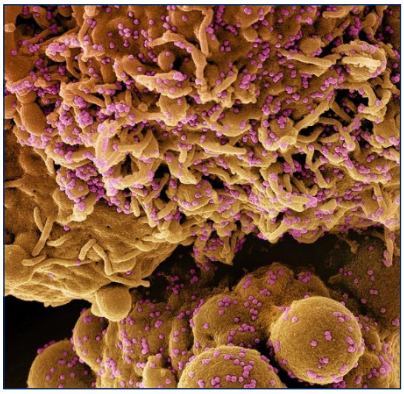
U.S. Department of Health & Human Services

Office of the Assistant Secretary for Preparedness & Response

Public Health Emergency Medical Countermeasures Enterprise

Multiyear Budget: Fiscal Years 2023-2027

MARCH 15, 2024



ASPR

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Dear Colleague,

Please find here the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Multi-Year Budget (MYB) as required by Section 2811(b)(7) of the Public Health Service Act. The last MYB covered 2022-2026 and was delivered in March 2023. I am pleased to provide this update to last year's report. As we built the MYB during continuing resolutions and a near-simultaneously released President's budget—this MYB is indicative of the assessed need and does not substitute for requested levels in the President's Budget or accompanying documents. If you have any further questions or would like more information, please do not hesitate to be in touch.

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Assistant Secretary for Preparedness and Response

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Executive Summary

Congress requires the Administration for Strategic Preparedness and Response (ASPR) to submit an annual Multi-Year Budget (MYB) for the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The PHEMCE MYB forecasts the funding required to conduct basic research, advanced research and development, regulatory review, procurement, stockpiling, and replenishment of the USG's civilian medical countermeasure (MCM) products for FY 2023-2027 without regard to the competing priorities considered in the annual budget formulation process. The PHEMCE MYB projects an estimated overall funding need of $79.5 billion over the five-year period, an increase of $15.5 billion over the FY 2022-2026 report. If funding continues at the FY2023 levels over the projected five-year period, the report estimates a shortfall of $46.4 billion from the total projected need.

There are notable differences to highlight compared to the 2022 report. These differences are driven primarily by the anticipated implementation of NIH's prototype pathogen approach for development of candidate vaccines, ASPR Biomedical Advanced Research and Development Authority (BARDA) development successes enabling the transition of 13 MCMs into the stockpile, and the inclusion of the Centers for Disease Control and Prevention (CDC) budget needs. Beyond the enacted FY 2023 levels, PHEMCE agencies identified the following activities to address existing preparedness gaps and meet the goals outlined in the *National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security* (National Biodefense Strategy) updated in October 2022:

- National Institutes of Health (NIH) will support activities to advance a robust pipeline of candidate medical countermeasures (MCMs) for the development of safe and effective products. For NIH, the largest spending estimates are for new products to address gaps in the broad-spectrum antimicrobial portfolio, support for severe acute respiratory syndrome-related coronavirus vaccines and therapeutics, pandemic and universal influenza vaccine development, and to support the implementation of the Prototype Pathogen Approach for development of candidate vaccines, therapeutics, and diagnostics for members of viral families known to cause human disease, in preparation for the likely emergence of new viral species or variants with pandemic potential. To fund these activities through 2027, NIH estimates a $8.5 billion need above enacted levels in FY 2023.

- ASPR BARDA will support the advanced development and initial procurement of FDA approved/licensed MCMs, including improvements to threat-agnostic technologies, rapid response capabilities, pandemic influenza vaccines, and novel therapeutics. To fund these activities through 2027, ASPR BARDA estimates a $29.5 billion need above enacted levels in FY 2023.

- ASPR Strategic National Stockpile (SNS) will support the transition of thirteen (13) MCM candidates from ASPR BARDA's Project BioShield (PBS) to stockpiling by the ASPR SNS by FY 2027. Increased funding needs, beginning in FY 2025, are driven by an Ebola therapeutic, a therapeutic in the Radiological/Nuclear portfolio, and a Smallpox antiviral; the planned transition of an Ebola therapeutic in FY 2027 makes up over half of the increase in projected need. The smallpox expenditures will backfill the MCMs distributed during the mpox response. To support these activities across the Ebola, Radiological/Nuclear, and Smallpox portfolios through 2027, ASPR SNS estimates a $6.7 billion increase above the enacted levels in FY 2023.

The ASPR SNS budget has not kept pace with the cost of stockpiling ASPR BARDA supported products approved by the FDA (up to 86 as of January 2024). In the absence of additional funding to move these products into the ASPR SNS, products without sustainable commercial pathways may be lost, costing the USG both the investments it has made in developing the products as well as the critical ability to build PHEMCE's preparedness posture against future threats.

In addition to accepting new products that are developed and approved by ASPR BARDA, the ASPR SNS must also maintain its current preparedness posture through replenishment of deployed or expired supplies, including antimicrobials necessary for post-exposure prophylaxis as part of the anthrax portfolio and antivirals as part of the pandemic influenza portfolio.

- Food and Drug Administration (FDA) will sustain its ability to foster the establishment of clear, scientifically supported regulatory pathways for MCMs as well as to fill critical scientific gaps that inform regulatory decision-making and support efforts to establish regulatory policies and mechanisms to facilitate the availability of MCMs. To support these activities through 2027, FDA estimates a $776 million increase above enacted levels in FY 2023.

- CDC, as a PHEMCE partner newly added to this year's report, supports both new and ongoing programs related to research and development activities and provides support functions including developing data-driven guidance for utilization, and monitoring of safety and real-world effectiveness during emergencies. To support these activities through 2027 CDC estimates a $921 million need above enacted levels in FY 2023.

Introduction

This Public Health Emergency Medical Countermeasures Multiyear Budget (PHEMCE MYB) Report is the seventh submission in response to the requirement in Section 2811(b)(7) of the Public Health Service Act.

Section 2811(b)(7) of the Public Health Service (PHS) Act requires ASPR to lead the development of a coordinated five-year budget plan for medical countermeasure (MCM) development and to update the plan annually.

Section 2811(b)(7) states:

> *(7) COUNTERMEASURES BUDGET PLAN.—Develop and update not later than March 15 of each year, a coordinated 5-year budget plan based on the medical countermeasure priorities described in subsection (d), including with respect to chemical, biological, radiological, and nuclear agent or agents that may present a threat to the Nation, including such agents that are novel or emerging infectious diseases, and the corresponding efforts to develop qualified countermeasures (as defined in section 319F– 1), security countermeasures (as defined in section 319F–2), and qualified pandemic or epidemic products (as defined in section 319F–3) for each such threat. Each such plan shall—*
>
> *(A) include consideration of the entire medical countermeasures enterprise, including—*
>
> *i. basic research and advanced research and development;*

ii. approval, clearance, licensure, and authorized uses of products;

iii. procurement, stockpiling, maintenance, and potential replenishment (including manufacturing capabilities) of all products in the Strategic National Stockpile;

iv. the availability of technologies that may assist in the advanced research and development of countermeasures and opportunities to use such technologies to accelerate and navigate challenges unique to countermeasure research and development; and

v. potential deployment, distribution, and utilization of medical countermeasures; development of clinical guidance and emergency use instructions for the use of medical countermeasures; and, as applicable, potential post deployment activities related to medical countermeasures;

(B) inform prioritization of resources and include measurable outputs and outcomes to allow for the tracking of the progress made toward identified priorities;

(C) identify medical countermeasure life-cycle costs to inform planning, budgeting, and anticipated needs within the continuum of the medical countermeasure enterprise consistent with section 319F–2;

(D) identify the full range of anticipated medical countermeasure needs related to research and development, procurement, and stockpiling, including the potential need for indications, dosing, and administration technologies, and other countermeasure needs as applicable and appropriate;

(E) be made available, not later than March 15 of each year, to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives; and

(F) not later than March 15 of each year, be made publicly available in a manner that does not compromise national security.

This report includes the multiyear budgets for FY 2023-2027 for the following Department of Health and Human Services (HHS) entities involved in medical countermeasure (MCM) development and stockpiling: the National Institutes of Health (NIH); the Administration for Strategic Preparedness and Response (ASPR); the Food and Drug Administration (FDA); and the Centers for Disease Control and Prevention (CDC).

The PHEMCE body includes representation from United States Government (USG) entities responsible for everything from global threat surveillance and analysis to eventual product deployment and use. However, the MYB report accounts for the budgetary aspects of MCM basic research, advanced research and development, regulatory review (including evaluation of real-world safety and effectiveness post-deployment), procurement, stockpiling, and replenishment of the USG's civilian MCM enterprise. The PHEMCE MYB takes this approach to improve fidelity of the numbers offered to Congress by eliminating steps of the MCM lifecycle that introduce the widest variability, such as distribution and dispensing. Though each of the PHEMCE agencies is critical to contributing to the MCM ecosystem, efforts beyond research, advanced research and development, regulatory advice and review, and stockpiling fall outside the specific requirements for this report.

NIH, ASPR, CDC, and FDA work closely together to prioritize investments and smooth MCM handoffs between each agency. NIH conducts and supports basic, translational, and early clinical research to better understand the biological effects of and to develop MCMs for chemical, biological, radiological/nuclear (CBRN) and certain emerging infectious disease threats. Once NIH has taken an

MCM through Phase 1, ASPR's Biomedical Advanced Research and Development Authority (BARDA) continues development of NIH's most promising MCM candidates and technologies against the highest priority threats, as informed by the intelligence community members in the PHEMCE. Once ASPR BARDA has carried a countermeasure through late-stage trials, ASPR BARDA works with the company to file for FDA approval. As of January 2024, ASPR BARDA has secured 86 approvals, licenses, and clearances for MCMs.[1]

The FDA provides advice and feedback in response to sponsor submissions throughout the development process and reviews the safety and effectiveness of MCMs and, in addition to its regulatory responsibilities, works closely with USG partners to build and sustain the MCM programs necessary to effectively respond to public health emergencies. Once a product has achieved FDA approval, licensure, or clearance, the product is intended to transition from ASPR BARDA's Project BioShield (PBS) funding to procurement by the ASPR SNS with SNS annual funds. Successful procurement of an MCM includes lifecycle expenditures from the ASPR SNS for storage, sustainment, maintenance, and replenishment upon expiry.

CDC's efforts complement those across NIH, ASPR, and FDA by supporting development across multiple areas including: diagnostics to rapidly diagnose an outbreak or presence of a toxin, chemical or radiological agent; identification of pathogen resistance to commercially available or stockpiled treatments; the smallpox research program; research into innovative personal protective equipment; and, collaborating with FDA, development and maintenance of regulatory mechanisms to facilitate access to stockpiled MCMs and ensure their safe and effective use for all populations for CBRN preparedness, among other activities.

Finally, the MYB projects gaps based on annual discretionary funding. Supplemental and mandatory funds are not considered in this document to keep year-over-year funding estimates as comparable as possible. This report includes professional judgement estimates and does not consider the competing priorities or budget totals that the Secretary, other HHS officials, and the President must consider when developing the annual President's Budget request.

Funding Landscape

The PHEMCE MYB projects an estimated overall funding need of $79.5 billion over the five-year period, an increase of $15.5 billion over the 2022 report, and an overall increase of $46.4 billion between the enacted level FY 2023 funding and the professional judgment level funding. The PHEMCE MYB reflects enacted FY 2023 levels and is consistent with the FY 2024 President's Budget request; therefore, FY 2025 is the first year that is projected using the methodology described in this report.

In total, HHS Divisions were appropriated $6.6 billion for MCMs and MCM-related activities in FY 2023 and have requested $7.2 billion to support these efforts in FY 2024. The estimated five-year spending across the HHS enterprise is delineated in Table 1 and Appendices C and D provide additional detail.

Beginning in FY 2025, PHEMCE members anticipate making the following investments in MCMs. These investments align with the corrective actions recommended by the PHEMCE as part of the 2022 Medical

[1] FDA Approvals, Licensures & Clearances for BARDA Supported Products. Available at https://medicalcountermeasures.gov/barda/fdaapprovals/ Accessed January 2024.

Countermeasure Preparedness Review (MCMPR) and address critical development or stockpiling gaps that exist within USG preparedness to meet the goals outlined in the National Biodefense Strategy.

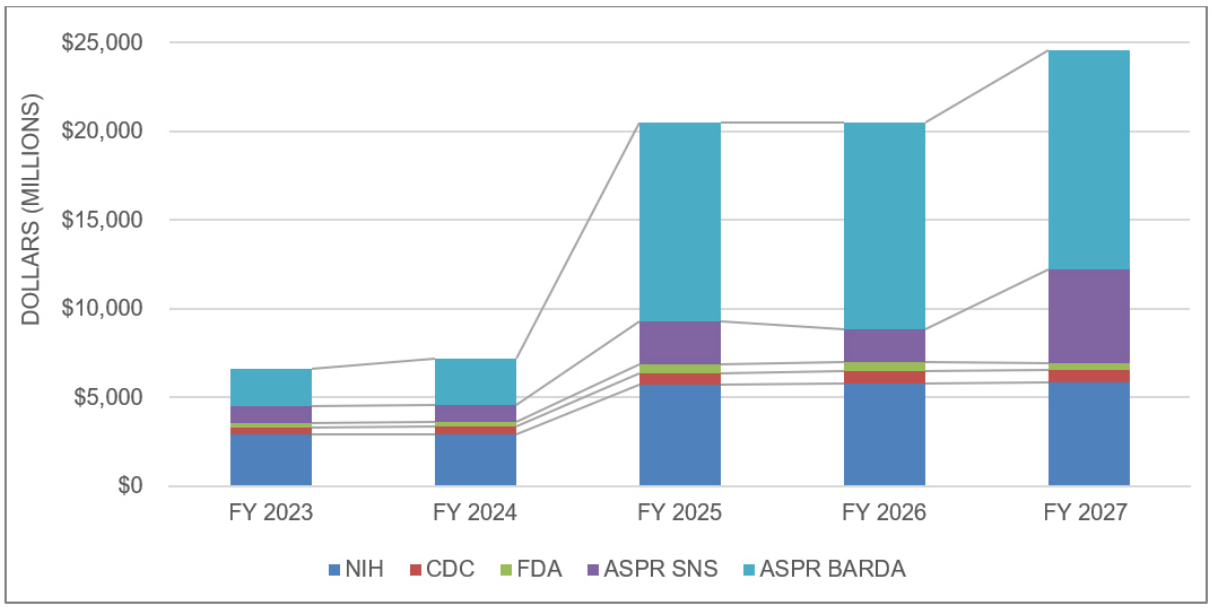
- NIH will support research to better understand the biological effects of, and to develop MCMs for chemical, biological, and radiological/nuclear threats. The bulk of the funds will support new products to address gaps in the broad-spectrum antimicrobial portfolio and the Prototype Pathogen approach in preparation for the likely emergence of new virus species or viral variants with pandemic potential,
- ASPR BARDA will make strategic investments across threat-agnostic efforts, encompassing platform technologies and manufacturing capability, which could be adapted towards new and emerging threats,
- CDC will support both new and ongoing research and laboratory capabilities to address especially dangerous pathogens, including influenza, SARS-COV-2, and other agents capable of causing a pandemic, as well as non-infectious hazards such as toxic substances and those stemming from chemical or radiological emergencies,
- ASPR SNS will transition thirteen (13) candidates from ASPR BARDA PBS by FY 2027, including an Ebola therapeutic, a therapeutic in the radiation/nuclear portfolio, and a smallpox antiviral; replenish existing products, including antimicrobials and antivirals; procure additional smallpox vaccine and therapeutics in order to replace MCMs used during the mpox outbreak; and sustain current levels of preparedness.
- FDA will sustain clear, scientifically supported regulatory pathways for MCMs and fill critical scientific gaps that inform regulatory decision-making.

Table 1: Estimated Total PHEMCE Spending by HHS Division and Fiscal Year (Dollars in Millions).

Division	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027	Total
NIH	$2,943	$2,943	$5,707	$5,779	$5,854	**$23,227**
ASPR BARDA	$2,098	$2,620[2]	$11,228	$11,673	$12,358	**$39,977**
CDC	$393	$424	$678	$689	$702	**$2,886**
FDA	$221	$228	$517	$524	$391	**$1,881**
ASPR SNS	$965	$995	$2,389	$1,862	$5,305	**$11,516**
Total	**$6,620**	**$7,211**	**$20,520**	**$20,527**	**$24,609**	**$79,487**

[2] The FY 2024 President's Budget proposes a $400 million Pandemic Preparedness and Biodefense fund for ASPR. The funds will be flexible and can be utilized to rapidly close critical gaps identified during the acute phase of response and accelerate progress, as need arises, within long-term programs. The intention is that these funds will be used for ASPR-wide needs. Funding is shown within BARDA in order to simplify the display of this report.

Figure 1: Distribution of Funding by Division (in millions).



Sustainment of stockpiled products remains the primary challenge to ensuring appropriate preparedness. Successful procurement of an MCM requires ASPR SNS to consider lifecycle funding for storage, sustainment, maintenance as necessary, replenishment upon expiry, appropriate training ahead of a response, and equitable deployment. The appropriations for the activities specified in this report have never been sufficient to meet all PHEMCE requirements, but HHS agencies are maximizing the use of existing resources to best prepare the nation for the next public health emergency or disaster. The wide gap in projected need versus available funding identified by this report makes it challenging for PHEMCE agencies to ensure our nation is best prepared to respond to future public health emergencies or disasters.

Threat-Based Approaches

Figure 2 shows the total five-year spending by HHS division for select high-priority threats. No single factor drives spending within any one portfolio, and each portfolio contains several types of MCMs (e.g., vaccine, therapeutic, diagnostic, or non-pharmaceutical interventions). CDC and FDA are excluded from Figure 2 and Table 2 as their contributions impact the entire PHEMCE environment as opposed to individual portfolios. Their portfolios are detailed in Appendix C and D.

Figure 2: MCM Estimated Spending by High-Priority Portfolio and HHS Division for FY 2023–2027.

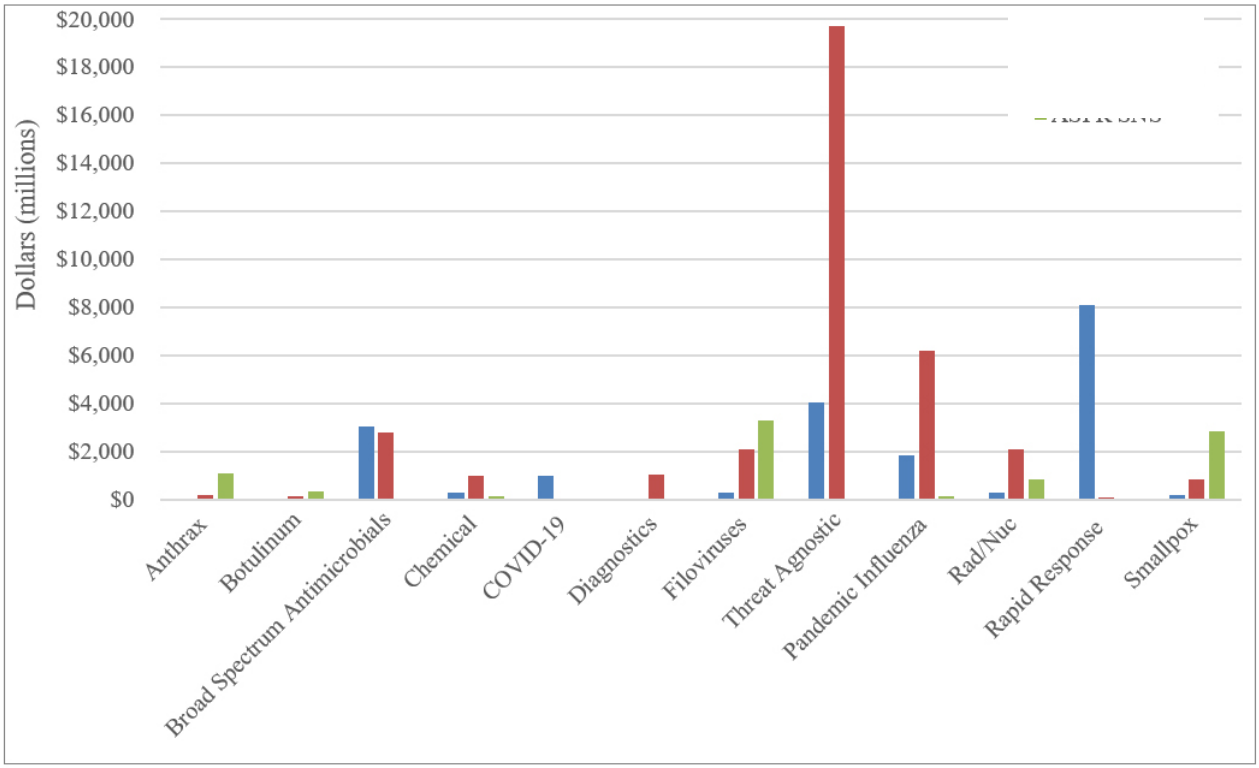


Table 2: MCM Estimated Spending by High-Priority Portfolio and HHS Division for FY 2023–2027 (Dollars in Millions).

Portfolio	NIH	ASPR BARDA	ASPR SNS
Anthrax	$21	$161	$1,078
Botulinum	$24	$115	$331
Broad Spectrum Antimicrobials	$3,081	$2,762	$0
Chemical	$272	$973	$144
COVID-19	$986	$25	$0
Diagnostics	$501	$1,022	$0
Filoviruses	$263	$2,092	$3,295
Threat Agnostic	$4,023	$19,704	$0
Pandemic Influenza	$1,810	$6,209	$107
Radiological/Nuclear	$292	$2,091	$838
Rapid Response Capabilities	$8,070	$75	$0
Smallpox	$165	$834	$2,850

Detailed PHEMCE Portfolio Activities

Anthrax

Five Year Need	Funding Activities
$1.3 billion to support the continued development and procurement of CYFENDUS (previously AV7909), a next-generation anthrax vaccine approved for post-exposure prophylaxis in 2023[3]	NIH will conduct a Phase 1 clinical trial evaluating the safety and immunogenicity of CYFENDUS in a lyophilized (thermostable) formulation.
	ASPR BARDA will support the initial procurement of CYFENDUS (as well as fulfillment of post-marketing commitments and operational clinical trials to inform potential dose-sparing or pre-exposure prophylaxis potential.
	ASPR SNS will support the transition of CYFENDUS to the stockpile (the timing and funds needed to support this transition are outlined in Table 3).

Botulinum

Five Year Need	Funding Activities
$470 million to support development of a next-generation interventions to treat exposure to botulinum neurotoxin (BoNT)	NIH will support the discovery and development of monoclonal antibody-based antitoxins against botulinum neurotoxin (BoNT) including BoNT/F subtypes and BoNT/G.
	ASPR BARDA will support the proof-of-concept development and testing of a monoclonal antibody (mAb) based product anticipated to have better safety and potency profiles than the current licensed product, BAT (Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) – (Equine)) produced from sera of an equine herd using an unsustainable process; and the development of at least one investigational product that has demonstrated the ability to reverse the symptoms of BoNT intoxication.
	ASPR SNS will support the continued procurement of BAT.

[3] In persons 18 through 65 years of age when administered in conjunction with recommended antibacterial drugs.

Broad-Spectrum Antimicrobials

Five Year Need	Funding Highlights
$5.8 billion to support the continued development of antimicrobials	NIH will continue to build a pipeline for antimicrobial candidates including continuing to evaluate and advance a small molecule antibiotic product, epetraborole (EBO) for treatment of acute melioidosis as its first indication followed by indications against other biothreat agents (e.g., Plague, Anthrax, and Tularemia);[4] support the development of multiple Gram-negative antimicrobial small molecule therapeutics with the potential to advance to clinical trials; develop a small-molecule antimicrobial product effective against the Gram-positive bacterium *Clostridioides difficile* with a Phase 2 clinical trial comparing the small molecule to oral vancomycin; continue to collaborate with Merck to develop a novel tuberculosis-specific oxazolidinone related to linezolid, a therapeutic candidate that is currently finishing IND-enabling toxicology studies and commenced a Phase 1 clinical trial early in CY 2023 with results expected early in CY 2024; and finalize evaluations and data in support of new label indications of already FDA-approved antibiotics for Anthrax, Plague and Tularemia.
	ASPR BARDA will support the development, submission of marketing applications for FDA review and procurement of more than five products to treat infections caused by biothreat pathogens and antimicrobial-resistant bacterial and fungal threats that complicate the ability to respond to and recover from any public health emergency; support the Combatting Antibiotic-Resistant Bacteria Accelerator (CARB-X) to accelerate the preclinical research and development of promising antimicrobial candidates targeting multi-drug resistant bacteria; support procurement of antibiotics and antifungals to treat multi-drug resistant pathogens and/or biothreat pathogens, including plague and tularemia; provide support for post-marketing commitments and expanding funding for domestic production of starting materials and finished drug products; and advance the development of diagnostics that quickly identify which antibiotics are effective to treat a patient and inform antibiotic stewardship.

Chemical

Five Year Need	Funding Activities
$1.4 billion to support the discovery and development of improved	NIH will support chemical threats MCM discovery research and early development portfolio that includes approximately 55 therapeutic candidates across the threat spectrum and is complemented by a robust basic research program comprised of over 40 highly innovative research project grants.

[4] There are plans for a potential prospective observational study in FY 2023-2024, with plans to file an Investigational New Drug Application (IND) in FY 2025 for a possible Phase 1 study to commence in FY 2026.

Five Year Need	Funding Activities
therapeutics to treat injuries caused by exposure to pharmaceutical-based agents (such as fentanyl), chemical warfare nerve agents, and vesicating chemicals, as well as toxic industrial pulmonary, cellular respiration, and anticoagulating agents/materials	ASPR BARDA will develop safe and more effective therapeutics for exposures to chemical threats; develop needleless devices for improved delivery of MCMs; repurpose host-targeted and threat-agnostic treatments for lung, skin, eye, and systemic injuries caused by chemical exposures, particularly those that can be used by first responders; develop enabling technologies, such as organs-on-chips and animal models, to identify the injuries caused by exposure to chemicals and to evaluate MCMs to treat those injuries; and develop through approval or clearance and procurement of next-generation drug delivery systems, including autoinjectors, that contain rapid treatments to reverse the effects of nerve agents and other organophosphates as well as synthetic opioids.
	Funding for ASPR SNS supports sustainment of the CHEMPACK program.

Severe Acute Respiratory Syndrome-Related Coronaviruses

Throughout the COVID-19 response, HHS made key investments that have contributed to the availability of life-saving vaccines, therapeutics, and devices (including diagnostic tests). Most of these previous investments were covered by COVID-19 supplemental appropriations. Due to the Fiscal Responsibility Act of 2023 (FRA), only select supplemental investments are able to be maintained through annual appropriations; thus, an estimated minimum of $1 billion over five years is needed to support these selected efforts.

The current estimate does not include funding that could support research, development, and procurement of next-generation vaccines, stockpiling of existing PPE, or any other investments currently planned to be funded by supplemental appropriations.

Five Year Need	Funding Activities
$1 billion to support the development and availability of MCMs for COVID-19	With $985.9 million, NIH will continue to support for basic research and clinical trials for therapeutics and vaccines.
	ASPR BARDA will use $25 million to support testing of MCMs against COVID-19 variants.
	CDC will support vaccine effectiveness activities initiated during the COVID-19 pandemic, including collecting and reporting higher quality and more representative data that allows for a better understanding of how well vaccines work in real-world settings (funding captured in the “other PHEMCE portfolios” below).
	Additionally, FDA will use $705.4 million to sustain regulatory support activities directly related to COVID-19 efforts (funding for these activities is captured in the “other PHEMCE portfolios” below).

Diagnostics

Funding will support advanced research and development of diagnostic countermeasures in preparation for biological threats, radiological/ nuclear threats, antimicrobial resistance, pandemic influenza as well as emerging infectious disease threats such as COVID-19.

Five Year Need	Funding Activities
$1 billion to advance the research and development of diagnostics for CBRN and emerging infectious pathogens	NIH will support platform development for untargeted (agnostic) diagnostic detection of biothreat and emerging or re-emerging infectious pathogens through third-generation metagenomic sequencing; fund development of diagnostic systems that can detect bacterial pathogens that lead to sepsis, the leading cause of death in hospitals, as well as identify and characterize antibiotic susceptibility profiles; fund platforms to detect, identify, and characterize novel and established fungal pathogens; and fund faster, more-sensitive, near-patient viral antigen detection systems for more-accurate diagnosing of viral infections.
	ASPR BARDA will support diagnostic countermeasures including, developing low-cost and high-sensitivity portable/home-use capable platforms that bring testing closer to the patient; reducing the time to test result to enable faster processing; where applicable, supporting automated result reporting for disease monitoring; increasing multiplex capabilities to allow for multiple agents to be interrogated in a single test action; and as outlined in the National Biodefense Strategy, support innovation and development of threat agnostic tests as well as broad-coverage pathogen family tests suitable for detecting novel, unknown biological threats.
	CDC will invest in the development, validation, assessment, deployment, and training for use of diagnostic tests and reagents for the rapid identification of high-risk threats that are utilized to inform MCM deployment decisions, including the development of new tests for detecting multidrug resistance in *Bacillus anthracis* and *Burkholderia pseudomallei,* and the development and maintenance of the diagnostics and radiobioassay laboratory capacity to rapidly identify a chemical or radiological/nuclear incident (funding captured in the "other PHEMCE portfolios" below).

Filoviruses

The filovirus portfolio combats Viral Hemorrhagic Fevers (VHF) caused by filoviruses such as Ebola virus species (Zaire ebolavirus and Sudan ebolavirus) and Marburg virus. At this funding level, current investments would continue to support activities associated with the transition of MCM candidates from early development supported by the NIH and the DoD to advanced development at ASPR BARDA and toward FDA approval, licensure, clearance, or authorization if safety and efficacy are demonstrated.

Five Year Need	Funding Activities
$5.7 billion to advance the development and availability of MCMs against VHF caused by filoviruses	NIH will support the development of therapeutic monoclonal antibodies for the treatment of Marburg virus with the goal of advancing the most promising candidates to Phase 1 trials, (including the development of a pan-ebolavirus monoclonal cocktail that neutralizes Ebola Zaire, Sudan, and Bundibugyo viruses); development of small molecule therapeutics, since monoclonal therapeutics alone do not clear infectious virus from all patients; development of an improved pre/post-exposure VSV-EBOV vaccine, including its characterization in preclinical models and the potential for low-dose protection efficacy of the VSV-Marburg virus (MARV), and VSV-Ebola virus (Ervebo by Merck) vaccine in the preclinical nonhuman primate model; development and manufacturing of adenovirus-vectored vaccines against Sudan (ChAd3- SUDV) and Marburg (ChAd3-MARV) viruses in preclinical models and Phase 1 human trials, which were completed in CY 2022; the characterization of the protective efficacy of the VSV-Sudan virus vaccine in preclinical models, with the target of GMP production as early as Q1-Q2 CY 2024; and development of MARV and SUDV international antibody standards for clinical sample testing.
	ASPR BARDA will support the continued development of the only FDA-licensed Zaire ebolavirus vaccine, ERVEBO, which achieved expansion of the label to include individuals 12 months of age and older in 2023; continue to purchase doses of the vaccine; support activities to achieve an intermediate level of preparedness for Marburg and Sudan ebolavirus vaccines, including clinical data and a supply of doses that could be used in large ring vaccination clinical studies for two candidates for each virus, with at least one candidate for each threat transitioning to PBS no later than 2026; continue to support late-stage manufacturing improvements, post-marketing requirements and commitments, and procurement of the licensed Ebola virus therapeutics; continue to invest in lead therapeutic candidates for Marburg and Sudan viruses, including advancing the lead antibody candidates to pivotal preclinical studies and validated manufacturing; support host-directed countermeasures that may improve morbidity and mortality of patients; support small molecule, broad acting antivirals that may be used in combination with antibody products; and support continued diagnostics development for Filovirus test panels and portable testing applications to better inform disease containment during outbreaks.
	ASPR SNS will support the transition of two products previously supported by ASPR BARDA (the timing and funds needed to support this transition are outlined in Table 3).

Threat-Agnostic

Five Year Need	Funding Activities
$23.7 billion to advance the development of threat-agnostic	NIH will use approximately $4 billion to support a cross-cutting science portfolio including support for capabilities such as animal models; diagnostics; animal alternative models (e.g., complex in vitro models, microphysiological systems); sequencing facilities; reagent manufacturing; well-characterized pathogen stocks

Five Year Need	Funding Activities
MCMs and capabilities	for diagnostics and pre-clinical studies; clinical training programs; epitope mapping; biosafety lab support; computational biology; and development of vaccine platform technologies.
	With $19.7 billion over five years, ASPR BARDA will advance development and procurement efforts that cut across multiple pathogens including further development of vaccine platform technologies that developers can rapidly adapt to address new threats; broad-spectrum therapeutics; innovative scientific approaches to MCM development and manufacturing to decrease time to production so that we can respond quickly to an outbreak to meet National Biodefense Strategy goals; and centralized manufacturing and testing capabilities.

Pandemic and Seasonal Influenza

Funding will support pandemic preparedness objectives as outlined in the HHS Pandemic Influenza Plan 2017 Update[5], Executive Order 13887[6] Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health, 2021 American Pandemic Preparedness Plan (APPP)[7], the National Biodefense Strategy and Implementation Plan (NBS)[8], and COVID-19 lessons learned. This includes HHS's establishment of one of its key actions to "support innovation in influenza vaccine production for improved efficiencies to enable the production and distribution of final presentation vaccines for pandemic response within 12 weeks from the declaration of an influenza pandemic."

Five Year Need	Funding Activities
$8.1 billion to advance pandemic influenza preparedness	NIH will support discovery of innovative new pandemic influenza vaccine prototypes while advancing the clinical development of current universal influenza vaccine candidates; support the clinical evaluation of novel vaccines and adjuvants to protect against seasonal and pandemic strains of influenza virus (candidates include broadly protective or universal influenza vaccines, and candidates against potential pandemic influenza strains such as H7N9); support preclinical and translational development of a diverse portfolio of improved seasonal, pandemic, and broadly protective universal influenza vaccines; support clinical trials of broadly protective "universal" influenza A virus vaccine candidates with the initial Phase 1 studies of two vaccine candidates underway or planned to begin as early as CY 2024; and pursue advanced nanoparticle-based vaccine candidates for both pandemic and seasonal strains of influenza with Phase 1 trials for candidates underway in CY 2023 and in early CY 2025.

[5] *Pandemic Influenza Plan, 2017 Update*. Available at https://www.cdc.gov/flu/pandemic-resources/pdf/pan-flu-report-2017v2.pdf

[6] *Executive Order 13887-Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health.* Available at https://www.govinfo.gov/app/details/DCPD-201900631

[7] *American Pandemic Preparedness: Transforming Our Capabilities*. September 2021. Available at https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf?page=29

[8] *National Biodefense Strategy and Implementation Plan*. October 2022. Available at https://www.whitehouse.gov/wp-content/uploads/2022/10/National-Biodefense-Strategy-and-Implementation-Plan-Final.pdf

Five Year Need	Funding Activities
	ASPR BARDA will expand the development for more effective vaccines that can be made faster and more flexible than currently available vaccines, including phase 2 clinical trials to test safety and immunogenicity of influenza vaccines targeted to potential pandemic influenza virus strains and sustainment of pandemic influenza vaccine manufacturing capabilities (e.g., warm-basing domestic adjuvant production, etc.); the development of therapeutics focused on pre-exposure prophylaxis for the most vulnerable populations (e.g., elderly) for seasonal influenza protection and for the most highly exposed populations (e.g., healthcare workers) during a pandemic; the development of host-directed therapeutics focusing on treatment of acute respiratory distress syndrome (ARDS), including ARDS caused by influenza infection; and diagnostics development in the home setting to inform more rapid detection and treatment for patients.
	CDC will support influenza laboratories and state public health lab networks, such as the National Influenza Resource Centers, involved in virus characterization and development of influenza vaccine candidates through enhancing viral characterization and genomic analysis capabilities to improve the rapid identification of influenza viruses and the national response to influenza viruses with pandemic potential (funding captured in the "other PHEMCE portfolios" below).
	ASPR SNS will support sustainment of current level of preparedness through replacement of expiring antivirals in addition to the procurement of Baloxavir, an antiviral being added to the ASPR SNS at the recommendation of PHEMCE.

Radiological and Nuclear Threats

Investment in this portfolio includes spending for basic and advanced clinical research and development of products to address the short and long-term multi-faceted injuries from radiation exposure, trauma, and thermal burns that would occur after a nuclear detonation.

Five Year Need	Funding Activities
$3.2 billion to advance the development and availability of MCMs to address injuries from radiation exposure, trauma, and thermal burns that would occur	NIH will support products to address radiation-induced damage to the gastrointestinal tract, skin, and lung; support at least one product type for each organ system injury under FDA regulatory consideration; development of diagnostic platforms to enable rapid triage of large numbers of radiation-exposed people, to guide medical management and scarce resource allocation; and support a clinical trial to study the safety of a novel oral product that can remove a broad range of radioactive particles from the body and expects to transition this drug to ASPR BARDA to continue work toward licensure and procurement.
	ASPR BARDA will continue to procure MCMs and invest in basic and advanced clinical research and development of products to address the short-term and long-term multi-faceted injuries resulting from radiation exposure, trauma, and

Five Year Need	Funding Activities
after a nuclear detonation	thermal burns anticipated from a nuclear detonation including: procurement of treatments for the loss of platelets and white blood cells, biodosimetry devices, and dried plasma products, which will augment our preparedness for effectively responding to radiological/nuclear incidents; development of next-generation blood products, with submission of an application for marketing approval of spray dried plasma anticipated in FY 2025; advanced development of therapies to address radiation and traumatic injury (with a focus in the near term on vascular injury and endotheliopathies); diagnostic tests for endotypes resulting from radiation and trauma injury to aid in treatment and continue targeted natural history studies to identify new MCM targets for treatment of trauma and radiation injury; development of platform technologies, like organ-on-a-chip, in development to accelerate evaluation and regulatory approval of MCMs to treat the injuries caused by nuclear detonation and diminish our dependency on animal models, including the needs of pediatric and special populations; continue investing in advanced research and development of burn and blast MCMs for detection and treatment of burn and blast injuries resulting from nuclear detonation to continue pre-positioning via vendor-managed inventory (VMI) for products used in routine burn and trauma care; and support advanced development of technologies used to detect and facilitate the timely care of internal injuries, including ultrasound, portable X-ray, development of biomarkers seen in traumatic brain injuries (TBI).
	ASPR SNS will support sustainment of current level of preparedness, replenishing expiring antimicrobials to treat infections related to acute radiation syndrome (ARS), decorporation agents, and supporting medical materiel; and continue procuring several products previously supported by ASPR BARDA, including an antineutropenic drug and a burn/blast bandage. The timing and funds needed to support this transition are outlined in Table 3.

Rapid Response Capabilities

Five Year Need	Funding Activities
$8.1 billion to advance the development of innovative MCMs against priority CBRN threats as well as novel emerging biological threats	NIH will support current and develop new innovative programs that systematically characterize pathogens of pandemic potential, increasing basic research and surveillance (of pathogen reservoirs) to identify threats before they emerge; establish structure-function studies, animal models, and immunological assays, among others to enable a rapid pivot and application to different pathogens in the future; support development of vaccines, monoclonal antibodies, and therapeutics (both pathogen specific and agnostic); and advance promising MCM candidates through Phase 1/2 clinical trials, shortening development timelines in future public health emergencies of both known and unknown threats.
	ASPR BARDA will develop and procure innovative MCMs against priority CBRN threats as well as novel emerging biological threats, including pathogen-directed therapeutics that are effective against broad classes of pathogens, therapeutic

Five Year Need	Funding Activities
	platforms that can pivot to rapidly develop safe and effective treatments, host-directed approaches that treat the medical consequences of infection, vaccines against current threats built on platforms that can be rapidly redirected to new strains as they emerge, and technologies that can be applied across a variety of MCMs.

Smallpox and Other Orthopoxviruses

Five Year Need	Funding Activities
$3.9 billion to advance the development of availability of MCMs against orthopoxviruses including smallpox	NIH will continue supporting the Study of Tecovirimat for Human Mpox Virus (STOMP) study, a clinical trial evaluating the antiviral tecovirimat (TPOXX) for the treatment of human mpox disease, and the DOSES study, a clinical trial evaluating alternative strategies for administering the JYNNEOS vaccine, licensed for the prevention of both smallpox and mpox disease, to increase the number of available doses; supporting production of a Mpox Plaque Reduction Neutralization Test (PRNT) for use in clinical trial testing; continue evaluating monoclonal antibodies with broad protection against several human poxviruses, including mpox, to identify optimal antibody cocktails as possible next generation therapeutic and prophylactic treatments; and support the development of mRNA- and protein nanoparticle-based vaccines that are broadly protective against orthopoxviruses.
	ASPR BARDA will support sustained investment in a more stable, lyophilized formulation of JYNNEOS and continue to pursue procurements of JYNNEOS to both bolster smallpox preparedness and replace doses used during the mpox outbreak; support the late stage and post-marketing activities for TPOXX and TEMBEXA, therapeutics licensed for smallpox; support procurement of these products and the development of a pediatric formulation for TPOXX; support an investigational antibody product for smallpox to mitigate against the risk of resistance and provide a countermeasure appropriate for special populations and advance the product through validated manufacturing and pivotal animal studies.
	CDC will assess the clinical algorithms and diagnostic assays used to identify, and MCMs used to prevent and treat, orthopoxvirus disease, including mpox, and will continue to evaluate the third-generation smallpox vaccine, JYNNEOS, using existing clinical study platforms and serological studies that began during the mpox outbreak (funding captured in the “other PHEMCE portfolios” below).
	Funding for ASPR SNS will support the transition of smallpox vaccine and therapeutic products previously supported by ASPR BARDA. The timing and funds needed to support this transition are outlined in Table 3.

Other PHEMCE Portfolios

Five Year Need	Funding Activities
$15.8 billion to support additional NIH, CDC, FDA, and ASPR, activities	The remaining funds will be allocated to • NIH multiplex diagnostics, and Other Threats portfolio, including investments that support activities against threats such as arboviruses, waterborne and foodborne pathogens, tuberculosis, adjuvant discovery/development, and activities investigating fundamental aspects of the human immune system, • ASPR BARDA Management and Administration, MCMs for Burkholderia, Plague, and Tularemia, MCMs for ancillary products, Federal Medical Stations (FMS) stockpile, • FDA Regulatory activities, • ASPR SNS sustainment and operating costs, • And CDC's development of o Animal models critical for MCM research and evaluation of novel compounds to support the next generation of MCMs, including screening antiviral candidates against viral hemorrhagic fevers and leveraging CDC's laboratories to identify potential targets for candidate therapeutic development against multiple high consequence pathogens. o Clinical guidance to inform use of MCMs, including treatment of Tularemia and continual updates for anthrax and other especially dangerous pathogens rarely encountered in U.S. healthcare settings. In collaboration with FDA, CDC will support the development and management of appropriate regulatory mechanisms against multiple high-risk pathogens, including Investigational New Drug applications (INDs), Emergency Use Authorization requests (EUAs) and/or Emergency Use Instructions (EUI). o PPE capabilities to improve timeliness, reliability, effectiveness, and impact to protect the nation's workforce and the public, including plans to develop a comprehensive research and conformity assessment program for respiratory protective devices, to help improve preparedness for future respiratory pandemics and CBRN events. o In collaboration with the FDA, CDC will monitor the safety of licensed and authorized vaccines and transparently communicate information on immunization safety to policymakers, the public, healthcare providers, manufacturers, and jurisdictional health departments. o Providing 24/7 consultation on MCM use to clinicians, hospitals and public health, and international partners and developing health and risk communications to support uptake of MCMs during responses.

Product Transitions

During FY 2023–2027, ASPR BARDA anticipates thirteen (13) potential MCM product transitions from Project BioShield to ASPR SNS. Transitioning these products will increase the need for funding in the ASPR SNS budget to support replenishment of expiring MCMs. Replenishment costs arise from products purchased previously by ASPR BARDA or SNS that expire and need to be restocked. A total of $5.3 billion is estimated to support the transition and replenishment of MCMs by ASPR SNS. As noted above, the ASPR SNS does utilize, when and where possible, the Shelf-Life Extension program. The funding projection below takes such considerations, when available, into account.

Although ASPR SNS's estimates ensure replenishment of current inventory and transition of MCM products from Project BioShield to ASPR SNS, it does not capture the resources needed to fully fund its PHEMCE requirements (i.e., expand its inventory to meet its requirement benchmarks).

ASPR, informed by consultation with the PHEMCE, establishes requirements for the capabilities, materiel, and quantities necessary to prepare for and respond to public health threats. These requirements drive MCM procurement and sustainment decisions. The requirements process is currently driven by assessing the threat landscape and a framework for prioritizing threats using a risk-based approach. Requirements are informed by material threat assessments and public health modeling of strategic scenarios selected to represent the national security threat. Requirements are established to guide MCM development, acquisition, and the capabilities that are needed to effectively utilize these MCMs to respond to national security threats.

Consistent with methodology used in prior reports, ASPR SNS estimates that in order to fully meet its PHEMCE requirements, an additional +$1.485 billion would be needed over the five-year period. This would bring the five-year total for ASPR SNS to $13.0 billion. Compared to the base estimates, the portfolios with the largest increase would be anthrax (+885 million), pandemic influenza (+$203.7 million), and ancillary (+$48 million).

Figure 3: FY 2025 – FY 2027 MCM Transition Amount (in millions).

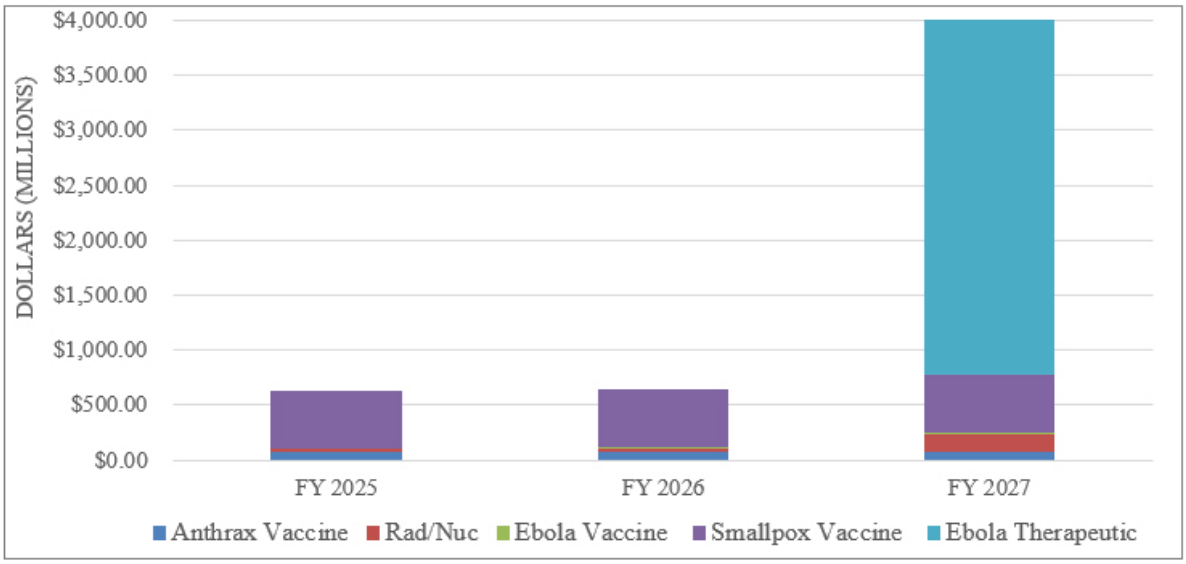


Table 3: Estimated ASPR SNS Spending Needed for MCM Product Replenishment of Products Previously Procured under Project BioShield, FY 2023–2027 (Dollars in Millions).

Estimated Transition Timeframe (FY)	Medical Countermeasure	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027	Total
FY 2024	Anthrax Vaccine	-	-	$79.6	$79.6	$79.6	$238.8
FY 2024	Rad/Nuc Other Supportive- A	-	-	$21.6	$21.6	$21.6	$64.9
FY 2024	Rad/Nuc Other Supportive- B	-	$10.0	$5.1	$5.1	$5.1	$25.4
FY 2024	Ebola Vaccine	-	-	-	$18.6	$18.6	$37.1
FY 2025	Smallpox Vaccine	-	-	$518.8	$518.8	$518.8	$1,556.3
FY 2027	Ebola Therapeutic	-	-	-	-	$3,239.4	$3,239.4
FY 2027	Rad/Nuc Other Supportive- C	-	-	-	-	$129.2	$129.2
Total		**-**	**$10.0**	**$625.1**	**$643.7**	**$4,012.3**	**$5,291.1**

Summary and Overview of Funding in Outyears

This report includes the multiyear budgets for FY 2023-2027 for HHS entities involved in MCM development and stockpiling, including NIH, ASPR, CDC, and FDA. The MYB report accounts for the budgetary aspects of MCM basic research, advanced research and development, regulatory review (including evaluation of real-world safety and effectiveness post-deployment), procurement, stockpiling, and replenishment of the USG's civilian MCM enterprise. Beyond the enacted FY 2023 levels, PHEMCE agencies identified the following activities to address existing preparedness gaps and meet the goals outlined in the *National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security* (National Biodefense Strategy) updated in October 2022:

- NIH will support activities to advance a robust pipeline of candidate medical countermeasures (MCMs) for the development of safe and effective products. For NIH, the largest spending estimates are for new products to address gaps in the broad-spectrum antimicrobial portfolio, and to support the implementation of the Prototype Pathogen Approach for development of candidate vaccines, therapeutics, and diagnostics for members of viral families known to cause human disease, in preparation for the likely emergence of new viral species or variants with pandemic potential. To fund these activities through 2027, NIH estimates a $8.5 billion need above enacted levels in FY 2023.

- ASPR BARDA will support the advanced development and initial procurement of FDA approved/licensed MCMs, including improvements to threat-agnostic technologies, rapid response capabilities, pandemic influenza vaccines, and novel therapeutics. To fund these activities through 2027, ASPR BARDA estimates a $29.5 billion need above enacted levels in FY 2023.

- ASPR SNS will support the transition of thirteen (13) MCM candidates from ASPR BARDA's PBS to stockpiling by the ASPR SNS by FY 2027. Increased funding needs, beginning in FY 2025, are driven by an Ebola therapeutic, a therapeutic in the radiation/nuclear portfolio, and a smallpox antiviral; the planned transition of an Ebola therapeutic in FY 2027 makes up over half of the difference between the flat level and the projected need. The smallpox expenditures are in order to backfill the ASPR SNS for the MCMs distributed during the mpox response. To support these activities through 2027 across Ebola, Radiological/Nuclear, and Smallpox portfolios, ASPR SNS estimates a $6.7 billion increase above the enacted levels in FY 2023. ASPR BARDA's successes in supporting the advanced development of 86 products that received FDA approval, licensure, clearance, or authorization have not been commensurate with the ASPR SNS budget for products to transition to the stockpile successfully. In the absence of a transition path, products without sustainable commercial pathways are likely to be lost, costing USG not only the investments along the way but also the critical ability to build PHEMCE's preparedness posture against future threats.

  In addition to the transition of products from development to procurement, the ASPR SNS is tasked with maintaining its current preparedness posture. This means the replenishment of existing supplies, including antimicrobials necessary for post-exposure prophylaxis as part of the anthrax portfolio and antivirals as part of the pandemic influenza portfolio, and the sustainment of ASPR SNS's current level of preparedness.

- FDA will sustain its ability to foster the establishment of clear, scientifically supported regulatory pathways for MCMs as well as to fill critical scientific gaps that inform regulatory decision-making and support efforts to establish regulatory policies and mechanisms to facilitate the availability of MCMs. To support these activities through 2027, FDA estimates a $776 million increase above enacted levels in FY 2023.

- CDC, as a critical PHEMCE partner newly added to this year's report, supports both new and ongoing programs related to research and development activities and provides critical support functions including developing data-driven guidance for utilization, and monitoring of safety and real-world effectiveness during emergencies. To support these activities through 2027, CDC estimates a $921 million need above enacted levels in FY 2023.

Appendix A: Multiyear Budget Methodology

Each agency and program developed its methodology for providing estimates for the PHEMCE MYB. The estimates for procurement costs are point-in-time estimates and could change in future reports to reflect current market prices.

- NIH assumed an inflationary increase in FY 2025, 2026, and 2027, using the NIH's Biomedical Research and Development Price Index (BRDPI) for all topic areas, except for Rapid Response Capabilities. Rapid Response Capabilities set forth in this MYB align strategically with pandemic preparedness, and additional funding beyond BRDPI is needed to meet the objectives laid out in the NIAID Pandemic Preparedness Plan and the American Pandemic Preparedness Plan. The $2.69 billion increase in FY 2025, 2026, and 2027 for Rapid Response Capabilities is a professional judgement for funding to implement the prototype pathogen approach to characterize pathogens of pandemic potential and develop vaccines, monoclonal antibodies, and therapeutic strategies with the knowledge obtained from this approach.

- ASPR BARDA assumed funding levels to address all DHS-identified threats with Material Threat Determinations and to meet the goals of the HHS Pandemic Influenza Plan 2017 Update and Executive Order 13887. This funding is also in alignment with American Pandemic Preparedness Plan, COVID-19 lessons learned, and several other Executive Orders, including EO 140001- A Sustainable Public Health Supply Chain, and EO 14005 Ensuring the Future is Made in All of America by All of America's Workers.

  Importantly, ASPR BARDA receives its funding from multiple sources, including Advanced Research and Development (ARD), PBS, and Pandemic Influenza (PI) funding. These sources have different authorities and periods of availability. For example, ASPR BARDA receives PI funding that is both annual (available for one fiscal year) and no-year (available until expended).

- FDA assumed a three percent increase for each of FY 2025, 2026, and 2027 for CBRN, pandemic influenza, and antimicrobial resistance funding. For COVID-19 sustainment, FDA assumed a 30 percent increase above total COVID-19 supplemental funding for FY 2025 and FY 2026 and a 15 percent increase above total COVID-19 supplemental funding for FY 2027.

- ASPR SNS assumed funding levels necessary to maintain the current inventory as of the date of this Report, including replenishment of all FDA approved/licensed/cleared/authorized MCMs and those not yet approved/licensed/cleared/authorized, including those originally acquired by Project BioShield. Also, ASPR SNS includes an estimate of the funding that will be needed in out-years to replenish products originally purchased by PBS that are not yet FDA approved but which are forecasted to become so and require replacement in those years. Consistent with prior reports the ASPR SNS methodology does not account for funding required to fully meet all its requirements (see *Product Transitions* section).

- As stated above, the intended scope of this report is to capture the budgetary aspects of MCM basic research, advanced research and development, regulatory review, procurement, stockpiling, and replenishment of the USG's civilian MCM enterprise. CDC is included in this year's MYB to the extent that their budget needs fall within this scope. CDC's budget estimates for FY 2025- FY 2027 are professional judgments of the resources that provide research and evaluation of new MCMs, diagnostic development, MCM clinical guidance and regulatory support, and monitoring of MCM safety and real-world effectiveness. Inclusion of these efforts more fully captures the activities required to develop, maintain, and ensure comprehensive PHEMCE MCM readiness and planning for

use of stockpiled MCMs in response to a public health emergency or natural disaster. Such inclusion is also consistent with the key role CDC plays in supporting implementation of the National Biodefense Strategy goals.

- The out-year funding levels (FY 2025, 2026, and 2027) for NIH, ASPR, FDA, and CDC were developed without regard to the competing priorities or budget totals considered in the annual President's Budget formulation process. These estimates are subject to change in the future.

Appendix B: PHEMCE MYB Agency Roles

National Institutes of Health (NIH)

The NIH conducts and supports basic, translational, and clinical research to better understand the biological effects of, and to develop medical countermeasures (MCMs) for chemical, biological, and radiological/nuclear threats. Most of this research is conducted or supported by the National Institute of Allergy and Infectious Diseases (NIAID) at the NIH and includes basic research on microbiology and immunology as well as applied and clinical research to evaluate candidate MCMs including diagnostics, therapeutics, and vaccines. This strategic effort includes advancing approaches that could be used to develop MCMs against multiple threats or pathogens, such as the development of vaccine platforms such as mRNA, the discovery and development of novel vaccine adjuvants, viral vectors, protein nanoparticles, mucosally delivered vaccines, and the discovery and development of targeted antibody therapeutics and broad-spectrum antibiotics and antivirals.

NIH works with partners in industry, academia, and the PHEMCE to ensure that promising countermeasures for biological, chemical, and radiological public health threats can proceed to advanced development. NIH has supported the early development of dozens of candidate MCMs for high-priority threats and ultimately transitioned support for those candidate MCMs to ASPR BARDA for advanced development, with the goal of FDA approval, licensure, clearance, or authorization, and for potential inclusion in the ASPR SNS.

NIH is well-positioned to respond rapidly to infectious disease threats as they emerge by conducting and collaborating on research efforts, enhancing domestic and international research infrastructure that can be quickly mobilized, and engaging in collaborative and highly productive partnerships with industry. NIH is also pursuing a prototype pathogen research strategy to further bolster preparedness for novel infectious disease threats by supporting the development of medical countermeasures for selective pathogens that belong to viral families of concern. Knowledge gained from studying prototype pathogens will build a framework for a rapid research and product development response for other viruses within the same virus family of the prototype pathogen, should an outbreak occur.

Administration for Strategic Preparedness and Response (ASPR)

ASPR leads the nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies by developing, stockpiling, and distributing response tools against multiple threats; deploying clinical response teams in times of crisis; and ensuring our healthcare and public health partners have the knowledge and tools they need to navigate today's challenges and confront whatever challenges lay ahead.

ASPR's BARDA provides an integrated, systematic approach to the development of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies such as CBRN accidents, incidents, and attacks; pandemic influenza (PI), and emerging infectious diseases (EID). Through partnerships, ASPR BARDA promotes the advanced development of MCMs against health security threats.

ASPR's SNS stockpiles a cache of MCM products needed by states, tribal nations, territories, and the largest metropolitan areas during public health emergencies. The supplies, medicines, and devices for lifesaving care contained in the stockpile can be used as a short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient. The ASPR SNS team works every day to prepare for and respond to emergencies, support state and local preparedness activities, and

ensure availability of critical medical assets to protect the health of Americans.

Centers for Disease Control and Prevention (CDC)

As the nation's public health agency, the CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats and responds when these arise. CDC provides global scientific leadership to address these threats, hosting 17 WHO collaborating centers across a range of public health issues, many for decades, including several threats within the PHEMCE mission space. The scale, scope, and duration of these leadership activities that drive global partnerships, norms, and standards are unique among institutions worldwide. Furthermore, CDC works domestically and globally to build local capacity to effectively use MCMs to prevent, detect, and respond to public health threats.

The Office of Readiness and Response (ORR) coordinates CDC's core capabilities to support strong global and domestic preparedness and ensure that CDC can rapidly respond to public health emergencies, wherever they occur. ORR, in collaboration across CDC and with FDA, develops the regulatory mechanisms needed to enable clinical testing of investigational MCMs or emergency use of MCMs. Through the Public Health Emergency Preparedness program, ORR helps state and local jurisdictions prepare to receive and distribute critical MCMs during emergencies.

CDC's National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) serves as a World Health Organization Collaborating Center for Smallpox and the USG lead for MCM research requiring live Variola virus. NCEZID is also responsible for the prevention, control, and management of more than 800 pathogens, including especially dangerous pathogens such as anthrax and Ebola virus disease, as well as more common illnesses like healthcare-associated infections. NCEZID provides technical and scientific expertise and supports MCM efforts for 11 of 13 PHEMCE High Priority Biological Threats. NCEZID conducts research on candidate vaccines and treatments and develops the clinical guidance needed to inform utilization. NCEZID collaborates with FDA to monitor the safety of licensed and authorized vaccines and transparently communicate information on immunization safety to policymakers, the public, healthcare providers, manufacturers, and jurisdictional health departments. NCEZID develops, validates, and deploys diagnostic assays and reagents for detection of and response to public health threats, including determining a pathogen's drug resistance in order to better inform MCM development and deployment.

The National Center for Immunization and Respiratory Diseases (NCIRD) seeks to prevent disease, disability, and death through immunization and by control of respiratory and related diseases. CDC's Influenza Division has served as a WHO Collaborating Center (CC) for Surveillance, Epidemiology, and Control of Influenza in Atlanta, Georgia since 1956 and is the largest global resource and reference center supporting public health interventions to control and prevent pandemic and seasonal influenza. CDC plays a major role in year-round surveillance for early detection and identification of antigenically drifted seasonal influenza viruses as well as novel influenza A viruses that may have pandemic potential. CDC collects and analyzes influenza viruses from around the world for epidemiological, antigenic (immune response), antiviral susceptibility and genetic characterizations. When a new respiratory disease, or a variant of existing pathogens such as influenza or COVID-19, arises with an outbreak or pandemic potential, NCIRD ensures the availability of the genomic sequence and population-based surveillance data needed to determine the effectiveness of existing medical countermeasures or to develop novel ones.

The National Center for Environmental Health (NCEH) and Agency for Toxic Substances and Disease Registry (ATSDR) seeks to prevent death and illness from non-infectious hazards, including those

stemming from toxic substances and chemical or radiological emergencies. NCEH/ATDSR develops the toxin detection, protein assays, and radiobioassay capability needed to support diagnosis, treatment, and prevention of toxin-mediated diseases such as botulism, anthrax, ricin, and abrin poisoning, as well as address internal radionuclide contamination.

The National Institute for Occupational Safety and Health (NIOSH) conducts research and provides services to improve the safety and health of workers who may be exposed to a variety of occupational hazards. NIOSH supports innovations in personal protective equipment (PPE), as well as the guidance and authoritative recommendations needed to protect those who rely on this PPE to prevent disease, injury, and death. NIOSH is also responsible for directing and conducting the Respirator Approval Program and its related laboratory, field, quality and research functions.

Food and Drug Administration (FDA)

The FDA plays a critical role in protecting the U.S. from CBRN and emerging/re-emerging infectious disease threats, such as SARS-CoV-2, Ebola, and mpox. FDA's responsibilities include reviewing the safety and effectiveness of MCMs—including drugs, therapeutic biologics, vaccines, and devices, such as diagnostic tests—to counter these threats.[9] In addition to its regulatory responsibilities, FDA works closely with USG partners to build and sustain the MCM programs necessary to effectively respond to public health emergencies. This includes numerous engagements through the PHEMCE as well as working closely with the U.S. Department of Defense (DoD) to facilitate the development and availability of MCMs to support the unique needs of American military personnel. FDA supports the PHEMCE and DoD by providing subject-matter expertise in MCM development and by providing scientific and regulatory input to inform MCM development, procurement, and stockpiling decisions. In addition, FDA facilitates access to available MCMs to respond to public health and military emergencies, even when products are still investigational or not yet approved for that particular use, provided certain criteria are met.

The FDA facilitates the development of and access to safe and effective MCMs to counter high-priority CBRN and emerging/re-emerging infectious disease threats through a variety of activities, including:

- Providing advice to developers, manufacturers, researchers, and others in the development of new and innovative MCMs to meet FDA's standards;
- Providing regulatory advice, guidance, and technical assistance to sponsors developing investigational MCMs for CBRN or emerging infectious disease threat indications;
- Discussing questions with potential product sponsors to help clarify requirements for approval, licensure, or clearance or emergency use authorization if needed;
- Reviewing MCM marketing applications and approving those that meet standards for approval, licensure or clearance;
- Supporting the establishment and sustainment of an adequate supply of MCMs, including interagency collaboration on efforts to advance MCM supply chains;

[9] MCMs include qualified countermeasures as defined in section 319F–1(a)(2)(A) of the Public Health Service Act (PHS Act) (42 USC. § 247d–6a(a))(2)(A); qualified pandemic or epidemic products as defined in section 319F–3(i)(7) of the PHS Act (42 USC. § 247d–6d(i)(7)); and security countermeasures as defined in section 319F-2(c)(1)(B) of the PHS Act (42 USC § 247d–6b(c)(1)(B)).

- Enabling access to available MCMs that are not yet approved for use—when necessary—through an appropriate regulatory mechanism, such as clinical trials, expanded access protocols, or EUA;
- Responding to emerging and re-emerging public health threats;
- Establishing and sustaining Public Health and Security Action Teams to identify and catalyze the resolution of regulatory and scientific challenges associated with MCMs to address high priority threats;
- Developing capabilities to monitor and assess MCMs used during public health emergencies and beyond, including by providing technical advice to application holders on scientifically rigorous methods of assessing MCM effectiveness based on real-world evidence and facilitating the production of reference panels to test the sensitivity and/or annual reactivity performance of certain EUA and cleared MCM in vitro diagnostic devices;
- Sustaining the MCMi Regulatory Science Program to create tools, standards, and approaches to develop and assess MCM safety, efficacy, quality, and performance;
- Encouraging manufacturers to develop innovative and emerging approaches to produce medicines through advanced manufacturing technologies[10];
- Ensuring that the FDA regulatory and policy framework[11] adequately supports MCM development and enables preparedness and response activities; and,
- Sustaining the MCMi professional development program[12] to ensure that FDA meets the regulatory challenges posed by the new scientific and technological developments to support the MCM mission.

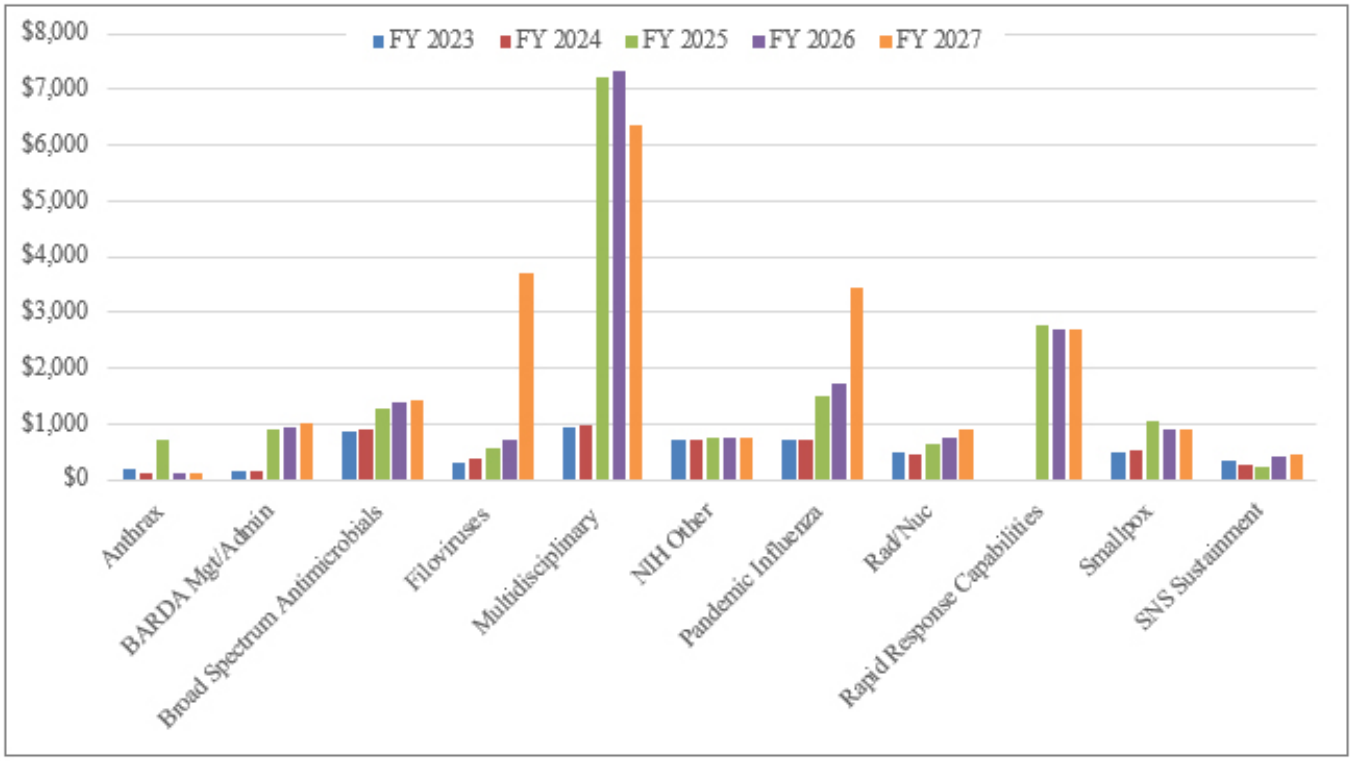
[10] *Advanced Manufacturing*. U.S. Food and Drug Administration. Available at https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/advanced-manufacturing

[11] *MCM Legal, Regulatory and Policy Framework*. U.S. Food and Drug Administration. Available at https://www.fda.gov/emergency-preparedness-and-response/medical-countermeasures-initiative-mcmi/mcm-legal-regulatory-and-policy-framework

[12] *MCMi Professional Development Activities.* U.S. Food and Drug Administration. Available at https://www.fda.gov/emergency-preparedness-and-response/medical-countermeasures-initiative-mcmi/mcmi-professional-development-activities

Appendix C: PHEMCE MYB Spending by Portfolio

Figure 4: Estimated Threat Portfolio Spending by Fiscal Year (Dollars in Millions).
Note, the different scale in Figure 4 for visual clarity.



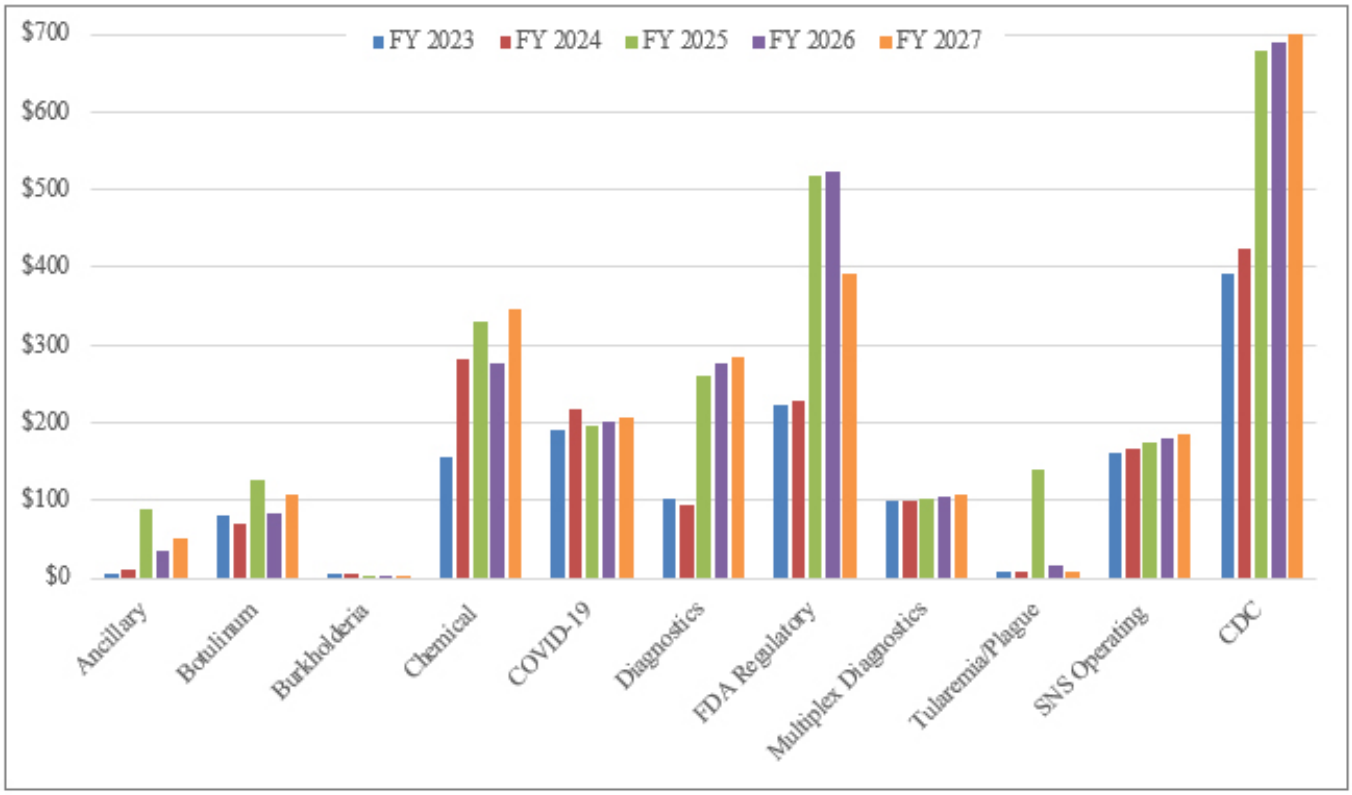


Table 4: Estimated Threat Portfolio Spending by Fiscal Year (Dollars in Millions).

Portfolio	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Anthrax	$206.6	$118.2	$700.8	$99.9	$134.0
ASPR BARDA Mgt and Admin	$153.3	$170.0	$908.2	$944.1	$999.5
Broad Spectrum Antimicrobials	$850.0	$898.5	$1,258.3	$1,372.9	$1,437.9
Filoviruses	$301.6	$363.1	$563	$716.2	$3,705.9
Threat Agnostic	$949.9	$987.4	$7,405.9	$7,330.1	$6,354.3
NIH Other	$715.6	$715.6	$733.5	$751.1	$769.1
Pandemic Influenza	$714.4	$726.4	$1,512.2	$1,733.5	$3,438.6
Rad/Nuc	$503.9	$447.2	$626.5	$756.2	$886.8
Rapid Response Capabilities	$0.0	$0.0	$2,765.0	$2,690.0	$2,690.0
Smallpox	$490.3	$516.8	$1,039.8	903.5	$898.2
ASPR SNS Sustainment	$339.9	$257.2	$226.7	398.9	$438.1
Ancillary	$4.7	$10.8	$87.3	$35.1	$50.1
Botulinum	$81.3	$69.5	$127.1	$84.4	$106.9
Burkholderia	$4.9	$6.5	$0.5	$0.8	$0.1
Chemical	$154.4	$283	$329.4	$276.5	$346
COVID-19	$191.5	$216.5	$196.2	$201	$205.8
Diagnostics	$103.3	$95	$260.5	$277.5	$285.5
FDA Regulatory	$221.4	$228.3	$517.3	$524.4	$390.5
FMS*	$1.2	$1.2	$1.3	$1.3	$1.4
Multiplex Diagnostics	$100.3	$100.3	$102.8	$105.3	$107.8
Tularemia/Plague	$8.5	$8.5	$140.7	$15.9	$9.1
ASPR SNS Operating	$160.4	$166.8	$173.9	$179.8	$185.9
CDC	$393.0	$424.0	$678.0	$689.0	$702.0

*FMS is excluded from Figure 4 graphic to improve visualization of the other portfolios.

Appendix D: PHEMCE MYB Spend Plan Tables

Table 5a: PHEMCE MYB Spend Plan Table (Dollars in Millions) for NIH.

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027	FY 2023-27 Total
NIH	NIAID	Direct Appropriation, Annual	Anthrax	Basic/Other Research	$3.9	$3.9	$4.0	$4.1	$4.2	$19.9
NIH	NIAID	Direct Appropriation, Annual	Anthrax	Vaccines	$0.3	$0.3	$0.3	$0.3	$0.3	$1.4
NIH	NIAID	Direct Appropriation, Annual	Botulinum	Antitoxin	$2.3	$2.3	$2.4	$2.4	$2.5	$11.9
NIH	NIAID	Direct Appropriation, Annual	Botulinum	Basic/Other Research	$1.5	$1.5	$1.5	$1.5	$1.6	$7.5
NIH	NIAID	Direct Appropriation, Annual	Botulinum	Vaccines	$0.8	$0.8	$0.8	$0.8	$0.9	$4.1
NIH	NIAID	Direct Appropriation, Annual	Broad Spectrum Antimicrobials	Antibiotics	$458.1	$458.1	$469.5	$480.8	$492.3	$2,358.8
NIH	NIAID	Direct Appropriation, Annual	Broad Spectrum Antimicrobials	Antiviral	$112.3	$112.3	$115.1	$117.9	$120.7	$578.4
NIH	NIAID	Direct Appropriation, Annual	Threat Agnostic	Animal Models	$26.0	$26.0	$26.7	$27.3	$28.0	$134.0
NIH	NIAID	Direct Appropriation, Annual	Threat Agnostic	Basic/Other Research	$500.5	$500.5	$513.0	$525.3	$537.9	$2,577.3
NIH	NIAID	Direct Appropriation, Annual	Threat Agnostic	Product Development	$126.6	$126.6	$129.7	$132.8	$136.0	$651.7
NIH	NIAID	Direct Appropriation, Annual	Threat Agnostic	Translational	$128.2	$128.2	$131.4	$134.6	$137.8	$660.4
NIH	NIAID	Direct Appropriation, Annual	Filoviruses	Basic/Other Research	$29.5	$29.5	$30.2	$30.9	$31.7	$151.8
NIH	NIAID	Direct Appropriation, Annual	Filoviruses	Vaccines	$21.6	$21.6	$22.2	$22.7	$23.2	$111.4
NIH	NIAID	Direct Appropriation, Annual	Pandemic Influenza	Basic/Other Research	$80.6	$80.6	$82.6	$84.6	$86.7	$415.2
NIH	NIAID	Direct Appropriation, Annual	Pandemic Influenza	Vaccines	$270.8	$270.8	$277.5	$284.2	$291.0	$1,394.4
NIH	NIAID	Direct Appropriation, Annual	Multiplex Diagnostics	Diagnostics	$96.5	$96.5	$98.9	$101.3	$103.8	$497.1
NIH	NIAID	Direct Appropriation, Annual	NIH Other	Basic/Other Research	$517.2	$517.2	$530.1	$542.8	$555.8	$2,663.1
NIH	NIAID	Direct Appropriation, Annual	NIH Other	Vaccines	$130.5	$130.5	$133.7	$137.0	$140.2	$671.9
NIH	NIAID	Direct Appropriation, Annual	Smallpox	Basic/Other Research	$12.2	$12.2	$12.5	$12.8	$13.1	$62.7
NIH	NIAID	Direct Appropriation, Annual	Smallpox	Vaccines	$19.9	$19.9	$20.4	$20.9	$21.4	$102.3

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027	FY 2023-27 Total
NIH	NIAID	Direct Appropriation, Annual	Tularemia/Plague	Basic/Other Research	$5.4	$5.4	$5.6	$5.7	$5.8	$28.0
NIH	NIAID	Direct Appropriation, Annual	Tularemia/Plague	Vaccines	$3.1	$3.1	$3.1	$3.2	$3.3	$15.8
NIH	NIAID	Direct Appropriation, Annual	COVID-19	Antivirals	$38.3	$38.3	$39.2	$40.2	$41.1	$197.0
NIH	NIAID	Direct Appropriation, Annual	COVID-19	Basic/Other Research	$93.3	$93.3	$95.6	$97.9	$100.2	$480.3
NIH	NIAID	Direct Appropriation, Annual	COVID-19	Vaccines	$59.9	$59.9	$61.4	$62.9	$64.4	$308.6
NIH	NIAID	Direct Appropriation, Annual	Rapid Response Capabilities	Pandemic Preparedness	$0.0	$0.0	$2,690.0	$2,690.0	$2,690.0	$8,070.0
NIH	Non-NIAID	Direct Appropriation, Annual	Broad Spectrum Antimicrobials	Antibiotics/ Antiviral	$23.1	$23.1	$23.7	$24.2	$24.8	$118.9
NIH	Non-NIAID	Direct Appropriation, Annual	Multiplex Diagnostics	Diagnostics	$3.8	$3.8	$3.9	$4.0	$4.1	$19.6
NIH	Non-NIAID	Direct Appropriation, Annual	Chemical	Chemical Countermeasures Research	$52.8	$52.8	$54.1	$55.4	$56.8	$272.0
NIH	Non-NIAID	Direct Appropriation, Annual	Rad/Nuc	Nuclear/ Radiological Countermeasures	$56.6	$56.6	$58.1	$59.4	$60.9	$291.7
NIH	Non-NIAID	Direct Appropriation, Annual	NIH Other	Basic/Other Research	$65.3	$65.3	$66.9	$68.5	$70.2	$336.3
NIH	Non-NIAID	Direct Appropriation, Annual	NIH Other	Vaccines	$2.6	$2.6	$2.7	$2.7	$2.8	$13.4
NIH TOTAL					**$2,943**	**$2,943**	**$5,707**	**$5,779**	**$5,854**	**$23,227**

Table 5b: PHEMCE MYB Spend Plan Table (Dollars in Millions) for ASPR.

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027	FY 2023-27 Total
ASPR	BARDA	ARD	Anthrax	Anthrax Medical Countermeasures	$0.6	$0.0	$0.0	$0.0	$0.0	$0.6
ASPR	BARDA	ARD	Botulinum	Botulinum Antitoxin	$3.5	$0.0	$60.0	$15.0	$25.0	$103.5
ASPR	BARDA	ARD	Broad Spectrum Antimicrobials	BARDA CARB	$151.5	$155.0	$350.0	$450.0	$450.0	$1,556.5

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027	FY 2023-27 Total
ASPR	BARDA	ARD	Chemical	Chemical Medical Countermeasures	$39.4	$80.0	$125.0	$133.0	$130.0	$507.4
ASPR	BARDA	ARD	COVID-19	Testing of MCMs Against COVID-19 Variants	$0.0	$25.0	$0.0	$0.0	$0.0	$25.0
ASPR	BARDA	ARD	Diagnostics	Diagnostics	$58.3	$50.0	$155.5	$167.5	$175.5	$606.8
ASPR	BARDA	ARD	Filoviruses	Filovirus Medical Countermeasures	$146.5	$162.0	$312.0	$374.0	$333.0	$1,327.5
ASPR	BARDA	ARD	Threat Agnostic	Manufacturing, Innovation and Support Network	$168.1	$206.1	$6,430.0	$6,510.0	$5,515.0	$18,829.2
ASPR	BARDA	ARD	Rad/Nuc	Rad/Nuc Medical Countermeasures	$210.2	$147.0	$223.7	$254.3	$257.8	$1,092.9
ASPR	BARDA	ARD	Smallpox	Smallpox Vaccines/Antivirals	$18.6	$20.0	$20.0	$63.0	$55.0	$176.6
ASPR	BARDA	PBS	Anthrax	Anthrax Medical Countermeasures	$80.1	$0.0	$80.0	$0.0	$0.0	$160.1
ASPR	BARDA	PBS	Botulinum	Botulinum Antitoxin	$1.0	$0.0	$0.0	$0.0	$10.2	$11.2
ASPR	BARDA	PBS	Broad Spectrum Antimicrobials	Broad Spectrum Antimicrobials	$105.0	$150.0	$300.0	$300.0	$350.0	$1,205.0
ASPR	BARDA	PBS	Chemical	Chemical Medical Countermeasures	$51.0	$90.0	$140.0	$60.0	$125.0	$466.0
ASPR	BARDA	PBS	Diagnostics	Diagnostics	$45.0	$45.0	$105.0	$110.0	$110.0	$415.0
ASPR	BARDA	PBS	Filoviruses	Filovirus Medical Countermeasures	$104.0	$150.0	$180.0	$270.0	$60.0	$764.0
ASPR	BARDA	PBS	Rad/Nuc	Rad/Nuc Medical Countermeasures	$184.0	$170.0	$140.0	$254.0	$249.9	$997.8
ASPR	BARDA	PBS	Rapid Response Capabilities	Rapid Response Capabilities	$0.0	$0.0	$75.0	$0.0	$0.0	$75.0
ASPR	BARDA	PBS	Threat Agnostic	Multidisciplinary	$0.0	$0.0	$175.0	$350.0	$350.0	$875.0
ASPR	BARDA	PBS	Smallpox	Smallpox Vaccines/Antivirals	$250.0	$225.0	$182.0	$0.0	$0.0	$657.0
ASPR	BARDA	PI - No-year	Pandemic Influenza	Diagnostics and Respiratory Protection Device Advanced Development	$25.0	$25.0	$143.0	$145.8	$96.0	$434.8

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027	FY 2023-27 Total
ASPR	BARDA	PI - No-year	Pandemic Influenza	Facilities and Infrastructure Readiness and Sustainability	$55.0	$87.0	$222.0	$145.0	$150.0	$659.0
ASPR	BARDA	PI - No-year	Pandemic Influenza	Therapeutics Advanced Development	$162.0	$50.0	$425.0	$625.0	$900.0	$2,162.0
ASPR	BARDA	PI - No-year	Pandemic Influenza	Vaccine Stockpile, Storage, Stability, and Testing	$50.6	$0.0	$164.0	$204.0	$253.0	$671.6
ASPR	BARDA	PI - No-year	Pandemic Influenza	Vx AD (Improved vaccines including cell and recombinant technologies)	$36.4	$185.0	$120.0	$180.0	$1,620.0	$2,141.4
ASPR	BARDA	PI - Annual	Pandemic Influenza	Facilities and Infrastructure Readiness and Sustainability	$1.8	$13.0	$28.0	$28.0	$28.0	$98.8
ASPR	BARDA	PI - Annual	Pandemic Influenza	Facilities and Infrastructure Readiness and Sustainability	$26.2	$15.0	$0.0	$0.0	$0.0	$41.2
ASPR	BARDA	ARD	BARDA Mgt & Admin	BARDA Mgt & Admin	$153.3	$170.0	$908.2	$944.1	$999.5	$3,175.1
ASPR	ASPR[13]	Direct Appropriation Annual	Pandemic Preparedness and Biodefense	Pandemic Preparedness and Biodefense	-	$400.0	-	-	-	$400.0
ASPR BARDA TOTAL					**$2,098**	**$2,600**	**$11,063**	**$11,583**	**$12,243**	**$39,316**

[13] The FY 2024 President's Budget proposes a $400 million Pandemic Preparedness and Biodefense fund for ASPR. The funds will be flexible and can be utilized to rapidly close critical gaps identified during the acute phase of response and accelerate progress, as need arises, within long-term programs. The intention is that these funds will be used for ASPR-wide needs. Funding is shown within BARDA in order to simplify the display of this report.

Table 5c: PHEMCE MYB Spend Plan Table (Dollars in Millions) for CDC.

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027	FY 2023-27 Total
CDC	NCEZID	Direct Appropriation Annual	CDC	Multidisciplinary	$149.6	$161.0	$225.0	$225.0	$225.0	$985.6
CDC	NCIRD	Direct Appropriation Annual	CDC	Multidisciplinary	$228.5	$240.0	$251.0	$262.0	$275.0	$1,256.5
CDC	NCEH	Direct Appropriation Annual	CDC	Multidisciplinary	$2.5	$10.0	$70.0	$70.0	$70.0	$222.5
ATSDR	ATSDR	Direct Appropriation Annual	CDC	Multidisciplinary	-	-	$30.0	$30.0	$30.0	$90.0
CDC	ORR	Direct Appropriation Annual	CDC	Multidisciplinary	$0.4	$1.5	$1.5	$1.5	$1.5	$6.4
CDC	NIOSH	Direct Appropriation Annual	CDC	Multidisciplinary	$12.0	$12.0	$100.0	$100.0	$100.0	$324.0
CDC TOTAL					**$393**	**$424**	**$678**	**$689**	**$702**	**$2,886**

Table 5d: PHEMCE MYB Spend Plan Table (Dollars in Millions) for FDA.

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027	FY 2023-27 Total
FDA	FDA	Direct Appropriation, Annual	FDA Regulatory	Antimicrobial Resistance MCM Funding	$29.9	$30.7	$31.7	$32.6	$33.6	$158.5
FDA	FDA	Direct Appropriation, Annual	FDA Regulatory	CBRN MCM Funding	$164.6	$169.9	$175.0	$180.3	$185.7	$875.5
FDA	FDA	Direct Appropriation, Annual	FDA Regulatory	Pandemic Influenza Funding	$26.9	$27.7	$28.5	$29.3	$30.2	$142.5
FDA	FDA	Direct Appropriation, Annual	FDA Regulatory	COVID-19 Sustainment	$0.0	$0.0	$282.2	$282.2	$141.1	$705.4
FDA TOTAL					**$221**	**$228**	**$517**	**$524**	**$391**	**$1,881**

Table 5e: PHEMCE MYB Spend Plan Table (Dollars in Millions) for ASPR SNS.

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027	FY 2023-27 Total
ASPR	SNS	Direct Appropriation, Annual	Ancillary	Anticonvulsant	-	-	$0.1	$0.0	$0.0	$0.1
ASPR	SNS	Direct Appropriation, Annual	Ancillary	Other supportive	$4.7	$10.8	$87.3	$35.1	$50.1	$188.0
ASPR	SNS	Direct Appropriation, Annual	Anthrax	Antibiotic	$50.9	$80.4	$432.0	$16.0	$49.9	$629.3
ASPR	SNS	Direct Appropriation, Annual	Anthrax	Therapeutic	$70.9	$33.7	$105.0	-	-	$209.6

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027	FY 2023-27 Total
ASPR	SNS	Direct Appropriation, Annual	Anthrax	Vaccine	-	-	$79.6	$79.6	$79.6	$238.9
ASPR	SNS	Direct Appropriation, Annual	Botulinum	Antitoxin	$72.2	$64.9	$62.4	$64.6	$66.8	$331.0
ASPR	SNS	Direct Appropriation, Annual	Burkholderia	Antibiotic	$4.9	$6.5	$0.5	$0.8	$0.1	$12.9
ASPR	SNS	Direct Appropriation, Annual	Chemical	Anticonvulsant		$8.0	$3.0	$6.5	$0.7	$18.2
ASPR	SNS	Direct Appropriation, Annual	Chemical	Nerve agent antidote	$10.1	$52.0	$6.1	$20.2	$32.3	$120.7
ASPR	SNS	Direct Appropriation, Annual	Chemical	Other supportive	$1.0	$0.2	$1.2	$1.3	$1.2	$4.9
ASPR	SNS	Direct Appropriation, Annual	Filoviruses	Therapeutic	-	-	-	-	$3239.4	$3239.4
ASPR	SNS	Direct Appropriation, Annual	Filoviruses	Vaccine	-	-	$18.6	$18.6	$18.6	$55.7
ASPR	SNS	Direct Appropriation, Annual	FMS	FMS	$1.2	$1.2	$1.3	$1.3	$1.4	$6.3
ASPR	SNS	Direct Appropriation, Annual	SNS Operating	Operating	$29.3	$30.2	$31.4	$32.3	$33.3	$156.5
ASPR	SNS	Direct Appropriation, Annual	SNS Operating	Program Support	$103.3	$106.4	$110.9	$114.2	$117.6	$552.5
ASPR	SNS	Direct Appropriation, Annual	SNS Operating	S&B	$27.8	$30.2	$31.7	$33.3	$34.9	$157.8
ASPR	SNS	Direct Appropriation, Annual	Pandemic Influenza	Antiviral	$6.0	-	$50.0	$36.9	$13.9	$106.8
ASPR	SNS	Direct Appropriation, Annual	Tularemia/Plague	Antibiotic	-	-	$132.0	$7.0	-	$139.0
ASPR	SNS	Direct Appropriation, Annual	Rad/Nuc	Antibiotic	-	-	$0.5	-	$0.5	$1.0
ASPR	SNS	Direct Appropriation, Annual	Rad/Nuc	Antineutropenic	$44.4	$50.1	$149.7	$149.7	$149.7	$543.6
ASPR	SNS	Direct Appropriation, Annual	Rad/Nuc	Antiviral	-	$0.8	-	-	-	$0.8
ASPR	SNS	Direct Appropriation, Annual	Rad/Nuc	Decorporation	$4.1	$3.4	$4.0	$4.0	$4.0	$19.5
ASPR	SNS	Direct Appropriation, Annual	Rad/Nuc	Other supportive	$4.5	$19.3	$50.5	$34.9	$164.1	$273.4
ASPR	SNS	Direct Appropriation, Annual	Smallpox	Antiviral	$11.3	$56.3	$112.5	$112.5	$112.5	$405.0
ASPR	SNS	Direct Appropriation, Annual	Smallpox	Vaccine	$178.4	$183.5	$692.5	$694.4	$696.3	$2445.0
ASPR	SNS	Direct Appropriation, Annual	SNS Sustainment	Sustainment	$37.3	$42.0	$43.3	$44.6	$45.9	$213.1
ASPR	SNS	Direct Appropriation, Annual	SNS Sustainment	Transportation	$25.4	$25.4	$26.1	$26.9	$27.7	$131.6
ASPR	SNS	Direct Appropriation, Annual	SNS Sustainment	Ventilator/PAPR VMI	-	-	-	$75.0	$75.0	$150.0
ASPR	SNS	Direct Appropriation, Annual	SNS Sustainment	Warehousing	$277.2	$189.8	$157.2	$252.4	$289.5	$1166.1
ASPR SNS TOTAL					**$965**	**$995**	**$2,389**	**$1,862**	**$5,305**	**$11,516**

Table 5f: PHEMCE MYB Spend Plan Table (Dollars in Millions) for HHS Pandemic Preparedness, Mandatory.

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027	FY 2023-27 Total
ASPR	ASPR	Mandatory**	Pandemic Preparedness	Pandemic Preparedness	-	$10,540.0	-	-	-	$10,540.0
FDA	FDA	Mandatory**	Pandemic Preparedness	Pandemic Preparedness	-	$670.0	-	-	-	$670.0
NIH	NIH	Mandatory**	Pandemic Preparedness	Pandemic Preparedness	-	$2,690.0	-	-	-	$2,690.0
CDC	CDC	Mandatory**	Pandemic Preparedness	Pandemic Preparedness	-	$6,100.0	-	-	-	$6,100.0
HHS PANDEMIC PREPAREDNESS TOTAL, MANDATORY					**-**	**$20,000**	**-**	**-**	**-**	**$20,000**

**Mandatory pandemic preparedness funding totals are displayed in FY 2024. Once enacted, HHS would develop detailed spend plans by activity for the five-year funding.