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ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6115

Majority (202) 225-3641

Minority (202) 225-2927

May 9, 2024

The Honorable Dawn O’Connell
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

We write to you regarding concerns about the mismanagement of the Strategic National Stockpile (SNS). As you know, the SNS plays a critical role in ensuring America is prepared against health security threats, including chemical, biological, radiological, nuclear, and pandemic threats. You have stated the Administration for Strategic Preparedness and Response’s (ASPR) primary goal is to “restore and maintain the public health emergency capacity that has been severely strained by the pandemic including replenishing the Strategic National Stockpile.”¹

Despite this apparent prioritization, in 2022, the non-partisan Government Accountability Office (GAO) placed the Department of Health and Human Services (HHS) management of public health emergencies, of which ASPR is a leading sub-agency, on its high-risk of government programs that “are vulnerable to waste, fraud, abuse, or mismanagement, or in need of transformation.”² In making this determination, the GAO raised concerns about ASPR’s ability to manage SNS and medical countermeasure contracts once support by the Department of Defense (DoD) ended in January 2022.³ As of the date of this letter, HHS’s management of public health emergencies remains on GAO’s high-risk list. Even though DoD contracting and logistics support was extended until at least late-July 2022, GAO’s warnings appear prescient in light of recent developments.⁴

¹ ADMINISTRATION FOR PREPAREDNESS AND RESPONSE (ASPR), U.S. DEP’T. OF HEALTH AND HUMAN SERVICES (HHS), 2022 MEDICAL COUNTERMEASURE PREPAREDNESS REPORT (2022) (on file with Committee staff).

² U.S. GOV’T. ACCOUNTABILITY OFFICE, GAO-23-106203, HIGH-RISK SERIES: EFFORTS MADE TO ACHIEVE PROGRESS NEED TO BE MAINTAINED AND EXPANDED TO FULLY ADDRESS ALL AREAS (Apr. 20, 2023).

³ U.S. GOV’T. ACCOUNTABILITY OFFICE, GAO-22-105291, COVID-19: SIGNIFICANT IMPROVEMENTS ARE NEEDED FOR OVERSEEING RELIEF FUNDS AND LEADING RESPONSES TO PUBLIC HEALTH EMERGENCIES (Jan. 27, 2022).

⁴ Press Release, U.S. Dep’t. of Defense, DoD Awards \$1.74 Billion Agreement to Moderna, Inc. to Secure Over 65 Million Doses of COVID-19 Vaccine for Fall Vaccinations (July 29, 2022), <https://www.defense.gov/News/Releases/Release/Article/3109705/dod-awards-174-billion-agreement-to-moderna-inc-to-secure-over-65-million-doses/>.

The Committee is alarmed by a pattern of fiscal mismanagement and a series of failed acquisitions that have left the SNS dangerously under resourced and likely underprepared to respond to future public health emergencies. Over the last year, ASPR let over \$850 million in emergency supplemental funding for the SNS go unused. These funds were eventually rescinded by the Office of Management and Budget (OMB) due to a lack of appropriate planning and urgency by ASPR. This rescission occurred despite ASPR regularly expressing concerns to Congress about adequately funding the resupply of the SNS after the COVID-19 pandemic. This Committee responded to ASPR’s concerns by increasing the authorization of SNS funding in its reauthorization of the Pandemic All-Hazards Preparedness Act. Similarly, the Fiscal Year 2024 Labor, Health, and Human Services Appropriation Bill also increased funding for the SNS. As such, the failure to commit funds in a timely and competent manner is particularly frustrating. Moreover, the continued procurement dysfunction at ASPR puts remaining SNS funds, as well as funds for advance research and development, at risk of future rescission by OMB.

ASPR has seen a growing number of successful bid protests and protest-like actions against the SNS. On May 5, 2022, the SNS awarded a \$236,437,117 service contract for managing the national capital region warehouse to a company whose previous relevant experience was managing two much smaller SNS warehouses, one of which experienced refrigeration and security issues. This company’s principal address is a condominium owned by the mother of one of its corporate officers. The winning bid was \$46 million dollars more than the latest competing proposal put forward by the company that had previously managed the warehouse without issue (the initial award was nearly \$38 million more). Since the contract was first awarded, it has been successfully challenged four times. The SNS continues to award the contract to the same company and continues to lose GAO protests and in court. Because of these contracting failures, as of the date of this letter, there is no SNS warehouse for the national capital region. In the event of an emergency, SNS material would have to be brought in from other regions, potentially delaying deployment.

On September 25, 2023, the SNS awarded a \$256 million contract to a small New York based company to procure disposable gowns for the stockpile.⁵ The company specialized in high-end fashion and had only limited and recent experience producing disposable medical-grade gowns. The price ASPR planned to pay per gown also appears to be unusually high at between \$1.88 to \$1.98 per gown.⁶ By contrast, an online retailer sells the same gowns that anyone can purchase for a discounted price of \$1.06 per gown if you place a minimum order of 250 gowns.⁷ The SNS contract planned to procure 150 million gowns. Such a large order should command a substantial volume discount, not a 77 to 87 percent premium. Unsurprisingly, this contract was successfully protested at the agency level, and the SNS has been forced to reevaluate the contracting process. To date, the contract has not been successfully reissued, and it is unclear whether the SNS still intends to procure medical gowns.

⁵ ASPR, HHS, CONTRACT AWARD FOR ISOLATION GOWNS LEVEL 3, DISPOSABLE 50% LARGE AND 50% X-LARGE, CONTRACT AWARD NO. 75A50323C00013 (Sept. 25, 2023), https://www.usaspending.gov/award/CONT_AWD_75A50323C00013_7505_-NONE--NONE-.

⁶ *Id.*

⁷ Uline Isolation Gowns – Blue, https://www.uline.com/Product/Detail/S-24019BLU/Disposable-Clothing/Uline-Isolation-Gowns-Blue?pricode=WC1297&gadtype=pla&id=S-24019BLU&gad_source=1&gclid=CjwKCAiAopuvBhBCEiwAm8jaMVdZHYd149zfkZFrDprekKfLD26dnRX-DHIN9OeBfkYr9HcULcHbRoCXMAQAvD_BwE (last visited March 18, 2024).

On November 17, 2023, ASPR issued a sole-source award for brand-name oseltamivir to replenish the SNS pandemic influenza antiviral outpatient requirement, with a total value of up to \$396 million over 5 years.⁸ Under this protested and now rescinded award, ASPR elected to purchase only brand-name product despite the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and 2023 Medical Countermeasure Preparedness Review both suggesting replenishment of generic oseltamivir antivirals and purchases of new Bloxivir antivirals.⁹ In addition, at the time ASPR awarded this contract, the agency held an active contract with a company to provide generic oseltamivir to the SNS as well as other active contracts for non-oseltamivir antivirals. Nevertheless, ASPR exclusively procured the brand-name product. Taken together, we are concerned these examples reflect poor prioritization and a lack of strategic decision-making regarding the use of limited SNS resources.

During your tenure as Assistant Secretary, you have publicly placed an emphasis on the use of vendor-managed inventory (VMI) contracts to ensure quick deployment of SNS supplies and cost-effective stockpiling strategies. The Committee supports the use of VMI to reduce SNS overhead expenses and improve readiness. Yet ASPR has awarded very few VMI contracts to resupply SNS products and, earlier this year, SNS terminated a VMI contract to provide logistical and supply chain support for SNS products. This termination comes just a month after a December 2023 investigation by the Associated Press found that at least 15 states were forced to throw away a vast amount of personal protective equipment (PPE) because of expiration, surpluses, and a lack of demand.¹⁰ The investigation found more than 18 million masks, 22 million gowns, 500,000 gloves, and more were discarded after the COVID-19 emergency ended.

Beyond budgeting, acquisition, and inventory management problems, it is our understanding that a significant number of products in the SNS, including influenza antivirals and smallpox vaccines, are several decades beyond their original FDA-approved expiration date, with some products now lacking a product sponsor to support shelf-life extension testing. A public health strategy that involves distributing these decades-old products raises serious concerns, both with respect to the medical efficacy of such products and for the impact on public confidence. Whether the FDA's shelf-life extension program is sufficient to ensure continued medical efficacy for years beyond a product's FDA-approved life span is an area of ongoing debate and, critically, has yet to be validated during an emergency response.

Many of these products, if distributed during an emergency, have expiration dates on their labels dating back over a decade. Parents may be reluctant to give their child flu medication that expired before the child was born. Based on our experience with the COVID-19 pandemic, it seems doubtful that federal public health officials enjoy the level of public trust necessary to convince

⁸ ASPR, HHS, PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE MULTIYEAR BUDGET: FISCAL YEARS 2023-2027 (Mar. 15, 2024), <https://aspr.hhs.gov/PHEMCE/Documents/2023-2027-PHEMCE-MYB-508.pdf>; see also ASPR, HHS, FEDERAL SUPPLY SCHEDULE LIMITED-SOURCES JUSTIFICATION: TAMIFLU 30MG AND 75MG CAPSULES (Nov. 17, 2023) (on file with Committee staff).

⁹ ASPR, HHS, 2023 MEDICAL COUNTERMEASURE PREPAREDNESS REVIEW (Apr. 2024) (on file with Committee staff).

¹⁰ Jennifer Petlz and David A. Lieb, *States are Trashing Troves of Masks and Pandemic Gear as Huge, Costly Stockpiles Linger and Expire*, ASSOCIATED PRESS, December 20, 2023, <https://apnews.com/article/coronavirus-pandemic-ppe-stockpiles-masks-50bf7739fc9d69f4b991a14daadecaba>.

large numbers of Americans to take expired countermeasures or to give them to their children in the event of an emergency.

The Committee requests your prompt written response to the following questions, not later than May 23, 2024:

- The GAO recently highlighted instances where ASPR chose to spend significantly more money than previous contracts to award new vendors, including with vendors that lacked the technical expertise to meet contract requirements. How many bidder protests were filed against the SNS in calendar years 2022 and 2023?
 - How many were dismissed by the agency, GAO, or other related protest entities?
 - How many protests or protest-like-actions resulted in modified contract offerings, canceled contracts, or new awards?
 - How do these rates of protest, action, and dismissals compare to GAO's annually published protest statistics?
- Given the SNS's limited funding relative to requirements from the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) multi-year budget, how is ASPR ensuring every SNS contract receives a true "best value" review to ensure prudent stewardship of the SNS's limited financial resources?
 - Is ASPR utilizing the Office of General Counsel's (OGC) contract review team and the Assistant Secretary for Financial Resources (ASFR) to ensure legal sufficiency and best value?
 - Since January 2021, how many SNS procurement awards have been sent for legal sufficiency review by OGC?
 - How was the interagency informed of impacts to all-hazards preparedness caused by procurement failures and delays? What was the reported impact?
 - How does ASPR prioritize cost-effective replenishment of aging or expired products in the SNS?
 - Why did ASPR stop purchasing prophylactic oral antibiotic to diversify holdings in the event of resistant bacteria? (For example, against multidrug-resistant anthrax or plague).
- What factors did ASPR consider when choosing to purchase only brand-name oseltamivir to replenish the SNS despite PHEMCE requirements for a mix of branded and generic antivirals?

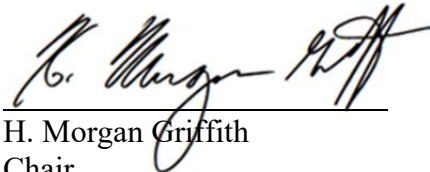
- How does ASPR intend to meet the stated requirement of 85 million treatment courses of flu antivirals?
- One of the fundamental principles of Federal Acquisitions Regulations (FAR)-based contracting requires conducting appropriate market research. In evaluating existing market research, did ASPR consider existing contracts when estimating the price of generic oseltamivir? Did ASPR conduct market research on any other commercially available antivirals to diversify the stockpile supply?
- Why did ASPR incorrectly estimate the price of generic oseltamivir to be five times higher than what the agency was already paying under existing contracts?
- The sole source justification to purchase the brand-name product referred to an automatic shelf-life extension and related testing costs. How did ASPR receive an exception to the FDA's Shelf-Life Extension Program (SLEP) that allows for automatic approval?
- How did ASPR evaluate, consult, and cost out all potential antiviral manufacturers' abilities to provide and pay for related SLEP testing?
- The Committee understands that ASPR has postponed the award of pandemic influenza antivirals. What is the status of this revised procurement and award?
- What is the outcome of the \$256 million contract to procure disposable gowns for the SNS?
 - What was the basis for source selection for a procurement that stated it was for ANSI/AAMI Level 2 disposable gowns at 50 percent large and 50 percent extra-large?
- How does ASPR define VMI?
 - Does ASPR consider VMI to be product held at a distribution center?
 - Does ASPR consider VMI to be holding and rotating product to avoid expiration?
 - Why has ASPR failed to prioritize VMI contracts for the SNS?
- With respect to reports that state stockpiles were forced to throw away more than 18 million masks, 22 million gowns, and 500,000 gloves after the COVID-19 emergency ended: Did ASPR consider working with any of these states to ensure viable products were returned to the SNS or sold into the larger commercial market? If not, why not?
 - How has ASPR utilized its authority to ensure the sale of near-expiry products into general use to provide best value to the government?

We appreciate your prompt attention to this inquiry. As Congress begins holding budget hearings, it is essential for the Committee to understand fully the depth and scale of procurement problems at ASPR. If you have any questions, please contact the Energy and Commerce Committee Majority staff at (202) 225-3641.

Sincerely,



Cathy McMorris Rodgers
Chair
Committee on Energy and
Commerce



H. Morgan Griffith
Chair
Subcommittee on Oversight and
Investigations



Brett Guthrie
Chair
Subcommittee on Health

CC: Frank Pallone Jr., Ranking Member, Energy and Commerce Committee
Anna Eshoo, Ranking Member, Subcommittee on Health
Kathy Castor, Ranking Member, Subcommittee on Oversight and Investigations

CC: The Honorable Gene L. Dodaro, Comptroller General of United States, Government
Accountability Office
The Honorable Shalanda Young, Director, Office of Management and Budget
Maj. Gen. Paul Friedrichs, M.D. (ret.) Director, Office of Pandemic Preparedness and
Response Policy