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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PUBLIC HEALTH PREPAREDNESS

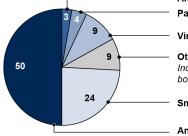
HHS Should Address Strategic National Stockpile Requirements and Inventory Risks

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



Ancillary & intravenous supplies (\$124 million)

Pandemic influenza (\$191 million)

Viral hemorrhagic fever (\$477 million)

Other threats (\$403 million)
Includes chemical, radiological, and nuclear threats;
botulism; and burkholderia

Smallpox (\$1.1 billion)

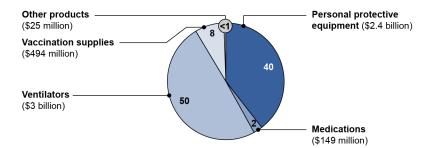
Anthrax (\$2.3 billion)

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.

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.