explained that supplemental appropriations provide critical resources for Federal, State, and local response efforts, but these funds are only a temporary fix.³¹ Additionally, in June 2020, Former Senate Majority Leader Bill Frist stated that the Stockpile would benefit from more financial resources.³²

Public health events in the United States during the past 20 years have led to a dramatic expansion of the Stockpile's responsibilities and strategic plans were not updated to define the goals and objectives associated with these expanded responsibilities. Because the Stockpile's budget authority has not kept pace with its expanded roles and responsibilities, the Stockpile could not address all high-priority threats and had to make critical choices about what items to acquire and replenish, including whether to maintain sufficient quantities of certain items needed to respond to a pandemic with the scope and magnitude of COVID-19.

³⁰ Testimony of Greg Burel on June 24, 2020, to the Committee on Homeland Security and Governmental Affairs. Available online at <https://www.hsgac.senate.gov/imo/media/doc/Testimony-Burel-2020-06-24.pdf>. Accessed on April 8, 2022.

³¹ Testimony of Tom Frieden on May 6, 2020, to the Subcommittee on the Departments of Labor, Health and Human Services, Education, and Related Agencies. Available online at <https://docs.house.gov/meetings/AP/AP07/20200506/110747/HHRG-116-AP07-Wstate-FriedenT-20200506.pdf>. Accessed on April 8, 2022.

³² Testimony of Bill Frist on June 23, 2020, to the Committee on Health, Education Labor, and Pensions. Available online at <https://www.help.senate.gov/imo/media/doc/Frist2.pdf>. Accessed on April 8, 2022.

The Required Stockpile Annual Review Report and PHEMCE Strategy and Implementation Plan Were Not Timely Developed, and the Stockpile Relied on Dated Information

Neither the Stockpile Annual Review Report nor the PHEMCE Strategy and Implementation Plan (SIP) were developed and submitted to Congress in the last few years leading up to the COVID-19 pandemic. The last Stockpile Annual Review Report before the pandemic focused on Stockpile inventory as of 2016, and the last PHEMCE SIP before the pandemic was developed in 2017. Therefore, the Stockpile did not have current information available to them when prioritizing inventory purchases during the pandemic.

To ensure that HHS's priorities reflect current national security concerns, scientific progress, and fiscal capabilities, PHEMCE annually assesses and updates the SIP. The PHEMCE SIP describes the priorities that HHS, in collaboration with its partners, will implement in the near-term, mid-term, and long-term. It provides the blueprint to enhance national health security through the prioritization of procurement activities and effective use of MCMs and is complemented by a multi-year MCM budget.

The intent of the Stockpile annual review is to comprehensively examine all the Stockpile contents against defined stockpiling goals and identify and prioritize gaps in MCM preparedness. The ultimate goal of this review is to guide the Stockpile to make the best use of limited resources. According to Stockpile personnel, HHS leadership decided approximately 10 years ago that PHEMCE would manage this annual process for the Stockpile, because it was the interagency group that could provide input on the regulatory status of MCMs or other threat issues. From 2006 through 2016, PHEMCE conducted the required annual reviews and managed the Stockpile's annual assessment of its inventory. Before 2017, PHEMCE participated in the three main steps of this annual planning and review process:

- a content review of Stockpile inventory,
- a review of threat-specific areas using threat-specific subject-matter expert groups from the interagency partners,³³ and
- a determination of whether available MCMs could be leveraged across multiple threats and whether additional MCMs should be purchased to provide coverage across multiple threats, if possible.

After those steps were completed, senior management within PHEMCE provided input on inventory gaps it defined as priorities as well as on the multi-year MCM budget and the SIP. The SIP and multi-year budget were completed and sent to the HHS Secretary for signature and submission to Congress.

³³ See Appendix B for a list of PHEMCE High Priority Threats as displayed in the *2017-2018 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan*. Available at <https://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx>. Accessed on April 8, 2022.

Beginning in mid-2017, ASPR began a reorganization of its entire division, and PHEMCE did not meet from 2018 to 2020. During this inactive period, PHEMCE also did not manage the Stockpile annual planning and review process that provides the Stockpile with recommendations about what inventory items should be purchased.³⁴ Thus, the Stockpile did not have updated information necessary to prioritize inventory gaps when making purchase and replenishment decisions and instead relied on the last completed Stockpile annual review (2016) and PHEMCE SIP (2017-2018) to prioritize inventory gaps and make inventory purchases until the onset of the COVID-19 pandemic. Additionally, the Secretary and Congress were not provided with the relevant information describing the vulnerabilities and gaps within the Stockpile. Without this updated information, the Stockpile could not accurately identify needed supplies to procure before the pandemic and therefore did not have sufficient quantities when it was called upon to respond to the COVID-19 pandemic.

During 2020, ASPR began reorganizing PHEMCE and the review process. However, due to the COVID-19 pandemic, neither the new PHEMCE structure nor the review process had been completed at the time of our audit.

The Stockpile Was Not Fully Integrated Into ASPR

Although HHS moved the Stockpile from CDC to ASPR on October 1, 2018, some aspects of the Stockpile had not been fully integrated into the ASPR organization at the time of our audit. For example, the items below had not been addressed 2 years after the transition:

- Stockpile personnel had not been fully integrated into ASPR. As a result, neither the Stockpile nor ASPR understood each other's operations. For example, according to Stockpile personnel, during their response to the pandemic, they had to take time away from responding to the pandemic to educate ASPR personnel on the Stockpile's process for allocating PPE and medical supplies during a pandemic.
- The Stockpile inherited ASPR's inventory of medical equipment from the National Disaster Medical System and deployment responsibilities related to that equipment. However, ASPR's equipment was not maintained in an inventory system such that it would translate easily into the Stockpile's inventory system. Additionally, these items were physically maintained in unsecured locations, unlike Stockpile inventory.
- During the pandemic, the Stockpile continued to use CDC's information technology systems, and Stockpile staff had to toggle between the CDC and ASPR systems to do their jobs, which took additional time.

ASPR had not fully integrated the Stockpile into its organizational structure because there was no integration plan to do so. Because of this, ASPR lost the opportunity to fully understand

³⁴ Separately, OIG plans to examine aspects of the initial HHS response to COVID-19. This planned work can be found at <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000519.asp>.

Stockpile responsibilities and processes, along with how to ensure that the Stockpile operated in an efficient and effective manner. ASPR stated that early planning meetings for the transfer began in March 2018 with joint briefings of Stockpile and ASPR leadership. ASPR stated that it conducted detailed planning meetings for the transfer in August 2018 to review processes and expectations. As part of this audit, we requested meeting notes, plans, and any documentation to confirm these meetings had taken place. We also requested the plan to integrate the Stockpile into ASPR. However, ASPR did not provide any related documentation. We asked ASPR personnel whether an integration plan existed, and personnel responded that they had never seen one.

Because the Stockpile was not fully integrated into ASPR when the COVID-19 pandemic began in 2020, Stockpile and ASPR personnel did not fully understand each other's roles, responsibilities, and capabilities, which disrupted the Stockpile's COVID-19 response efforts.

Communications Were Disrupted

Federal and State agency communication with ASPR and the Stockpile during the COVID-19 pandemic broke down when the White House Coronavirus Task Force changed the lead Federal agency for pandemic response from HHS to FEMA.

Before the pandemic, the Stockpile and ASPR had established communication channels and points of contacts that SLTTs used when requesting assistance, which generally flowed through State public health agencies. During the early phases of the pandemic, ASPR and the Stockpile used these communication channels and established processes to begin determining what to ship to numerous jurisdictions.

Under the National Response Framework, Emergency Support Function 8, HHS is the agency charged with leading the Federal response to a public health emergency. Thus, HHS was initially the lead Federal agency in charge of the Federal response. However, on March 19, 2020, after the President declared the ongoing COVID-19 pandemic of sufficient severity and magnitude to warrant a national emergency declaration under the Stafford Act, the White House designated FEMA as the lead Federal agency in charge of the U.S. Government's COVID-19 response.^{35, 36} While HHS was in charge of the Federal response, ASPR used its Regional Emergency Coordinators (RECs) to coordinate directly with Public Health Departments in the States and territories communicating Stockpile requests and needs. Just 2 weeks before FEMA took over the COVID-19 response in March 2020, ASPR RECs provided instructions to

³⁵ The Robert T. Stafford Disaster Relief and Emergency Assistance Act, P.L. No. 100-707 (Nov. 23, 1988) and the COVID-19 Emergency Declaration (March 14, 2020). Available at <https://www.fema.gov/press-release/20210318/covid-19-emergency-declaration>. Accessed on August 3, 2022.

³⁶ Although the March 14, 2020, Stafford Act declaration specifically stated that HHS would maintain its role as the lead Federal agency for the Federal Government's response to COVID-19, FEMA assumed the lead role for the Federal response on March 19, 2020. See [COVID-19 Emergency Declaration | FEMA.gov and OIG-21-64 - Lessons Learned from FEMA's Initial Response to COVID-19 \(dhs.gov\)](#).

States on the process of requesting PPE from the Stockpile. RECs stated that after FEMA was placed in charge of the pandemic response efforts, some State Governor's offices took charge of running their States' response efforts. FEMA is an emergency response organization that responds mainly to infrastructure issues, while HHS has historically led a public health response. Changing the lead Federal agency during the pandemic resulted in the breakdown of existing relationships and communication channels the Stockpile used to handle routine issues such as requests for medical items and supplies associated with a public health response.

As a result of the breakdown in established relationships and communication channels, ASPR personnel stated that Stockpile communication with State officials was confusing, and State officials received conflicting information when they attempted to communicate with their Federal counterparts. This led to the arrival of some Stockpile deployments at State warehouse locations at times when State personnel were not available to receive them. Also, ASPR personnel stated that some States were frustrated because they were providing the same information to multiple agencies (HHS and FEMA) while they were also actively responding to the pandemic.

CONCLUSION

Although external and internal factors impacted the Stockpile's effectiveness in responding to the COVID-19 pandemic, the Stockpile contributed to the pandemic response and distributed its limited inventory based on established policies and procedures. The Stockpile has a history of successfully supplying SLTTs with medicines and supplies during regional and local public health emergencies, sending qualified staff to assist local officials in impacted areas, and training SLTTs. However, the Stockpile may not be successful in responding to future pandemics unless the external and internal factors we identified are addressed.

RECOMMENDATIONS

We recommend that the Administration for Strategic Preparedness and Response:

- mitigate the risk presented by relying on foreign supply chains and JIT inventory strategies when determining annual Stockpile purchases;
- develop a strategic plan for the Stockpile, that clearly defines the goals and objectives of the Stockpile, and the Stockpile's roles and responsibilities for responding to emergency events, including pandemics;
- work to increase the Stockpile's annual funding to keep pace with the Stockpile's increased responsibilities;
- reinstate the annual planning and review process and issue to Congress an updated PHEMCE SIP, PHEMCE Multiyear Budget, and Stockpile Annual Review Report;

- develop a plan and timeline for fully integrating the Stockpile within ASPR; and
- develop a response plan, to include communication plans, for situations in which the Stockpile needs to respond to changes in roles and responsibilities during large-scale emergency responses.

ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE COMMENTS AND OIG RESPONSE

In response to our draft report, ASPR concurred with our first and third recommendation. ASPR neither concurred nor non-concurred with our second, fourth, fifth, and sixth recommendation. For these recommendations, ASPR instead discussed actions it has taken or plans to take to implement our recommendations.

ASPR concurred with our first recommendation and stated that it has permanently established the Office of Industrial Base Management and Supply Chain (IBMSC) to address the risk of relying on foreign supply chains and JIT inventory strategies. The IBMSC invests in onshoring the manufacture of key supplies and products which will ultimately reduce the country's reliance on foreign supplies for critical material used to make PPE and Active Pharmaceutical Ingredients. In addition, ASPR has invested funds to establish domestic manufacturing of several important medical supplies including PPE to not only increase domestic manufacturing, but also work toward mitigating the risks of relying on foreign supply chains and JIT inventory strategies. ASPR also stated that it requested domestic construction authority in its FY24 President's Budget Request, which would support contracts for sustained domestic manufacturing. This authority was previously extended through COVID supplementals but ends with the COVID funding.

For our second recommendation, ASPR concurred with our finding and stated that the Stockpile continues to find ways to clarify capabilities for SLTT partners, but it is challenging as the mission of Stockpile continues to expand. ASPR stated that it hopes to work with Congress to ensure funding commensurate with the mission. Furthermore, the Stockpile is continuing to evaluate strategies to support the implementation of the National Strategy for a Resilient Public Health Supply Chain.³⁷

In response to our third recommendation, ASPR concurred with the recommendation and provided information on Congressional outreach activities it has taken regarding Stockpile requirements and gaps in resources. ASPR stated that it will continue to advocate for additional funding. ASPR also disagreed with the categorization of this finding as an internal factor. ASPR stated the finding should have been considered an external factor because Congress ultimately determines the funding level.

³⁷ The National Strategy ...provides a strategic approach to design, build, and sustain a long-term capability in the United States to manufacture supplies for future pandemics and biological threats.

Regarding our fourth recommendation, ASPR stated that it relaunched the PHEMCE in February 2022 and the PHEMCE has met routinely since its restart to review and contribute to many efforts including: (a) reviewing the current threat landscape, (b) reviewing the 2022 Medical Countermeasure Preparedness Report, (c) providing critical feedback on the development of the new requirements or updating any outdated requirements, and (d) conducting a listening session with industry partners to better understand the challenges in MCM preparedness. Additionally, the PHEMCE SIP was delivered to Congress in October 2022, the PHEMCE Multiyear Budget for Fiscal Years 2022-2026 was delivered to Congress in March 2023, and the 2022 MCM Preparedness Review was delivered to Congress in May 2023. Going forward, ASPR indicated that it has set a schedule for each of these to be updated as required.

With respect to our fifth recommendation, ASPR stated that with the end of the acute response to COVID-19, it has shifted to fully integrating Stockpile capabilities within ASPR. One important step in this effort, ASPR stated, was the elevation of the Stockpile as part of the February 2023 ASPR reorganization. The Stockpile was realigned to be a standalone office and reports directly to the ASPR to increase accountability of and visibility into the program. ASPR stated that Stockpile personnel are included in all ASPR communications, and the Stockpile is almost fully transitioned to ASPR at this time.

For our final recommendation, ASPR stated that the Stockpile continues to develop and share additional resources with SLTT partners to ensure they are ready for large-scale emergency responses and that they are familiar with how to access resources quickly and efficiently. The Stockpile released updated guidance for SLTTs on requesting Stockpile assets in March 2023 and is also in the process of updating its overall guidance document on receiving, distributing, and dispensing medical countermeasures from the Stockpile for SLTTs.

During the audit we had the opportunity to share our preliminary results with ASPR officials, and we commend ASPR on the actions it has taken or is taking to address our recommendations. We would also note that while the report addresses the Stockpile's PPE distributions, it includes a broader review of Stockpile's ability to respond effectively to the COVID-19 pandemic. In regard to how we classified insufficient annual funding, we categorized this finding as internal because this directly impacted the Stockpile's ability to respond to the COVID-19 pandemic. Our external factors were categorized as such because they pertain to the global issues that indirectly affected the Stockpile.

ASPR and CDC provided technical comments which we addressed, as appropriate, in the report. ASPR's written comments, excluding the technical comments, are included as Appendix C.

APPENDIX A: SCOPE AND METHODOLOGY

SCOPE

We used the Green Book and GPRA as the basis of our review of operational and strategic internal controls.

The Green Book states that effective operations produce the intended results of an organization through operational processes (Green Book Overview 2.19). In evaluating operating effectiveness, management determines whether controls were applied at relevant times during the period under evaluation, the consistency with which those controls were applied, and by whom or by what means they were applied (Green Book Overview 3.06).

We reviewed Stockpile operations by reviewing all five components of Green Book internal controls as follows (Figure 2 on the following page):

1. Control Environment – The control environment provides the foundation of an internal control system. It provides the structure that management and the oversight body use to achieve its objectives.
2. Risk Assessment – Management assesses the risks from both external and internal sources facing an entity. This assessment provides the basis for developing appropriate responses to those identified risks.
3. Control Activities – Control activities are the actions management establishes through policies and procedures to achieve objectives and respond to risks.
4. Information and Communication – This component pertains to the quality information management and personnel communicate and use to support the internal control system. Access to relevant and reliable communication related to internal as well as external events is vital for an entity to be effective.
5. Monitoring – This component pertains to activities that management establishes and operates to assess the quality of performance over time. The internal control system must be monitored in order to keep it aligned with changing objectives, environment, laws, resources, and risks.

Figure 2: The 5 Components and 17 Principles of Internal Control

<p>Control Environment</p> <ol style="list-style-type: none"> 1. The oversight body and management should demonstrate a commitment to integrity and ethical values. 2. The oversight body should oversee the entity's internal control system. 3. Management should establish an organizational structure, assign responsibility, and delegate authority to achieve the entity's objective. 4. Management should demonstrate a commitment to recruit, develop, and retain competent individuals. 5. Management should evaluate performance and hold individuals accountable for their internal control responsibilities. <p>Risk Assessment</p> <ol style="list-style-type: none"> 6. Management should define objectives clearly to enable the identification of risks and define risk tolerances. 7. Management should identify, analyze, and respond to risks related to achieving the defined objectives. 8. Management should consider the potential for fraud when identifying, analyzing, and responding to risks. 9. Management should identify, analyze, and respond to significant changes that could impact the internal control system. 	<p>Control Activities</p> <ol style="list-style-type: none"> 10. Management should design control activities to achieve objectives and respond to risks. 11. Management should design the entity's information system and related control activities to achieve objectives and respond to risks. 12. Management should implement control activities through policies. <p>Information and Communication</p> <ol style="list-style-type: none"> 13. Management should use quality information to achieve the entity's objectives. 14. Management should internally communicate the necessary quality information to achieve the entity's objectives. 15. Management should externally communicate the necessary quality information to achieve the entity's objectives. <p>Monitoring</p> <ol style="list-style-type: none"> 16. Management should establish and operate monitoring activities to monitor the internal control system and evaluate the results. 17. Management should remediate identified internal control deficiencies on a timely basis.
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We used GPRA to assess the strategic effectiveness of decisions made on behalf of the Stockpile on what should be included in its inventory. GPRA requires Federal agencies to have strategic goals and objectives that contain:

- a comprehensive mission statement covering the major functions and operations of the agency,
- a description of how the goals and objectives are to be achieved including the operational process, and
- key factors beyond the agency's control that could significantly affect the achievement of the general goal and objectives.

We did not review the decision making process used by the ASPR, nor did we review ASPR's response protocols during the pandemic because they included several other HHS divisions.³⁸ While we did not review the Stockpile's internal inventory management systems during the course of this audit, we plan to conduct such an audit in the future.³⁹ We limited our review of Stockpile operations to the first 6 months of 2020 and assessed related strategies, operations, and various factors that ultimately affected the Stockpile's ability to effectively respond to the pandemic.

METHODOLOGY

To conduct this audit, we assessed the Stockpile's internal controls related to distributing available inventory during early COVID-19 response efforts. In addition, we used available testimony and documentary evidence to determine what impact other organizations' strategic decisions (related to Stockpile inventory) had on the Stockpile's pandemic response. We interviewed officials from ASPR, CDC, the Stockpile, BARDA, and the U.S. Marshals Service and assessed available documentation related to our audit period, which covered January through June 2020. We reviewed ASPR and others' roles in shaping the strategy of the Stockpile.

To achieve our objective, we:

- reviewed Federal laws, policies, and guidance applicable to ASPR and the Stockpile's response to the COVID-19 pandemic;
- sent questionnaires to ASPR and Stockpile officials pertaining to the processes and procedures surrounding their COVID-19 response activities;
- reviewed ASPR and Stockpile responses to questionnaires and conducted interviews of ASPR and Stockpile personnel involved in the COVID-19 response to obtain clarity regarding those responses; and
- discussed the results of our audit with ASPR and Stockpile officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

³⁸ We are currently conducting a risk assessment to determine whether ASPR has implemented controls and mitigating strategies to address identified risks associated with coordinating the Government's response to emergency events.

³⁹ The purpose of this audit will be to follow up on prior audit findings related to inventory management and the physical security of Stockpile sites, and it should include a review of selected Stockpile sites.

APPENDIX B: PHEMCE HIGH-PRIORITY THREATS

The 2017-2018 PHEMCE SIP defines high-priority threats as follows:

PHEMCE will continue to address MCM needs to protect against high-priority threats that pose a material threat to national security. This year, PHEMCE added three chemical agents (chlorine, phosgene, and vesicants); otherwise, the high-priority threats are unchanged from those listed in the 2016 PHEMCE SIP. PHEMCE high-priority threats are (in alphabetical order by threat area):

Biological Threats

Bacillus anthracis (anthrax)* and Multi-drug resistant *B. anthracis* (MDR anthrax)*
Burkholderia mallei (glanders)* and *Burkholderia pseudomallei* (melioidosis)*
Clostridium botulinum toxin (botulism)*
Ebola virus (Ebola hemorrhagic fever)*
Emerging infectious diseases
Francisella tularensis (tularemia)*
Marburg virus (Marburg hemorrhagic fever)*
Pandemic influenza
Rickettsia prowazekii (typhus)*
Variola virus (smallpox)*
Yersinia pestis (plague)*

Chemical Threats

Acetylcholinesterase inhibitor nerve agents*
Chlorine
Cyanide salts (potassium and sodium cyanide)*
Hydrogen cyanide*
Phosgene
Vesicants*

Radiological* and Nuclear* Threats

*Threats identified under the following authorities related to MCMs: (1) emergency use authorities that rely on section 564(b)(1)(D) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); (2) priority review vouchers (PRVs) under section 565A of the FD&C Act; and (3) procurements of security countermeasures under section 319F-2 of the PHS Act.



DATE: August 21, 2023

TO: Amy J. Frontz
Deputy Inspector General for Audit Services

FROM: Dawn O'Connell
Assistant Secretary for Preparedness and Response (ASPR)

SUBJECT: Office of the Inspector General (OIG) Draft Report: *The Strategic National Stockpile was not Positioned to Respond Effectively to the COVID-19 Pandemic*

The Administration for Strategic Preparedness and Response (ASPR) appreciates the report detailing challenges of the Strategic National Stockpile's (SNS) distribution of Personal Protective Equipment (PPE) during the COVID-19 pandemic. ASPR acknowledges the findings and recommendations included in the report issued by the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) reviewing the SNS's PPE response during the first few months of the COVID-19 pandemic.

Given that OIG's review period was between January and June 2020 and over three years have lapsed since that period and the release of the report, I am pleased to share that ASPR identified many of the same issues on its own and has already taken several important steps to implement corrective actions. I would like to highlight some of these steps here.

Recommendation 1: Mitigate the risk presented by relying on foreign supply chains and JIT inventory strategies when determining annual Stockpile purchases

- General comments: ASPR concurs with this recommendation and has permanently established the Office of Industrial Base Management and Supply Chain (IBMSC) which invests in onshoring the manufacture of key supplies and products which will ultimately reduce the country's reliance on foreign suppliers for critical material. This office has invested \$17 billion in over 80 contracts to establish domestic manufacturing of several important medical supplies including PPE. These efforts will not only increase domestic manufacturing but will work toward mitigating risks of relying on foreign supply chains and JIT inventory strategies, especially related to materials in the SNS.
- Actions:
 - Using COVID supplemental funding provided by Congress, ASPR has invested in over 80 contracts to support domestic manufacturing of critical material. These

investments aim to bring production and manufacturing of critical items used to make PPE and Active Pharmaceutical Ingredients (API) specifically to domestic soil to limit dependence on foreign production. It is important to note that all efforts related to sustained investment in domestic manufacturing will be dependent on Congressional appropriations. ASPR officially requested annual funding for this work in the Fiscal Year 2024 (FY 24) President's Budget request. A portion of the requested \$400 included in the FY 24 request for Pandemic and Biodefense Preparedness would support this office and investments in these contracts for sustained domestic manufacturing.

- Also included in the FY 24 President's Budget Request, ASPR requested domestic construction authority. This authority was first extended to ASPR through COVID supplemental bills, but sunsets with the COVID funding.

Recommendation 2: Develop a strategic plan for the Stockpile that clearly defines the goals and objectives of the Stockpile, and the Stockpile's roles and responsibilities for responding to emergency events, including pandemics

- General comments: ASPR appreciates the findings in this report regarding the Stockpile's mission. Specifically, that it was, "established by Congress in 2002, has never changed. However, the role of the Stockpile has expanded, as more responsibilities were placed on it. Compounding matters, Stockpile funding has not been adequate to meet these expanding responsibilities." ASPR concurs with this assessment. The SNS continues to find ways to clarify capabilities for SLTT partners, but this continues to be challenging when the mission continues to expand. ASPR hopes to be able to work with Congress to ensure funding commensurate with the mission. Furthermore, there have been executive orders issued that address these challenges since the review period of this report. For example, the SNS is continuing to evaluate strategies to support the implementation of the National Strategy for a Resilient Public Health Supply Chain (National Strategy), developed in response to Section 4 of Executive Order (EO) 14001: Sustainable Public Health Supply Chain. Among the plan's implementation tasks include formalized and expanded SLTT and private-sector engagement; discussion of best practices and new approaches for stockpiling, storage, and distribution; and providing expanded training, technical assistance and information sharing for Federal, SLTT, and private-sector partners on SNS capabilities and capacity to support and sustain coordinated response to pandemics, natural disasters, and man-made threats.

Recommendation 3: Work to increase the Stockpile's annual funding to keep pace with the Stockpile's increased responsibilities

- General comments: ASPR concurs with this recommendation. However, the report details funding challenges as an internal factor. ASPR disagrees with the assessment that funding is controlled internally because funding is appropriated by Congress. Despite ASPR's best efforts to advocate for increased funding, the agency has yet to see an increase in funding which would allow the SNS to execute against, as OIG notes, the

increased responsibilities of the Stockpile. ASPR will continue to advocate for additional funding, but strongly recommends that the characterization of funding be moved from “internal” to “external.”

- Actions:
 - ASPR has produced the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multiyear Budget for FY 2022-2026 and is in the process of the next iteration of this report. OIG should be aware that the most recent iteration of the PHEMCE Multiyear Budget for Fiscal Years 2022-2026 projected an overall funding need of \$2.6 billion over the five-year period for SNS procurement of products approved or soon to be approved. This is in stark contrast to the \$965 million SNS was appropriated in FY 23. This document is publicly available via ASPR’s website and is used to promote general gaps in resources across the entire medical countermeasure spectrum (available online: <https://aspr.hhs.gov/PHEMCE/Documents/2022-2026-PHEMCE-Budget.pdf>).
 - In addition, and to increase Congressional awareness of SNS requirements and gaps, the ASPR Office of Legislative Affairs (OLA) has supported a dynamic strategy offering briefings on SNS operations, general information sessions on MCM requirements, and have offered tours of the SNS warehouse for Congressional Members and staff. For awareness, in 2023: OLA supported over 40 meetings with Congressional staff to discuss ASPR’s organization, highlighting the role and operations of the SNS; supported two SNS site visits in 2023 (two additional site visits are planned in 2023; one in August 2023 and another during the fall Congressional recess); and hosts monthly briefings with majority and minority, House and Senate Appropriations Committee staff providing program and funding updates in real-time.

Recommendation 4: Reinstate the annual planning and review process and issue to Congress an updated PHEMCE SIP, PHEMCE Multiyear Budget, and Stockpile Annual Review Report

- General comments: *ASPR considers this recommendation closed.* We view these policy planning documents as critical to ensuring awareness for SNS needs and have prioritized these documents for completion and circulation with Congressional and external stakeholders.
- Actions:
 - ASPR relaunched the PHEMCE in February 2022. Since the relaunch, the PHEMCE has met routinely to review and contribute to many efforts including:
 - Reviewing the current threat landscape;
 - Reviewing the 2022 Medical Countermeasure Preparedness Report (MCMPR) (i.e., the annual threat-based review of the SNS) report;
 - Providing critical feedback on the development of new requirements or updating outdated requirements; and

- Conducting a listening session with industry partners to better understand challenges in MCM preparedness.
- The PHEMCE Strategy and Implementation Plan (SIP) was delivered to Congress in October 2022 and was also posted on the ASPR website (available here: <https://aspr.hhs.gov/PHEMCE/2022-SIP/Documents/PHEMCE-SIP-2022-508.pdf>). This document is set to be delivered biannually with the next iteration due in March 2024.
- The PHEMCE Multiyear Budget for Fiscal Years 2022-2026 was delivered to Congress in March 2023 and posted on the ASPR website. This document is set to be updated in March of 2024.
- The 2022 MCM Preparedness Review (MCMPR) (formally the SNS Annual Review) was delivered to Congress in May 2023. This document is not publicly released due to procurement sensitivities but was finalized and delivered to Congress as required. The 2023 MCMPR is in development and due to Congress in March 2024.

Recommendation 5: Develop a plan and timeline for fully integrating the Stockpile within ASPR

- General comments: *ASPR considers this recommendation closed.*
- Actions:
 - With the initial transfer, a Memorandum of Understanding was established between ASPR and CDC that outlined the plans for transitioning personnel and Information Technology components. Because of the warehouse footprint, it was determined to not physically relocate the majority of SNS staff from the primary SNS headquarters outside Atlanta. As ASPR was working through the transition (specifically the transfer of IT capabilities), the COVID-19 pandemic began. All efforts were put on hold due to the required response support.
 - With the end of the acute response to COVID-19, ASPR has again shifted to fully integrating SNS capabilities. One important step in this effort was the elevation of the SNS as part of the February 2023 ASPR reorganization. The SNS was realigned to be a standalone office and report directly to the ASPR. This increased accountability of and visibility into the program. This also established a direct line of communication to leadership to discuss SNS resources, personnel issues, organizational requirements, and challenges. The ASPR and SNS Director meet weekly.
 - SNS personnel are included in all ASPR communications, all-hands meetings, senior staff meetings, strategic organizational offsites, and exercises. SNS is a critical component of ASPR and, from all perspectives, is fully transitioned to ASPR with the exception of email addresses at this time.

Recommendation 6: Develop a response plan, to include communication plans, for situations in which the Stockpile needs to respond to changes in roles and responsibilities during large-scale emergency responses

- General comments: *ASPR considers this recommendation closed*. The SNS continues to develop and share additional resources with SLTT partners in order to ensure they are ready for large-scale emergencies responses and that they are familiar with how to access resources quickly and efficiently.
- Actions:
 - The SNS did release updated guidance for SLTTs (available on the ASPR website, <https://aspr.hhs.gov/SNS/Pages/Requesting-SNS-Assets.aspx>) on how to requests assets. This updated guidance was posted in March 2023.
 - The SNS is also in the process of updating its overall guidance document on receiving, distributing, and dispensing medical countermeasures (MCM) from the SNS for SLTTs. This guidance provides an all-hazards framework for MCM planning and will include feedback from STLT partners and information operational updates implemented during the COVID-19 and mpox responses. Dissemination is planned for fall 2023.



Dawn O'Connell
Assistant Secretary for Preparedness and Response