

What is the Alliance?

The Alliance for Biosecurity is a coalition of biopharmaceutical companies and partners that advocates for medical countermeasure (MCM) development, production, and distribution to protect Americans at home and abroad from deadly natural and man-made health threats. For additional information on the Alliance, please visit www.allianceforbiosecurity.com or contact info@allianceforbiosecurity.com.

The Importance of Funding Preparedness and Response:

Sustainable Federal funding for MCM infrastructure and biosecurity preparedness and response programs is imperative to safeguard the United States against chemical, biological, radiological, and nuclear (CBRN) attacks and deadly pathogens. Global health threats posed by our adversaries, such as bioterrorism threats from anthrax and smallpox, pose urgent risks to our nation's economy, national security, military readiness, and public health. Biosecurity preparedness and response programs serve as our primary defense against these and other deadly threats, however, they have historically suffered from inadequate funding.

While the Federal government is a critical partner in supporting our biosecurity capabilities, the government cannot protect against biodefense threats alone. Robust and consistent federal funding is essential to foster vital public-private partnerships that fill our preparedness gap. These partnerships are crucial for the efficient and sustained development and production of essential MCMs, including diagnostic tests, therapeutics, and vaccines. By facilitating collaboration between key Federal agencies and private industry counterparts, these partnerships bolster both government and private sector preparedness and response capabilities, fortifying the nation's defenses against biosecurity threats.

Alliance for Biosecurity FY 2026 Appropriations Requests

Alliance for Biosecurity FY 2026 Funding Request (in millions)	FY 2025 Enacted	PHEMCE Multi-year Budget for FYs 2023-27	FY 2026 Alliance Request
Department of			
Health & Human Services			
BARDA			
Advanced Research and	\$1,015	\$8,851	\$1,400
Development			
Project BioShield SRF	\$825	\$1,630	\$1,000
Pan Flu Preparedness	\$335	\$1,913	\$410
Strategic National Stockpile	\$980	\$1,588	\$1,588
Office of Preparedness	N/A	N/A	7

Funding levels subject to change depending on the President's FY2026 Budget Request

Biomedical Advanced Research Development Authority (BARDA)

FY 2026 Funding Request: \$1,400,000,000

Program Title: Biomedical Advanced Research Development

Authority (BARDA)

Subcommittee: Labor-Health and Human Services-Education

(LHHS)

Agency: Department of Health and Human Services

(HHS)

Account: Office of the Secretary, Public Health and Social

Services Emergency Fund, Office of the Assistant Secretary for Preparedness and

Response (ASPR), BARDA

Sub-Activity Group (SAG)/Budget Line

Item (BLI)/Program Element Number

(PE):

N/A

Previous Year(s) Funding Amount: \$1,015,000,000 (FY 2024 & FY 2025)

\$950,000,000 (FY 2023) \$745,000,000 (FY 2022)

Justification: BARDA has a vital role by partnering with biopharmaceutical companies to support advanced research and development of life-saving MCMs. Presently, the BARDA pipeline encompasses over 200 candidate MCMs, such as broad-spectrum antimicrobials, rapid diagnostics, and next-generation products to address CBRN threats. Insufficient support for BARDA's programs risks squandering resources invested in the earlier stages of research and decreases the nation's readiness to safeguard Americans at home and our men and women in uniform.

The \$1.4 billion request represents consensus between industry leaders and ensures the nation maintains a sufficient level of preparedness to protect our citizens and the warfighter by building upon resources invested in prior fiscal years. The request represents an increase from FY 2024 enacted levels. In addition to the \$1.4 billion request to support the historic needs for Advanced R&D initiatives, the Alliance requests a line-item of \$300 million to provide sustained advanced development and manufacturing funding dedicated to BARDA's Emerging Infectious Diseases (EID) program to take these products, platforms, and capabilities from early development to licensure.

Project BioShield

FY 2026 Funding Request: \$1,000,000,000

Program Title: Project BioShield

Subcommittee: Labor-Health and Human Services-Education

(LHHS)

Agency: Department of Health and Human Services

(HHS)

Account: Office of the Secretary, Public Health and Social

Services Emergency Fund, Office of the Assistant Secretary for Preparedness and Preparedness (ASPR) Prepared Pic Shield SPE

Response (ASPR), Project BioShield SRF

Sub-Activity Group (SAG)/Budget Line Item (BLI)/Program Element Number

(PE):

N/A

Previous Year(s) Funding Amount: \$825,000,000 (FY 2024 & FY 2025)

\$820,000,000 (FY 2023) \$780,000,000 (FY 2022)

Justification: Project BioShield establishes the Emergency Use Authorization (EUA) to provide access to the best available MCMs following a declaration of emergency. The SRF was originally funded at \$5.6 billion for 10 years to support private development and supply of products to address CBRN threats. Over the last decade, SRF has led to the support of 30 products that are critical to prepare for and treat the effects of the highest priority threats (*e.g.*, smallpox, anthrax, radiological, etc.). These products have no commercial market, and without robust, stable, and consistent Federal funding to fill our preparedness gaps, this public-private partnership to create life-saving MCMs will be in jeopardy.

The \$1 billion request represents a \$175 million increase from FY 2024 enacted levels. The request is based on an increased scope to support all procurement activity for all DHS threat assessments not funded in the current level without emergency supplemental funds. For example, past Federal government estimates of required funding have not contemplated recent public health threats, like COVID-19, and the associated costs to procure necessary diagnostics, therapeutics, vaccines, and additional MCMs.

Pandemic Influenza Preparedness

FY 2026 Funding Request: \$410,000,000

Program Title: Pan Flu Preparedness

Subcommittee: Labor-Health and Human Services-Education

(LHHS)

Agency: Department of Health and Human Services

(HHS)

Account: Office of the Secretary, Public Health and Social

N/A

Services Emergency Fund, Office of the Assistant Secretary for Preparedness and

Response (ASPR), Pan Flu Preparedness

Sub-Activity Group (SAG)/Budget Line Item (BLI)/Program Element Number

(PE):

Previous Year(s) Funding Amount: \$335,000,000 (FY 2024 & FY 2025)

\$328,000,000 (FY 2023) \$347,000,000 (FY 2022)

Justification: Pandemic flu remains an annual and long-term public health threat. However, no commercial market for pandemic flu products currently exists, meaning private development and manufacturing of influenza vaccines, therapeutics, and diagnostics requires Federal funding. Increased investments are needed in order to adequately prepare for the next pandemic flu outbreak through R&D of next generation flu products, testing and evaluation of existing products, and sustaining and replenishing stockpiles.

Based on continued pandemic influenza threats, including the ongoing global H5N1 avian influenza outbreak, the Alliance's \$410 million request is consistent with funding requests submitted in FY 2023 and FY 2022 and represents a modest increase over FY 2024 enacted levels to sustain preparedness capabilities. The Alliance's request is based on estimates of funding necessary to sustain previous investments in critical domestic influenza vaccine manufacturing facility infrastructure, and support development of improved vaccines.

Strategic National Stockpile

FY 2026 Funding Request: \$1,588,000,000

Program Title: Strategic National Stockpile

Subcommittee: Labor-Health and Human Services-Education

(LHHS)

Agency: Department of Health and Human Services

(HHS)

Account: Office of the Secretary, Public Health and Social

N/A

Services Emergency Fund, Office of the Assistant Secretary for Preparedness and Response (ASPR), Strategic National Stockpile

Sub-Activity Group (SAG)/Budget Line Item (BLI)/Program Element Number

(PE):

Previous Year(s) Funding Amount: \$980,000,000 (FY 2024 & FY 2025)

\$965,000,000 (FY 2023) \$975,000,000 (FY 2022)

Justification: The Strategic National Stockpile (SNS) is the nation's largest reserve of potentially life-saving pharmaceuticals and medical supplies designated for use in a national emergency. Tasked with strategic procurement and stockpiling of MCMs, medical supplies, and equipment necessary to protect Americans' health and save lives, the SNS is a pivotal procurement mechanism. It secures numerous FDA-approved MCMs, including those with no commercial market such as licensed vaccines and drugs against smallpox and anthrax. Additionally, the SNS includes BARDA-developed and supported vaccines, drugs, therapies, and diagnostic tools for public health emergencies, terrorist attacks, and other emergencies. As the sole resource readily available to respond to CBRN and infectious disease threats within the US, the SNS is indispensable. In the beginning days of the COVID-19 pandemic, the Trump Administration quickly mobilized the SNS to distribute N-95 masks, ventilators, and other personal protective equipment to states and major cities.

The SNS has historically been underfunded. The \$1.588 billion request considers documented funding needs of the SNS, as well as needs of companion state stockpiles. The Alliance supports independent funding to support state stockpiles which ensures the SNS is appropriated sufficient Federal funding, at or above PHEMCE-recommended levels, to adequately respond to future public health threats. As a result, the recommended funding level in the Alliance's FY 2026 request should be considered the minimum funding necessary to support the SNS.

FY 2026 Report Language Requests

The Alliance requests the Committee include the following report language on CBRN threats and Department of Defense coordination, as previously included in the FY 2024 Senate Labor-HHS Report:

- ➤ CBRN Threats. The committee expresses deep concern regarding the heightened risks posed by chemical, biological, radiological, and nuclear (CBRN) weapons worldwide. Consequently, Congress provides robust funding for BARDA's core national security mission to protect American citizens and servicemembers against these deliberate, manmade threats. The committee urges ASPR and BARDA to prioritize the development and stockpiling of critical CBRN vaccines, treatments, and personal protective equipment (PPE) to ensure uninterrupted access to these life-saving medical countermeasures (MCMs) within the SNS. The committee urges ASPR, BARDA, and SNS to engage more frequently with private sector partners in the Broad Agency Announcement process to speed the development of new MCMs and stockpiling of existing MCMs against CBRN threats.
- Department of Defense Coordination. The committee understands the critical role of the Department of Defense (DoD) in the government's response to address chemical, biological, radiological, and nuclear (CBRN) threats as well as emerging infectious diseases. The DoD possesses unique capabilities that contribute to interagency efforts to prevent, detect, and respond to outbreaks of infectious disease worldwide. The committee encourages prioritizing and aligning government-wide capabilities with private industry to bolster the medical countermeasures enterprise. The committee supports utilizing the engineering and technology capabilities provided and established within private industry, and recommends that the DoD Defense increase efforts to ensure that the capabilities at these organizations are coordinated with the broader CBRN priorities within the DoD, and with civilian priorities through the Public Health Emergency Medical Countermeasures Enterprise.

The Alliance also requests the Committee include the following report language on the need for effective public-private partnerships in medical countermeasures (MCM) development:

Increased Collaboration with Private Sector. The Committee recognizes that effective public-private partnerships are indispensable for bolstering our nation's preparedness and response capabilities, particularly since these private sector partners serve as the primary developers of critical medical countermeasures (MCMs) such as diagnostics, therapeutics, and vaccines which have no commercial market. Recognizing the costly, risky, and time-consuming nature of MCM development, the Committee underscores the necessity for consistent government funding to enable private sector partners to engage in long-term planning for MCM development, thus enhancing the United States' capacity to prepare for and respond to chemical, biological, nuclear, and radiological (CBRN) events.

In November 2021, the National Academies of Sciences, Engineering and Medicine released a study report titled *Ensuring the Public Health Emergency Medical Countermeasures Enterprise* (PHEMCE), which outlined four priority areas of improvement emerged including collaborating more effectively with external public and private partners. The Committee endorses these recommendations and directs the

PHEMCE to establish an advisory committee incorporating private sector and non-federal partners and stakeholders to enhance transparency and communication, identify and close gaps, and build collaborative solutions. This advisory committee should encompass a diverse array of external partners to ensure comprehensive expertise in addressing various threats, thus fortifying the nation's overall preparedness.

Additionally, the Committee stipulates that PHEMCE's strategic planning and decision-making around stockpile needs, requirements, and interactions with other government agencies, as well as the communications of such decisions, shall be made in concert with the advisory committee, taking into account private partner input. These efforts can help retain our capabilities and capacities for MCM development and manufacturing. The Committee therefore directs the PHEMCE to provide an update on these efforts to the Congress within 120 days.