



October 2022

PUBLIC HEALTH PREPAREDNESS

HHS Should Address Strategic National Stockpile Requirements and Inventory Risks

GAO Highlights

Highlights of [GAO-23-106210](#), a report to congressional addressees

Why GAO Did This Study

Recent emergencies have highlighted the importance of preparedness. One key component of the nation's medical response infrastructure is the SNS. The SNS inventory may be deployed to state, local, territorial, tribal, and international governments when needed. GAO placed HHS's leadership and coordination of public health emergencies on its High Risk List in January 2022 (GAO-22-105291) in part due to deficiencies in HHS's management of countermeasures.

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 included a provision for GAO to review the SNS. This report examines: (1) the process used to make inventory decisions; (2) non COVID-19 obligations for countermeasures and their alignment with recommendations; and (3) obligations for countermeasures using COVID-19 relief funds, and inventory and operations changes in response to the COVID-19 pandemic.

To conduct this work, GAO reviewed standard operating procedures, statutory requirements, inventory and obligations data, and other documentation; compared HHS actions to risk management practices; and interviewed HHS officials.

This report is a public version of a sensitive report issued in August 2022.

What GAO Recommends

GAO is making three recommendations, including that HHS update procedures for SNS reviews and manage risks associated with inventory gaps. HHS concurred with GAO's recommendations.

View [GAO-23-106210](#). For more information, contact Mary Denigan-Macauley at (202) 512-7114 or DeniganMacauleyM@gao.gov.

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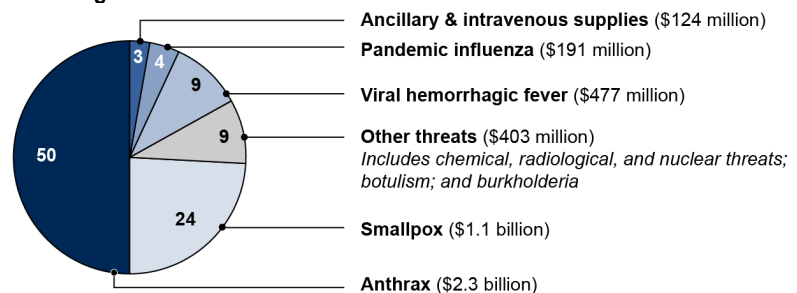
HHS Should Address Strategic National Stockpile Requirements and Inventory Risks

What GAO Found

The Strategic National Stockpile (SNS) is a multibillion dollar inventory of drugs, vaccines, supplies, and other medical countermeasures that can be used in emergencies. GAO reported in August 2022 that to guide inventory purchases from 2015 through 2019, the Department of Health and Human Services (HHS) used a multi-step process involving interagency experts, resulting in annual SNS reviews with inventory recommendations. This process was suspended when the expert group underwent a reorganization, and annual reviews were not completed to inform inventory decisions for fiscal years 2020 through 2022, resulting in purchases based on past reviews and HHS discretion. HHS has since completed reviews to inform inventory decisions for fiscal years 2023 and 2024. However, these reviews did not meet most statutory requirements—such as by including the amount of additional medical countermeasures procured—because HHS did not update its procedures to account for changes enacted in 2019. Until HHS updates its procedures, the agency risks not meeting the statutory requirements designed to give Congress additional information about the SNS inventory.

From fiscal years 2015 through 2021, HHS obligated nearly \$5 billion in non COVID-19 appropriations to purchase medical countermeasures, mostly for anthrax and smallpox.

Obligations from Non COVID-19 Appropriations for Strategic National Stockpile from Fiscal Years 2015 through 2021



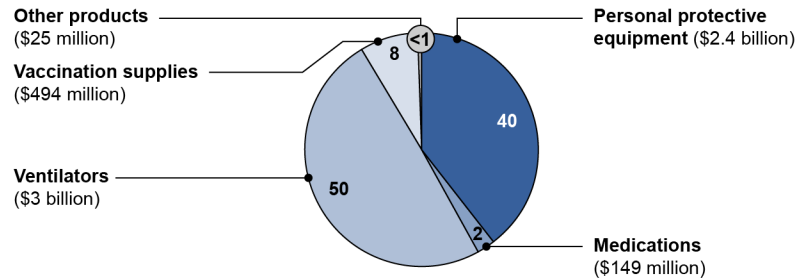
Source: GAO analysis of data from the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS). | [GAO-23-106210](#)

GAO's analysis of SNS reviews shows the SNS contained most medical countermeasure types recommended, but often not in the recommended quantities. HHS officials noted that gaps in quantities are due to budget constraints and acknowledge these gaps present risks. However, the reviews lack key information needed for managing these risks and communicating them to stakeholders, including to Congress. Risk management principles include guidance related to the management and communication of risk. Without an approach for regularly managing risks, HHS and Congress lack assurance the department is most effectively preparing for public health emergencies.

HHS obligated \$6.1 billion in COVID-19 relief funds for supplies for the SNS that significantly increased the amount of certain medical countermeasures and expanded the types of countermeasures in the SNS inventory. For example, most of the funding went toward ventilators and personal protective equipment, which

resulted in substantial increases in the amount of these medical countermeasures in the SNS relative to what was held prior to the COVID-19 pandemic.

Obligations Using COVID-19 Relief Funds for COVID-19 Supplies Delivered to the Strategic National Stockpile, Fiscal Years 2020 and 2021



Source: GAO analysis of data from the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS). | GAO-23-106210

Additionally, the SNS inventory now contains additional finished pharmaceutical products, such as sedatives for use with ventilators. In response to recommendations from HHS, ASPR also took steps to add testing supplies to the SNS inventory in late 2020, including nasal swabs and transfer media. Prior to the COVID-19 pandemic, the SNS did not hold these medical countermeasures.

The COVID-19 response has also been a catalyst for HHS to re-examine SNS operations, including the role, responsibilities, expertise, and inventory needed moving forward. As such, HHS is working to develop a strategic plan to guide future SNS efforts.

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Abbreviations

ASPR	Office of the Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
COVID-19	Coronavirus Disease 2019
CDC	Centers for Disease Control and Prevention
DOD	Department of Defense
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
MCM	medical countermeasure
OMB	Office of Management and Budget
PAHPAI Act	Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
POAM	plan of action and milestone
PPE	personal protective equipment
PRROC	Preparedness and Response Requirements Oversight Council
SNS	Strategic National Stockpile

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October 17, 2022

Congressional Addressees

Recent emergencies—including natural disasters and infectious disease outbreaks—have highlighted the importance of national efforts to prepare for, respond to, and recover from such events. One key component of the nation’s medical response infrastructure is the Strategic National Stockpile (SNS), which is overseen by the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS).¹ The SNS is a multibillion dollar federal inventory of medical countermeasures (MCM)—drugs, vaccines, supplies, and other materials—that can be used to respond to a broad range of emergencies. The contents of the stockpile may be deployed to state, local, tribal, territorial, and international governments when their supplies are depleted or when the necessary MCMs are not commercially available, such as the antitoxin used to treat botulism.

Originally created to help respond to chemical or biological attacks, the SNS’s mission has expanded since its inception in 1999. SNS activities now include stockpiling any supplies to provide for and optimize the emergency health security of the United States in the event of a bioterrorist attack or other public health emergency. For example, inventory from the SNS has been deployed to respond to Hurricane Katrina (2005), the H1N1 influenza pandemic (2009), the Ebola outbreak in West Africa (2014-2016), the Zika virus outbreak (2016), and the COVID-19 pandemic (2020-2022), among other emergencies.

In its fiscal year 2018-2022 budget plan for MCM development, HHS noted the challenge of maintaining a stockpile of MCMs to use against many low-probability, high-consequence threats, while also maintaining the capacity to rapidly respond to novel threats, like emerging infectious diseases.² Regular appropriations for the SNS over the past decade

¹In July 2022, the Secretary of Health and Human Services removed ASPR from the HHS Office of the Secretary and created a new operating division in the department, to be known as the Administration for Strategic Preparedness and Response. In this report, we refer to ASPR under the organizational name and structure in place at the time we conducted our review.

²U.S. Department of Health and Human Services, *Public Health Emergency Medical Countermeasures Enterprise: Multiyear Budget Fiscal Years 2018-2022* (Dec. 2019).

ranged between \$522 million (fiscal year 2013) to \$845 million (fiscal year 2022).³

Since 2020, through our CARES Act work, we have reported on challenges related to both the immediate SNS COVID-19 response as well as longer-standing challenges related to the management and contents of the SNS. For example, in our June 2020 report, we noted that the nationwide need for critical supplies to respond to the COVID-19 pandemic quickly exceeded the quantity contained in the SNS.⁴ Further, in our January 2021 report, we described ASPR's efforts to address vulnerabilities identified during the COVID-19 pandemic, including developing new capabilities for, and the role of, the SNS in future pandemics.⁵ Additionally, in our March 2021 report, we discussed the long-term challenges of determining the appropriate role of the SNS in a pandemic, aligning SNS's role and funding, allocating limited inventory, and clarifying roles and responsibilities among response partners.⁶ Finally, in January 2022, we added HHS's leadership and coordination of public health emergencies to our High Risk List, in part due to persistent deficiencies in HHS's management of MCMs, including through the SNS.⁷

Ensuring the nation is prepared to respond to a variety of health security events—including emerging infectious diseases—is a key interest of Congress. As such, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAI Act) included a provision for GAO to review the management and contents of the SNS.⁸ Specifically, the act provided that the review should include the processes, decisions,

³The SNS has received supplemental funding in certain years, including \$3.25 billion in fiscal year 2021.

⁴GAO, *COVID-19: Opportunities to Improve Federal Response and Recovery Efforts*, [GAO-20-625](#) (Washington, D.C.: June 25, 2020).

⁵GAO, *COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention*, [GAO-21-265](#) (Washington, D.C.: Jan. 28, 2021).

⁶GAO, *COVID-19: Sustained Federal Action Is Crucial as Pandemic Enters Its Second Year*, [GAO-21-387](#) (Washington, D.C.: Mar. 31, 2021). Please see the related GAO products section for a full list of our CARES Act work related to the SNS.

⁷GAO, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies*, [GAO-22-105291](#) (Washington, D.C.: Jan. 27 2022).

⁸Pub. L. No. 116-22, § 403(a)(5), 133 Stat. 905, 946-47.

and spending related to the procurement of MCMs for the stockpile, among other things. In addition, this report is part of our body of work in response to the CARES Act, which includes a provision for us to report on the federal response to the COVID-19 pandemic.⁹ In this report, we

1. examine the process HHS used to make MCM inventory decisions for the SNS beginning with fiscal year 2015.
2. examine the obligations made for MCMs in the SNS in fiscal years 2015 through 2021 using funds other than COVID-19 relief funds, and the extent to which the MCM inventory aligns with recommendations, and
3. describe the obligations made for MCMs in the SNS using COVID-19 relief funds, and any changes to the SNS's inventory and operations in response to the pandemic.

The PAHPAI Act included a provision for us to report on information related to the transition of the SNS to ASPR; plans developed for the deployment, distribution, and dispensing of MCMs; and the status of any recommendations made by GAO or the HHS Office of Inspector General. In response, we provide this information in appendix II.

This report is a public version of a sensitive report that we issued on August 12, 2022.¹⁰ HHS deemed some of the information in our August report to be sensitive, which must be protected from public disclosure. This subsequent report publishes the findings discussed in our August 2022 report, but omits certain information about the types and amount of MCMs in the stockpile. Although the information provided in this report is more limited, the report addresses the same objectives as the sensitive report and uses the same methodology.

To examine the process HHS used to make MCM inventory decisions for the SNS beginning with fiscal year 2015, we reviewed documentation related to the SNS—including documentation from ASPR and the Centers for Disease Control and Prevention (CDC)—and an interagency group of experts involved in these decisions known as the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). This

⁹Pub. L. No. 116-136, § 19010, 134 Stat. 281, 579-81 (2020). All of GAO's reports related to the COVID-19 pandemic are available on GAO's website at <https://www.gao.gov/coronavirus>.

¹⁰GAO, *Public Health Preparedness: HHS Action Needed to Address Strategic National Stockpile Statutory Requirements and Risks Related to Inventory Gaps*, GAO-22-104718SU (Washington, D.C.: August 12, 2022).

documentation included standard operating procedures for SNS annual reviews (SNS review) as well as 7 years of SNS reviews (2012 - 2016, and 2020 - 2021). SNS reviews are used to guide purchases several years in the future, so we reviewed all available SNS reviews developed to inform purchases for fiscal years 2015 through 2024. We compared the two most recent SNS reviews (2020 and 2021) to statutory requirements enacted in 2019 under the PAHPAI Act. We also assessed the process used to develop those two reviews against GAO's leading practices for collaboration.¹¹ We also interviewed current and former ASPR officials who participated in the management of the SNS and governance of the PHEMCE.

To examine obligations made for MCMs in the SNS in fiscal years 2015 through 2021 using funds other than COVID-19 relief funds, we analyzed data on obligations for the procurement of MCMs for the SNS provided by two ASPR offices, the Division of the Strategic National Stockpile and the Biomedical Advanced Research and Development Authority (BARDA).¹² For obligations made using appropriations for the SNS, our analysis is limited to obligations that were \$1 million or greater.¹³ To examine the extent to which the SNS inventory aligns with recommendations, we reviewed recommendations made and SNS inventory levels reported in the aforementioned SNS reviews. Because PHEMCE recommendations are intended to affect the types and quantities of MCMs held by the SNS in the future, we compared the latest available data on MCM inventory levels, as reported in the 2021 SNS review, to the recommendations for the types and quantities of MCM made in the 2016 SNS review. We also assessed the information reported in the SNS reviews against GAO's

¹¹GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012).

¹²An obligation is a definite commitment that creates a legal liability of the U.S. government for the payment of goods and services ordered or received, or a legal duty on the part of the U.S. government that could mature into a legal liability by virtue of actions on the part of another party that are beyond the control of the U.S. government.

¹³Obligations \$1 million and greater account for 99 percent of total MCM obligations during this time frame. Our analysis of obligations by threat is limited to obligations \$1 million and greater that contained a description of the MCM in the data, which accounts for 97.5 percent of total obligations during this time frame.

Enterprise Risk Management principles and Office of Management and Budget (OMB) guidance.¹⁴

To describe obligations made for MCMs in the SNS using COVID-19 relief funds, we analyzed data provided by ASPR on obligations made for fiscal years 2020 and 2021 using funds appropriated by the six COVID-19 relief laws.¹⁵ We limited our analysis to obligations for MCMs that were held in the SNS rather than those that were used to send supplies immediately to state, local, tribal, and territorial entities. To describe changes to the SNS's inventory and operations in response to the COVID-19 pandemic, we analyzed inventory data for MCMs procured in response to the COVID-19 pandemic provided by the Division of the Strategic National Stockpile. Additionally, we interviewed the head of each branch of the SNS as well as the SNS director about how the COVID-19 pandemic had impacted operations. We also reviewed the *National Strategy for a Resilient Public Health Supply Chain* and the associated plan of action and milestones (POAM) for the comprehensive SNS transformation strategy, with reference to the six characteristics of effective national strategies we have identified in our prior work.¹⁶

To ensure the reliability of the obligations data we analyzed, we reviewed related documentation, interviewed knowledgeable ASPR officials, and conducted checks on the data. These checks included completing a variety of descriptive analyses and comparing the data to other ASPR documents, such as spend plans and SNS reviews. We found the data to be sufficiently reliable for the purposes of presenting obligations for MCMs for the SNS inventory. Please see appendix I for a more detailed discussion of our objectives, scope, and methodologies.

¹⁴GAO, *Enterprise Risk Management: Selected Agencies Experiences Illustrate Good Practices in Managing Risk*, [GAO-17-63](#) (Washington, D.C.: Dec 1, 2016); and Office of Management and Budget, *Management's Responsibility for Enterprise Risk Management and Internal Control*, OMB Circular No. A-123 (July 15, 2016).

¹⁵See American Rescue Plan Act of 2021, Pub. L. No. 117-2, 135 Stat. 4; Consolidated Appropriations Act, 2021, Pub. L. No. 116-620, 134 Stat. 1182 (2020); Paycheck Protection Program and Health Care Enhancement Act, Pub. L. No. 116-139, 134 Stat. 620 (2020); CARES Act, Pub. L. No. 116-136, 134 Stat. 281; Families First Coronavirus Response Act, Pub. L. No. 116-127, 134 Stat. 178 (2020); and the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. No. 116-123, 134 Stat. 146. We refer to funds appropriated by these laws as COVID-19 relief funds.

¹⁶GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, [GAO-04-408T](#) (Washington, D.C.: February 3, 2004).

The performance audit upon which this report is based was conducted from January 2021 to August 2022 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. We subsequently worked from August 2022 to October 2022 to prepare this version of the original sensitive report for public release. This public version also was prepared in accordance with those standards.

Background

HHS first established a stockpile of vaccines and other pharmaceuticals in 1999 to respond to biological or chemical attacks.¹⁷ This effort was sometimes referred to as the “National Pharmaceutical Stockpile” in annual appropriations acts, until the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 created the “Strategic National Stockpile.”¹⁸ See sidebar for a description of the contents and uses of the MCMs held in the SNS.

The stockpile has generally been the responsibility of HHS, except for a brief period from 2002 to 2004 when it was transferred to the Department of Homeland Security.¹⁹ The Secretary of Health and Human Services transferred responsibility for the SNS from CDC to ASPR in 2018.²⁰

¹⁷The Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 provided \$51 million “for pharmaceutical and vaccine stockpiling activities.” Pub. L. No. 105-277, § 705, 112 Stat. 2681, 2681-358 (1998).

¹⁸Pub. L. No. 107-188, § 121, 116 Stat. 594, 611-13 (codified, as amended, at 42 U.S.C. § 247d-6b).

¹⁹The Homeland Security Act of 2002 transferred the SNS and all related functions of the Secretary of Health and Human Services to the Secretary of Homeland Security. Pub. L. No. 107-296, § 503, 116 Stat. 2135, 2213. Two years later, the Project BioShield Act of 2004 transferred the SNS back to HHS. Pub. L. No. 108-276, § 3(c), 118 Stat. 835, 853.

²⁰Under 42 U.S.C. § 300hh-10(c)(3)(B), the Assistant Secretary for Preparedness and Response is to exercise the Secretary’s responsibilities with respect to coordination of the SNS.

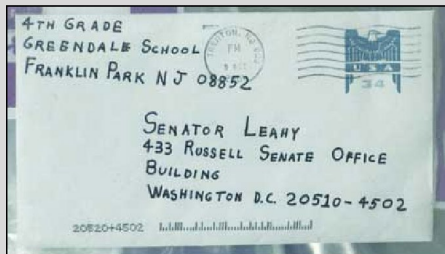
Strategic National Stockpile Appropriations

Contents of the Strategic National Stockpile (SNS)

The SNS contains a variety of medical countermeasures including drugs (e.g. antibiotics), vaccines, biological toxin antidotes, personal protective equipment (e.g. masks, gloves and gowns), and supportive care devices (e.g. ventilators, dressings, and burn creams).

These medical countermeasures can be used for different purposes. For example, vaccines are available for the prevention of smallpox and anthrax; antitoxins are available to treat botulism; and antivirals are available in the case of pandemic influenza.

The SNS was first used during the September 11, 2001, terrorist attacks and subsequent anthrax attacks. During these two incidents, the SNS provided pharmaceuticals, medical supplies, vaccines, and medicines to prevent anthrax symptoms.

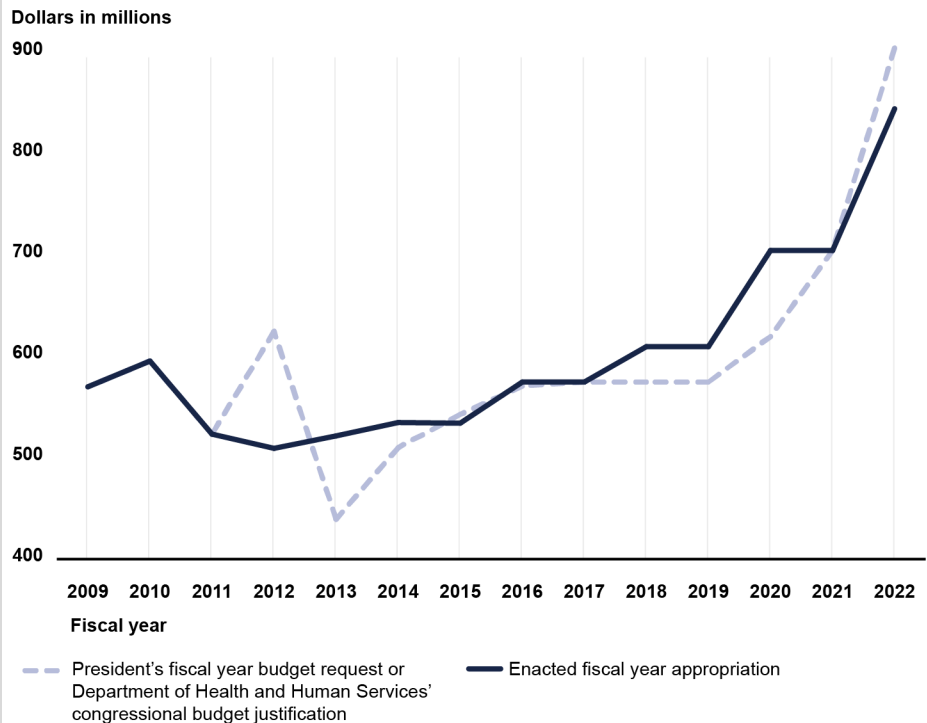


Soon after the terrorist attacks of 9/11, letters laced with anthrax began appearing in the U.S. mail.

Source: GAO analysis of SNS inventory (data) and Federal Bureau of Investigation (photo). | GAO-23-106210

As we have previously reported, annual appropriations for the SNS fluctuated between fiscal years 2009 and 2013; however, since that time, the SNS experienced increases in annual appropriations through fiscal year 2022 (see fig. 1).²¹ In most years since fiscal year 2009, appropriations for the SNS were equal to or more than what the administration requested.

Figure 1: Strategic National Stockpile (SNS) Requested and Regular Appropriations



Source: GAO analysis of Department of Health and Human Service (HHS) data. | GAO-23-106210

Note: The figure only depicts enacted regular appropriations for the SNS. For the requested amounts, we used the Department of Health and Human Services' congressional budget justification for fiscal years 2019 and 2020 and the President's budget request for all other fiscal years.

²¹GAO-21-265.

Examples of Infectious Disease Outbreaks and Strategic National Stockpile (SNS) Response



A microscopic image of the Ebola virus.

Ebola: Ebola virus disease is an acute, serious illness, which is often fatal if untreated. Symptoms of infection include fever, muscle pain, and impaired kidney and liver function, among other symptoms. Ebola virus is introduced into human populations through close contact with the blood and bodily fluids of infected animals. The SNS provided personal protective equipment as well as staff to support the 2014 response in the United States and West Africa.



A mosquito.

Zika: Zika virus is primarily transmitted through mosquito bites and causes symptoms that include fever, rash, headache, and joint and muscle pain, though many infected individuals do not have symptoms or only experience mild symptoms. In pregnant women, this infection has been linked to adverse pregnancy and birth outcomes. In 2016, the SNS obtained Zika prevention products, such as insect repellent, assembled Zika prevention kits for pregnant women, and deployed stockpile staff to United States territories.

Source: Office of the Assistant Secretary for Preparedness and Response (information) and Centers for Disease Control and Prevention (information and photos). | GAO-23-106210

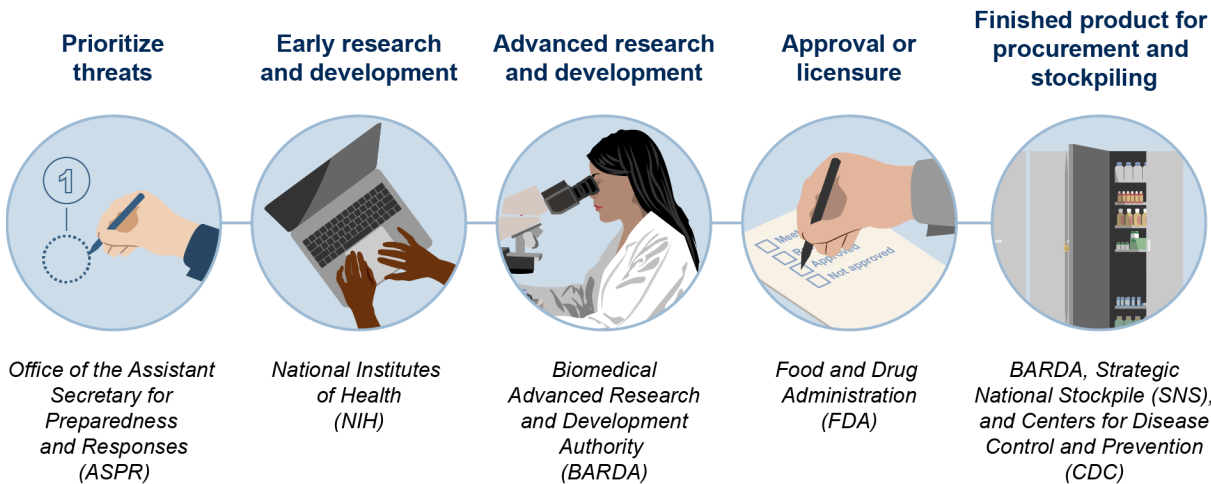
Additionally, supplemental appropriations enacted in response to particular emergencies, such as the 2009 H1N1 influenza pandemic and the 2014 outbreak of Ebola virus disease, could be used to purchase MCMs for the SNS (see sidebar for examples of the diseases the SNS has responded to). Most recently, various laws providing funds to respond to the COVID-19 pandemic were enacted. These laws appropriated funding for HHS activities, and, in some cases, specifically authorized their use for the SNS. HHS reported it had obligated about \$10.5 billion of the \$13.9 billion it planned to use for the SNS, as of February 2022.

Interagency Responsibilities for MCM Development

HHS leads the federal government’s public health and medical response to emergencies, which involves identifying critical MCMs for development and procurement for civilian populations.²²

Within HHS, ASPR has the lead responsibility for emergency preparedness and response policy coordination and strategic direction. This includes leading the PHEMCE interagency group of experts; overseeing advanced research, development, and procurement of MCMs; and managing the SNS.²³ Several HHS agencies play distinct roles related to MCMs (see fig. 2).

Figure 2: Department of Health and Human Services’ (HHS) Responsibilities for Medical Countermeasure Assessment, Development, Procurement, and Stockpiling



Source: GAO analysis of Department of Health and Human Service (HHS) information. | GAO-23-106210

Note: BARDA and the Division of the Strategic National Stockpile, which manages the SNS, are within ASPR. BARDA supports the advanced development and procurement of drugs, vaccines, and other medical countermeasures (MCM). In some cases, BARDA also funds earlier stage research and development for MCMs as well as procurement of finished products. CDC supports development of clinical guidance for finished products and conducts other efforts to help ensure the safe and effective use of MCMs in a public health emergency, such as by helping to build state and local capacity to effectively administer MCMs.

²²The Secretary of Homeland Security is required to assess current and emerging threats from chemical, biological, radiological, and nuclear agents on an ongoing basis and determine which agents present a material threat against the United States sufficient to affect national security. Using these material threat determinations, the Secretary of Health and Human Services is required to assess potential public health consequences of exposure to agents and determine which MCMs are necessary to protect public health. 42 U.S.C. § 247d-6b(c)(2)(A) and (B).

²³ASPR’s leadership of the PHEMCE includes staffing, developing organizational documents, and convening meetings.

For example, BARDA, an office within ASPR, supports the advanced research and development of MCMs by providing technical assistance, contracts or other funding, and engagement with industry through public-private partnerships. This includes support for the development and manufacture of new MCMs to respond to threats that can be added to the SNS inventory. For example, BARDA administers Project BioShield funding, which is used for the development and purchase of MCMs to address biological, chemical, radiological and nuclear threats.²⁴ According to HHS, BARDA can use Project BioShield funding to purchase MCMs that are in advanced development but not yet approved, licensed, or cleared by the Food and Drug Administration (FDA); these MCMs could later be distributed by the SNS under an emergency use authorization, if needed.²⁵

HHS established the PHEMCE in 2006 to advance national preparedness for natural, accidental, and intentional threats by coordinating MCM development and procurement efforts within HHS and in cooperation with other federal agencies. In addition to the HHS agencies identified in fig. 2, the Departments of Defense and Homeland Security, as well as other federal agencies, participate in the PHEMCE. The PHEMCE was codified in 2019 by the PAHPAI Act.²⁶ The act specified that the PHEMCE is to make recommendations to the Secretary of Health and Human Services regarding research, procurement, and stockpiling of MCMs and assist the

²⁴Funds to implement Project BioShield are provided through annual appropriations acts. For example, the Consolidated Appropriations Act, 2022 provided \$780 million for the procurement of MCMs under Project BioShield. Pub. L. No. 117-103, div. H, tit. II, 136 Stat. 49, 464-65.

²⁵Typically, FDA must approve, license, or clear a new product before it can be marketed in the United States. See 21 U.S.C. § 355 (drugs); 21 U.S.C. § 360e(c) and 360(k) (devices); and 42 U.S.C. § 262 (biologics). However, during an emergency, FDA may temporarily allow the use of products that have not been approved, licensed, or cleared by issuing an emergency use authorization, provided certain statutory criteria are met. See 21 U.S.C. § 360bbb-3.

²⁶Pub. L. No. 116-22, § 402(a), 133 Stat. at 942-43 (codified at 42 U.S.C. § 300hh-10a).

Secretary in developing strategies for logistics, deployment, distribution, dispensing, and use of MCMs from the SNS.²⁷

The Strategic National Stockpile Annual Review

The SNS review was a year-long process—managed by ASPR—that started with an examination of the SNS inventory, including any gaps, and resulted in recommendations for MCM procurements for the subsequent budget cycle. Because the budget cycle process begins 3 years prior to the appropriation year, SNS reviews have been used to guide procurements 3 years in advance. For example, the 2016 SNS review examined the SNS inventory in 2016, was finalized in 2017, and made recommendations for the procurement of MCMs for fiscal year 2019. The PHEMCE has historically played a key role in the SNS review process.

The PAHPAI Act established several new requirements for SNS reviews, referred to in the act as “annual threat-based reviews.”²⁸ For example, the act specified that SNS reviews must provide information regarding quantities of MCMs procured for the SNS, the threat such procurement is intended to address, and planning considerations for appropriate manufacturing capacity, among other information.

ASPR Suspended Process for Informing Inventory Decisions, Resulting in Missing SNS Reviews and Unmet Requirements

SNS inventory decisions for fiscal years 2015 through 2019, were guided by a multi-step process led by ASPR. This process involved guidance from the PHEMCE’s expert interagency partners and resulted in the completion of the SNS review. However, ASPR suspended this process after initiating a reorganization of the PHEMCE. As a result, SNS reviews were not completed for 3 years; these reviews would have informed inventory decisions for fiscal years 2020 through 2022. Instead of completing annual reviews, SNS officials told us they used recommendations from a previously completed review to inform inventory decisions for these years. ASPR officials completed SNS reviews to inform fiscal year 2023 and 2024 inventory decisions. However, the processes used to develop these reviews differed from that of prior reviews in that they relied on ASPR officials for development with limited input from PHEMCE interagency partners. Additionally, these reviews did

²⁷Although the act does not specify that states, local government, tribes and territories should be represented on the PHEMCE, in July 2021, we noted that ASPR had considered incorporating the insights of public health organizations that represent these groups into the PHEMCE process in order to focus on issues related to the deployment and use of MCMs. [GAO-21-551](#).

²⁸Pub. L. No. 116-22, § 403(a)(3), 133 Stat. at 944-45 (codified at 42 U.S.C. § 247d-6b(a)(2)).

not address most statutory requirements, in part, because ASPR did not update its review procedures to account for the requirements.

PHEMCE-Guided Reviews Informed SNS Inventory Decisions for Fiscal Years 2015 Through 2019

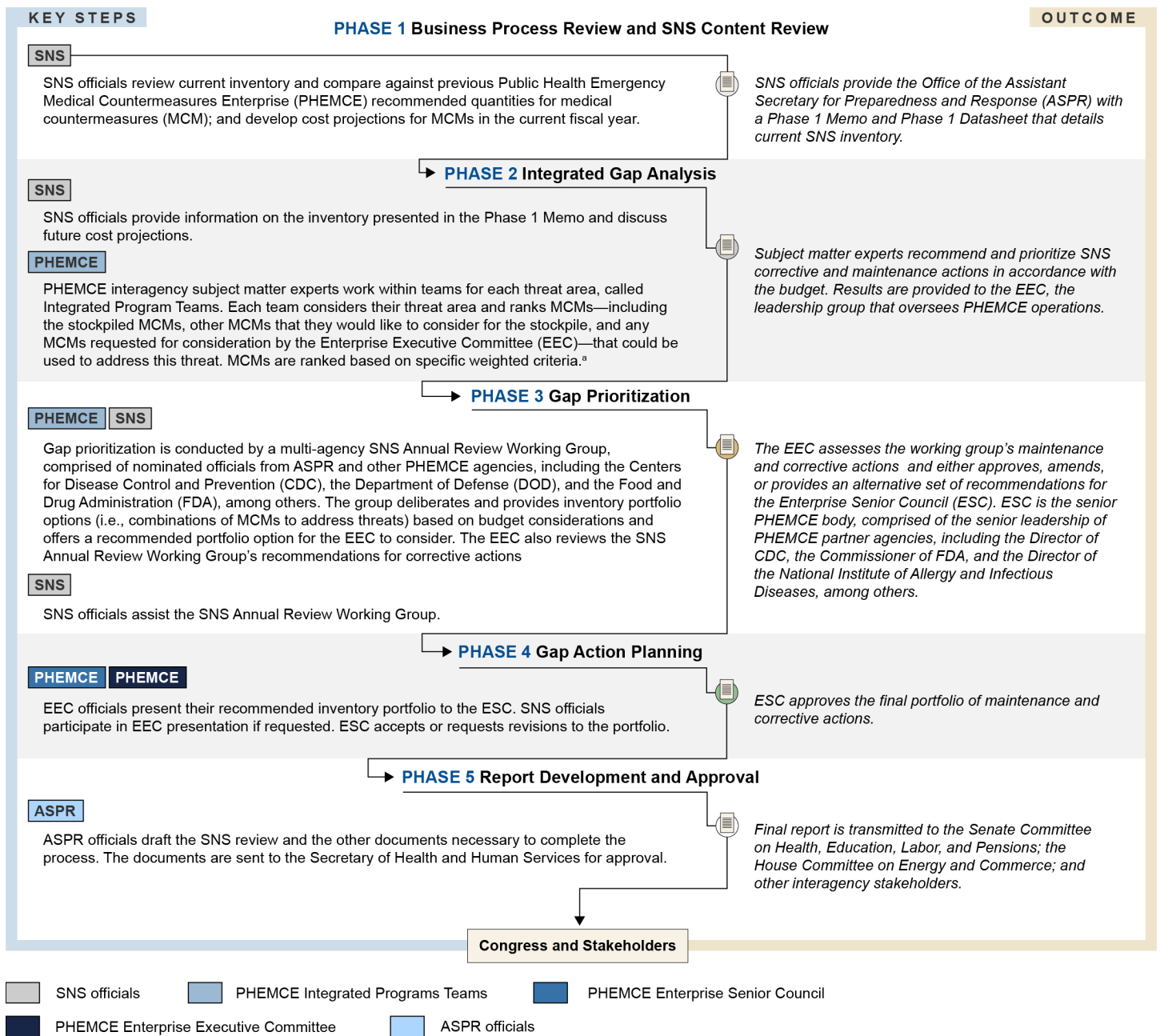
According to ASPR documentation and interviews with ASPR officials and PHEMCE interagency partners, ASPR used a multi-step process that resulted in an SNS review to inform SNS inventory decisions for fiscal years 2015 through 2019. This process was managed by ASPR through the PHEMCE and included input from the PHEMCE's expert interagency partners. According to a 2014 standard operating procedure outlining the steps of the SNS reviews and interviews with SNS officials, developing the SNS review was a five-phase process. This process incorporated inventory data and spending projections from SNS officials as well as review by subject matter experts from PHEMCE interagency partners and leadership.

For example, subject matter experts ranked each MCM based on the following five weighted criteria, resulting in a prioritized ranking of MCMs used by PHEMCE leadership to guide inventory recommendations:

- **Criticality:** examined how critical the MCM was to addressing health consequences in emergency scenarios;
- **Flexibility:** examined how versatile the MCM was to address other threat agents;
- **Performance:** examined how well the MCM worked;
- **Sustainability:** examined the ease and cost of maintaining the MCM once acquired; and
- **Usability:** examined how readily the MCM could be used, such as the level of sophistication needed to administer it.

See fig. 3 for a description of the multi-step process used to develop the SNS review.

Figure 3: Multi-Step Development Process for Strategic National Stockpile (SNS) Review, As Outlined in 2014 Procedures



Source: GAO analysis of documentation, including 2014 Standard Operating Procedures for the SNS review, from the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS). | GAO-23-106210

^aThe five criteria used to rank MCMs were criticality, flexibility, performance, sustainability, and usability, and were weighted by the PHEMCE's Enterprise Executive Committee based on relative importance. In total, there were 10 Integrated Program Teams. Seven expert teams focused on a specific threat portfolio, with three additional teams—one focused on monitoring and assessment (i.e., collecting and analyzing data on MCM safety, compliance, and clinical benefits during and after an emergency event), one focused on diagnostics, and one focused on children and pregnant people.

The end result of the SNS review process was a report to Congress and other stakeholders that included information on the SNS inventory and recommendations for SNS inventory procurement for a future fiscal year. For example, the 2016 SNS review examined the SNS's inventory as of March 2016, was finalized in May 2017, and made recommendations for the procurement of MCMs for fiscal year 2019.

Each SNS review represented the culmination of PHEMCE input and contained information to help with decisions related to the SNS's inventory, including:

Recommendations in Strategic National Stockpile (SNS) Reviews

Each SNS review contains multiple recommendations related to medical countermeasures (MCM).

Recommended MCM Types: SNS reviews identify the types of MCMs to hold in the SNS inventory. Each MCM type may include more than one specific MCM.

Recommended MCM Quantities: For each MCM type, SNS reviews identify a recommended quantity, which is the amount of that MCM type the SNS should have in the inventory. This quantity is determined based on threat assessments and specific response scenarios (e.g., the number of individuals to be treated). SNS reviews also report on-hand quantities for each MCM type and the percentage of the recommended quantity reached.

Recommended Corrective Actions: SNS reviews list recommended actions to take related to the inventory, including increases to the amount of stockpiled MCMs to help close gaps between on-hand quantities and the recommended quantity. Recommended corrective actions, if implemented, may not fully close the gap between on-hand quantities and the recommended quantity. Sometimes SNS reviews recommend actions to decrease the amount of stockpiled MCMs to prioritize resources elsewhere.

Source: GAO analysis of SNS reviews. | GAO-23-106210

According to ASPR officials, for fiscal years 2015 through 2019, SNS officials used SNS reviews to develop a draft spend plan that listed the specific MCMs to purchase, along with their associated costs. Spend plans were developed for the corresponding years of funding needs, and prioritized planned MCMs for purchase within the expected budget. SNS officials stated they presented the spend plan to senior HHS officials to determine further prioritization, make trade-off decisions, and obtain approval. ASPR officials explained the spend plan was then refined and used to develop a budget request for the SNS. After funds were appropriated, ASPR officials explained, the spend plan was used to determine how to obligate appropriated funds. They noted that if appropriations were less than the requested amount, the spend plan

would be revised to account for any additional budgetary constraints before making obligations based on the spend plan.

SNS Review Process Suspended; Inventory Decisions for Fiscal Years 2020 through 2022 Informed by Previous Review

As we have previously reported, ASPR began a major reorganization of the PHEMCE after 2017, which resulted in the suspension of certain PHEMCE operations, including the multi-step process for developing SNS reviews to inform SNS inventory decisions for fiscal years 2020 through 2022 (see sidebar for more detail about the PHEMCE reorganization).²⁹ This resulted in SNS reviews that were not completed. In their absence, ASPR relied on a previously completed review for inventory decisions. Specifically,

- ASPR did not conduct statutorily required SNS reviews for 3 years. ASPR officials told us that SNS reviews were not conducted in 2017, 2018, and 2019 (which would have informed inventory decisions for fiscal years 2020 through 2022) due to the PHEMCE reorganization. This resulted in no one within ASPR being assigned the responsibility for ensuring completion of these reviews, ASPR officials told us.
- In the absence of the reviews, SNS officials told us they developed spend plans and procured MCMs for fiscal years 2020 through 2022 based on recommendations from a prior SNS review and real-time direction from the Assistant Secretary. SNS officials said that for many years, much of the appropriations for the SNS had been used to maintain the existing inventory (e.g., replacing expired MCMs already in the SNS), leaving little funding for new MCMs recommended to be added to inventory. Similarly, for fiscal years 2020 through 2022, SNS officials said they focused on purchasing expiring MCMs that address priority recommendations identified in the 2016 SNS review. Additionally, SNS officials told us they also used corrective actions from the 2016 review to guide multi-year purchases that would address inventory gaps.

ASPR Resumed Reviews to Inform Fiscal Years 2023 and 2024 Using an Abbreviated Process, but Reviews Have Not Met PAHPAI Act Requirements

ASPR resumed annual reviews to inform SNS inventory decisions for fiscal years 2023 and 2024. ASPR officials told us the reviews for these years were developed using an abbreviated processes that relied on ASPR officials with limited input from PHEMCE interagency partners.

²⁹GAO, *COVID-19: Continued Action Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity*, [GAO-21-551](#) (Washington, D.C.: July 19, 2021).

Reorganization of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

We reported in July 2021 that the PHEMCE reorganization included:

- narrowing the focus of the PHEMCE to medical countermeasure (MCM) development and procurement instead of also providing input on deployment strategies and other MCM issues;
- limiting the range of threats it reviewed; and
- reducing the number of subject matter expert teams that regularly met.

The Office of the Assistant Secretary for Preparedness and Response (ASPR) and its PHEMCE partners reported that ASPR made these changes in response to concerns about the PHEMCE structure, including that the decision-making process was too slow.

We recommended ASPR 1) develop and document plans for restructuring the PHEMCE, to ensure a transparent deliberative process that engages interagency partners; and 2) implement records management practices to document the factors considered, rationale for decisions made, and final outcomes, including those related to the Strategic National Stockpile. The Department of Health and Human Services concurred with these recommendations and reported working to implement them.

Source: [GAO-21-551](#). | [GAO-23-106210](#)

ASPR officials described using an abbreviated process to develop these reviews—the 2020 and 2021 SNS reviews—due to the PHEMCE being non-operational and unable to guide the SNS review process, and COVID-19 response efforts.³⁰ Officials told us the process generally involved ASPR officials, including those within BARDA, who compared the SNS inventory to the quantities of MCM types recommended in past reviews. Officials stated that the office relied on the past reviews and input from ASPR to make changes to requirements for MCM types and quantities. They stated that for both the 2020 and 2021 reviews, the process consisted of reviewing previous recommendations and making internal decisions about what changes were needed moving forward. In providing technical comments to this draft, HHS officials stated that the abbreviated process resulted in recommendations to fill gaps, but did not involve more rigorous analysis.

ASPR officials noted that they shared drafts of these reviews with the agencies that participate in the PHEMCE to obtain feedback on them, engaging in multiple rounds of reviews. CDC officials noted that while ASPR shared copies of the 2020 and 2021 SNS reviews as part of the HHS process to finalize these documents, this was a formality. Specifically, CDC officials noted these reviews were not developed with the participation of CDC subject matter experts and they expressed concerns to ASPR about establishing new recommended quantities for some MCM types when the PHEMCE was not operating.

Our analysis of the 2020 and 2021 SNS reviews found that the reviews addressed several requirements, such as including all types of MCMs contained in the SNS inventory and providing information on which threat or threats the MCM is intended to address. However, they did not meet most of the new statutory requirements established in the PAHPAI Act. Table 1 provides examples of requirements that were not met.

³⁰The 2020 SNS review, which was due on March 15, 2021, was submitted to the Secretary of Health and Human Services for review in November 2021 and to Congress in April 2022, according to ASPR officials. The 2021 SNS Review, due on March 15, 2022, was finalized and submitted to Congress in March 2022, according to ASPR officials.

Table 1: Examples of Statutory Requirements Not Met by the 2020 and 2021 Strategic National Stockpile (SNS) Reviews

Statutory Requirement	2020 and 2021 SNS Reviews
SNS reviews should provide, for each new or modified medical countermeasure (MCM) procurement or replenishment, information on the quantities of additional or modified MCMs procured or contracted to be procured.	The 2020 and 2021 SNS reviews did not include this information; rather, they provided quantities of the inventory currently stockpiled without any information about how quantities had changed from the past or if any procurements had been contracted for the future.
SNS reviews should provide, for each new or modified MCM procurement or replenishment, information on planning considerations for appropriate manufacturing capacity and capability to meet the goals of such additions or modifications, including consideration of the effect such additions or modifications would have on the availability of those products across the health care system.	The 2020 and 2021 SNS reviews did not include this information. Both reviews provided recommendations for how to close gaps between recommended quantities and quantities of MCMs contained in the SNS, but none of these recommendations included consideration of manufacturing capacity or capabilities. Both reviews explicitly noted that the recommendations assume there are no manufacturing constraints or limitations. The 2021 review provides some information on actions the federal government took during the COVID-19 pandemic to enhance domestic MCM manufacturing capabilities, including using the Defense Production Act and creating ASPR's Office of Innovation and Industrial Base Expansion and the Supply Chain Control Tower. However, this information did not address manufacturing capacity and capability for each MCM, nor did it analyze the effect MCM procurements might have across the health care system. ^a
SNS reviews should provide, for each new or modified MCM procurement or replenishment, information on how such additions or modifications align with investments projected in previous MCM budget plans, including expected life-cycle costs, procurement expenditures to address identified threats, replenishment dates, and manufacturing capacity required to replenish MCMs.	The 2020 and 2021 SNS reviews did not provide any information on how additional or modified MCMs align with projections in previous budget plans.
SNS reviews should provide for each new or modified MCM procurement or replenishment, information on appropriate protocols and processes for the deployment, distribution, and dispensing of the MCM at the state and local level, including plans for relevant capabilities of state and local entities to dispense, distribute, and administer the MCM.	While the 2020 and 2021 SNS reviews stated that response plans and guidance, such as clinical guidelines, are developed to facilitate the use of MCMs during a public health emergency, they did not provide or make reference to any specific protocols or processes for the deployment, distribution, and dispensing of each MCM at the state and local level.

Source: GAO analysis of the 2021 and 2020 SNS annual reviews (SNS reviews) compared to statutory requirements. | GAO-23-106210

^aAs we previously reported, during the COVID-19 pandemic, the Office of the Assistant Secretary for Preparedness and Response (ASPR) did take some action to mitigate the effect that procurement of COVID-19 supplies would have on the availability of those products across the health care system. Specifically, we reported in November 2020 that ASPR delayed delivery of some purchased supplies to allow manufacturers to make them available to the commercial market and alleviate supply constraints. GAO, COVID-19: *Urgent Actions Needed to Better Ensure an Effective Federal Response*, GAO-21-191 (Washington, D.C.: Nov 30, 2020).

ASPR officials told us that the new statutory requirements outlined in the PAHPAI Act were not met in these reviews for a few reasons, including that the PHEMCE was not active and SNS officials were considering a new operational strategy that could affect which MCMs are stockpiled. ASPR officials also told us that the office was quickly trying to come into

compliance with its statutory obligation to complete SNS reviews. However, neither of the recent SNS reviews acknowledges the existence of the new statutory requirements. The standard operating procedures for developing SNS reviews were developed in 2014, before the new requirements were established in law, and have not been updated.

ASPR officials stated that they re-established the PHEMCE in February 2022 and are working on developing the PHEMCE structure, policies and procedures, including those related to SNS reviews. ASPR officials noted that they are trying to be very deliberate in their approach to ensure that the PHEMCE, and its policies and procedures, take into account lessons learned in order to be successful moving forward. However, ASPR officials could not provide a time frame, or any documentation, related to this effort. Additionally, ASPR officials said they were still determining how a new body called the Preparedness and Response Requirements Oversight Council (PRROC), that comprised senior acting or career ASPR officials formed to review and approve changes to requirements for MCMs, among other things, would fit into the new PHEMCE process.

ASPR officials noted that they intend to address the statutory requirements in the 2022 SNS review, due by March 2023. In addition, in commenting on a draft of this report, HHS re-affirmed its commitment to reinstate a comprehensive approach to develop the 2022 SNS review.

Until ASPR updates its procedures for SNS reviews to account for changes made by the PAHPAI Act, the office risks not meeting the statutory requirements that are designed to give Congress additional information about the SNS inventory. Further, updating the procedures to account for the roles and responsibilities of internal and external partners within the new PHEMCE structure is consistent with our prior work on leading collaboration.³¹

Moreover, the PAHPAI Act also requires ASPR, in managing the SNS inventory, to ensure that each MCM under consideration for purchase receives the same consideration regardless of whether it received development funding from BARDA.³² ASPR had an opportunity in the 2020 SNS review to describe the approach it uses to provide such an

³¹GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012).

³²See 42 U.S.C. § 247d-6b(a)(3)(I).

assurance. Specifically, the PAHPAI Act required that the first SNS review completed after the law's enactment—the 2020 SNS review—include a description of the processes and procedures in place for ensuring this consideration.³³

However, our review found that ASPR did not include this description in the 2020 SNS review. In addition, ASPR has not yet documented the approach the office will use going forward to ensure equal consideration when determining which MCMs to purchase for the SNS inventory. ASPR officials told us that the PHEMCE had previously established a process to prioritize MCMs to purchase for the SNS inventory and this process provided for all MCMs to be considered equally, regardless of whether they were developed with support from BARDA. That process—outlined in ASPR's 2014 standard operating procedures for SNS reviews—involved subject matter experts ranking stockpiled and commercially available MCMs for each threat using five established criteria: criticality, flexibility, performance, sustainability, and usability.

But this process has not been used since the 2017 PHEMCE reorganization, and the 2014 standard operating procedures lack the detail needed to provide assurance that the prior process would address the statutory requirement. Additionally, CDC officials stated it is important that BARDA-supported products be evaluated for inclusion in the SNS using a clearly defined and transparent process.

ASPR officials told us they are in the process of documenting their policies and procedures related to the PHEMCE, recently relaunched after a period of inactivity. As part of this effort, they intend to document the process ASPR will use to ensure all MCMs are considered equally, regardless of whether they were developed with support from BARDA. Specifically, ASPR officials noted that they plan to implement the process used prior to the 2017 PHEMCE reorganization and will document this process in updated standard operating procedures.

ASPR did not provide its draft standard operating procedures outlining its approach to meet this requirement, stating it was still under development. Additionally, ASPR officials could not provide a time frame for completion. Without a documented approach—one that also provides sufficient detail to describe how BARDA-supported products are considered for the SNS inventory—it is unclear the extent to which ASPR will be able to fulfill this

³³See Pub. L. No. 116-22, § 403(b), 133 Stat. at 947.

statutory responsibility to ensure products under consideration for SNS procurement receive the same consideration regardless of whether they received development funding from BARDA. Ensuring the SNS contains the most appropriate MCMs is critical to optimizing the nation's preparedness for public health emergencies.

Nearly \$5 Billion Obligated in Non COVID-19 Appropriations for SNS MCMs in Fiscal Years 2015 through 2021; Recommended Quantities Often Not Met

HHS Obligated \$4.8 Billion for SNS MCMs in Fiscal Years 2015 through 2021, Mainly for Anthrax and Smallpox

Our review of HHS obligations data shows that from fiscal years 2015 through 2021, HHS obligated about \$4.8 billion to purchase MCMs for the SNS, exclusive of obligations made using COVID-19 relief funds.³⁴ These obligations were made using \$2.7 billion from appropriations for the SNS (57 percent), \$1.5 billion from appropriations for Project BioShield (33 percent), and \$477 million from appropriations for Ebola relief (10 percent).³⁵ In addition to money obligated for MCMs, HHS obligated \$1.6 billion for other SNS costs during this time frame, including storage, transportation, and staffing.

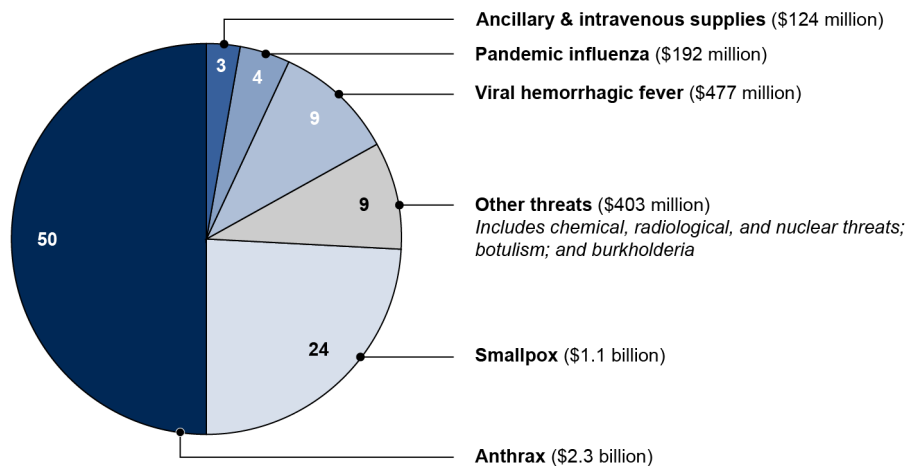
³⁴During the time frame of our analysis, both CDC and ASPR obligated funds to purchase MCMs for the SNS. Specifically, CDC obligated funds from fiscal years 2015 through 2018, when it was responsible for the SNS, and ASPR obligated funds from fiscal years 2019 through 2021.

Obligations in this analysis are limited to those \$1 million and greater, which accounts for 99 percent of total MCM obligations during this time frame, according to our analysis of HHS data.

³⁵Appropriations for Project BioShield and the \$477 million in appropriations for Ebola relief are administered by BARDA.

About three-quarters of funds obligated for MCMs during this time period (nearly \$3.5 billion) were for the purchase of anthrax and smallpox MCMs. The remaining obligations were for the purchase of MCMs to address a range of potential public health threats, such as viral hemorrhagic fever, pandemic influenza, botulism, and chemical and nuclear threats.³⁶ Figure 4 illustrates obligations for the purchase of MCMs by threat.

Figure 4: HHS Obligations for the Purchase of SNS MCMs in Fiscal Years 2015 through 2021, by Threat



Source: GAO analysis of data from the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS). | GAO-23-106210

Notes: The Centers for Disease Control and Prevention obligated funds to purchase medical countermeasures (MCM) for the Strategic National Stockpile (SNS) in fiscal years 2015 through 2018, and ASPR obligated funds for this purpose from fiscal years 2019 through 2021. Obligations to purchase MCMs for the SNS were made using regular appropriations for the SNS, appropriations for Project BioShield, and appropriations for Ebola relief. Appropriations for Project BioShield and Ebola relief are administered by the Biomedical Advanced Research and Development Authority. Obligations reported in this figure are exclusive of those made using COVID-19 relief funds and are limited to those \$1 million and greater for which a MCM was specified, which accounts for 97.6 percent of total MCM obligations for the SNS during this time frame. The ancillary and intravenous supplies category includes personal protective equipment, for which obligations totaled approximately \$6 million (0.1 percent of total obligations). Some MCMs for anthrax can be used for plague and tularemia, so obligations for those threats are included with anthrax.

³⁶Obligations by threat are limited to those \$1 million and greater and those with a description of the MCM in the data, which accounts for 97.6 percent of total obligations during this time frame.

According to SNS officials, there are several factors that explain the large proportion of obligations for anthrax and smallpox MCMs including:

- MCMs for anthrax and smallpox have been priorities for many years and multiple MCMs are available for them; as such, they were held in the SNS inventory throughout the time frame we examined. For other threats, more MCMs were in development with fewer available to be stockpiled. This resulted in lower MCM obligations for these other threats.
- Some smallpox and anthrax MCMs are stockpiled in large quantities (see sidebar for a description of diseases the MCMs are intended to address). As these MCMs expire, they need to be replaced. For example, FDA has specified that an antiviral pill to treat smallpox expires 7 years after it is manufactured. Similarly, a vaccine for anthrax expires after 4 years. The SNS has worked with FDA to conduct stability testing for some MCMs, which can lead to extensions of expiration dates and delay the need for replacement. However, MCMs eventually expire and need to be replaced, requiring sustained investment, according to the PHEMCE Multi-year Budget Report for fiscal years 2018-2022.³⁷

³⁷The Assistant Secretary for Preparedness and Response is required to develop a coordinated 5-year budget plan for MCMs, including procurement, stockpiling, maintenance, and potential replenishment of all products in the SNS, among other information, and to update the plan annually. 42 U.S.C. § 300hh-10(b)(7). This plan is known as the PHEMCE Multi-year Budget Report. The PHEMCE Multi-year Budget Report for fiscal years 2018 through 2022 details budgets for ASPR, FDA, and the National Institutes of Health to conduct MCM-related activities.

Smallpox and Anthrax Diseases

Smallpox and anthrax are two naturally occurring diseases that could be used intentionally to harm the public, according to the Centers for Disease Control and Prevention.



A view of smallpox pustules on the skin.

Smallpox is caused by a virus that spreads from person to person. It causes a fever and a distinctive skin rash. Some people may die from it. Vaccines were used to prevent smallpox until the world's last case of smallpox was reported in 1977. If people today were exposed to the virus, they would be at risk of becoming sick because most people have no immunity to it. ASPR reported that the SNS has also deployed smallpox vaccines as part of its response to the 2022 monkeypox outbreak.



A view of an anthrax lesion on the skin.

Anthrax is caused by bacteria that lives in soil and commonly affects animals such as cattle. People can get infected when spores from the bacteria get on their skin or into their bodies, such as breathing them into the lungs, but infected persons cannot spread it to other people. Inhaled anthrax can lead to fever, shortness of breath, coughing, and body aches. Anthrax can often be cured if it is treated early, but if treatment is started late, it can cause severe illness and death.

Source: Centers for Disease Control and Prevention and Assistant Secretary for Preparedness and Response (information) and Centers for Disease Control and Prevention (photos). | GAO-23-106210

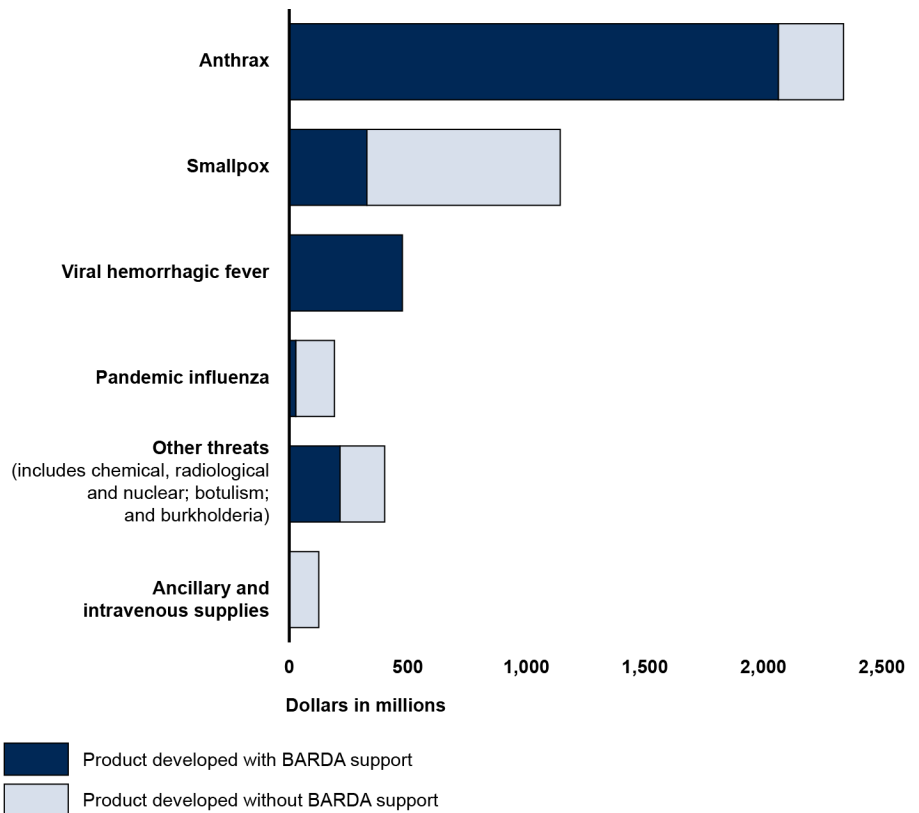
- Anthrax and smallpox vaccines—similar to other MCMs in the SNS that are primarily used to treat illness related to public health emergencies—are not commercially available and lack competition. Furthermore, as we previously reported, experts have suggested that the added cost and difficulty of developing such MCMs may also hinder competition, and research suggests that fewer competitors are generally associated with higher prices in the drug industry.³⁸ Thus, the lack of competition for MCMs may increase HHS's costs to purchase these MCMs for the SNS. In fact, the 2016 SNS review identified five MCMs that should be prioritized for purchase to keep manufacturing capabilities active; four of these were for anthrax and smallpox. The obligations data we reviewed show that HHS obligated \$1.7 billion for these four MCMs from fiscal years 2015 through 2021, accounting for over one-third of obligations to purchase MCMs for the SNS during this time frame. According to the manufacturer of these four MCMs in publicly available financial filings, while they do sell the products to foreign governments, the U.S. government is the principal customer for these MCMs. Because of the limited market for these products, companies have little financial incentive to develop competing products.

More than half of HHS's obligations to purchase MCMs in recent years were for MCMs that have been developed with support from BARDA. Specifically, from fiscal years 2015 through 2021, HHS obligated \$3.1 billion to purchase BARDA-supported MCMs for the SNS, which is 66 percent of total MCM obligations during that time frame, according to our analysis of HHS data. A large proportion of the obligations to purchase BARDA-supported MCMs (77 percent) were to purchase smallpox and anthrax MCMs. See figure 5 below for HHS obligations for the SNS, including information on whether the MCMs were developed with BARDA support.

³⁸GAO, *Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals*, GAO-18-40, (Washington, DC: November 17, 2017).

Figure 5: Department of Health and Human Services (HHS) Obligations for Strategic National Stockpile (SNS) Medical Countermeasures (MCM) in Fiscal Years 2015 through 2021, by Type of Research and Development Support

Subtitle: The Biomedical Advanced Research and Development Authority (BARDA) supported the advanced research and development of some MCMs included in the SNS inventory. From fiscal years 2015 through 2021, 66 percent of all HHS obligations for the SNS were for products developed with BARDA's support.



Source: GAO analysis of data from the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS). | GAO-23-106210

Notes: The Centers for Disease Control and Prevention obligated funds to purchase MCMs for the SNS in fiscal years 2015 through 2018, and ASPR obligated funds for this purpose from fiscal years 2019 through 2021. Obligations to purchase MCMs for the SNS were made using regular appropriations for the SNS, appropriations for Project BioShield, and appropriations for Ebola relief. Appropriations for Project BioShield and Ebola relief are administered by BARDA. Obligations reported in this figure are exclusive of those made using COVID-19 relief funds and are limited to those \$1 million and greater for which a MCM was specified, which accounts for 97.6 percent of total MCM obligations for the SNS during this time frame. The ancillary and intravenous supplies category includes personal protective equipment, for which obligations totaled approximately \$6 million (0.1 percent of total obligations). Some MCMs for anthrax can be used for plague and tularemia, so obligations for those threats are included with anthrax.

Example of Biomedical Advanced Research and Development Authority (BARDA)-supported product: silver-impregnated bandages

Silver-impregnated bandages were designed to quickly and easily cover burns and acute wounds, forming an antimicrobial barrier to prevent infection.

In 2013, BARDA awarded the developer of silver-impregnated bandages a contract to conduct studies evaluating this product for new uses, including burns from radiation or chemical weapons, such as sulfur mustard. BARDA purchased the bandages for the Strategic National Stockpile in 2015 while these studies were being conducted.

The bandages ultimately gained Food and Drug Administration approval for use with sulfur mustard burns in 2019 and the Strategic National Stockpile began to obligate funds to maintain it in inventory in fiscal year 2020.

Source: Office of the Assistant Secretary for Preparedness and Response. | GAO-23-106210

Since it was created in 2006, BARDA has worked to increase preparedness for public health emergencies by funding the advanced research and development of MCMs, including more than 60 authorized, approved, licensed, or cleared by FDA as of May 2022. See sidebar for an example of a BARDA-supported product. However, not all BARDA-supported MCMs have been added to SNS inventory. For example, some BARDA-supported products are developed for broader commercial use outside of the SNS. This is the case with influenza vaccines and some tests to detect Ebola and Zika virus, which are not included in the SNS inventory. According to ASPR, as of February 2022, the SNS contained 20 BARDA-supported products, such as treatments for anthrax, smallpox, botulism, and thermal burn injuries, and a vaccine to prevent Ebola virus disease.

SNS Inventory Includes Recommended MCMs but Not Quantities; Reviews Lack Key Information for Managing This Risk

Our analysis of SNS reviews shows that the SNS inventory contained most of the MCMs types recommended by the PHEMCE, although often not in the quantities recommended, according to the most recently available inventory data reported by ASPR. Specifically, when we analyzed the most recent inventory data, as of July 2021, we found that the SNS had not reached the quantities for most of the MCMs recommended in the 2016 SNS review.³⁹ Specific details of these recommended quantities and goals were omitted because ASPR officials have identified the information as sensitive.

³⁹As previously noted, the SNS reviews are used to inform procurements for the subsequent budget cycle (i.e., 3 years in the future). Procurements for 2021 should have been informed by recommendations in the 2018 SNS review, but ASPR did not complete SNS reviews in 2017, 2018, or 2019. For this reason, we compared the recommended quantities from the 2016 SNS review to the inventory as of July 2021 (as noted in the 2021 SNS review).

In some cases, the PHEMCE had recommended an MCM type and quantity to address a threat, but the inventory did not include it because a corresponding treatment had not been identified or developed, according to the SNS reviews we analyzed. Overall, there were five MCM types with no identified treatment options at the time of the 2021 SNS review.

Further, while the recommended MCM types and quantities can change in subsequent SNS reviews—potentially affecting the SNS’s ability to reach recommended quantities—our analysis showed a consistency over time, with the exception of recent additions made in response to the COVID-19 pandemic, which will be discussed below.⁴⁰ According to ASPR officials, this stability is intentional. Officials explained that recommended MCM types and quantities in the SNS reviews are designed to be stable because consistency is important for the private sector, which needs to develop or supply MCMs. ASPR officials added that unless there are changes in intelligence or threats, the recommended MCM types and quantities are relatively stable. Specifically, we found that most of the recommended MCM types and recommended quantities—the amount of each MCM type recommended for the SNS inventory—were the same in both the 2015 and 2021 SNS reviews.

While our analysis generally showed a consistency in inventory recommendations over time, more recent changes to the recommended MCM types and quantities may have been due to ASPR’s use of the abbreviated process to develop the 2020 and 2021 SNS reviews because the PHEMCE was not fully operational. For example, the recommended quantities for three MCM types were increased in the 2020 SNS review and, in the 2021 SNS review, were changed back to the quantities recommended in the 2016 SNS review.

CDC officials stated that the changes ASPR made to these recommended quantities while the PHEMCE was not operational lacked clear rationale or basis. They also noted that these changes were made without the typical subject matter expert input that had been used to inform procurements in earlier years. As noted earlier, in July 2021, we recommended ASPR develop and document plans for restructuring the PHEMCE to ensure a transparent deliberative process that engages interagency partners and implement records management practices to

⁴⁰Recommended quantities had not been established for MCM types added to the SNS inventory in response to the COVID-19 pandemic as of the 2021 SNS review.

ensure the rationale for decisions made are documented, including those related to the SNS.⁴¹ HHS concurred with these recommendations and has stated that ASPR is in the process of developing plans and analyses for a relaunched PHEMCE. However, as of April 2022, ASPR has not provided us with any documentation related to the new PHEMCE.

HHS officials and others have identified several factors that have limited ASPR's ability to reach recommended quantities, including insufficient budget, costs of ongoing responsibilities, and costs to purchase BARDA-supported products:

- **Insufficient budget to close inventory gaps.** HHS and other groups have noted a misalignment between the PHEMCE recommended quantities and the SNS budget for many years. In 2013, a working group report compiled by two HHS advisory bodies concluded that the SNS was increasingly confronted with “unfunded requirements” as its responsibilities expanded and, without action, anticipated a widening gap between the responsibilities of the SNS and the resources available to fulfill them.⁴² One senior SNS official noted that the SNS has not had the increase to its budget needed to simply maintain and replenish MCMs, and currently cannot buy everything needed for the stockpile.

Over the past 10 years, the SNS has received appropriations similar to the level of funding requested in the President's budget. This notwithstanding, HHS's congressional budget justification for fiscal year 2019 notes that despite requesting additional funding, the amount requested in the President's budget request for the fiscal year, if appropriated, would not be sufficient to purchase all the products required to reach the recommended quantities for MCMs. Similarly, as we reported in March 2021, ASPR officials said that the amount of funding requested has not always fully reflected SNS funding needs.⁴³ They explained that this is because there are competing priorities and tradeoffs and the budget process involves aligning SNS budgetary needs with broader HHS needs and the

⁴¹GAO-21-551.

⁴²See National Biodefense Science Board and the Office of Public Health Preparedness and Response Board of Scientific Counselors, *Anticipated Responsibilities of the SNS in the Year 2020: An Examination with Recommendations*, April 3, 2013, accessed May 20, 2020, <https://www.phe.gov/Preparedness/legal/boards/nbsb/recommendations/Documents/nbsb-bsc-sns-2020-final.pdf>.

⁴³GAO-21-387.

President's budget priorities. One ASPR official said that in order to purchase enough MCMs to meet all recommended quantities for the stockpile, the annual cost would be billions of dollars higher than the SNS's current budget allocation.

- **Costs of ongoing responsibilities, such as MCM replenishment and addressing threat priorities.** SNS officials noted there is limited flexibility in terms of what MCMs can be purchased using appropriations for the SNS, due to the large portion of the SNS budget allocated to anthrax and smallpox MCMs, funding needed to maintain manufacturing capabilities of certain MCMs without a commercial market, and the need to replenish MCMs already in the inventory. As described earlier, purchases of anthrax and smallpox MCMs comprise about three-quarters of the obligations for MCMs made from fiscal years 2015 through 2021.⁴⁴ In addition, a substantial part of the SNS budget is also allocated to non-product costs such as storage; in recent years, about one-third of total obligations supported non-product costs.
- **Costs of BARDA-supported products.** In recent years, the SNS has had difficulty funding the purchase of MCMs that were developed with support from BARDA, according to ASPR and BARDA officials. BARDA officials stated that products funded by BARDA are generally intended to meet an identified public health threat, so some of these MCMs historically have been added to the SNS inventory. Although BARDA officials explained that there are no agreements, statutory requirements, or other policies requiring the SNS to purchase BARDA-supported products, officials said that BARDA-supported products historically have been purchased by the SNS after receiving authorization, approval, licensure, or clearance from FDA.⁴⁵

BARDA officials told us that BARDA used Project BioShield funding to purchase BARDA-supported MCMs for the SNS in recent years because the SNS did not have sufficient funds to purchase these products. Specifically, our analysis shows that for fiscal years 2015 through 2022, Project BioShield spent \$257 million to purchase eight BARDA-supported MCMs.⁴⁶ Additionally, the President's budget

⁴⁴These obligations did not include COVID-19 relief funds.

⁴⁵The SNS may purchase products that have not been authorized, approved, licensed, or cleared by FDA, provided those products are held and not distributed for use. See 21 U.S.C. § 360bbb-3b.

⁴⁶Funding for Project BioShield may be used for the development and purchase of MCMs to address biological, chemical, radiological and nuclear threats.

request for fiscal year 2022 includes a “professional judgment” budget estimate that states the SNS would need \$672 million in fiscal year 2022 to purchase all BARDA-supported products transitioning to the SNS, with a total of \$1.8 billion necessary to purchase those products and maintain current inventory levels. This request would be approximately twice the amount appropriated to the SNS for fiscal year 2022 (\$845 million).

ASPR acknowledges that the inability to reach recommended quantities creates risks, including being underprepared to respond to a public health emergency. These budgetary constraints have affected HHS’s ability to complete recommended corrective actions and meet recommended quantities, according to the President’s budget request for fiscal year 2019 and interviews with ASPR officials. In the PHEMCE Multi-year Budget Report for fiscal years 2018 through 2022, ASPR describes the implications of insufficient funding to both maintain current capabilities and absorb new products:

These tradeoffs translated to increasing levels of risk across the threat portfolios and potentially jeopardizing the nation’s ability to realize the full benefits of prior research and development investments. For example, prior SNS Annual Reviews proposed reducing anthrax vaccine holdings and in 2015 proposed reducing both anthrax vaccine and antibiotics to meet budget constraints.

Given resource constraints, it may not be possible to reach all the recommended quantities for MCMs in the short term. However, managing and communicating this risk is key to ASPR fulfilling its mission of enhancing the nation’s preparedness to respond to public health emergencies by maintaining an inventory of MCMs. Our review shows that ASPR has not adequately communicated an approach for managing the risks associated with the gaps between recommendations and its SNS inventory. The SNS reviews—HHS’s main document for monitoring the SNS inventory, identifying gaps, and recommending actions to address gaps—show the unmet recommended quantities and include recommended corrective actions to address risk. However, the reviews lack key information needed for ASPR to manage risks and to communicate those risks to Congress and other stakeholders. ASPR officials noted that the PHEMCE Multi-year Budget and the President’s budget request also are used to communicate progress made and challenges faced by the SNS in acquiring inventory. However, unlike the SNS reviews, these documents do not include specific information about

the magnitude of stockpiling gaps or corrective actions recommended to address gaps.

Applying risk management principles could help ASPR to address the risk of these unmet recommended quantities. Specifically, both Enterprise Risk Management principles and OMB Circular No. A-123 include guidance related to managing and communicating risk, including communicating risk to Congress. Specific risk management practices include:

- **Prioritizing risks:** Enterprise Risk Management principles state that risks should be ranked based on organizational priorities in relation to strategic objectives.
- **Tracking progress on risk management activities:** Both GAO's Enterprise Risk Management principles and OMB Circular A-123 note the importance of tracking progress of risk management activities. For example, OMB Circular A-123 states that progress against the corrective actions must be periodically reported to agency management.
- **Estimating resources needed to address risks:** OMB Circular A-123 states that agencies must determine the resources required to correct a deficiency as part of a corrective action plan. In addition, OMB Circular A-123 states that for significant deficiencies, including those that may deprive the public of needed services, an agency should communicate these deficiencies and a summary of corrective actions to Congress and OMB.

According to these principles, while ASPR may not be able to fully address the deficiency using these principles, it helps provide a more complete picture of the actions and resources needed to address gaps in inventory quantities, as well as the risk of inaction. However, ASPR's SNS reviews lack key elements of the risk management principles. For example,

- **SNS reviews do not consistently prioritize risks.** For example, the two most recent SNS reviews—the 2020 and 2021 SNS reviews— included a list of recommended corrective actions to completely address every gap in recommended quantities. However, these recommended corrective actions were not listed in order of priority or greatest risk. As noted earlier, the SNS currently cannot buy everything needed for the stockpile, according to HHS documentation and interviews with SNS officials.

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- **SNS reviews do not clearly track the progress made on risk management activities.** The SNS reviews list previously recommended corrective actions to address risks, but do not show when actions were first identified or the progress made in addressing them. Instead, the reviews include a description of the status, such as “procurement is ongoing,” which does not indicate how close the action is to being completed, or the risks associated with not completing the corrective action. Additionally, ASPR officials noted that the office does not maintain a comprehensive list of corrective actions—and their associated statuses—from past SNS reviews, so it is unclear whether an action was pursued or not and the associated reasons. Also, the SNS reviews do not describe the extent to which a corrective action will fully close the gap between recommended quantities and the on-hand inventory level.
 - **SNS reviews do not describe resources needed to address risks.** For example, the two most recent SNS reviews—the 2020 and 2021 reviews—do not include information on the amount of funding required to close gaps in recommended quantities. Additionally, ASPR officials told us they have not estimated the full cost of meeting recommended quantities for all MCM types.

In addition, the 2020 and 2021 SNS reviews note that the recommendations to close all gaps were made assuming there are “no budgetary, manufacturing or inventory constraints or limitations, nor MCM alternatives.” However, listing all the identified gaps without prioritizing them, while assuming unlimited resources and no other constraints, does not provide HHS with the information necessary for assessing, mitigating, and communicating risks.

ASPR officials stated that the SNS reviews do not align with these risk management principles because doing so was not required by statute and because they do not believe the intent of the SNS reviews is to manage and communicate risk. However, ASPR officials stated that there is no other document that includes this type of information. Additionally, ASPR officials noted that they did not prioritize the recommendations in the 2020 and 2021 reviews because they are still determining how to create a state of readiness with the MCMs in the inventory. They added that they are working through the challenges created by COVID-19 pandemic and the effect it may have on the inventory.

Without an approach for regularly managing risks—one that prioritizes risks, tracks progress made, and estimates resources needed—HHS and Congress lack assurance the department is most effectively preparing for

public health emergencies. Using risk management principles to guide SNS planning efforts—especially for managing the risk associated with gaps between inventory levels and recommended quantities—could enable HHS to better manage and communicate risks that could help the SNS achieve its mission. Additionally, without incorporating risk management principles and communicating risks, Congress and stakeholders may continue to not have key information that could inform their decision making.

\$6.1 Billion Obligated in COVID-19 Funding for SNS Inventory; ASPR Re-Examining the Role of the SNS

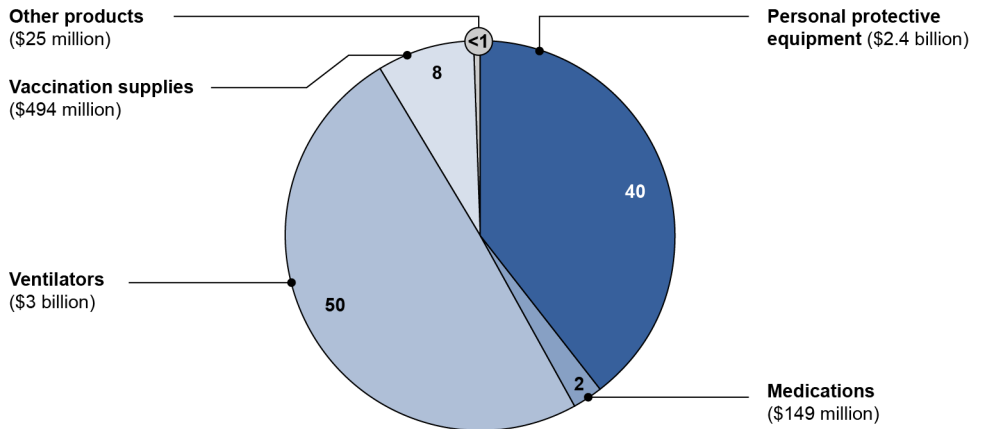
ASPR Obligated \$6.1 Billion in COVID-19 Funding for Critical COVID-19 Supplies for SNS Inventory

According to our analysis of ASPR data, the office obligated \$6.1 billion in fiscal years 2020 and 2021 for critical COVID-19 supplies delivered directly to the SNS, using COVID-19 relief funds.⁴⁷ These obligations were part of a total of approximately \$10.6 billion ASPR reported to GAO that it had obligated for the SNS using COVID-19 relief funds in fiscal years 2020 and 2021.⁴⁸ See figure 7 below for breakdown of COVID-19 relief spending on supplies delivered to the SNS, by category. For comparison, ASPR reported that from fiscal year 2015 through 2020, HHS obligated about \$3.6 billion total to purchase MCMs and on operations costs for the SNS.

⁴⁷Of the \$6.1 billion ASPR obligated for critical COVID-19 supplies, about 25 percent were for interagency agreements with other federal agencies that procured supplies on behalf of ASPR. Approximately half of the obligations for personal protective equipment (PPE) and vaccination supplies, such as syringes and needles, were through these agreements.

⁴⁸In February 2022, HHS reported that it planned to obligate \$13.9 billion for the SNS using COVID-19 relief funds. This amount includes \$3.25 billion in supplemental funding received in fiscal year 2021. According to HHS, as of April 2, 2021, the department transferred \$850 million from the Public Health and Social Services Emergency Fund, Strategic National Stockpile, to the Unaccompanied Children Program within the Administration for Children and Families, under authority in the Consolidated Appropriations Act, 2021. See Pub. L. No. 116-260, div. M, tit. III, § 304, 134 Stat. at 1923. However, subsequent to HHS's transfer of \$850 million in April 2021, HHS allocated \$850 million in COVID-19 relief funds to the SNS. Thus, the total amount of funding HHS allocated to the stockpile was not affected by the transfer to the Unaccompanied Children Program, according to HHS's Office of the Assistant Secretary for Financial Resources.

Figure 6: Office of the Assistant Secretary for Preparedness and Response (ASPR) Obligations Using COVID-19 Relief Funds for COVID-19 Supplies Delivered to the Strategic National Stockpile (SNS), Fiscal Years 2020 and 2021



Source: GAO analysis of data from ASPR within the Department of Health and Human Services (HHS). | GAO-23-106210

Note: This analysis is of obligations for COVID-19 supplies (\$6.1 billion) that were delivered directly to the SNS inventory, and excludes obligations for supplies that were shipped directly to state, local, territorial, and tribal governments. Vaccination supplies include syringes and needles distributed for COVID-19 vaccine administration. Other products include cloth face coverings, hand sanitizer, supplies to assist children with breathing, and containers used to ship temperature-sensitive products.

Based on our analysis of obligation data, the supplies for which ASPR made obligations using COVID-19 relief funds were different from those in the years prior to the pandemic. For example, HHS data show that from fiscal year 2015 through fiscal year 2019, HHS obligated about \$33 million for ventilators and made no obligations over \$1 million for personal protective equipment (PPE) for the SNS, compared to the approximately \$5.5 billion ASPR obligated for these types of supplies using COVID-19 relief funds.

In addition to the \$6.1 billion in obligations for COVID-19 supplies for the SNS, ASPR obligated the remainder of the \$10.6 billion using COVID-19 relief funds in fiscal years 2020 and 2021 for other purposes. Specifically, ASPR obligated \$3.4 billion for other services and MCMs—such as transportation, warehousing, and MCMs that were shipped directly to state, local, territorial, and tribal governments—and \$1.1 billion for vendor-managed inventory services.

Under SNS contracts for vendor-managed inventory services, a vendor stores and, when needed, distributes supplies on behalf of the SNS. SNS officials told us that prior to the COVID-19 pandemic, the SNS did not

have any active vendor-managed inventory contracts.⁴⁹ According to ASPR, the office used vendor-managed inventory contracts for a few different purposes, including managing ventilator inventory, distributing testing supplies, and assembling vaccine administration supplies. For example, according to ASPR data, about 60 percent of the obligations for vendor-managed inventory contractors were for a vendor to pack and distribute COVID-19 vaccine administration kits, which included supplies such as needles and syringes.⁵⁰ (See Table 2 for a listing of vendor-managed inventory contracts and their scope of work.)

Table 2: Strategic National Stockpile Vendor-Managed Inventory Contracts Executed with COVID-19 Relief Funds

Fiscal year	Obligation (Dollars in millions)	Scope of work
2020	193	Short-term storage, maintenance and management services of medical ventilators ^a
	264	Purchasing some supplies for, assembling, and distributing vaccine administration kits
	4	Logistical support for storage, distribution and delivery of ancillary supplies purchased in support of vaccination campaign requirements.
2021	34	Short-term storage, maintenance and management services of medical ventilators ^a
	57	Storage and distribution of pharmaceutical products related to COVID-19
	2	Storage and distribution of a pharmaceutical product with limited shelf life that requires product rotation.
	60	Storage and distribution services of personal protective equipment and testing supplies
	73	Storage and distribution of personal protective equipment & testing supplies
	189	Purchasing some supplies for, assembling, and distributing vaccine administration kits
	183	Purchasing some supplies for, assembling, and distributing vaccine administration kits for booster shots, pediatric vaccinations, and global humanitarian efforts
Total	1,058	

Source: Data from the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS). | GAO-23-106210

^aThese contracts were for the short-term storage, maintenance, and management of ventilators. ASPR has since drafted a revised solicitation and an award is expected by July 2022 for a 5-year contract estimated at \$111 million per year to maintain, store, repair, deploy, recover, sanitize, reconstitute, and manage services of all medical ventilators.

In most of these contracts, the product the vendor was managing was purchased under separate agreements; however, for the three contracts to provide vaccine administration kits, the vendor was responsible for

⁴⁹SNS officials stated that the office terminated the use of vendor-managed inventory contracts in 2017 because they were found not to be cost effective or did not aide in preparedness, for example, because distribution sites were not geographically disbursed.

⁵⁰The SNS was not involved in the distribution of COVID-19 vaccines.

providing some items in the kits, such as face shields and surgical masks. Additionally, one contract involved rotating product with a short shelf life. ASPR officials said that for this product—an expensive pharmaceutical with a short shelf life—it made sense to have a vendor-managed inventory contract with product rotation; for other products, such as PPE—which are less expensive and last longer—it is generally more expensive to have a vendor manage and rotate the product.

COVID-19 Pandemic Response Resulted in Changes to the SNS Inventory

Our review of information obtained from ASPR shows that ASPR significantly increased the amount of certain MCMs in the SNS inventory in response to the COVID-19 pandemic. As we have previously reported, the nationwide need for critical PPE and other supplies to protect responders and treat individuals who had COVID-19 quickly exceeded the quantity contained in the SNS.⁵¹

In 2020 and 2021, ASPR and the Department of Defense (DOD) awarded contracts that allowed the SNS to expand its inventory of products. For example, ASPR significantly increased the amount of PPE and ventilators held in the SNS inventory relative to what was held prior to the COVID-19 pandemic. See sidebar for a description of how inventory was prioritized for acquisition during the COVID-19 pandemic.

⁵¹[GAO-20-625](#).

Strategic National Stockpile (SNS) Inventory Priorities during the COVID-19 Pandemic

As we outlined in our September and November 2020 reports, overall efforts to address supply challenges experienced by states and other entities early in the response were led by the Unified Coordination Group. This group is the primary field lead for federal emergency response efforts and was jointly led by the Administrator of the Federal Emergency Management Agency, the Assistant Secretary for Preparedness and Response, and a Centers for Disease Control and Prevention representative.

Specific tasks related to medical supply acquisition were assigned to multiple federal task forces and work groups. For example, the Logistics, Supply Chain, Next Generation SNS Work Group, which consisted of various federal agencies and the White House, identified and acquired critical items to enable the SNS to meet the needs of the nation for the duration of the pandemic response.

Specifically, these federal partners determined that the SNS needed to acquire a 90-day supply of certain critical supplies.

Source: GAO-20-701 and GAO-21-191. | GAO-23-106210

Most PPE contained in the SNS prior to the COVID-19 pandemic was acquired in response to the 2009 H1N1 pandemic, according to ASPR officials. See table 3 below for more on the SNS’s inventory, before and during the COVID-19 pandemic, through February 2022.

Table 3: Strategic National Stockpile (SNS) Inventory of Personal Protective Equipment (PPE) and Ventilators from December 2019 to February 2022

PPE and ventilators	Dec. 2019 inventory on hand (in millions)	Oct 2020 inventory on hand (in millions)	Feb. 2021 inventory on hand (in millions)	Feb. 2022 inventory on hand (in millions)	90-day inventory goal ^a (in millions)
Gloves	16.9	2.0	227.0	4,300.0	4,500.0
N95 respirators	12.6	107.0	307.0	626.0	300.0
Surgical or procedural masks	30.8	157.0	411.0	412.0	400.0
Gowns or coveralls	4.8	1.0	65.8	79.0	265.0
Eye protection or face shields	5.8	19.0	17.6	19.5	18.0
Ventilators	0.019	0.150	0.152	0.158	0.168

Source: Data from the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services | GAO-23-106210

Note: The SNS continues to deploy supplies, including PPE, in response to state requests and government initiatives. For example, beginning in January 2022, 400 million N95 respirators were deployed from the SNS as part of a White House initiative to make them broadly available to the U.S. population. These deployments could also result in some fluctuation in inventory quantities over time.

^aThese goals were established during the COVID-19 response and are separate from recommended quantities in the SNS reviews. ASPR officials said the 90-day inventory goals will be reviewed and changes may be made to them in the future.

Additionally, the SNS inventory now contains new types of MCMs. As we reported in November 2020, ASPR and Federal Emergency Management Agency officials told us that the pandemic called attention to the need for the SNS to have in its inventory sedatives for use with ventilators, and other drugs, such as an antibiotic, not previously contained in the SNS. We also reported in November 2020 that ASPR planned to include active pharmaceutical ingredients in the inventory.⁵² In total, ASPR officials reported attempting to build an inventory of 21 finished pharmaceuticals—13 of which were not previously held in the SNS inventory—and 25 active pharmaceutical ingredients, none of which were held in the SNS inventory before the COVID-19 pandemic.

As of March 2022, ASPR officials noted that they had completed their purchases of finished pharmaceuticals. They added that one product was never procured and three other products continue to be difficult to procure due to additional shortages caused by the COVID-19 pandemic. Therefore, the SNS is not yet at the inventory goal for these MCMs, most of which are intensive care medications primarily used to treat patients on ventilators.

Additionally, in March 2022, ASPR officials reported that the office cancelled the effort to purchase active pharmaceutical ingredients. They noted that this was because the initiative to purchase active pharmaceutical ingredients for the SNS was started under the prior administration and ASPR is now considering other approaches. For example, ASPR officials stated that other offices, including BARDA, are now responsible for developing approaches for utilizing active pharmaceutical ingredients, as they have more capacity to link the ingredients to the production of patient ready medications.⁵³ See table 4 below for information on the SNS's pharmaceutical inventory, before the COVID-19 pandemic and through March 2022.

⁵²An active pharmaceutical ingredient refers to any substance that is intended for incorporation into a finished pharmaceutical and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

⁵³For more information about active pharmaceutical ingredients, see GAO, *Drug Safety: FDA Should Take Additional Steps to Improve Its Foreign Inspection Program*, [GAO-22-103611](#) (Washington, D.C.: Jan 7, 2022).

Table 4: Status of Strategic National Stockpile (SNS) Inventory of Pharmaceutical Products, from December 2019 to March 2022

Pharmaceuticals	Dec. 2019 inventory on hand	March 2022 inventory on hand
Finished pharmaceuticals (21 products)	8 of 21 products held	20 of 21 products held
Active pharmaceutical ingredients (25 ingredients)	0 of 25 ingredients held	Not applicable – effort cancelled

Source: Officials from the Office of the Assistant Secretary for Preparedness and Response within the Department of Health and Human Services. | GAO-23-106210

Finally, in response to recommendations from HHS, ASPR also took steps to add testing supplies to the SNS inventory in late 2020, including nasal swabs, transfer media, and pipette tips (disposable plastic attachments used to uptake and dispense small volumes of liquid). Prior to the COVID-19 pandemic, the SNS did not hold these testing supplies. According to ASPR officials, the office is currently discussing the best strategies for acquiring testing supplies to reach established goals, including by using vendor managed inventory arrangements or by increasing domestic production. They also stated that maintaining testing supplies in the future would require additional resources and in some instances—such as with COVID-19 test kits—the supplies are disease-specific and raise questions about the value in holding them. ASPR officials added that guidance on this will come from the PHEMCE. See table 5 below for information on the SNS’s testing supply inventory.

Table 5: Strategic National Stockpile (SNS) Inventory of Testing Supplies, from December 2019 to March 2022

Testing supplies	Dec. 2019 inventory on hand	Oct. 2020 inventory on hand (in millions)	March 2022 inventory on hand (in millions)	90-day inventory goal ^a (in millions)
Nasal swabs	Not applicable	18	0.74	54
Transport media	Not applicable	36	1.1	36
Pipette tips	Not applicable	0	0	36

Source: Officials with the Office of the Assistant Secretary for Preparedness and Response (ASPR) and the Office of the Assistant Secretary for Health (OASH), within the Department of Health and Human Services, as well as Department of Health and Human Services, Report to Congress: COVID-19 Strategic Testing Plan (May 24, 2020). | GAO-23-106210

^aThese goals were established during the COVID-19 response and are separate from recommended quantities in the SNS reviews. ASPR officials said the 90-day inventory goals will be reviewed and changes may be made in the future.

ASPR Is Re-Examining SNS Operations in Light of COVID-19 Response

As we reported in March 2021, the COVID-19 pandemic highlighted long-standing challenges related to the SNS's operations during emergencies.⁵⁴ The COVID-19 response has required new responsibilities and inventory, as outlined above, and has been a catalyst for re-examining SNS operations, including the role, responsibilities, expertise, and inventory needed moving forward.

Specifically, in March 2021, we noted that the near depletion of PPE in the SNS's inventory early in the pandemic response raised questions among the state officials and experts we interviewed about the role, expectations, and transparency of the SNS during a nationwide pandemic.⁵⁵ ASPR officials, however, told us the SNS was not designed to provide states with supplies for a prolonged nationwide event such as the COVID-19 pandemic.

HHS has been discussing the proper role of the SNS for many years. For example, in 2016, HHS convened a National Academies of Sciences, Engineering, and Medicine workshop to, among other things, re-evaluate the SNS's emphasis on potential chemical, biological, radiological, and nuclear attacks on the United States.⁵⁶ Participants noted that the role of the SNS was already broad and potentially needed better focus to be as effective as possible.

The COVID-19 response only exacerbated questions about the role of the SNS due to the additional responsibilities and expertise that were needed for both the immediate response and potentially for the long-term management of the SNS. For example, SNS officials we interviewed identified a variety of new responsibilities they have due to the COVID-19 pandemic that may shape SNS operations moving forward. These include: (1) managing the contracts, storage, and inventory requirements of new PPE, pharmaceuticals, and other products; (2) determining the SNS's role, especially for areas outside its traditional work responsibilities, such as supply chain management; and (3) hiring new staff with specific MCM and supply chain expertise.

⁵⁴[GAO-21-387](#).

⁵⁵Ibid.

⁵⁶See National Academies of Sciences, Engineering, and Medicine, *The Nation's Medical Countermeasures Stockpile: Opportunities to Improve the Efficiency, Effectiveness, and Sustainability of the CDC Strategic National Stockpile: Workshop Summary*. Washington, D.C.: National Academies Press. 2016.

SNS officials told us these additional responsibilities have required, or will require, additional resources. For example, during the COVID-19 pandemic, SNS officials created a new branch devoted exclusively to acquisitions because of the need for additional staff with contracting expertise. In addition, one SNS official discussed the additional responsibilities that come with storing and managing newly added PPE and ventilators. This SNS official noted that maintaining 160,000 ventilators is an expensive and resource-intensive endeavor. They added that ventilators require annual or biannual service and there could be a large effect in the future if the SNS needs significantly more staff and funding to manage the increase in inventory. Finally, another SNS official noted that if the SNS continues to maintain huge quantities of PPE, there will be significant workload requirements related to replenishment and product expiration that will require additional PPE expertise. This official added that only two people in this SNS branch are experts in PPE and additional staff are needed if these efforts are to be sustained.

In response to questions about the SNS's roles, responsibilities, expertise, and inventory, ASPR has developed several work streams and draft strategies to try to help define the future of the SNS. For example, as we reported in January 2021, one of these strategies, entitled "SNS 2.0 Strategy: Modernize the SNS", outlined the capabilities that HHS must acquire—including, but not limited to, the SNS—to address the challenges identified by the pandemic.⁵⁷ However, according to ASPR officials, with the change in administrations, this strategy has been put on hold. In January 2021, we reviewed the draft strategy and recommended that the Assistant Secretary should establish a process for regularly engaging with Congress and nonfederal stakeholders as HHS refines and implements its supply chain strategy for pandemic preparedness, to include the role of the SNS. HHS generally concurred with the recommendation; however, as of April 2022, that recommendation has not been implemented.

Subsequently, additional SNS roles, responsibilities, and inventory were outlined in the *National Strategy for a Resilient Public Health Supply Chain* (National Supply Chain Strategy) issued in September 2021 in response to

⁵⁷[GAO-21-265](#).

**Strategic National Stockpile (SNS)
Ability to Sell Inventory**

The SNS added significantly more commercially available medical countermeasures to the inventory during the COVID-19 pandemic. This was especially true of personal protective equipment—for example, masks, gloves, and gowns. As these products expire, they need to be replaced or rotated out of the inventory and replaced with new inventory. Prior to their expiration, these products could be used by other entities, such as health care providers, especially when such products are in short supply.

However, according to officials in the Office of the Assistant Secretary for Preparedness and Response (ASPR), the SNS lacks the statutory authority to sell products that are in the inventory. ASPR officials told us the office had requested statutory changes that would allow the office to sell products, including the authority to retain and use the funds without fiscal year limitation. These funds could then be used to purchase replacement product for inventory.

Source: SNS documentation and interviews with SNS officials. | GAO-23-106210

Executive Order 14001.⁵⁸ For example, the National Supply Chain Strategy states that the SNS should build an inventory of raw materials, inputs, and supplies to counter pandemics and other biological threats, and should rotate SNS products into the commercial market or use them for humanitarian needs before expiration (see sidebar for certain challenges related to the SNS’s ability sell its inventory).

As we reported in April 2022, implementation of the National Supply Chain Strategy is ongoing.⁵⁹ HHS and its interagency partners have developed plans of action and milestones (POAM), following a template that outlines specific sections to include in each POAM and related guidance, to facilitate the implementation of each action item related to the National Supply Chain Strategy. One of the action items and POAMs that is included is the development of a “comprehensive Strategic National Stockpile transformation strategy” (SNS transformation strategy).

As we noted in April 2022, our review of the National Supply Chain Strategy along with the POAM template indicates that ASPR and its interagency partners are in the process of developing a national strategy for making the public health supply chain more resilient—for example, by enhancing U.S. manufacturing capability—if they continue to develop and implement the POAMs as planned. Specifically, we reported that the POAM template complements the National Supply Chain Strategy by outlining many of the characteristics we have identified that national strategies should contain in order to serve as effective, comprehensive management tools. (See fig. 8 below.)

⁵⁸A *Sustainable Public Health Supply Chain*, Exec. Order No. 14001, § 4, 86 Fed. Reg. 7,219, 7220-21 (Jan. 21, 2021). The order directed DOD, HHS, and the Department of Homeland Security, among others, to develop a supply chain resilience strategy to include an approach to design, build, and sustain long-term capability in the United States to manufacture medical supplies for future pandemics and biological threats.

⁵⁹GAO, *COVID-19: Current and Future Federal Preparedness Requires Fixes to Improve Health Data and Address Improper Payment*, [GAO-22-105397](#) (Washington, D.C.: Apr. 27, 2022).

Figure 7: Six Characteristics of an Effective National Strategy



Source: GAO. | GAO-23-106210

According to ASPR, the POAM is intended to guide the development of a strategy designed to build a more robust SNS to help ensure the nation is prepared for intentional, natural, and emerging pandemic threats. It also follows the POAM template established to implement the National Supply Chain Strategy actions; as such, it also contains many of the characteristics we have identified for effective national strategies.

However, the draft POAM itself is not a strategy but a guide for the development of a strategy. As we have previously reported, it is important for strategies to incorporate the above characteristics to ensure that challenges are addressed.⁶⁰ For example, the draft POAM provides cost estimates for the development of the strategy and notes that skilled personnel from across the government are available to assist with strategy creation. However, bigger questions exist that will affect HHS's ability to implement the resulting strategy. These include questions about securing long-term funding, adding workforce expertise, and maintaining new inventory. As we have reported in the past, incorporating the six characteristics of national strategies into planning efforts can help agencies to address challenges.⁶¹ For example, when developing the SNS transformation strategy ASPR may need to consider a variety of actions including requesting appropriate funding, managing workforce

⁶⁰GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, [GAO-04-408T](#). (Washington, D.C.: February 3, 2004).

⁶¹[GAO-04-408T](#).

needs, allocating resources and investments according to priorities and constraints, tracking costs and performance, and shifting such investments and resources as appropriate.

Addressing the longer-term challenges that we and others have identified—such as the role of the SNS in future pandemics, budget planning for that role, and sustainment of current PPE inventory—will be complex and require significant, continued efforts across the federal government; state, local, tribal, and territorial governments; the private sector; and other stakeholders.

We acknowledge the steps HHS and its interagency partners are taking to begin the National Supply Chain Strategy implementation process. ASPR's efforts related to the SNS transformation strategy are encouraging; the draft POAM provides a good structure that is consistent with best practices and recognizes how long-standing challenges can affect progress. However, it is still too early in the strategy's development and implementation to know whether ASPR will be able to sufficiently address many of the challenges the SNS is facing.

Additionally, we have previously identified concerns about the workforce capacity at ASPR, given its increasing responsibilities.⁶² This is an issue that may also affect the SNS as it develops and implements actions as part of the SNS transformation strategy. For example, HHS's congressional budget justification for fiscal year 2022 indicates that ASPR seeks to increase SNS staff by 70 positions, nearly a 30 percent increase.

We will continue to monitor efforts to develop plans and implement strategies to address challenges raised by the COVID-19 pandemic regarding the SNS's operations and other efforts to create resiliency in the medical supply chain, as part of our ongoing and planned work.

Conclusions

The SNS continues to be a critical piece of the nation's broader national preparedness and response infrastructure, especially for non-commercially available MCMs intended to address dangerous threats such as anthrax and smallpox. However, we have concerns about ASPR's ability to prepare for, and respond to, public health emergencies given recent management challenges related to the SNS.

⁶²GAO-22-105397 and GAO, *COVID-19: HHS and DOD Transitioned Vaccine Responsibility to HHS, but Need to Address Outstanding Issues*, GAO-22-104453 (Washington, D.C.: Jan. 19, 2022).

For example, statutorily required SNS reviews had not been completed for 3 years, and the 2020 and 2021 reviews, which will inform SNS inventory decisions for fiscal years 2023 and 2024, did not address most of the statutory requirements that were enacted by the PAHPAI Act in 2019. Until ASPR updates procedures for how SNS reviews will be conducted in accordance with new statutory requirements, including the roles and responsibilities of its interagency partners, the office risks not meeting the statutory requirements that are designed to give Congress additional information about the SNS inventory.

Additionally, the PAHPAI Act requires the Assistant Secretary, in managing the SNS inventory, to ensure that each MCM under consideration for procurement receives the same consideration regardless of whether it received development funding from BARDA. ASPR does not have a documented approach to make such a consideration. Without a documented approach, it is unclear the extent to which the Assistant Secretary will be able to fulfill this statutory responsibility. Moreover, ensuring the SNS contains the most appropriate MCMs is critical to optimizing the nation's preparedness for public health emergencies.

Further, ASPR's main document for presenting information about the SNS—the SNS review—lacks critical risk information. Until ASPR develops and documents an approach for regularly managing the risks associated with the gaps between inventory levels and recommended quantities—one that clearly prioritizes risks, tracks progress made, and estimates resources needed—HHS and Congress will lack the assurance that the department is most effectively preparing for public health emergencies.

If left unaddressed, these deficiencies will continue to hamper ASPR's ability to be prepared for, effectively respond to, and recover from future threats. Through our ongoing and planned work, we will continue to monitor HHS and ASPR's efforts to develop plans and implement strategies to prepare for and address public health emergencies.

Recommendations for Executive Action

We are making the following three recommendations to the Assistant Secretary for Preparedness and Response:

The Assistant Secretary for Preparedness and Response should update procedures for how SNS reviews will be conducted in accordance with statutory requirements, including a description of the roles and

responsibilities of its interagency partners in the development of the SNS reviews. (Recommendation 1.)

The Assistant Secretary for Preparedness and Response should develop and document an approach—whether through the standard operating procedures for the SNS reviews or some other mechanism—for ensuring that MCMs under consideration for SNS procurement receive the same consideration regardless of whether they received development funding from BARDA, in accordance with statutory requirements. (Recommendation 2.)

The Assistant Secretary for Preparedness and Response should develop and document an approach for regularly managing the risks associated with the gaps between SNS MCM inventory levels and recommended quantities. Such an approach, which could occur as part of the SNS reviews, should clearly prioritize risks, track progress made in addressing the risks, and estimate resources needed to address risks. This approach should involve communicating this information to key decision makers, including Congress. (Recommendation 3.)

Agency Comments and Our Evaluation

We provided a draft of the sensitive report to HHS for review and comment. The department's comments on the sensitive report are reprinted in appendix III. In its written comments, HHS concurred with our recommendations and reiterated the importance of the SNS in responding to public health emergencies. In addition, HHS provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees and the Secretary of Health and Human Services. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or DeniganMacauleyM@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report.

A handwritten signature in black ink that reads "Mary Denigan-Macauley". The signature is written in a cursive style with a long horizontal flourish at the end.

Mary Denigan-Macauley
Director, Health Care

List of Addressees

The Honorable Patrick Leahy
Chairman

The Honorable Richard Shelby
Vice Chairman
Committee on Appropriations
United States Senate

The Honorable Ron Wyden
Chairman

The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate

The Honorable Patty Murray
Chair

The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Gary C. Peters
Chairman

The Honorable Rob Portman
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Rosa L. DeLauro
Chair

The Honorable Kay Granger
Ranking Member
Committee on Appropriations
House of Representatives

The Honorable Frank Pallone, Jr.
Chairman

The Honorable Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Honorable Bennie G. Thompson
Chairman

The Honorable John Katko
Ranking Member
Committee on Homeland Security
House of Representatives

The Honorable Carolyn B. Maloney
Chairwoman

The Honorable James Comer
Ranking Member
Committee on Oversight and Reform
House of Representatives

The Honorable Richard Neal
Chairman

The Honorable Kevin Brady
Republican Leader
Committee on Ways and Means
House of Representatives

The Honorable Michael Bennet
United States Senate

Appendix I: Scope and Methodology

The objectives of this report were to (1) examine the process the Department of Health and Human Services (HHS) used to make medical countermeasure (MCM) inventory decisions for the Strategic National Stockpile (SNS) beginning with fiscal year 2015; (2) examine the obligations made for MCMs in the SNS in fiscal years 2015 through 2021 using funds other than COVID-19 relief funds, and the extent to which the MCM inventory aligns with recommendations, and (3) describe the obligations made for MCMs in the SNS using COVID-19 relief funds, and any changes to the SNS's inventory and operations in response to the pandemic.

In August 2022, we issued a report that addressed these objectives.¹ However, we designated that report as "for official use only" and did not release it to the general public because of the sensitive information it contained.

This subsequent report publishes the findings discussed in our August 2022 report, but we have removed all references to the sensitive information. Specifically, we deleted information that HHS officials determined was sensitive and requested we redact. We also provided a draft of this report to HHS officials to review and comment on the sensitivity of the information contained herein and to affirm that the relevant portions of the report can be made available to the public without jeopardizing public health emergency preparedness. Although the information provided in this report is more limited, the report addresses the same objectives as the sensitive report and uses the same methodology.

To examine the process HHS used to make MCM inventory decisions for the SNS beginning with fiscal year 2015, we reviewed documentation related to the SNS and the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), including standard operating procedures for the development of SNS annual reviews (SNS review); available SNS reviews; PHEMCE Strategy and Implementation Plans and Multi-year Budget Reports; and Office of the Assistant Secretary for

¹GAO, *Public Health Preparedness: HHS Action Needed to Address Strategic National Stockpile Statutory Requirements and Risks Related to Inventory Gaps*, GAO-22-104718SU (Washington, D.C.: August 12, 2022).

Preparedness and Response (ASPR) spend plans for MCM purchases.² We compared the 2020 and 2021 SNS reviews against statutory requirements for the SNS review.³ Additionally, we used GAO's best practices for interagency collaboration to consider ASPR's approach to updating standard operating procedures for developing the SNS reviews.

We also interviewed current and former ASPR officials who participated in the management of the SNS and governance of the PHEMCE and who had responsibility for (1) administering the PHEMCE prior to and after the December 2017 reorganization; (2) developing SNS reviews; and (3) implementing recommendations in the SNS reviews. We also drew upon our past work, including the report in response to the CARES Act issued in July 2021. See our related work on the SNS conducted in response to the CARES Act at the end this report.

To examine obligations for MCMs in the SNS in fiscal years 2015 through 2021 using funds other than COVID-19 relief funds, we analyzed data on obligations obtained from ASPR's Division of the Strategic National Stockpile and Biomedical Advanced Research and Development Authority (BARDA) for the procurement of MCMs.⁴ These data included obligations made using appropriations for the SNS, appropriations for Project BioShield, and appropriations for Ebola relief.⁵ For obligations made using appropriations for the SNS, data for fiscal years 2015 through 2020 included all MCM obligations that were \$1 million or greater; for fiscal year 2021, the data included all MCM obligations, regardless of

²In July 2022, the Secretary of Health and Human Services removed ASPR from the HHS Office of the Secretary and created a new operating division in the department, to be known as the Administration for Strategic Preparedness and Response. In this report, we refer to ASPR under the organizational name and structure in place at the time we conducted our review.

³See 42 U.S.C. § 247d-6b(a)(2).

⁴An obligation is a definite commitment that creates a legal liability of the U.S. government for the payment of goods and services ordered or received, or a legal duty on the part of the U.S. government that could mature into a legal liability by virtue of actions on the part of another party that are beyond the control of the U.S. government.

⁵Appropriations for Project BioShield and Ebola relief are administered by BARDA.

dollar value.⁶ Data on obligations for the SNS made using appropriations for Project BioShield and Ebola relief included those of any dollar value for all years in our review.

As a result of these data limitations and to ensure consistency for our analysis, we restricted our analysis to obligations \$1 million and greater. These obligations account for 99 percent of total obligations for SNS MCMs made during that time period, according to our analysis of HHS data. Additionally, to group obligations according to the threats that MCMs were intended to address, we also excluded (1) obligations under \$1 million for the reasons previously noted and (2) obligations of \$1 million or greater for which the SNS could not easily determine the specific MCMs purchased.⁷ Obligations excluded from our review totaled approximately 2.4 percent of MCM obligations for fiscal years 2015 through 2021, and those for which the SNS could not easily determine the specific MCMs purchased were made in fiscal years 2015 and 2016.

To examine the extent to which the SNS inventory aligned with recommendations, we reviewed recommendations and inventory levels in the SNS reviews available for our period of analysis. Specifically, we reviewed the inventory data reported in the 2015, 2016, 2020, and 2021 SNS reviews and compared the inventory data against PHEMCE recommendations for types and quantities of MCMs to include in the SNS.⁸ We also reviewed the 2012, 2013, and 2014 SNS reviews for context; these reviews informed procurements during our period of analysis. We compared the inventory in a given year to the recommended quantities established 3 years prior, when available, since SNS reviews

⁶According to ASPR officials, providing obligations below the \$1 million dollar threshold was too time intensive due to the higher number of these contracts and the line item obligations they contain. The SNS fiscal year 2021 data suggests that many obligations below \$1 million are for ancillary supplies that could be used for a variety of public health emergencies, such as syringes and tourniquets; thus, ancillary MCMs may be underestimated in our analyses.

⁷According to officials, the financial system used by the SNS tracks obligated amounts at the contract level. The system does not track obligated amounts per MCM for contracts that include multiple MCMs. SNS officials noted that such a determination would require a review of the contracts, which was too time intensive.

⁸SNS officials told us that providing inventory information for the years in which SNS reviews were not completed would be too time intensive due to the functionality of their inventory management system.

are developed to inform procurements for the subsequent budget cycle (i.e. 3 years in the future).

Additionally, we compared the corrective actions reported in the SNS reviews to inventory data reported in the SNS reviews, using SNS obligations data and spend plans to verify our understanding of corrective actions taken. Further, we assessed the SNS reviews against GAO's *Enterprise Risk Management* principles and Office of Management and Budget (OMB) guidance.⁹ Finally, we interviewed ASPR and Centers for Disease Control and Prevention (CDC) officials—both of which had key responsibilities for the SNS during the period of our review—including those officials responsible for developing the SNS and BARDA budget and spend plans as well as participating in, and managing, the PHEMCE SNS review process.

To describe obligations made for MCMs in the SNS using COVID-19 relief funds, we analyzed obligations data provided by ASPR for fiscal years 2020 and 2021 using funds appropriated by the six COVID-19 relief laws.¹⁰ We limited our analysis to obligations for MCMs that were added to the SNS inventory rather than those that were shipped directly to state, local, tribal, and territorial governments. To describe changes to the SNS's inventory and operations in response to the COVID-19 pandemic, we analyzed inventory data for MCMs procured in response to the COVID-19 pandemic provided by the Division of the Strategic National Stockpile. Additionally, we interviewed the head of each branch of the SNS as well as the SNS director about how the COVID-19 pandemic had impacted operations. We also reviewed the *National Strategy for a Resilient Public Health Supply Chain* and the associated plan of action and milestones (POAM) for the comprehensive SNS transformation

⁹GAO, *Enterprise Risk Management: Selected Agencies Experiences Illustrate Good Practices in Managing Risk*, [GAO-17-63](#) (Washington, D.C.: Dec 1, 2016); and Office of Management and Budget, *Management's Responsibility for Enterprise Risk Management and Internal Control*, OMB Circular No. A-123 (July 15, 2016).

¹⁰See American Rescue Plan Act of 2021, Pub. L. No. 117-2, 135 Stat. 4; Consolidated Appropriations Act, 2021, Pub. L. No. 116-620, 134 Stat. 1182 (2020); Paycheck Protection Program and Health Care Enhancement Act, Pub. L. No. 116-139, 134 Stat. 620 (2020); CARES Act, Pub. L. No. 116-136, 134 Stat. 281 (2020); Families First Coronavirus Response Act, Pub. L. No. 116-127, 134 Stat. 178 (2020); and the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. No. 116-123, 134 Stat. 146. We refer to funds appropriated by these laws as COVID-19 relief funds.

strategy, and compared the POAM against our six characteristics for effective national strategies.¹¹

To examine deployment, distribution, and dispensing plans, we reviewed CDC documentation related to the deployment, distribution, and dispensing of inventory from the SNS and ASPR documentation related to receiving and deploying new SNS inventory. We also interviewed and received written responses from ASPR and CDC officials familiar with these plans. To describe reports or reviews by the Secretary of Health and Human Services or the Comptroller General, we conducted a search for relevant GAO and HHS Office of Inspector General reports within a 10-year period. Additionally, we discussed relevant reports and recommendations with ASPR officials and an official with the HHS Office of Inspector General. Finally, to discuss changes to the management of the SNS after its move from CDC to ASPR, we interviewed SNS leadership, including individual branch managers, as well as CDC officials.

To ensure the reliability of the obligations data we analyzed, we reviewed related documentation, interviewed knowledgeable ASPR officials, and conducted checks on the data. These checks included reviewing the data for possible errors and comparing it to other documents from the office, such as spend plans and SNS reviews; for obligations made using COVID-19 relief funds, we also compared the total to total obligations reported to us by the HHS Office of the Assistant Secretary for Financial Resources. We found the data to be sufficiently reliable for the purposes of presenting obligations for MCMs for the SNS inventory.

¹¹HHS, *National Strategy for a Resilient Public Health Supply Chain*, September 2021; and GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, [GAO-04-408T](#). Washington, D.C.: February. 3, 2004.

Appendix II: Additional Mandate Information

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAI Act) included a provision for GAO to review the management and contents of the Strategic National Stockpile (SNS).¹ This appendix provides information on three aspects of that provision not covered earlier in this report: deployment, distribution, and dispensing plans; previous relevant reports or reviews by the Secretary of Health and Human Services or the Comptroller General; and changes to the management of the SNS.

Deployment, distribution and dispensing plans. The Department of Health and Human Services (HHS) leads the federal government’s public health and medical response to emergencies. Within HHS, the Office of the Assistant Secretary for Preparedness and Response (ASPR) has the lead responsibility for emergency preparedness and response policy coordination and strategic direction.² ASPR officials noted that in this capacity, they utilize a variety of response plans in an integrated and layered manner proceeding from the broader strategic level down to the more tactical level.

Deployment, distribution, and dispensing of medical countermeasures (MCM) from the SNS consist of:³

- **Deployment:** The process by which the SNS provides MCMs to state, local, tribal, and territorial (SLTT) governments. Generally, this process begins with an SLTT government request to the SNS for MCMs during an emergency and concludes with the SNS delivering MCMs to designated facilities within the SLTT.
- **Distribution:** Once the SLTT, generally the state, receives MCMs from the SNS at its designated facility, the SLTT government is responsible for moving those assets to dispensing sites and in some cases to an intermediate or regional distribution site.

¹Pub. L. No. 116-22, § 403(a)(5), 133 Stat. 905, 946-47.

²In July 2022, the Secretary of Health and Human Services removed ASPR from the HHS Office of the Secretary and created a new operating division in the department, to be known as the Administration for Strategic Preparedness and Response. In this report, we refer to ASPR under the organizational name and structure in place at the time we conducted our review.

³Centers for Disease Control and Prevention, *Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide to Preparedness, Version 11* (2014). The Secretary of Health and Human Services transferred responsibility for the SNS from the CDC to ASPR in 2018. While the SNS is now a part of ASPR, this document continues to guide receiving, distributing, and dispensing activities.

- Dispensing: Dispensing MCMs to the public falls predominantly to local public health departments, although planners at the SLTT health department may provide guidance and assistance to their local counterparts on developing MCM dispensing plans. Such plans may address at-risk populations, community resources, and dispensing methods, among other things.

HHS and ASPR rely on the SNS to provide MCMs to support their response to public health emergencies. In April 2022, ASPR officials confirmed that ASPR had not integrated SNS deployment into planning documents due to a small number of staff that lacked the capacity to provide the updates. However, ASPR officials noted there is not an individual response plan for every MCM in the SNS inventory as deployment is based on case-by-case requirements and needs. Additionally, ASPR officials noted that HHS is in the process of updating the HHS All Hazards Base Plan. As part of this effort, ASPR officials noted that they are developing annexes to address how HHS will meet its public health and medical responsibilities. They added that they will incorporate the deployment of SNS resources into these annexes, as appropriate.

ASPR officials noted that, as needed, they plan for the deployment of new MCMs by working with the manufacturer—and, in some cases, the Biomedical Advanced Research and Development Authority (BARDA)—to understand how the product is packaged as well as temperature requirements for storage and shipping. For example, as SNS officials were considering adding a new Ebola vaccine to the SNS, officials discussed storage and temperature requirements with the vaccine manufacturer. SNS officials noted that they had to modify freezer capacity as well as ensure the necessary shipping materials were available. This information was put into a shipping and storage product information sheet that could be provided to end users.

SNS officials noted that, generally, SLTT governments are responsible for distributing and dispensing MCMs. Additionally, Centers for Disease Control and Prevention (CDC) officials noted that recipients of Public Health Emergency Preparedness funding submit MCM distribution and dispensing work plans as part of their funding applications.⁴ According to CDC officials, additional guidance or metrics are needed for SLTT

⁴CDC's Public Health Emergency Preparedness program is a source of funding, guidance, and technical assistance for state, local, and territorial public health departments to strengthen their public health preparedness capabilities and improve their response readiness.

governments that align with SNS priorities and are incorporated into jurisdictional plans, training, and exercises.

Further, SNS officials noted several ways in which they plan for MCM deployment, distribution, and dispensing from the SNS, including (1) considering usability for end users; (2) ensuring appropriate authorization, approval, licensure, or clearance by the Food and Drug Administration prior to use; (3) educating SLTT governments on the contents of the SNS and how to receive, distribute and dispense MCMs; and (4) developing shipping and packaging protocols to share with those receiving the MCMs.

As noted earlier in this report, the PAHPAI Act established several new requirements for SNS annual reviews (SNS reviews), referred to in the act as “annual threat-based reviews.”⁵ One such requirement was that the review provide information on appropriate protocols and processes for the deployment, distribution, and dispensing of each MCM at the state and local level. ASPR did not address this and other requirements in the 2020 and 2021 SNS reviews, and we are making a related recommendation. We have planned work examining ASPR and SNS’s coordination with SLTT governments where we plan to examine deployment plans in more detail.

Reports or reviews by the Secretary of Health and Human Services or the Comptroller General. Over the past 10 years, GAO has issued two relevant reports looking at the SNS inventory for thermal burns and MCMs for children in the event of chemical, biological, radiological, or nuclear incidents.⁶ In 2013, we found that HHS had taken steps to obtain information about needed MCMs, develop pediatric formulations for existing MCMs, and prepare needed regulatory approval ahead of emergencies. Our analysis of the 2021 SNS inventory for this report, the most recent data available, shows a variety of pediatric MCMs as well as supportive care items for thermal burns such as dressings, pain medications, intravenous fluids, and topical antimicrobial creams. Additionally, according to ASPR documentation, the process for making recommendations on MCMs includes consideration of at-risk populations

⁵Pub. L. No. 116-22, § 403(a)(3), 133 Stat. at 944-45 (codified at 42 U.S.C. § 247d-6b(a)(2)).

⁶GAO, *National Preparedness: Countermeasures for Thermal Burns*, [GAO-12-304R](#) (Washington, D.C.: Feb 22, 2012); GAO, *National Preparedness: Efforts to Address the Medical Needs of Children in a Chemical, Biological, Radiological, or Nuclear Incident*, [GAO-13-438](#) (Washington, D.C.: Apr 30, 2013).

(e.g. children, older adults, or pregnant people) as well as national preparedness gaps (see sidebar earlier in the report for an example related to the development of dressings for radiation burns).

The HHS Office of Inspector General has issued reports and made recommendations related to the SNS over the past 10 years. These reports discussed the management of the inventory, including audits of specific warehouse sites and inventory accuracy, rather than the actual contents. For example, a 2017 report summarized the findings of five audits of selected stockpile sites covering fiscal years 2013 and 2014.⁷ The objective of the report was to identify systematic issues that could prevent CDC—which, at the time, managed the SNS—from ensuring inventory was readily deployable in a public health emergency. The 2017 report identified the inventory management system as one systematic issue and made a recommendation that CDC improve its automated system so that it could accurately identify inventory movements and locations. CDC concurred with the recommendation and outlined improvements to the automated inventory system to track inventory. Assessing the inventory management system of the SNS, similar to the above Office of Inspector General’s reports, was beyond the scope of this work.

Changes to the management of the SNS. The Secretary of Health and Human Services transferred responsibility for the SNS from CDC to ASPR in 2018. Based on documentation and interviews with senior SNS officials, the reason for this move included a better operational fit in ASPR that would create efficiencies. Senior SNS officials stated they were told that the transfer of the Division of the Strategic National Stockpile (DSNS) to ASPR would align SNS, BARDA, and ASPR activities, such as product investment, budgeting, and emergency response. This included alignment with the National Disaster Medical System.⁸

Senior SNS officials reported that the entire DSNS moved wholesale from CDC to ASPR with division policies, procedures, and staff generally

⁷HHS OIG, *Readiness of CDC’s Strategic National Stockpile Could Be at Risk in Case of a Public Health Emergency* (A-04-16-03554).

⁸ASPR is the head of the National Disaster Medical System, which is a coordinated effort between federal, state, and private entities to respond to public health emergencies. Public health and medical responders, including doctors, nurses, and paramedics, may enroll in the National Disaster Medical System to provide, among other things, health services to victims of public health emergencies. See 42 U.S.C. § 300hh-11.

remaining the same. Each senior official we interviewed—which included the manager of each DSNS branch—noted their roles and responsibilities remained the same. Some added that they needed to learn the structure, functions and standards of ASPR.⁹

Senior SNS officials told us they still rely on CDC for several support functions, including human resources, certain information technology systems (including the inventory management system), office space, library assistance, and regulatory affairs assistance. SNS and CDC officials noted that they are working to phase out some of these support functions. However, CDC officials noted that they will continue to play an important role in the MCM enterprise by evaluating MCMs, developing clinical guidelines, and disseminating MCM communications material for clinicians and the public.

Senior SNS officials noted certain challenges related to the transfer, including migrating data systems and contracts, and developing working relationships with other ASPR officials. They added that there was limited time to work through these challenges before the COVID-19 pandemic required their complete attention. For example, one SNS branch chief noted that their branch is still determining what normal finance processes look like for the SNS under ASPR.

ASPR and CDC officials also noted that the transfer and COVID-19 response disrupted some of the coordination between the agencies. For example, local emergency preparedness trainings, which include the DSNS, were put on hold because of the pandemic. CDC and SNS officials noted that, after an initial transition period, coordination has generally improved since the transfer. CDC officials noted that CDC and ASPR resumed coordination meetings in July 2021 related to MCM preparedness planning. In these meetings, they said that they discuss preparedness funding, MCM trainings, and review recipients' MCM warehouse sites.

Senior SNS officials we interviewed generally felt that the transfer to ASPR has resulted in better SNS operational efficiency, communication with leadership, coordination with others, including BARDA, and budget support for SNS activities. For example, one senior SNS official noted

⁹The SNS is organized under an Office of the Director and includes six branches: Acquisition Branch, Information and Planning Branch, Management and Business Operations Branch, Operational Logistics Branch, Science Branch, and Strategic Logistics Branch.

that being able to interact directly with ASPR leadership during the COVID-19 response—including on rapidly creating additional SNS capabilities—was valuable. They said they were unsure whether such interactions would have happened at CDC. According to ASPR officials, the full integration of the SNS into ASPR remains an ongoing activity that will receive more attention once the response to the pandemic begins to subside.

Appendix III: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

July 19, 2022

Mary Denigan-Macauley
Director, Healthcare
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Mary Denigan-Macauley:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "**PUBLIC HEALTH PREPAREDNESS: HHS Action Needed to Address Strategic National Stockpile Statutory Requirements and Risks Related to Inventory Gaps**" (GAO-22-104718SU).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED — PUBLIC HEALTH PREPAREDNESS: HHS Action Needed to Address Strategic National Stockpile Statutory Requirements and Risks Related to Inventory Gaps(22-104718SU)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

General Comments

The Strategic National Stockpile (SNS) is critical for a successful response to public health emergencies. Ongoing COVID-19 response efforts have highlighted the critical need for having access to a robust stockpile of supplies, medicines, and devices that can be used as a short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient. HHS appreciates the review by GAO to examine current procedures and policies used by the SNS to meet requirements for current and future public health emergencies. HHS concurs with the three recommendations included in this report and looks forward to working with GAO to continue improving response capabilities.

Recommendation 1

The Assistant Secretary for Preparedness and Response should update procedures for how SNS reviews will be conducted in accordance with statutory requirements, including a description of the roles and responsibilities of its interagency partners in the development of the SNS reviews.

HHS Response

HHS Concurs with GAO's recommendation.

Recommendation 2

The Assistant Secretary for Preparedness and Response should develop and document an approach—whether through the standard operating procedures for the SNS reviews or some other mechanism—for ensuring that MCMs under consideration for SNS procurement receive the same consideration regardless of whether they received development funding from BARDA, in accordance with statutory requirements.

HHS Response

HHS Concur with GAO's recommendation.

Recommendation 3

The Assistant Secretary for Preparedness and Response should develop and document an approach for regularly managing the risks associated with the gaps between SNS MCM inventory levels and recommended quantities. Such an approach, which could occur as part of the SNS reviews, should clearly prioritize risks, track progress made in addressing the risks, and estimate resources needed to address risks. This approach should involve communicating this information to key decision makers, including Congress.

HHS Response

HHS Concur with GAO's recommendation.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact:

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Staff**Acknowledgment:**

In addition to the individual named above, Shannon Legeer (Assistant Director), Dan Klabunde (Analyst-in-Charge), Caroline Hale, Kevin Dong, Jennel Lockley, and Jennifer Lucado made key contributions to this report. Also contributing were Kaitlin Farquharson, Sam Amrhein, Ethiene Salgado-Rodriguez, and Janet Wilson.

Related GAO products

GAO, *COVID-19: Opportunities to Improve Federal Response and Recovery Efforts*, [GAO-20-625](#) (Washington, D.C.: Jun 25, 2020).

GAO, *COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions*, [GAO-20-701](#) (Washington, D.C.: Sep. 21, 2020).

GAO, *COVID-19: Urgent Actions Needed to Better Ensure an Effective Federal Response*, [GAO-21-191](#) (Washington, D.C.: Nov 20, 2020).

GAO, *COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention*, [GAO-21-265](#) (Washington, D.C.: Jan. 28, 2021).

GAO, *COVID-19: Sustained Federal Action Is Crucial as Pandemic Enters Its Second Year*, [GAO-21-387](#) (Washington, D.C.: Mar. 31, 2021).

GAO, *COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity*, [GAO-21-551](#) (Washington, D.C.: July 19, 2021).

GAO, *COVID-19: Current and Future Federal Preparedness Requires Fixes to Improve Health Data and Address Improper Payment*, [GAO-22-105397](#) (Washington, D.C.: Apr.27, 2022)

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