



**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 public health and improve national security. For additional information on the Alliance, please visit [www.allianceforbiosecurity.com](http://www.allianceforbiosecurity.com) or contact [info@allianceforbiosecurity.com](mailto:info@allianceforbiosecurity.com).

**The Importance of Funding Preparedness and Response:**

Sustainable federal funding for biosecurity preparedness and response programs is imperative to safeguard the United States against infectious diseases and chemical, biological, radiological, and nuclear (CBRN) attacks. Infectious disease threats like pandemic influenza and COVID-19, alongside CBRN threats such as anthrax and smallpox pose urgent challenges to the nation’s economy, national security, and public health. While biosecurity preparedness and response programs serve as our primary defense against these deadly threats, they have historically suffered from inadequate funding.

The government cannot protect against biodefense threats alone. Robust and consistent federal funding is essential to foster vital public-private partnerships. These partnerships are crucial for the 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 2025 Appropriations Requests**

<b>Alliance for Biosecurity FY 2025 Funding Request (in thousands)</b>	<b>FY 2023 Omnibus</b>	<b>President Biden’s FY 2025 Budget</b>	<b>FY 2025 of FY 2022-26 PHEMCE Report</b>	<b>FY 2025 Alliance Request</b>
<b>Department of Health &amp; Human Services</b>				
<b>BARDA</b>				
-- <i>Advanced Research and Development</i>	\$950,000	\$970,000	\$8,851,000	<b>\$1,400,000</b>
<b>Project BioShield SRF</b>	\$820,000	\$820,000	\$1,630,000	<b>\$1,000,000</b>
<b>Pan Flu Preparedness</b>	\$300,000	\$328,000	\$1,913,000	<b>\$395,000</b>
<b>Strategic National Stockpile</b>	\$965,000	\$965,000	\$1,588,000	<b>\$1,588,000</b>
<b>Office of Preparedness</b>	N/A	N/A	N/A	<b>7,000</b>

*The Alliance takes into consideration the FY 2025 President’s Budget Request and funding levels recommended in the Department of Health and Human Service’s Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multiyear Budget Report (FY 2022-2026). The PHEMCE is the only national coordinating body of federal agencies and private entities focused on MCM procurement and distribution and provides the most comprehensive estimate of funding necessary to support the MCM enterprise.*

## **Biomedical Advanced Research Development Authority (BARDA)**

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<b>FY 2025 Funding Request:</b>	<b>\$1,400,000,000</b>
<b>Program Title:</b>	Biomedical Advanced Research Development Authority (BARDA)
<b>Subcommittee:</b>	Labor-Health and Human Services-Education (LHHS)
<b>Agency:</b>	Department of Health and Human Services (HHS)
<b>Account:</b>	Office of the Secretary, Public Health and Social Services Emergency Fund, Office of the Assistant Secretary for Preparedness and Response (ASPR), BARDA
<b>Sub-Activity Group (SAG)/Budget Line Item (BLI)/Program Element Number (PE):</b>	N/A
<b>Previous Year(s) Funding Amount:</b>	\$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.

The \$1.4 billion request represents consensus between industry leaders and ensures the nation maintains a sufficient level of preparedness to protect our citizens by building upon resources invested in prior fiscal years. The request represents an increase from the U.S. Department of Health and Human Services’ FY 2025 request included in the President’s Budget Request. 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

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<b>FY 2025 Funding Request:</b>	<b>\$1,000,000,000</b>
<b>Program Title:</b>	Project BioShield
<b>Subcommittee:</b>	Labor-Health and Human Services-Education (LHHS)
<b>Agency:</b>	Department of Health and Human Services (HHS)
<b>Account:</b>	Office of the Secretary, Public Health and Social Services Emergency Fund, Office of the Assistant Secretary for Preparedness and Response (ASPR), Project BioShield SRF
<b>Sub-Activity Group (SAG)/Budget Line Item (BLI)/Program Element Number (PE):</b>	N/A
<b>Previous Year(s) Funding Amount:</b>	\$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 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 \$200 million increase from FY 2023 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

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<b>FY 2025 Funding Request:</b>	<b>\$395,000,000</b>
<b>Program Title:</b>	Pan Flu Preparedness
<b>Subcommittee:</b>	Labor-Health and Human Services-Education (LHHS)
<b>Agency:</b>	Department of Health and Human Services (HHS)
<b>Account:</b>	Office of the Secretary, Public Health and Social Services Emergency Fund, Office of the Assistant Secretary for Preparedness and Response (ASPR), Pan Flu Preparedness
<b>Sub-Activity Group (SAG)/Budget Line Item (BLI)/Program Element Number (PE):</b>	N/A
<b>Previous Year(s) Funding Amount:</b>	\$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, the \$395 million (\$360M/ No Year and \$35M/ annual) request is consistent with funding requests submitted in FY 2023 and FY 2022 and represents a modest increase over FY 2023 enacted levels. The request falls significantly short of the FY 2025 level recommended in the PHEMCE Multiyear Budget Report (FY 2022-2026), released in March 2023. 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

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<b>FY 2025 Funding Request:</b>	<b>\$1,588,000,000</b>
<b>Program Title:</b>	Strategic National Stockpile
<b>Subcommittee:</b>	Labor-Health and Human Services-Education (LHHS)
<b>Agency:</b>	Department of Health and Human Services (HHS)
<b>Account:</b>	Office of the Secretary, Public Health and Social Services Emergency Fund, Office of the Assistant Secretary for Preparedness and Response (ASPR), Strategic National Stockpile
<b>Sub-Activity Group (SAG)/Budget Line Item (BLI)/Program Element Number (PE):</b>	N/A
<b>Previous Year(s) Funding Amount:</b>	\$965,000,000 (FY 2023) \$975,000,000 (FY 2022)

**Justification:** The Strategic National Stockpile (SNS) is the nation's largest reservoir of potentially life-saving pharmaceuticals and medical supplies designated for use in a public health 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. 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 SNS was quickly mobilized to distribute N-95 masks, ventilators, and other personal protective equipment to states and major cities.

The SNS has historically been underfunded and has not received the recommended funding by the PHEMCE. The \$1.588 billion request is equal to the FY 2025 level in the PHEMCE Multiyear Budget Report (FY 2022-2026), released in March 2023. In addition, the Alliance's funding request for the SNS does consider funding needs of 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 2025 request should be considered the minimum funding necessary to support the SNS.

## **FY 2025 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 Americans against these deliberate, man-made 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 acknowledges the critical role of the Department of Defense (DoD) in the larger U.S. Government and private sector efforts 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 investments in medical countermeasures among all Federal stakeholders to ensure that effective countermeasures are developed to meet both military and civilian needs, and to prevent potential duplication of efforts. The committee urges the DoD to leverage private industry expertise to meet these needs. The committee supports utilizing the engineering and technology capabilities provided and established within private industry and recommends that the DoD 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.