



**MEMORANDUM**

**TO:** SAMS Membership **DATE:** December 21, 2022  
**FROM:** Michael Rattner **CC:**  
**RE:** Relevant Provisions withing the FY23 Omnibus

**Executive Summary**

The Fiscal Year 2023 (FY23) omnibus appropriations package raised discretionary funding levels for public health agencies, included numerous provisions from the PREVENT Pandemics Act which strengthen the domestic medical supply chain, and distanced the new Advanced Research Projects Agency for Health (ARPA-H) from the National Institutes of Health (NIH).

This memorandum highlights provisions within the omnibus which are most relevant for SAMS members under the following categories:

- Federal Agency Funding Levels
- The PREVENT Pandemics Act Provisions
- ARPA-H Provisions

**Federal Agency Funding Levels**

The omnibus raised the funding levels for public health agencies, including the Biomedical Research and Development Agency (BARDA), the Strategic National Stockpile (SNS), and ARPA-H. No supplemental funds were specifically allocated for COVID-19 relief.

Funding	FY2022	FY2023 - Pres.	FY2023 - House	FY2023 - Senate	FY2023 - FINAL?	FY2022 Δ
	Received	<i>Proposed</i>	<i>Proposed</i>	<i>Proposed</i>	<i>Under Negotiation</i>	
BARDA AR&D (CBRN)	\$745	\$828	\$845	\$819	\$950	\$205
Project BioShield	\$780	\$770	\$800	\$790	\$820	\$40
Pandemic Influenza	\$300	\$375	\$382	\$382	\$335	\$35
<b>BARDA TOTAL</b>	<b>\$1,825</b>	<b>\$1,973</b>	<b>\$2,027</b>	<b>\$1,991</b>	<b>\$2,105</b>	<b>\$280</b>
Strategic National Stockpile	\$845	\$975	\$855	\$875	\$965	\$120

The headline funding increases are:

- **\$3.8 billion for the Office of the Secretary—Public Health and Social Services Emergency Fund (PHSSEF)**, an increase of \$568 million above the fiscal year 2022 level.
- **\$950 million for the Biomedical Advanced Research and Development Authority (BARDA)** an increase of \$205 million above the fiscal year 2022 enacted level.
- **\$965 million for the Strategic National Stockpile**, an increase of \$120 million above the fiscal year 2022 enacted level.
- **\$820 million for Project BioShield** an increase of \$40 million above the fiscal year 2022 enacted level.
- **\$335 million for pandemic influenza**, an increase of \$35 million above the fiscal year 2022 enacted level.

## **PREVENT Pandemics Provisions**

The omnibus included provisions from the PREVENT Pandemics Act which was championed by Senators Richard Burr (R-NC) and Patty Murray (D-WA). The Act makes numerous changes to the way the United States conducts surveillance for novel biological threats, responds to future pandemics, and stockpiles critical medical goods.

### **Key Provisions**

#### **Study on Incentives for Domestic Production of Generic Medicines**

- Directs the Assistant Secretary for Planning and Evaluation at the HHS to conduct a study investigating the feasibility and utility in providing incentives for domestic manufacturing of generic medications and API within one year.

#### **Made in America Strategic National Stockpile**

- Strongly urges the Secretary to develop a long-term sustainable procurement plan that gives preference to and results in purchases directly from domestic manufacturers of PPE or PPE raw materials to the maximum extent practicable.

#### **Increased Manufacturing Capacity for Certain Critical Antibiotics**

- Authorizes the ASPR to issue contracts to increase domestic production of antibiotic drugs with identified supply chain vulnerabilities, or the active pharmaceutical ingredient or key starting material of such antibiotic drugs.

#### **Warm Base Manufacturing Capacity for Medical Countermeasures**

- Directs BARDA to support the establishment and maintenance of warm-base domestic manufacturing surge capacity to ensure rapid responses to public health emergencies.
- Improves coordination between private sector partners, BARDA, and the FDA to ensure long-term efficiency of manufacturing practices.

#### **Vendor Managed Inventories for the Strategic National Stockpile**

- Authorizes the Secretary of HHS to enter into contracts with vendors to maintain and replenish the SNS without the Secretary of Homeland Security's approval.
- These contracts can be carried out through vendor managed inventory and warm-base domestic manufacturing capacity arrangements to ensure surge capacity.

#### **Supply Chain Considerations for the Strategic National Stockpile.**

- Amends the SNS Annual Threat-Based Review to include considerations for supply chain vulnerabilities of the products that the SNS plans to purchase.

#### **Strategic National Stockpile Equipment Maintenance**

- Creates a "regular" review process to ensure that all contents of the SNS are in working condition and are fit to combat emerging threats.
- Items that fail this review may be disposed of and replaced with new products that address the potential threat.

#### **Grants for State Strategic Stockpiles**

- Directs the Secretary of HHS to work with the ASPR to issue grants or cooperative agreements in a pilot program to at least five states to establish, expand, or maintain a stockpile of critical medical supplies.

## **ARPA-H**

The FY23 omnibus appropriations package increased the funding for ARPA-H to \$1.5 billion and distanced the agency from the NIH. The omnibus bill requires ARPA-H to have offices in at least three locations that are “physically distant” from the NIH headquarters, places restrictions on ARPA-H hiring NIH staff, and calls for ARPA-H to have a distinct culture from the NIH.

### **Key Provisions**

**Funding** – The omnibus allocates an additional \$500 million for ARPA-H in FY23, on top of the \$1 billion the agency was allocated earlier this year. It also removes the requirement that no more than 15 percent of funds can be spent on administrative expenses.

**Location** – The omnibus calls for at least three locations for ARPA-H’s offices and permits up to eight locations. These locations must be “physically distant” from the main NIH campus in Bethesda, Maryland. The bill directs the Department of Health and Human Services to brief Congress no later than 30 days prior to conducting the location search for ARPA-H and Congress should be notified of the decision on locations no less than 5 days prior to a location being announced publicly.

**Governance** – It remains unclear if ARPA-H will be housed within NIH. Although the omnibus attempts to distance ARPA-H geographically and culturally from NIH, the bill states that the Secretary of Health and Human Services “may transfer ARPA-H... within 30 days of enactment of this Act to any agency or office of the Department of Health and Human Services, including the NIH.” The authorizing language within the package states that ARPA-H will be within NIH, but these provisions are superseded by the appropriations language.

**Staffing** – The omnibus directs ARPA-H to hire up to 210 people and prohibits the agency from hiring persons employed by the NIH in the last three years except under special circumstances. ARPA-H program managers will have terms of three years while the director of the agency will have a four-year term. The omnibus specifically directs ARPA-H to prioritize hiring individuals from outside the government, including those employed in private industry, academia, and think-tanks.

**Culture** – The omnibus stresses that ARPA-H should have a “high-risk, high-reward” approach to health research and recommends extensive partnerships with private companies. The omnibus also orders that the director of ARPA-H prioritize working with minority-serving institutions.

**FDA Cooperation** – The omnibus retains language calling for close cooperation between ARPA-H and the Food and Drug Administration, but excluded language that directs the FDA to accelerate products developed by ARPA-H.