



Who is the Alliance?

Mission: The Alliance is the leading industry voice on biosecurity issues and is an efficient, strategic organization committed to building and strengthening the partnership between government and industry to provide solutions to threats facing our nation.

Vision: Advocate for public policies and funding to support rapid development, production, stockpiling, and distribution of critically needed medical countermeasures.

Why we are here:

The COVID-19 pandemic and a number of other recent public health crises have highlighted the need to improve the nation's biosecurity preparedness and response infrastructure and the importance of sustainable funding for these issues.

- To lessen the burden of the historic economic and public health impacts caused by COVID-19, Congress authorized unprecedented funding for biosecurity programs to equip federal and state agencies with the resources needed to respond to COVID-19. The supplemental and emergency funding provided underscores the importance of long-term sustained funding for these critical biodefense programs to ensure the country is better prepared for the next pandemic.

We continue to face real, imminent threats from intentional chemical, biological, radiological, and nuclear (CBRN) attacks.

- The Department of Homeland Security's (DHS) most recent Homeland Security Threat Assessment identifies multiple high consequence threats that threaten our economic, public health and national security.
- Recent terrorist attacks and terrorists' use of chemical weapons and the stated intent of state and non-state adversaries to use biological weapons all increase the risk that such weapons will be used against our interests and homeland.
- Infectious diseases do not respect borders. We must prepare for serious naturally occurring potential pandemics and disease threats like pandemic influenza, COVID-19, and Ebola.

The government cannot do this alone. An effective, highly functioning public-private partnership is the best way to prepare.

- Alliance for Biosecurity members share a strong commitment to improving our nation's national security.
- As government partners, Alliance for Biosecurity members played an integral role in the initial COVID-19 response and will support ongoing pandemic preparedness and response through the development of critical medical countermeasures (MCMs).



Drug and vaccine development is costly, risky, and time consuming – it often takes over a decade and \$2 billion to develop a new product.

- As experienced through Operation Warp Speed, it takes a tremendous amount of funding, time, and energy to bring a vaccine to market.
- A commercial market for MCMs does not exist for the needed diagnostics, therapeutics, and vaccines.
- Private sector partners rely on predictable government funding to facilitate future planning and maintain momentum in developing medical countermeasures.

Strong, consistent funding is needed for critical federal programs to enhance the United States’ ability to respond to biological agents such as anthrax, smallpox or pandemic influenza for the enterprise:

- Biomedical Advanced Research Development Authority (BARDA);
- Project BioShield Special Reserve Fund (SRF);
- Pandemic Influenza funding; and
- Strategic National Stockpile Fund (SNS)

A constant sense of urgency, vigilance, and uninterrupted funding for these programs is critical to ensuring the United States is building and maintaining diagnostics, therapeutics and vaccines necessary for our country’s emergency response.

Alliance for Biosecurity FY 2024 Appropriations Requests

In addition to the President’s FY 2024 Budget Request, the Alliance’s FY 2024 Appropriations Requests take into consideration the FY 2024 funding levels in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multiyear Budget Report (FY 2022-2026). Note that the Alliance’s FY2024 Appropriations Requests do not factor in increases in Federal budget caps, thus these requests should be considered the minimum needed to support the MCM enterprise.

Alliance for Biosecurity FY 2024 Funding Request (\$000)	FY 2023 Omnibus	FY 2024 of FY 2022-26 PHEMCE Report	President Biden’s FY 2024 Budget	FY 2024 Alliance Request
Department of Health & Human Services				
BARDA				
-- <i>Advanced Research and Development</i>	\$950,000	\$8,860,000	\$1,000,000	\$8,860,000
Project BioShield SRF	\$820,000	\$1,704,000	\$830,000	\$1,704,000
Pan Flu Preparedness	\$300,000	\$2,628,000	\$375,000	\$2,628,000
Strategic National Stockpile	\$965,000	\$1,963,000	\$995,000	\$1,963,000



Biomedical Advanced Research Development Authority (BARDA) - \$8.860 billion

- BARDA plays a critical role in partnering with biopharmaceutical companies to support advanced research and development of life-saving MCMs.
 - Pipeline currently includes over 200 candidate MCMs, such as broad- spectrum antimicrobials, rapid diagnostics, and next-generation products to address CBRN threats.
 - Typically requires ten years and significant long-term financial investment to develop a new drug or vaccine, and MCMs are often riskier to develop than other products due to scientific and regulatory complexities.
- The \$8.860 billion request is equal to the FY 2024 level in the PHEMCE Multiyear Budget Report (FY 2022-2026), released in March 2023.
- A lack of adequate support for BARDA’s programs risks squandering resources invested in the earlier stages of research and decreases the nation’s level of preparedness to protect our citizens.
 - BARDA leveraged its pre-COVID programs regarding sepsis surveillance and emerging infectious disease monitoring to perform COVID-19 case monitoring and virus surveillance. Without early investments in BARDA and its Division of Research, Innovation, and Ventures (DRIVE) these programs would not have been available to assist in the pandemic response.



Project BioShield Special Reserve Fund (SRF) - \$1.704 billion

- Project BioShield establishes the Emergency Use Authorization (EUA) to provide access to the best available medical countermeasures following a Declaration of Emergency by the Secretary of Health and Human Services. Established in 2004 by the Project BioShield Act, the SRF was originally funded at \$5.6 billion for 10 years to support companies' development and supply of products to address biological, chemical, radiological, or nuclear agents that could cause a public health emergency. The initial appropriation was effective in inspiring investment and producing needed medical products to address the highest priority threats (e.g., smallpox, anthrax, radiological, etc.).
 - Over the last decade, SRF has led to the support of 30 products that are critical to prepare for, and treat the effects of these threats. 22 of these products have been delivered to the SNS, with additional products to be delivered in 2024.

- The SRF has been critical to our nation's biodefense for over a decade by advancing the development of more than 50 million doses of drugs against anthrax, smallpox, botulinum toxin and radiological threats. There is no commercial market for these products.
 - Without robust, stable, and consistent funding to fill our preparedness gaps, this public-private partnership to create life-saving countermeasures against our nation's most pressing CBRN threats will be in jeopardy.
 - The SRF represents the only market for many MCMs that are not yet approved by the FDA.
 - While the federal, government's focus has understandably solely revolved around COVID-19, funding for the SRF is critical in continuing research and development of other MCMs.

- Recent public health threats, like COVID-19, resulted in costs to procure necessary diagnostics, therapeutics, vaccines, and additional MCMs. The request is based on an increased scope to support all procurement activity for all DHS threat assessments

- The \$1.704 billion request is equal to the FY 2024 level in the PHEMCE Multiyear Budget Report (FY 2022-2026), released in March 2023.



Pandemic Flu Preparedness - \$2.628 billion

- While quarantining, mask mandates, and social distancing decreased the spread of the flu during the COVID-19 pandemic, pandemic flu remains an annual and long-term public health threat:
 - We know with certainty this will strike again in the future and no commercial market for these products exist.
 - The development and manufacturing of influenza vaccines, therapeutics, and diagnostics by industry is dependent on Federal funding to support the scale and scope of requirements. With the decrease in flu cases, researchers will need to employ more advanced research techniques to predict future years' flu strains without adequate case data.
 - Increased investments are needed in order to adequately prepare through R&D for next generation flu products, testing and evaluation of existing products, and sustaining and replenishing stockpiles.

- The \$2.628 billion request is equal to the FY 2024 level in the PHEMCE Multiyear Budget Report (FY 2022-2026), released in March 2023.

- This 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 (SNS) - \$1.963 billion

- The SNS is the nation's largest supply of potentially life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to run out.
 - It is responsible for strategic procurement and stockpiling of MCMs, medical supplies, and equipment for all populations, which is necessary to protect Americans' health and save lives.
 - It ensures the right medicines and supplies are available when and where needed.
 - It is the procurement mechanism for many FDA-approved MCMs, some of which have no commercial market, such as licensed vaccines and drugs against smallpox and anthrax.
 - It includes BARDA developed and supported vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies.
 - Organized for scalable response to a variety of public health threats, the repository contains enough supplies to respond to multiple large-scale emergencies, ranging from the COVID-19 pandemic to Hurricanes Katrina and Rita in 2005.

- If a CBRN event were to occur on U.S. soil, the SNS is the only federal resource readily available to respond.
 - 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 large cities. As vaccine administration is underway, the SNS is also playing an integral role in delivery needed ancillary vaccine supplies to support these efforts.
 - However, the SNS has historically been underfunded and has not received the recommended funding by the PHEMCE.

- The \$1.963 billion request is equal to the FY 2024 level in the PHEMCE Multiyear Budget Report (FY 2022-2026), released in March 2023.

- The SNS is a critical leg in the MCM enterprise and proved its importance during the COVID-19 pandemic. If we develop the capability but do not procure or maintain the stock for an emergency, we put Americans and risk wasting the up front-end investment.



Report Language

- *CBRN Threats.* The committee notes with concern the elevated risks posed by chemical, biological, radiological, and nuclear (CBRN) weapons across the globe and 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 to ensure there is no disruption in the availability of these life-saving medical countermeasures (MCMs) in the SNS. The committee encourages 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.

- *ASPR Private Sector Partnerships.* The Committee recognizes effective public-private partnerships are the best way to support our nation's preparedness and response capabilities, as these private sector partners are the sole developers of critical medical countermeasures (MCMs) such as diagnostics, therapeutics, and vaccines which have no commercial market. Given the development of these MCMs is costly, risky, and time consuming, the Committee recognizes the need for predictable government funding that will allow these private sector partners to engage in long-term planning for the development of MCMs and enhance the United States' ability to prepare 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 detailed four priority areas of improvement emerged including collaborating more effectively with external public and private partners. The Committee supports these recommendations and directs the PHEMCE to create 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. The advisory committee should include a balance of external partners to ensure the expertise of a variety of threats are addressed and considered for the holistic preparedness of the country. Additionally, PHEMCE's strategic planning and decision-making around stockpile needs, requirements, and interactions with other government agencies and the communication of such decisions shall be made in concert with the advisory committee considering the inputs from private partners to ensure the capability and capacity to manufacture MCMs must be retained and subsequently communicated to Congress within 120 days.

- *Department of Defense Coordination.* The committee understands 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

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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 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.