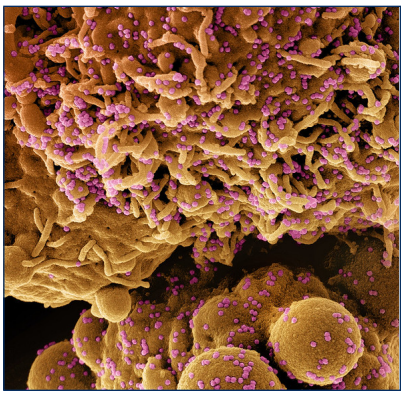
U.S. Department of Health & Human Services
Administration for Strategic Preparedness & Response

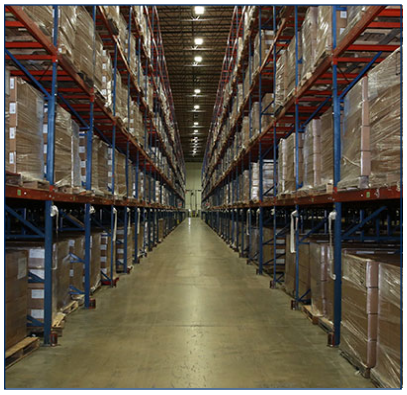
Public Health Emergency Medical Countermeasures Enterprise

Multiyear Budget: Fiscal Years 2022-2026

March 21, 2023



ASPR



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Dear Colleagues:

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 2018-2022 and was delivered in 2019. I am pleased that after three full years of an all-hands-on-deck response to the once-in-a-lifetime COVID-19 pandemic, we are once again able to provide the PHEMCE MYB. This year's installment picks up where the last one left off covering 2022-2026. As this MYB was built over a period of time in which there were continuing resolutions, omnibus spending bills, 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.

Dawn O'Connell

Assistant Secretary for Preparedness and Response

Introduction

This Public Health Emergency Medical Countermeasures Multiyear Budget (PHEMCE MYB) Report is the sixth submission in response to the requirement in Section 2811(b)(7) of the Public Health Service Act. This report includes the multiyear budgets for fiscal years 2022-2026 for the following Department of Health and Human Services (HHS) entities involved in MCM development and stockpiling: the National Institutes of Health (NIH); the Administration for Strategic Preparedness and Response (ASPR) Biomedical Advanced Research and Development Authority (BARDA) and Strategic National Stockpile (SNS); and the Food and Drug Administration (FDA). The Centers for Disease Control and Prevention (CDC) is and will continue to be an important member of the PHEMCE; however, this report does not include information on CDC's specific outyear budget. While CDC has activities related to Medical Countermeasure (MCM) utilization, those efforts fall outside the specific requirements for this Report.

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.

Congress requires ASPR to submit a PHEMCE MYB that includes consideration of the entire medical countermeasures enterprise and provide such document to Congress annually. The last PHEMCE MYB was delivered in late 2019 and covers FYs 2018-2022. ASPR is revising internal processes to ensure that future iterations of this critical professional judgment budget document will reflect both current resources provided by Congress as well as projected needs that build on requested levels in the President's Budget. ASPR will continue to evaluate its resources, as appropriated by Congress, to ensure the highest priority MCM needs are met. HHS appreciates the partnership with Congress to authorize and appropriate resources for critical missions and commits to improving the regularity of these reports.

ASPR is pleased to deliver the current PHEMCE MYB which will forecast the funding required to develop and support the transition of ten (10) MCM candidates from BARDA's Project BioShield (PBS) to stockpiling by the SNS by FY 2026. While some of these MCMs may not have FDA approval, at the time of initial delivery to the SNS, they could be held and later used in certain circumstances, such as under investigational drug protocols, clinical trials or under the FDA provisions for Emergency Use Authorization (EUA) under the Federal Food, Drug and Cosmetic (FD&C) Act.

The table below shows the enacted funding provided to PHEMCE member agencies in FY 2022, requested funding in FY 2023 President's Budget, and estimated funding through FY 2026 to improve preparedness and response for future public health emergencies. The funding levels do not account for supplemental appropriations (most notably COVID-19 supplemental appropriations) or requested mandatory funding to keep year-over-year funding estimates as comparable as possible. As described in the table below, the PHEMCE MYB projects an estimated overall funding need of $64.0 billion over the five-year period[1]. The report estimates a

[1] The previous report (FY 2018-2022) included a different calculation methodology than the current report. The last report included two professional judgment estimates (FY 2021, FY 2022), the current report includes three years.

gap of $35.3 billion between the flat (FY 2022) level[2] and projected five-year total, which would make it challenging for PHEMCE agencies to meet some of the programmatic goals described in this report within the five-year period. In addition, the table below depicts a sharp rise in projected costs for BARDA beginning in FY 2024 with slight decreases in projected needs in FY 2025 and FY 2026. The projected increase in FY 2024 aligns with a multitude of 'start up' costs that are not needed in FY 2025 and FY 2026.The PHEMCE MYB reflects past appropriated levels (e.g. FY2022) and is consistent with the FY 2023 President's Budget request; therefore, FY 2024 is the first year that is projected using the methodology described in this report. It is important to note this report's projections beginning in FY 2024 align to the principles described in the American Pandemic Preparedness Plan.

Table 1: Estimated Total PHEMCE Spending by HHS Division and Fiscal Year (dollars in millions)

Division	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	Total
NIH	$2,835	$2,825	$3,065	$3,131	$3,199	**$15,055**
ASPR BARDA	$1,818	$1,973	$13,192	$12,394	$10,928	**$40,305**
ASPR SNS	$845	$975	$1,963	$1,588	$1,439	**$6,809**
FDA	$216	$224	$371	$519	$527	**$1,857**
Total	**$5,714**	**$5,997**	**$18,590**	**$17,632**	**$16,093**	**$64,025**

This report represents HHS's current estimates for the basic research, advanced research and development, regulatory review, procurement, stockpiling, and replenishment of the U.S. government's (USG's) civilian medical countermeasure enterprise. This budget forecast does not take into account 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.

As noted in the FY 2018–2022 Multiyear Budget that was delivered in 2019, and other reviews of federal stockpiling efforts, the primary challenge faced by the PHEMCE is the sustainability of the MCM response capabilities and capacities of the SNS. Successful development and procurement of an MCM by BARDA obligates SNS to expend additional funding for sustainment. PBS funding is used for initial MCM procurement for the SNS but is rarely used for replacement once the product is approved by FDA. Once products are approved, authorized, cleared, or licensed by FDA, SNS assumes costs associated with ongoing maintenance and replacement. In the past, the PHEMCE SNS Annual Review recommended tradeoffs when available SNS funds were insufficient to both maintain current capabilities and absorb additional products. These tradeoffs translated to increasing levels of risk across the threat portfolios, potentially jeopardizing the nation's ability to realize the full benefits of prior research and development investments. For example, to meet budget constraints prior SNS Annual Reviews proposed reducing anthrax vaccine and antibiotics holdings. Such tradeoffs have led to the SNS inventory being below the established stockpiling goals for several types of MCMs.

Beyond these immediate challenges, the PHEMCE must address the entire range of capabilities required to effectively use stockpiled MCMs in response to a public health emergency or natural

[2] Flat level calculation assumes enacted FY 2022 funding for five-year period.

disaster. These include: the ability to rapidly and accurately detect that an incident has occurred that requires MCM assets; the capability to rapidly generate the data necessary to support the emergency use of MCMs using appropriate frameworks including clinical trials as well as expanded access and other emergency use authorization when necessary; the availability of evidence-based guidance on the appropriate use of these MCMs in all populations; the ability to monitor efficacy and safety of MCMs in all populations during and after an emergency to inform future actions; and the ability of state and local partners to receive, distribute, and dispense MCMs. These capabilities, the costs for which are only partially reflected in this report as this report only reflects HHS requirements and components within the PHEMCE enterprise, are as important as establishing and maintaining a complete inventory of the appropriate pharmaceuticals and medical supplies.

ASPR looks forward to working with Congress to overcome these challenges and ensure America is prepared for whatever threat is around the corner.

Overview of Funding in Outyears

The PHEMCE MYB forecasts the funding required to develop and support the transition of ten (10) MCM candidates from BARDA's Project BioShield (PBS) to stockpiling by the SNS by FY 2026.

National Institutes of Health

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 work is conducted by the National Institute of Allergy and Infectious Diseases (NIAID) at the NIH. NIAID supports 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. These approaches include the development of vaccine platforms such as mRNA, discovery and development of novel vaccine adjuvants, 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 BARDA for advanced development, with the goal of FDA approval, licensure, clearance, or authorization, and for potential inclusion in the SNS.

NIH is well-positioned to respond rapidly to infectious disease threats as they emerge by leveraging research efforts, domestic and international research infrastructure that can be quickly mobilized and utilizing collaborative and highly productive partnerships with industry. For example, the accelerated COVID-19 response was made possible in part due to decades of research on vaccine platforms, vaccine adjuvants, and immunogen design, as well as the mobilization of several NIAID-supported clinical trial networks, including the HIV Vaccine Trials

Network (HVTN), the HIV Prevention Trials Network (HPTN), the AIDS Clinical Trials Group (ACTG) and the Infectious Disease Clinical Research Consortium (IDCRC).

NIH continues to expand and increase its support for the research infrastructure required to better prepare and respond to public health threats. For example, in 2021 NIH and BARDA launched the Antiviral Program for Pandemics (APP), which aims to build sustainable platforms for targeted drug discovery and to develop a robust pipeline of antivirals against viruses with pandemic potential.

Innovative technologies and approaches supported by NIH are enabling the accelerated development of new MCMs. High-throughput sequencing and platform-based technologies are facilitating the development and manufacture of MCM candidates to expedite their clinical evaluation. NIH continues to explore the use of antibodies to treat emerging and re-emerging infectious diseases, and as a first line intervention to prevent or slow the progress of infectious disease outbreaks as vaccines are being developed. Another innovative approach specific to vaccine development is the use of adjuvants. Adjuvants are valuable tools that boost immune responses to otherwise modestly effective vaccines, redirect immune responses to be more efficacious against specific pathogens, improve immunity in populations that otherwise respond poorly to vaccines (elderly, newborns, immunocompromised patients), and potentially can expedite development of vaccines for emerging pandemic threats. By providing antigen dose sparing, adjuvants can also stretch the vaccine supply.

These NIH-supported activities are advancing a robust pipeline of candidate MCMs needed to ensure the development of safe and effective products to protect the public's health. As detailed in Table 1, NIH projects that the five-year funding estimate is $880.8 million above the flat level.

Administration for Strategic Preparedness and Response

In 2005, Hurricane Katrina demonstrated the need for a federal agency to coordinate public health emergency preparedness and response, and the following year, the Pandemic and All-Hazards Preparedness Act (PAHPA) established the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS). Last summer, 2022, HHS Secretary Becerra determined that ASPR would be elevated to an HHS Operating Division and renamed the Administration for Strategic Preparedness and Response. This designation signals the important work that ASPR supports in the area of preparedness, response, and recovery.

ASPR's BARDA leads the advanced research and development and some acquisition of MCMs. ASPR's SNS leads the stockpiling of MCMs.

As detailed in Table 1, ASPR projects that the five-year BARDA funding estimate is $31.1 billion above the flat level. Funds will primarily support BARDA's continued advanced development across Chemical, Biological, Radiological, and Nuclear (CBRN) threats, procurement of MCMs and new activities focused on COVID-19, and cross-CBRN threat advanced development. Ultimately, while BARDA has been successful in supporting the advanced development of 69 products that received FDA approval, licensure, clearance, or authorization, the SNS's budget

has not had a commensurate increase to support stockpiling targets identified and set by the PHEMCE to aid in preparedness against identified public health and medical threats.

As detailed in Table 1, ASPR projects that the five-year funding estimate for SNS is $2.6 billion above the flat level. For SNS, increased funding needs in FY 2024 are driven by the Anthrax, Ebola, and Smallpox portfolios. While the planned transition of Ebola vaccine to SNS procurement in FY 2024 makes up a relatively small portion of the SNS overall five- year budget plan, sustainment of Anthrax and Smallpox capacity is expected to account for approximately two thirds of SNS's procurement budget during FY 2022 to 2026.

Food and Drug Administration

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.[3] 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.[4]

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

- Supporting 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 or emergency access if needed;
- Reviewing MCM marketing applications and approving those that meet standards for approval;

[3] 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)).

[4] See e.g., sections 561 and 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

- Supporting the establishment and sustainment of an adequate supply of MCMs, including interagency collaboration on efforts to advance MCM supply chains;
- 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 investigational new drug (IND) 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 during real-world use 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;
- Ensuring that the FDA regulatory and policy framework adequately supports MCM development and enables preparedness and response activities; and,
- Sustaining the MCMi professional development program to ensure that FDA meets the regulatory challenges posed by the new scientific and technological developments to support the MCM mission.

As detailed in Table 1, FDA projects that the five-year funding estimate is $777.2 million above the flat level. This increase is essential to enable FDA to 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 efficient use of available MCMs.

Conclusion

This report represents HHS's current estimates for the basic research, advanced research and development, regulatory review, procurement, stockpiling, and replenishment of the U.S. government's (USG's) civilian medical countermeasure enterprise. Estimates are subject to change.

Appendix A: PHEMCE MYB Detailed Portfolio Analysis

Background on the Multiyear Budget Methodology

Each agency and program developed its own 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 2024, 2025, and 2026, using the NIH's Biomedical Research and Development Price Index (BRDPI). For COVID-19 sustainment, NIH assumed based funding to support efforts for preparedness and response, such as evaluating effectiveness of countermeasures against COVID-19 variants and the discovery and development of pan-coronavirus vaccines.
- BARDA assumed funding levels to address all DHS-identified threats with Material Threat Determinations and to meet the goals of the HHS 2017 Pandemic Influenza Plan Update and Executive Order 13886 Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health. 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.
- The 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, 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.
- FDA assumed a three percent increase for each of FY 2024, 2025, and 2026 for CBRN, pandemic influenza, and AMR funding. For COVID-19 sustainment, FDA assumed 15 percent of the total COVID-19 sustainment received for FY 2024 and 30 percent of the total COVID-19 sustainment received for FY 2025 and FY 2026.

The out-year funding levels (FY 2024, 2025, and 2026) for NIH, BARDA, SNS, and FDA, 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.

Summary of PHEMCE MYB MCM Investments

This section provides an overview of spending across NIH, ASPR, and FDA, and describes accomplishments and projections over the course of the five-year period. Congress does not appropriate funding directly to the PHEMCE, but PHEMCE members, coordinated by ASPR, contributed information to provide the below summary of PHEMCE achievements.

Overview

In total, the three HHS Divisions were appropriated $5.7 billion for non-COVID-19 MCMs and MCM-related activities in FY 2022 and have requested $6 billion to support these efforts in FY 2023. Estimated five-year spending across the HHS enterprise is delineated in Table 1. The Appendix B – PHEMCE MYB Spend Plan Tables provide additional detail. PHEMCE investments for the five-year period total of over $64 billion.

ASPR BARDA receives its funding from multiple sources including Advanced Research and Development (ARD) funding, Project BioShield (PBS), and Pandemic Influenza (PI) funding. These sources (Table 2) have different authorities and periods of availably. For example, BARDA receives PI funding that is both annual (available for one fiscal year) and no-year (available until expended).

Table 2: Estimated BARDA MCM Spending by Funding Source, FY 2022–2026 (dollars in millions)

Funding Source	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026
ARD, Two-Year	$745	$828	$8,860	$8,851	$7,665
PI, Annual Appropriations	$28	$28	$28	$28	$28
PI, No-Year	$265	$347	$2,600	$1,885	$1,215
PBS, No-Year	$780	$770	$1,704	$1,630	$2,020
Total	**$1,818**	**$1,973**	**$13,192**	**$12,394**	**$10,928**

Threat-Based Approaches

Figure 1 shows total five-year spending by HHS division for select high-priority threats. No single factor drives spending within any one portfolio, and each portfolio may contain several types of MCMs (e.g., vaccine, therapeutic, and diagnostic, etc.). A significant investment by BARDA may lead to a novel MCM that could be procured and stockpiled by the SNS during this report's timeframe, such that:

- Relatively less mature portfolios will show an absence of SNS spending (e.g., broad-spectrum antimicrobials emerging portfolios of earlier state research and development).
- Those MCMs that reflect a transition from early stage to advanced research are reflected by larger spending in BARDA's portfolio (e.g., chemical, filoviruses, radiological countermeasures).
- Relatively more mature portfolios emphasize sustainment and reflect investments in replenishment costs (e.g., anthrax, smallpox).

Figure 1: MCM Estimated Spending by High-Priority Portfolio and HHS Division for FY 2022–2026[5]

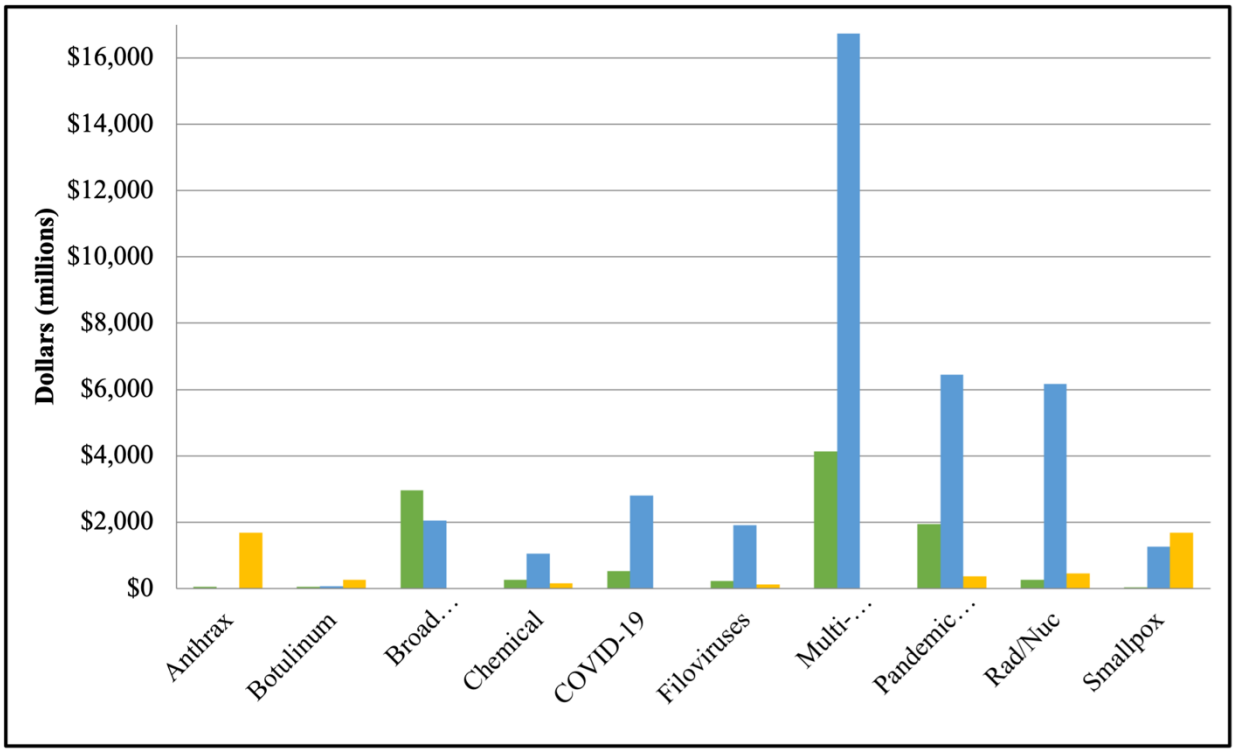

Table 3: MCM Estimated Spending by High-Priority Portfolio and HHS Division for FY 2022–2026

	Anthrax	Botulinum	Broad Spectrum Antimicrobials	Chemical	COVID-19	Filoviruses	Multidisciplinary	Pandemic Influenza	Rad/Nuc	Smallpox
NIH	$47	$49	$2,970	$264	$525	$223	$4,143	$1,942	$260	$41
ASPR BARDA	$11	$76	$2,047	$1,044	$2,796	$1,902	$16,734	$6,452	$6,160	$1,260
ASPR SNS	$1,675	$263	$0	$150	$0	$130	$0	$370	$458	$1,688

The following is a combined summary of select PHEMCE investments as depicted in Figure 1. A detailed explanation of investments in each of these areas follows this summary and describes how funding supports research, development, and stockpile activities.

- Anthrax: $1.7 billion over five years. Part of this funding will support the advanced development, licensure, and procurement of the next-generation anthrax vaccine, AV7909, which will potentially lower future stockpiling and replenishment costs by reducing the number of doses of vaccine needed to treat patients.
- Botulinum: $388 million over five years. Funding will support sustainment of investments in preparedness for the misuse of botulinum toxin. This also includes development of a next-generation intervention to treat botulinum neurotoxin (BoNT).
- Broad Spectrum Antimicrobials: $5.0 billion over five years. Funding will support improved preparedness to treat infections caused by urgent and severe threats, as defined by the U.S. Centers for Disease Control and Prevention (CDC), including

[5] Figure does not include FDA regulatory support.

antimicrobial-resistant bacteria and biothreat pathogens, as well as drug-resistant fungal infections.

- Chemical: $1.5 billion over five years. The chemical threats portfolio includes: research directed by the NIAID across six NIH institutes; BARDA's advanced development of safe and more effective therapeutics for exposures to pharmaceutical-based agents (including synthetic opioids); chemical warfare nerve agents and vesicating chemicals; toxic pulmonary, cellular respiration, and anticoagulating agents/materials; and, various other toxic materials that inhibit respiration and clotting processes. The portfolio also includes funding to support sustainment of SNS's current level of preparedness through replacement of expiring anticonvulsants, nerve agent antidotes, and other supportive medical materiel.

- COVID-19: $3.3 billion over five years at minimum. Funding will allow HHS to continue key investments in vaccines, therapeutics, and devices (including diagnostic tests) and ensure they continue to improve and are effective against new COVID-19 variants. Separately, FDA estimates an additional $705.4 million would be needed to support its COVID-19 regulatory efforts (included in the "other PHEMCE portfolios" section below). This figure does not include funding that could support research, development, and procurement of next generation mucosal vaccines.

- Filoviruses: $2.3 billion over five years. Funding will support continued advancement of countermeasures in preparedness and response for the filoviridae family. The portfolio supports the late-stage development and procurement of MCMs against the Ebola virus. The PHEMCE 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 BARDA and toward FDA approval if safety and efficacy are demonstrated. For vaccines, BARDA will support the advance development of two to three leading candidates each for Marburg virus and Sudan ebolavirus with the goal of having at least one of each in Phase 3trials in five years. For therapeutics, BARDA will support the advanced development of one to two monoclonal antibody therapeutics each for Marburg virus and Sudan ebolavirus with the goal of having one candidate each in Phase 3trials in five years. NIAID will continue to develop monoclonal antibodies against Ebola Zaire, Sudan, and Marburg viruses that provide protection when administered prophylactically. BARDA would also support advanced development of one to two broad-spectrum antivirals, targeting to have one candidate in Phase 2. All of these efforts will work toward the goal of FDA approval/licensure/clearance/authorization. Additional, funding would support BARDA's efforts to scale up manufacturing and procurement of Ebanga for Zaire ebolavirus and continue to support procurement of Inmazeb for Zaire ebolavirus. Funds would also support the transition of procurement of Ebola vaccine (Ervebo for prevention of Zaire ebolavirus) from BARDA to SNS procurement.

- Multidisciplinary Efforts: $20.8 billion over five years. BARDA will use $16.7 billion to develop the tools and platforms that cut across multiple pathogens in the CBRN space to improve our preparedness and response posture. Similarly, NIH continues to support its

cross-cutting science portfolio which includes research activities that cannot be assigned to a specific threat ($4.1 billion).

- Seasonal and Pandemic Influenza: $8.8 billion over five years. This funding, across NIH, BARDA, SNS, and FDA, supports pandemic preparedness objectives as outlined in the 2017 Pandemic Influenza Plan Update, Executive Order 13886 Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health, and COVID-19 lessons learned.
- Radiological/Nuclear: $6.9 billion over five years. This investment 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 anticipated from a nuclear detonation.
- Smallpox: $2.5 billion over five years. Funding will support sustained investment in a lyophilized (freeze dried) formulation of JYNNEOS, a non-replicating smallpox vaccine that is licensed for the prevention of smallpox and mpox disease. This portfolio also includes procurement of vaccine doses and oral and IV TPOXX to replenish products used to respond to the mpox outbreak.

Detailed PHEMCE Portfolio Activities

Anthrax

The anthrax portfolio has a total estimated spending of almost $1.7 billion over the five-year period. The portfolio includes significant cross-agency support for a next-generation anthrax vaccine, AV7909. Funding will support a NIH Phase 1 clinical trial evaluating the safety and immunogenicity of this lyophilized (thermostable) anthrax vaccine, AV7909. Enrollment is complete, immunizations are underway, and the trial will be completed within five years. Similarly, BARDA is supporting the development, preparation of an application for approval, and procurement of AV7909. Submission of a Biologics Licensure Application (BLA) for AV7909 for post-exposure prophylaxis (PEP) is expected in 2023.

In addition, NIH is supporting the development of a small molecule inhibitor of Anthrax Lethal Factor and an IND submission to FDA enabling GLP toxicology and safety pharmacology studies. Chemistry, manufacturing, and control (CMC) submission to the FDA for drug substance and drug product is nearing completion in FY 2023. The goal is to advance to Phase 1 clinical trial as soon as FY 2024. The anthrax therapeutics portfolio is a mature SNS-managed portfolio of three FDA-licensed monoclonal antibody therapeutics. BARDA maintains a small program to test the long-term stability and efficacy of these stockpiled products. This portfolio also supports the replenishment of significant quantities of expiring antibiotics used for post-exposure prophylaxis after an anthrax incident. Estimated spending for antibiotics to prevent and treat plague and tularemia to meet PHEMCE requirements are largely supported by the anthrax portfolio as the antibiotic requirement for the former is much lower (fewer doses) than the latter.

Botulinum

The botulinum neurotoxin (BoNT) portfolio, $388 million over five years, will support development of a next-generation intervention to treat exposure to BoNT. The current approved product is produced from sera of an equine herd using an unsustainable process. BARDA is supporting development of a mAb based product that is anticipated to have better safety and potency profiles than the current product. Funding will advance the proof-of-concept development and testing of this product. NIH is supporting the development of a monoclonal antibody cocktail against the botulinum toxin (BoNT) serotype F. A master cell bank, critical to the production of antibodies, is being generated with the potential to deliver product in FY 2023, followed by continued process development towards compliance with Current Good Manufacturing Practice (cGMP) manufacturing regulations for a Phase 1 clinical trial.

Broad-Spectrum Antimicrobial

Consistent with the *National Strategy for Combating Antibiotic-Resistant Bacteria (2020-2025)*[6], one of the largest spending estimates is for new products to address gaps in the broad-spectrum antimicrobial portfolio. The estimated spending total is $5.1 billion over five years. NIH continues to build a pipeline for candidates in early development. NIH will continue to evaluate and advance a small molecule antibiotic product, epetraborole (EBO), for treatment of acute melioidosis as the first indication sought, and then potentially later indications of other biothreat agents (i.e., Plague, Anthrax, and Tularemia). There are plans for a potential prospective observational study in FY 2023-2024, with plans to file an IND in FY 2025 for a possible Phase 1 study to commence in FY 2026. NIH is supporting the development of multiple gram-negative antibacterial small molecule therapeutics with potential to advance to clinical trials. NIH is supporting the development of a small molecule antibacterial produce effective against the gram-positive bacterium Clostridium difficile that may complete a Phase 2 clinical trial as early as CY 2023.

NIH and Merck have collaborated to discover a novel tuberculosis specific oxazolidinone related to linezolid, a therapeutic candidate that is currently finishing IND-enabling toxicology studies and is scheduled to commence a Phase 1 clinical trial early in CY 2023.

Building on this, BARDA funding will support development and procurement of products to treat infections caused by antimicrobial resistant bacterial and fungal threats that complicate the ability to respond to and recover from any public health emergency. Funding will ensure these life-saving drugs are available to treat infections in both adults and children. Our goal is to develop through FDA approval five to six new innovative antibiotic candidates to treat urgent and severe threats, as defined by the CDC and one or two novel antifungal candidates to treat drug-resistant fungal infections. Further, we will pursue pediatric indications for up to four of these drugs. Significant investment is also planned for development of diagnostics that quickly identify which antibiotics are effective to treat a patient and inform antibiotic stewardship.

[6] The National Strategy can be found here, accessed 10/13/2022, https://www.hhs.gov/sites/default/files/carb-national-action-plan-2020-2025.pdf

Chemical

Spending on MCMs to mitigate harm from chemical threats is forecasted to have a five-year total of $1.5 billion. The chemical threats portfolio includes early-stage MCM research directed by the NIAID across six NIH institutes and advanced research and development by BARDA. The NIH and BARDA chemical threat portfolios are both focused on the development of improved therapeutics to treat the 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. The NIH chemical threats MCM discovery research and early development portfolio includes approximately 80 therapeutic candidates.

In addition to chemical threat MCM advanced research and development, BARDA funding will also support needleless devices for improved delivery of MCMs. BARDA will invest in repurposing of host-targeted and threat-agnostic treatments for lung, skin, eye, and systemic injuries, particularly those that can be used by first responders. In addition, we will continue to 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. Finally, funding will support the advanced development through approval or clearance and procurement of next generation autoinjectors that contain rapid treatments to reverse the effects of nerve agents and other organophosphates.

Filoviruses

In the filovirus portfolio, which combats Viral Hemorrhagic Fevers (VHF) caused by filoviruses such as Ebola virus species (Zaire ebolavirus and Sudan ebolavirus) and Marburg virus, the PHEMCE estimates five-year spending to be $2.3 billion. This portfolio supports the late-stage development and procurement of MCMs against the Ebola 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 BARDA and toward FDA approval/licensure/clearance/authorization if safety and efficacy are demonstrated.

NIH is supporting development of two to three therapeutic monoclonal antibodies for treatment of Marburg virus with the goal of advancing the most promising candidates to Phase 1 trials as early as CY 2024. NIH is supporting preclinical development of a pan-ebolavirus monoclonal cocktail that neutralizes Ebola Zaire, Sudan, and Bundibugyo viruses. NIH anticipates the manufacturing of clinical trial material and initiation in CY 2023 or 2024 of Phase 1 clinical trials to evaluate two different vaccine platforms for Sudan ebolavirus and one vaccine platform for Marburg virus. NIH is developing an improved pre/post-exposure VSV-EBOV vaccine and will characterize the vaccine in preclinical models, including nonhuman primates. This candidate will be available for clinical development through industry partnerships. NIH is exploring 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. NIAID is supporting the development and manufacturing of adenovirus-vectored vaccines against Sudan (ChAd3-SUDV) and Marburg (ChAd3-MARV) viruses in preclinical models and Phase 1 human trials. Finally, NIH is characterizing the protective efficacy of the VSV-Sudan virus vaccine in

preclinical models, with the target of GMP production and implementing clinical trials as early as CY 2023.

BARDA will support activities to achieve an intermediate level of preparedness for Marburg virus and Sudan ebolavirus, meaning at least two vaccine candidates for each threat with clinical data and a supply of doses that can be used in clinical trials. With current funding, BARDA will complete Phase 2 clinical development for two candidates each to prevent infections caused by Marburg virus and Sudan ebolavirus by 2024, with at least one program transitioning to advanced development and procurement under PBS in 2025. For therapeutics, BARDA will continue to support the late-stage development, manufacturing of clinical doses, and efforts toward licensure of mAb products for Sudan ebolavirus and Marburg virus. In addition, BARDA will bring an additional mAb product for Sudan ebolavirus and Marburg virus and a broad acting antiviral with the potential to complement the mAb products and reduce long term persistence leading to viral re-emergence into the portfolio. Finally, funds within this portfolio would support the transition of procurement of Ebola vaccine from BARDA procurement to SNS procurement.

Pandemic and Seasonal Influenza

Across NIH, BARDA, SNS, and FDA, estimated spending on pandemic and seasonal influenza is $8.8 billion over the five-year period. This amount supports pandemic preparedness objectives as outlined in the *2017 Pandemic Influenza Plan Update,* Executive Order 13886 Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health, and COVID-19 lessons learned. This update 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."[7] Other objectives include the need for improvements in diagnostics and treatment options.

NIH would continue to support discovery of innovative new pandemic influenza vaccine prototypes, while advancing the clinical development of current universal influenza vaccine candidates. NIH is supporting the clinical evaluation of vaccines and adjuvants to protect against seasonal and pandemic strains of influenza. Candidates include broadly protective or universal influenza vaccines, and candidates against pandemic influenza strains such as H7N9. NIH is supporting preclinical and translational development of a diverse portfolio of improved seasonal, pandemic, and broadly protective universal influenza vaccines. Five novel seasonal and universal influenza vaccines including mRNA, inactivated, recombinant protein, H7N9, and live attenuated vaccines have entered GMP manufacturing with Phase 1 trials anticipated to be initiated in FY 2023-2024. An Outer Membrane Vesicle (OMV)-based universal influenza vaccine is targeted to advance to a Phase 1 trial in CY 2024. An adenoviral-based pandemic and universal influenza vaccine is targeted to advance to a Phase 1 trial by CY 2027. NIH continues to support clinical trials of broadly-protective "universal" influenza A virus vaccine candidates. The initial Phase I study of one vaccine candidate is underway, and Phase 1 studies of another vaccine candidate are planned to begin as early as CY 2024. Phase 2

[7] The Pandemic Influenza Plan: 2017, can be found here, accessed 3/21/2023, https://www.cdc.gov/flu/pandemic-resources/pdf/pan-flu-report-2017v2.pdf

efficacy studies in the human volunteer influenza challenge model could begin as early as CY 2023. NIH is currently pursuing advanced nanoparticle-based vaccine candidates for both pandemic and seasonal strains of influenza. As nanoparticle-based influenza vaccine candidates have shown promising results in proof-of-principle Phase 1 trials, it is possible that an additional candidate designed to provide broad protection against pandemic and seasonal influenza strains will advance to Phase 1 trials as early as CY2023.

The increased spending estimate supports BARDA efforts to include: the development of more effective and accessible influenza vaccines, including next-generation pandemic influenza vaccines that could potentially be delivered without needles and syringes. Modernized manufacturing capabilities to support transition to next generation platforms and further increase domestic vaccine manufacturing as well as fill/finish capabilities. Development of diagnostic tests for use across the spectrum of care to include at home tests, point of care tests, and tests that can differentiate influenza-like illnesses. Development of therapeutics for pre-exposure prophylaxis, treatment of acute respiratory distress syndrome, or products with new mechanisms of action for acute, uncomplicated influenza infections.

Funding for SNS supports sustainment of SNS's current level of preparedness through replacement of expiring antivirals in addition to the procurement of Baloxavir, an antiviral being added to the SNS at the recommendation of PHEMCE.

Radiological and Nuclear Threats

Spending by BARDA and NIAID on MCMs against radiological and nuclear threats, the next largest investment for this five-year period, totals $6.9 billion. This investment 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. NIAID will continue funding early and advanced research activities for products to address radiation-induced damage to the gastrointestinal tract, skin, and lung, and plans to have at least one product type of each organ system injury under FDA regulatory consideration. NIAID has initiated a clinical trial to study 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 BARDA for licensure and procurement activities. NIAID funds development of diagnostic platforms to enable rapid triage of large numbers of radiation-exposed people, to guide medical management and scarce resource allocation, and plans to approach the FDA to seek clearance for several biomarker panels/devices.

BARDA will procure treatments for the loss of platelets and white blood cells, biodosimetry devices, and artificial skin to treat thermal burns, which will augment our preparedness for radiological/nuclear incidents. BARDA will continue the development of next generation blood products, with approval anticipated in FY 2025. Blood products will help address the anticipated deficit of blood products from a nuclear detonation and may help address blood supply sustainability issues. BARDA will also lead the advanced development of therapies to address traumatic injury, a diagnostic test for traumatic brain injury, imaging systems to detect fractures and tissue damage, and treatments for burn wounds and penetrating injuries. If these products receive FDA approval or clearance, they will be deployed to healthcare facilities and first

responders to be integrated into routine care. Platform technologies, like organ-on-a-chip, are 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.

For SNS, funding included within the radiological and nuclear threat portfolio supports sustainment of SNS's current level of preparedness, replenishing expiring antimicrobials to treat infections related to ARS, decorporation agents, and supporting medical materiel. Between FY 2022 and 2026, SNS expects to continue procuring several products previously supported by BARDA including an antineutropenic drug and a burn/blast bandage.

Smallpox

Investment in MCMs to mitigate smallpox is forecasted to have a five-year total of $2.5 billion.

IH is 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 smallpox/mpox vaccine to increase the number of available doses. NIH is working with United States Army Medical Research Institute of Infectious Diseases (USAMRIID) and the CDC to screen, evaluate and develop new therapeutics against Orthopoxviruses with different mechanisms of action than the FDA approved drugs, TPOXX and TEMBEXA. NIH is currently working with Battelle to produce a Mpox Plaque Reduction Neutralization Test (PRNT) for use in clinical trial testing, with plans to develop an assay for use in clinical trials as early as FY 2023. NIH is 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. NIAID is additionally supporting the development of mRNA-based vaccines that are broadly protective against orthopoxviruses.

Funding will support sustained investment in a lyophilized (freeze dried) formulation of JYNNEOS, a non-replicating vaccine that is licensed for the prevention of smallpox and mpox disease in adults 18 years of age and older determined to be at high risk for smallpox or mpox infection, which is a mandate under the PHS Act. BLA submission for the lyophilized formulation in expected in late 2024 or early 2025. BARDA will also utilize this funding to support the manufacturing of additional doses to bolster domestic supply of JYNNEOS. The increase in estimated spending also includes procurement of vaccine doses and oral and IV TPOXX to replenish products used to respond to the 2022 mpox outbreak. BARDA will also support the development of a next generation monoclonal antibody-based therapeutic to treat smallpox. This mAb product will advance to GMP manufacture and adequate and well-controlled animal studies to support licensure.

BARDA/Multidisciplinary Advanced Development Efforts (new)

ASPR will apply lessons learned from the COVID-19 response in developing the tools and platforms that cut across multiple pathogens in the CBRN space to improve our preparedness

and response posture, as outlined in the American Pandemic Preparedness Plan[8], the FY 2023 President's Budget request for mandatory Pandemic Preparedness funding[9], and several publications including 'Advancing development of medical countermeasures: Incorporating COVID-19 lessons learned into future pandemic preparedness planning' by Johnson, White and Disbrow[10]. These efforts include further development of vaccine platform technologies that developers can rapidly adapt to address new threats, and broad-spectrum therapeutics. Funding will also support innovative scientific approaches to MCM development and manufacturing to decrease time to production so that we can respond quickly to an outbreak. This work will be critical to our response to current and future public health needs. In total, five-year spending for this effort is forecasted to be $16.7 billion.

NIH Multi-Disciplinary Advanced Development Efforts

The Multi-Disciplinary Advanced Development Efforts in the cross-cutting science portfolio includes the NIAID research activities that cannot be assigned to a specific threat. These investments support capabilities such as animal models, diagnostics, sequencing facilities, reagent manufacturing, clinical training programs, epitope mapping, biosafety lab support, computational biology, and development of vaccine platform technologies. The five-year budget plan estimate for this portfolio is $4.1 billion.

NIH/Other Threats

The NIH/Other Threats portfolio is the next largest area of estimated spending and includes investments at NIAID 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. Total five-year spending on these investments is estimated to be $4.0 billion.

Other PHEMCE Portfolios

The remaining funds, $6 billion for the five-year period are allocated to: SNS Non-Procurement Costs and federal medical stations, FDA Regulatory activities, NIH's Multiplex Diagnostics, BARDA's Management and Administration, MCMs for plague and tularemia, MCMs for glanders and melioidosis, ancillary products, and biodiagnostics.

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[8] American Pandemic Preparedness: Transforming Our Capabilities (September 2021), can be found here, accessed 3/21/2023, https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf?page=29

[9] Fact Sheet: The Biden Administration's Historic Investment in Pandemic Preparedness and Biodefense in the FY 2023 President's Budget, can be found here, accessed 3/21/2023, https://www.whitehouse.gov/briefing-room/statements-releases/2022/03/28/fact-sheet-the-biden-administrations-historic-investment-in-pandemic-preparedness-and-biodefense-in-the-fy-2023-presidents-budget/#:~:text=The%20FY23%20President%27s%20Budget%20includes,Prevention%20(CDC)%2C%20the%20National

[10] Advancing development of medical countermeasures: Incorporating COVID-19 lessons learned into future pandemic preparedness planning, can be found here, accessed 3/21/2023, https://pubmed.ncbi.nlm.nih.gov/36302122/

COVID-19 (new)[11]

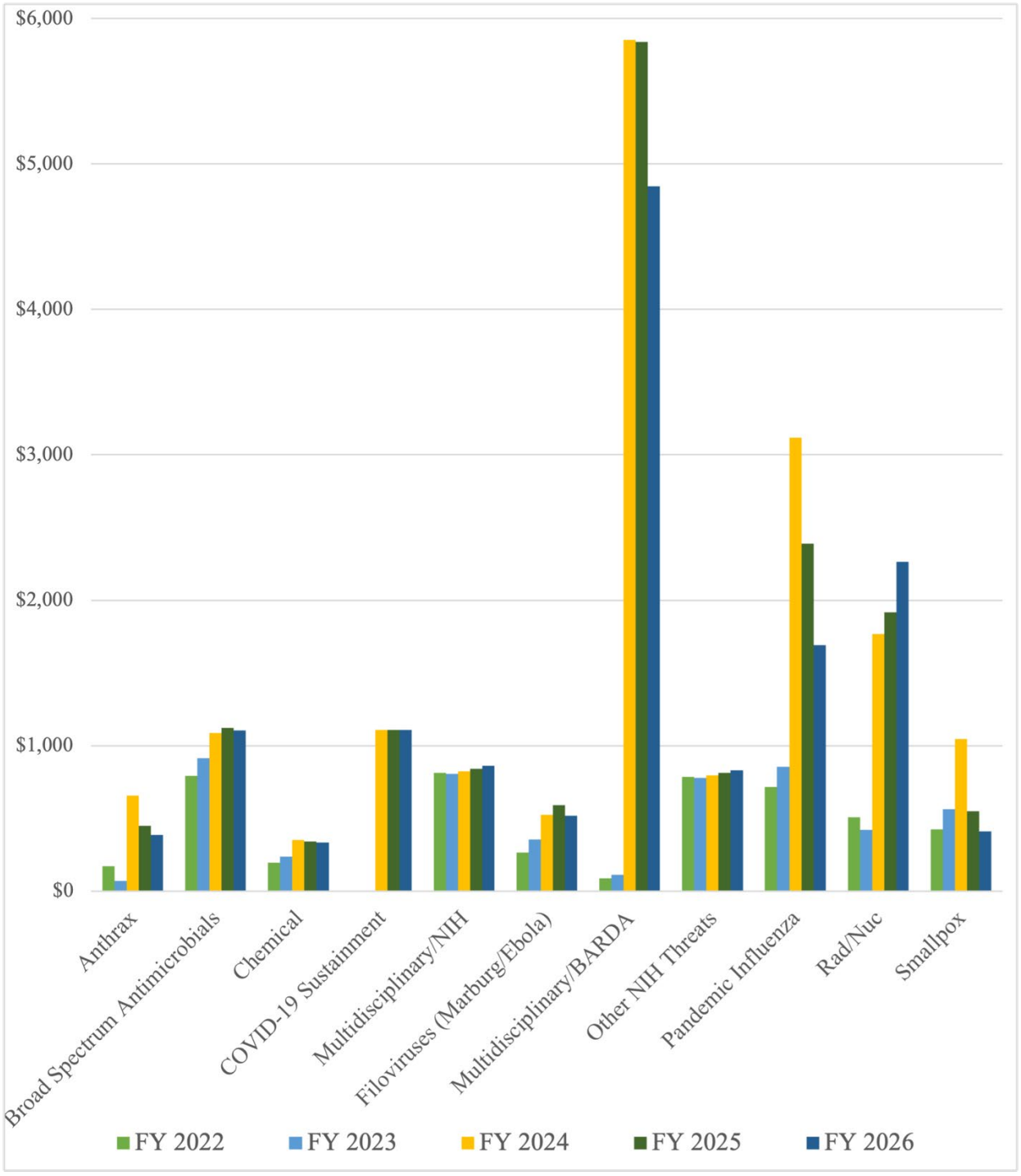
Throughout the COVID-19 response, HHS made key investments that have contributed to the availability of life saving vaccines, therapeutics, and devices (including diagnostic tests). An estimated minimum of $3.3 billion over five years is needed to support of these efforts, which build on activities initiated or accelerated with supplemental resources provided in FY 2021 and FY 2022. ASPR estimates an additional $2.3 billion is necessary to continue advanced development of some vaccines with broader protection and durability than current products, and antivirals that could be used if a variant were to emerge that demonstrates resistance to our currently available antivirals. Additional funding would be required for multiple candidates of intranasal vaccines and development of monoclonal antibodies with broader protection against multiple variants. This funding is critical to our continued response to the COVID-19 pandemic. Additionally, $546 million is required to sustain manufacturing capabilities, non-clinical and assay testing, and storge of MCMs and $525 million to continue NIH clinical trial support. Separately, $705.4 million of FDA's regulatory support activities would directly support COVID-19 efforts (funding included in "other PHEMCE portfolios" above). For COVID-19 sustainment, FDA assumed 15 percent of the total COVID-19 sustainment received for FY 2024 and 30 percent of the total COVID-19 sustainment received for FY 2025 and FY 2026.

Mandatory Pandemic Preparedness (new)

Finally, to generate greater preparedness to future public health needs and in line with the goals set forth in the American Pandemic Preparedness Plan, the FY 2023 President's Budget proposed $81.7 billion in in mandatory funds for HHS to enhance efforts to develop MCMs to respond to pathogens with pandemic potential. The report does not present this mandatory funding within the funding totals or exhibits, given its broad, cross-cutting nature.

[11] The COVID-19 Portfolio estimate does not include SNS or next generation mucosal vaccine funding. The future COVID-19 SNS requirements are still under review.

Figures 2 and 3: Estimated PHEMCE Spending by Portfolio and Fiscal Year (dollars in millions) [12]



[12] **Figures 2 and 3** depict estimated spending by portfolio for FY 2022–2026 in the MCM development life cycle of early and advanced R&D, development, acquisition, stockpiling, and regulatory approval. The data in Figure 1 show the suite of investments directed towards CBRN and EID MCMs. Allocation of these existing resources is made based on a variety of criteria including available market prices, maintain a balanced portfolio, precedence from previous commitments, and acquisition of new products to the Stockpile.

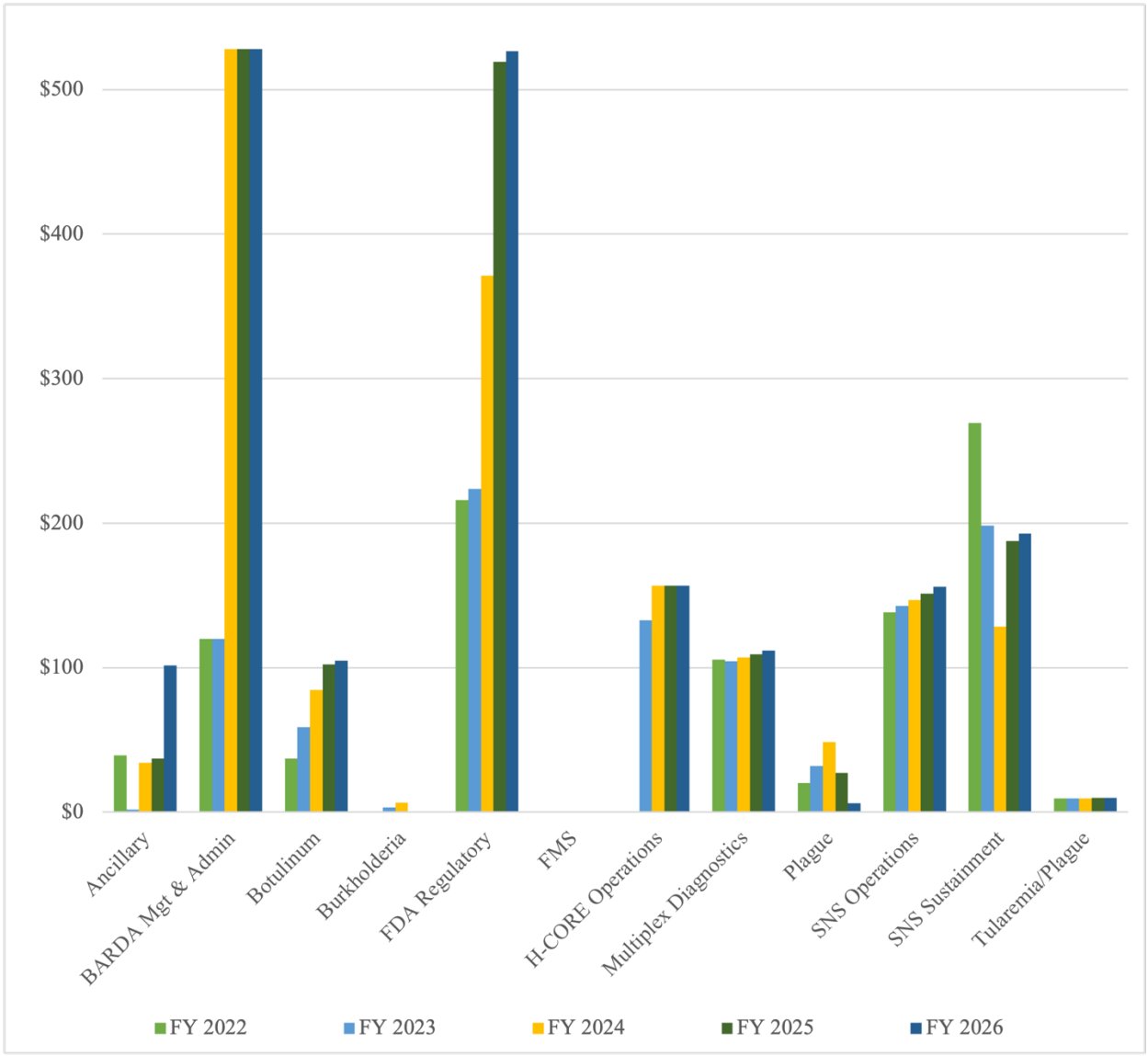


Table 4: Estimated PHEMCE Spending by Portfolio and Fiscal Year (dollars in millions)

Portfolio	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026
Anthrax	$170	$71	$657	$450	$385
Broad Spectrum Antimicrobials	$793	$912	$1,087	$1,122	$1,104
Chemical	$195	$235	$352	$342	$334
COVID-19 Sustainment	$0	$0	$1,107	$1,107	$1,107
Multidisciplinary/NIH	$813	$804	$823	$842	$861
Filoviruses (Marburg/Ebola)	$265	$355	$524	$593	$518
Multidisciplinary/BARDA	$87	$111	$5,851	$5,838	$4,846
Other NIH Threats	$785	$777	$795	$813	$832

Portfolio	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026
Pandemic Influenza	$750	$853	$3,117	$2,387	$1,691
Rad/Nuc	$509	$420	$1,766	$1,917	$2,265
Smallpox	$424	$562	$1,044	$548	$410
Ancillary	$39	$2	$34	$37	$102
BARDA Mgt & Admin	$120	$120	$528	$528	$528
Botulinum	$37	$59	$85	$102	$105
Burkholderia	$1	$3	$6	$0	$1
FDA Regulatory	$216	$224	$371	$519	$527
FMS	$1	$0	$1	$1	$1
H-CORE Operations	$0	$133	$157	$157	$157
Multiplex Diagnostics	$106	$104	$107	$109	$112
Plague	$20	$32	$49	$27	$6
SNS Operations	$138	$143	$147	$151	$156
SNS Sustainment	$270	$198	$128	$188	$193

Product Transitions

During FY 2022–2026, BARDA anticipates ten (10) potential MCM product transitions from Project BioShield to SNS. Transitioning these products will increase the need for funding in the SNS budget to support replenishment of expiring MCMs. Replenishment costs arise from products purchased previously by BARDA or SNS that expire and need to be restocked. A total of $2.175 billion is estimated to support replenishment of MCMs by SNS. As noted above, the SNS does utilize, when and where possible, the Shelf-Life Extension program. The funding projection below takes such considerations, when available, into account.

Table 5: Estimated SNS Spending Needed for MCM Product Replenishment of Products Anticipated to Have Date Sufficient to Support Seeking FDA Approval Previously Procured by BARDA under Project BioShield, FY 2022–2026

Estimated Transition Timeframe (FY)	Medical Countermeasure	Estimated Cost (dollars in millions)					
		FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	Total FY 2022-2026
FY 2022	Anthrax Therapeutic	$32.000	$35.472	$99.609	$99.609	$99.609	**$366.300**
FY 2022	Rad/Nuc Antineutropenic- A	$29.941	-	$92.090	$92.090	$99.090	**$306.213**
FY 2022	Rad/Nuc Other Supportive- A	$4.000	$4.000	$4.000	$4.000	-	**$16.000**

Estimated Transition Timeframe (FY)	Medical Countermeasure	Estimated Cost (dollars in millions)					
		FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	Total FY 2022-2026
FY 2023	Smallpox Antiviral- A	-	$99.538	$116.821	$116.821	$116.821	**$450.000**
FY 2024	Anthrax Vaccine	-	-	$216.667	$216.667	$216.667	**$650.000**
FY 2024	Ancillary Anticonvulsant	-	-	$8.000	$16.800	$24.800	**$49.600**
FY 2024	Ebola Vaccine	-	-	$130.000	-	-	**$130.000**
FY 2024	Smallpox Vaccine	-	-	$110.000	$57.000	-	**$167.000**
FY 2024	Rad/Nuc Other Supportive- B	-	-	$20.000	-	-	**$20.000**
FY 2025	Rad/Nuc Other Supportive- C	-	-	-	$20.000	-	**$20.000**
Total		**$65.941**	**$139.011**	**$797.187**	**$622.987**	**$549.987**	**$2,175.113**

Appendix B: PHEMCE MYB Spend Plan Table

Table 6: PHEMCE MYB Spend Plan Table (dollars in millions)

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	FY 2022 FY 2026 Total
NIH	NIAID	Direct Appropriation, Annual	Anthrax	Basic/Other Research	$4.0	$3.9	$4.0	$4.1	$4.2	$20.1
NIH	NIAID	Direct Appropriation, Annual	Anthrax	Vaccines	$5.2	$5.2	$5.3	$5.4	$5.5	$26.6
NIH	NIAID	Direct Appropriation, Annual	Botulinum	Antitoxin	$7.3	$7.2	$7.4	$7.6	$7.8	$37.2
NIH	NIAID	Direct Appropriation, Annual	Botulinum	Basic/Other Research	$1.5	$1.5	$1.6	$1.6	$1.6	$7.8
NIH	NIAID	Direct Appropriation, Annual	Botulinum	Vaccines	$0.8	$0.8	$0.8	$0.9	$0.9	$4.2
NIH	NIAID	Direct Appropriation, Annual	Broad Spectrum Antimicrobials	Antibiotics	$415.9	$411.7	$421.1	$430.8	$440.7	$2,120.2
NIH	NIAID	Direct Appropriation, Annual	Broad Spectrum Antimicrobials	Antiviral	$148.9	$147.3	$150.7	$154.2	$157.8	$759.0
NIH	NIAID	Direct Appropriation, Annual	COVID-19 Sustainment	COVID-19 Sustainment	$0.0	$0.0	$175.0	$175.0	$175.0	$525.0
NIH	NIAID	Direct Appropriation, Annual	Cross-Cutting Science	Animal Models	$26.6	$26.3	$26.9	$27.5	$28.2	$135.5
NIH	NIAID	Direct Appropriation, Annual	Cross-Cutting Science	Basic/Other Research	$480.0	$475.1	$486.0	$497.2	$508.6	$2,446.9
NIH	NIAID	Direct Appropriation, Annual	Cross-Cutting Science	Product Development	$170.3	$168.5	$172.4	$176.4	$180.4	$868.0
NIH	NIAID	Direct Appropriation, Annual	Cross-Cutting Science	Translational	$135.9	$134.5	$137.6	$140.7	$144.0	$692.7
NIH	NIAID	Direct Appropriation, Annual	Filoviruses (Marburg/ Ebola)	Basic/Other Research	$25.6	$25.3	$25.9	$26.5	$27.1	$130.4
NIH	NIAID	Direct Appropriation, Annual	Filoviruses (Marburg/ Ebola)	Vaccines	$18.1	$18.0	$18.3	$18.7	$19.2	$92.3
NIH	NIAID	Direct Appropriation, Annual	Pandemic Influenza	Basic/Other Research	$80.9	$80.0	$81.9	$83.8	$85.7	$412.3
NIH	NIAID	Direct Appropriation, Annual	Pandemic Influenza	Vaccines	$285.5	$300.5	$307.4	$314.5	$321.7	$1,529.7
NIH	NIAID	Direct Appropriation, Annual	Multiplex Diagnostics	Diagnostics	$100.0	$98.9	$101.3	$103.6	$106.0	$509.8
NIH	NIAID	Direct Appropriation, Annual	Other	Basic/Other Research	$577.8	$571.8	$585.0	$598.4	$612.2	$2,945.2
NIH	NIAID	Direct Appropriation, Annual	Other	Vaccines	$129.5	$128.1	$131.1	$134.1	$137.2	$660.0
NIH	NIAID	Direct Appropriation, Annual	Smallpox	Basic/Other Research	$8.1	$8.0	$8.2	$8.4	$8.6	$41.3
NIH	NIAID	Direct Appropriation, Annual	Smallpox	Vaccines	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
NIH	NIAID	Direct Appropriation, Annual	Tularemia/ Plague	Basic/Other Research	$6.6	$6.6	$6.7	$6.9	$7.0	$33.7
NIH	NIAID	Direct Appropriation, Annual	Tularemia/ Plague	Vaccines	$2.9	$2.9	$2.9	$3.0	$3.1	$14.7
NIH	Non-NIAID	Direct Appropriation, Annual	Broad Spectrum Antimicrobials	Antibiotics/Antiviral	$17.9	$17.7	$18.1	$18.5	$18.9	$91.1

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	FY 2022 FY 2026 Total
NIH	Non-NIAID	Direct Appropriation, Annual	Multiplex Diagnostics	Diagnostics	$5.6	$5.5	$5.7	$5.8	$5.9	$28.5
NIH	Non-NIAID	Direct Appropriation, Annual	Chemical	Chemical Countermeasures Research	$51.4	$51.4	$52.6	$53.8	$55.2	$264.4
NIH	Non-NIAID	Direct Appropriation, Annual	Rad/Nuc	Nuclear/ Radiological Countermeasures	$50.6	$50.6	$51.8	$53.0	$54.2	$260.2
NIH	Non-NIAID	Direct Appropriation, Annual	Other	Basic/Other Research	$76.7	$76.1	$77.9	$79.7	$81.5	$391.9
NIH	Non-NIAID	Direct Appropriation, Annual	Other	Vaccines	$1.2	$1.2	$1.2	$1.2	$1.3	$6.0
ASPR	BARDA	Project BioShield SRF, No-Year	Botulinum	Botulinum Antitoxin	$6.0	$0.0	$0.0	$0.0	$0.0	$6.0
ASPR	BARDA	Project BioShield SRF, No-Year	Broad Spectrum Antimicrobials	Broad Spectrum Antimicrobials	$66.8	$150.0	$274.2	$212.4	$167.7	$871.1
ASPR	BARDA	Project BioShield SRF, No-Year	Chemical	Chemical Medical Countermeasures	$50.0	$90.0	$162.0	$160.0	$130.0	$592.0
ASPR	BARDA	Project BioShield SRF, No-Year	Filoviruses (Marburg/ Ebola)	Ebola Medical Countermeasures	$95.6	$150.0	$177.0	$400.0	$357.0	$1,179.6
ASPR	BARDA	Project BioShield SRF, No-Year	Rad/Nuc	Rad/Nuc Medical Countermeasures	$226.6	$185.0	$555.0	$770.0	$1,320.0	$3,056.6
ASPR	BARDA	Project BioShield SRF, No-Year	Smallpox	Vaccine/ Antivirals	$335.0	$195.0	$535.4	$87.4	$45.0	$1,197.8
ASPR	BARDA	Pandemic Influenza - PHSSEF, Annual Appropriations	Pandemic Influenza	International MCM and Sample Testing Initiative	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
ASPR	BARDA	Pandemic Influenza - PHSSEF, Annual Appropriations	Pandemic Influenza	Vaccine Stockpile, Storage, Stability, and Testing	$15.0	$15.0	$15.0	$15.0	$15.0	$75.0
ASPR	BARDA	Pandemic Influenza - PHSSEF, Annual Appropriations	Pandemic Influenza	Vx AD (Universal, Cell and Recomb)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
ASPR	BARDA	Pandemic Influenza - PHSSEF, Annual Appropriations	Pandemic Influenza	Ventilators/ Respirators/ Diagnostics AD	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
ASPR	BARDA	Pandemic Influenza - PHSSEF, Annual Appropriations	Pandemic Influenza	Facilities, Infrastructure Readiness, and Sustainability	$13.0	$13.0	$13.0	$13.0	$13.0	$65.0

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	FY 2022 FY 2026 Total
ASPR	BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Facilities, Infrastructure Readiness, and Sustainability	$53.1	$87.0	$1,000.0	$250.0	$0.0	$1,390.1
ASPR	BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Therapeutics Advanced Development	$50.0	$50.0	$500.0	$635.0	$700.0	$1,935.0
ASPR	BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Vx AD (Improved vaccines including cell and recombinant technologies)	$133.0	$185.0	$800.0	$800.0	$300.0	$2,253.0
ASPR	BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Vaccine Stockpile, Storage, Stability, and Testing	$3.9	$0.0	$50.0	$50.0	$50.0	$153.9
ASPR	BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	MCM Innovation	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
ASPR	BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Diagnostics and Respiratory Protection Device Advanced Development	$25.0	$25.0	$250.0	$150.0	$165.0	$615.0
ASPR	BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Facilities, Infrastructure Readiness, and Sustainability	$53.1	$87.0	$1,000.0	$250.0	$0.0	$1,390.1
ASPR	BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Therapeutics Advanced Development	$50.0	$50.0	$500.0	$635.0	$700.0	$1,935.0
ASPR	BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Vx AD (Improved vaccines including cell and recombinant technologies)	$168.0	$185.0	$800.0	$800.0	$300.0	$2,253.0
ASPR	BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Vaccine Stockpile, Storage, Stability, and Testing	$3.9	$0.0	$50.0	$50.0	$50.0	$153.9
ASPR	BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	MCM Innovation	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
ASPR	BARDA	Direct Appropriation, Multiyear	Anthrax	Anthrax Medical Countermeasures	$10.2	$0.0	$0.3	$0.3	$0.3	$11.1
ASPR	BARDA	Direct Appropriation, Multiyear	Botulinum	Next generation candidates	$10.0	$0.0	$10.0	$25.0	$25.0	$70.0

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	FY 2022 FY 2026 Total
ASPR	BARDA	Direct Appropriation, Multiyear	Multidisciplinary Advanced Development Efforts	Manufacturing, Innovation and Support Network	$87.3	$111.0	$5,851.1	$5,838.0	$4,846.2	$16,733.6
ASPR	BARDA	Direct Appropriation, Multiyear	BARDA Mgt & Admin	BARDA Mgt & Admin	$120.0	$120.0	$528.0	$528.0	$528.0	$1,824.0
ASPR	BARDA	Direct Appropriation, Multiyear	Broad Spectrum Antimicrobials	BARDA CARB	$143.0	$185.4	$223.0	$306.0	$318.4	$1,175.8
ASPR	BARDA	Direct Appropriation, Multiyear	Chemical	Chemical Medical Countermeasures	$37.9	$75.0	$120.3	$109.3	$109.3	$451.8
ASPR	BARDA	Direct Appropriation, Multiyear	Filoviruses (Marburg/Ebola)	Ebola Medical Countermeasures	$125.9	$162.0	$173.1	$147.4	$114.3	$722.7
ASPR	BARDA	Direct Appropriation, Multiyear	Rad/Nuc	Rad/Nuc Medical Countermeasures	$191.7	$175.0	$1,015.1	$951.3	$769.9	$3,103.0
ASPR	BARDA	Direct Appropriation, Multiyear	Smallpox	Vaccine/Antivirals	$19.0	$0.0	$7.0	$14.0	$22.0	$62.0
ASPR	BARDA	Direct Appropriation, Multiyear	COVID-19 Sustainment	Sustainment	$0.0	$0.0	$157.0	$157.0	$157.0	$471.0
ASPR	BARDA	Direct Appropriation, Multiyear	COVID-19 Sustainment	Mgt and Admin	$0.0	$0.0	$25.0	$25.0	$25.0	$75.0
ASPR	BARDA	Direct Appropriation, Multiyear	Next Generation Vaccines and Therapeutics	Next Generation Vaccines and Therapeutics	$0.0	$0.0	$750.0	$750.0	$750.0	$2,250.0
FDA	FDA	Direct Appropriation, Annual	FDA Regulatory	Antimicrobial Resistance MCM Funding	$24.8	$26.7	$27.6	$28.4	$29.3	$136.8
FDA	FDA	Direct Appropriation, Annual	FDA Regulatory	CBRN MCM Funding	$162.5	$167.5	$172.6	$177.8	$183.1	$863.5
FDA	FDA	Direct Appropriation, Annual	FDA Regulatory	Pandemic Influenza Funding	$28.6	$29.3	$30.2	$31.1	$32.0	$151.2
FDA	FDA	Direct Appropriations, Annual	FDA Regulatory	COVID-19 Sustainment	$0.0	$0.0	$141.1	$282.2	$282.2	$705.4
ASPR	SNS	Direct Appropriation, Multiyear	Ancillary	Anticonvulsant	$0.0	$0.0	$8.0	$16.8	$24.8	$49.6
ASPR	SNS	Direct Appropriation, Multiyear	Ancillary	Other supportive (incl. antimicrobials)	$39.4	$1.8	$26.2	$20.2	$76.8	$164.4
ASPR	SNS	Direct Appropriation, Multiyear	Anthrax	Antibiotic	$118.4	$26.6	$330.9	$124.0	$59.2	$659.1
ASPR	SNS	Direct Appropriation, Multiyear	Anthrax	Therapeutic	$32.0	$35.5	$99.6	$99.6	$99.6	$366.3
ASPR	SNS	Direct Appropriation, Multiyear	Anthrax	Vaccine	$0.0	$0.0	$216.7	$216.7	$216.7	$650.0
ASPR	SNS	Direct Appropriation, Multiyear	Botulinum	Antitoxin	$11.5	$49.4	$64.9	$67.2	$69.6	$262.6
ASPR	SNS	Direct Appropriation, Multiyear	Burkholderia	Antibiotic	$0.8	$3.4	$6.5	$0.1	$0.8	$11.7
ASPR	SNS	Direct Appropriation, Multiyear	Chemical	Anticonvulsant	$7.5	$0.5	$0.0	$5.6	$2.2	$15.8
ASPR	SNS	Direct Appropriation, Multiyear	Chemical	Nerve agent antidote	$48.7	$17.0	$16.8	$13.3	$37.2	$133.0

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	FY 2022 FY 2026 Total
ASPR	SNS	Direct Appropriation, Multiyear	Chemical	Other supportive (incl. antimicrobials)	$0.0	$1.4	$0.2	$0.0	$0.0	$1.6
ASPR	SNS	Direct Appropriation, Multiyear	Filoviruses (Marburg/Ebola)	Filoviruses (Marburg/Ebola)	$0.0	$0.0	$130.0	$0.0	$0.0	$130.0
ASPR	SNS	Direct Appropriation, Multiyear	FMS	FMS	$0.8	$0.2	$0.8	$0.9	$0.9	$3.5
ASPR	SNS	Direct Appropriation, Multiyear	Pandemic Influenza	Antiviral	$55.7	$97.8	$99.8	$76.0	$40.3	$369.7
ASPR	SNS	Direct Appropriation, Multiyear	Plague	Antibiotic	$20.1	$31.8	$48.5	$27.1	$6.3	$133.9
ASPR	SNS	Direct Appropriation, Multiyear	Rad/Nuc	Antineutropenic	$29.9	$0.0	$92.1	$92.1	$92.1	$306.2
ASPR	SNS	Direct Appropriation, Multiyear	Rad/Nuc	Antiviral	$0.0	$0.0	$0.8	$0.8	$0.8	$2.3
ASPR	SNS	Direct Appropriation, Multiyear	Rad/Nuc	Decorporation	$0.0	$3.4	$0.0	$0.0	$0.0	$3.4
ASPR	SNS	Direct Appropriation, Multiyear	Rad/Nuc	Other supportive (incl. antimicrobials)	$10.0	$6.2	$51.7	$50.2	$28.1	$146.3
ASPR	SNS	Direct Appropriation, Multiyear	Smallpox	Antiviral	$1.3	$100.5	$116.8	$116.8	$116.8	$452.3
ASPR	SNS	Direct Appropriation, Multiyear	Smallpox	Uricosuric	$0.1	$0.0	$0.0	$0.0	$0.0	$0.1
ASPR	SNS	Direct Appropriation, Multiyear	Smallpox	Vaccine	$60.7	$258.5	$376.9	$321.2	$217.9	$1,235.1
ASPR	SNS	Direct Appropriation, Multiyear	SNS Operations	Operating	$22.6	$23.3	$23.9	$24.7	$25.4	$119.8
ASPR	SNS	Direct Appropriation, Multiyear	SNS Operations	Program Support	$89.3	$92.0	$94.7	$97.6	$100.5	$474.0
ASPR	SNS	Direct Appropriation, Multiyear	SNS Operations	S&B	$26.6	$27.4	$28.2	$29.1	$29.9	$141.2
ASPR	SNS	Direct Appropriation, Multiyear	SNS Sustainment	Sustainment	$34.1	$35.1	$36.1	$37.2	$38.3	$180.8
ASPR	SNS	Direct Appropriation, Multiyear	SNS Sustainment	Transportation	$5.1	$13.1	$13.5	$13.9	$14.3	$59.8